Comments on the Inert Ingredients in Organic Pesticide Products Proposal dated August 13, 2024

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Executive Summary

We understand that the NOSB has long struggled with the question of what “inert” ingredients or coformulants in pesticides should be allowed for use in organic production. We understand the desire and practical need to resolve the underlying issues that have made it so difficult to reach agreement on a path forward.

However, we cannot support either of the two options proposed in the discussion document. We urge the NOSB to consider other options at this meeting and give more time for the public to reach consensus on a more effective and realistic alternate option. Our comments explain the need for additional options. We propose that a hybrid option will better serve the organic community in the long run. Our key points are:

- The NOSB should *not* make a Final Recommendation at this meeting, or if it does, it should preserve the *status quo*.
- Both proposed options are incomplete and raise unanswered procedural questions that will fall short of what is needed to resolve this complex and difficult issue.
- Option 1 presumes all synthetic substances are "Presumed Incompatible With Organic" (PIWO) unless they are evaluated and meet the OFPA criteria.
- Option 2 presumes all synthetic substances are "Presumed Compatible With Organic" (PCWO) unless they are evaluated and don't meet the OFPA criteria.
- Risk-based certification should apply to all ingredients in formulated pesticide products because every ingredient in a formulation has a function that can change health and environmental risks arising from altered environmental fate, exposure levels, metabolism, and toxicity.
- Full disclosure of all ingredients and their concentrations in pesticide products approved for use in organic is essential to maintain organic integrity and should be among the critical new components of future NOP policy applicable to inerts.
- The two proposed “either / or” approaches could be combined in a hybrid option that will both meet the needs of the organic community, support incremental progress in reducing pesticide-related risks, and spare the NOSB and NOP from most of the time and resource-intensive tasks triggered by the need to evaluate and make decisions on hundreds, if not thousands of inert ingredients.
- Before making a final recommendation to the USDA, the NOSB should request a timely Technical Review of the current and recommended policy option to sharpen understanding of likely consequences.

Introduction

Thank you for the opportunity to comment on the National Organic Standards Board's (NOSB) proposal regarding coformulants or inert ingredients in pesticides. These comments are submitted on behalf of the ORG-Tracker team which we lead, and the Heartland Health Research Alliance (HHRA). ORG-Tracker is a project of HHRA.

We appreciate the NOSB's efforts to resolve a long-standing, festering problem in organic standards: how to deal with currently undisclosed ingredients in formulated pesticide products approved for use in organic production and handling. In these comments, we refer to and build upon our earlier comments on inert issues raised by the 2022 Advanced Notice of Proposed Rulemaking, as well as previous comments to the NOSB.

The NOSB proposes two options: 1) List inert ingredients individually, or individually by group, and 2) adopt the EPA List with restrictions and prohibitions.

Each alternative has advantages and offers a way forward from the increasingly problematic status quo of relying on an obsolete list of mostly low-risk substances that was compiled based on limited data.

Both alternatives also have significant disadvantages. The greatest disadvantages are that both alternatives as presented are unlikely to meet the pest-management and pesticide-risk reduction needs of the organic community, nor the expectations of consumers. Both options impose obligations on the NOSB and NOP beyond what can realistically be accomplished given available resources and the requirements set forth in the OFPA. For these reasons, we anticipate that neither of the two options in the discussion document will be acceptable to the organic community. For that reason, we doubt that the NOSB can craft and vote on a path forward at this meeting that will lead to a robust and durable solution to the underlying issues and challenges.

After so much NOSB and NOP work on this cluster of policy issues, we urge the NOSB to work through and substantively address the issues we raise. Both options are too focused on specific outcomes and neither truly provides for a process that is consistent with the spirit and letter of OFPA. We believe it is possible to create a hybrid of the two proposals that would meet the needs of the organic community, while also breaking the decades-long deadlock on the issue.

We acknowledge that more time is needed to create a hybrid option. To allow for such time, we urge the NOSB to not sunset the current listings of inert ingredients on the National List. Instead, List 4 ingredients should be retained on the National List until a consensus alternative is agreed upon and implemented, and preferably after consideration of the information gained from a Technical Review. Such a review is needed for:

- Continuity in the supply of valuable biopesticides, and
- To identify and deal decisively with those inert ingredients that meet, and do not meet, OFPA requirements based on past existing technical reviews (i.e. avoid the need to re-analyze inerts that have already gone through a robust review and about which there is general consensus).

A technical review will also support NOSB/NOP actions needed to provide a greater degree of clarity for manufacturers regarding the inerts they can draw upon, and should avoid, in their efforts to continuously improve the efficacy of biopesticide products approved for use in organic production.

The status quo will remain a viable alternative until a consensus is reached within the organic community. While less than ideal, the NOSB still has the option to recommend not sunsetting the current language in the NOP rule. Based on our many conversations with a wide range of stakeholders actively engaged in deliberations on NOP inerts policy, we doubt that there is a strong community understanding and consensus in support of either of the two options set forth in the inerts policy discussion document. Until there is greater clarity regarding impacts and consensus on the path forward, the NOSB should preserve the status quo, work on a hybrid, and consider the implications on inerts policy of other pesticide-related policy reforms and/or amendments to the OFPA likely to occur upon passage of the next farm bill.

We urge the USDA and NOSB to work for consensus rather than force the organic community to choose between the two approaches presented, an outcome that will likely not prove durable because of procedural difficulties, legal challenges, and implementation burdens—not to mention a federal election in two weeks. We suggest that a hybrid of the two alternatives be developed as an alternative. In the Appendix, we propose draft regulatory language for the NOSB and NOP to consider as a model.

Under either option, before the NOSB can make an informed decision and before the public can comment on any recommendation, those who want to formulate pesticide products for organic production with synthetic ingredients must fully and publicly disclose (1) what they want to use and at what concentration, (2) why they need such substances for organic production, and (3) how they meet all criteria required by OFPA to add synthetic substances to the National List. Unless and until the NOSB has that information, it will struggle to carry out its Congressionally mandated responsibilities to advise the USDA.

Our hope is that the NOSB will recommend to the NOP a third option: retention of the status quo until the spring 2025 meeting. While few prefer the status quo, it remains at present the least disruptive option, and the only one that will allow the organic community the time needed to craft a more widely embraced and durable hybrid.

Finally we propose an Option 4, which is a hybrid of the two options. Our proposal requires more reflection and public input, but in the long run we see it as the most viable, responsive, and sustainable option. We ask that the NOSB consider Option 4 on its procedural merits and not be distracted by any specific outcome. Our opinion is that if the NOSB recommends a transparent and fair process that is compatible with the spirit and letter of OFPA, the outcomes will be the best for all in the organic community.

Options in the Discussion Document

The two options presented would create an untenable burden on the NOSB and the individuals serving on it. The NOSB already has an overwhelming workload given the steady flow of petitions, sunset reviews, and urgent problems that it needs to address with fraud and emerging challenges

like PFAS and other persistent pollutants. New agricultural technologies—such as gene editing and nanopesticides—are expected to impose new demands on certifiers. Such demands will also compel Congress and the organic community to revisit some of the core definitions and provisions in OFPA, an essential step in modernizing OFPA.

The NOSB can save considerable time and effort by taking the approach in Option 2 of incorporating by reference specific sections of the EPA regulations. However, rather than allowing all to remain on the National List, while making needed exceptions for many, we suggest that the National List only include those inert ingredients that are either exempt from regulation [40 CFR 152.25(f)(2)], classified as minimal risk [40 CFR 180.950] or as polymers [40 CFR 180.960], or those allowed for use in passive pheromone dispensers [40 CFR 180.1122].This specific subset of EPA determinations can be safely presumed to be "Presumed Compatible With Organic" or PCWO. This draws upon Option 2 but narrows the scope of its impact to the hundreds that are non-controversial and agreed by consensus to be compatible with organic farming systems. It excludes those that are "Presumed Incompatible With Organic" or PIWO. Such inerts cannot be safely assumed to meet the OFPA criteria. To get onto the National List, such a substance would take the path envisioned in Option 1, requiring a petition and case-by-case evaluation using the OFPA criteria, as well as an NOSB recommendation to be added to the National List.

For the remaining ingredients that fall outside of the PCWO and PICWO categories, the NOSB can then focus its attention on those coformulants that are shown to be necessary to formulate biopesticide products. Such inerts will then need to be evaluated on a case-by-case basis when some entity petitions the NOP/NOSB to add a new chemical to the National List. Chemical families of substances that have similar properties, functions, and risk profiles can be addressed as a group. We also understand that some non-synthetic substances pose significant health risks, and under both options may need to be prohibited by being placed on the National List. We give an example in the discussion of Option 2.

While the number of inerts needing such an evaluation to remain or get onto the National List may seem great, it likely to be no greater than what the NOSB has dealt with in the past, such as with non-organic agricultural ingredients on §606 in the mid-2000s. We also anticipate that with cooperation from both the pesticide industry and EPA that the number can be reduced even further, as was the case for non-organic agricultural ingredients.

Any option will still require evaluation and approval for use by certifiers of every formulated pesticide product that is included in an Organic System Plan, and before a certified organic operator can apply such pesticide products.

Questions for Option 1

- Who is responsible for petitioning substances that should be added or remain on the National List?
- Is the NOSB proposing to add all historic EPA List 4 substances individually to the National List, or is the proposal to list only those substances currently used in organic production?
- If the latter, who is responsible for submitting the information required by the OFPA criteria related to human health and the environment that the NOSB needs to evaluate the petitioned substance?

Problems with Option 1

The greatest concern, as noted in the Discussion Document, is that only a subset of List 4 inerts are used in pesticide products approved for organic production. Listing only those inerts in current use would remove future options for formulators. A few of those currently unused options are proposed for prohibition under Option 2, but most are not. As a result, the workload of the NOSB would increase markedly, and likely without a corresponding increase in technical support for what will be a daunting task.

With our proposed option 4, the two inerts addressed in the document as examples are PCWO. The first, 1,2,3-Octadecenoate, better known as polyglyceryl oleate, is exempt under 40 CFR 180.25(f)(2) Table 1. The second, 12-Hydroxystearic acid-polyethylene glycol copolymer, is a polymer that appears on 40 CFR 180.960 Table 1. The PIWO all appear on §§910, 920, 930 of 40 CFR 180 or are in InertsFinder, and some do not appear anywhere in the on-line published version of 40 CFR 180.

Questions for Option 2

- Who is responsible to petition substances that should be excluded from use in organic production?
- What OFPA criteria will the NOSB use to evaluate whether a substance should be approved with limitations or excluded from use in organic production, and who will provide a technical review of proposed limitations?
- How are the ingredients in pesticide formulations decided upon and evaluated for compliance with OFPA in countries that are not subject to EPA regulations, nor covered by an equivalency arrangement?
- How will the entire list of inert ingredients exempted by EPA from the requirement of tolerance be evaluated for compatibility with organic production and handling?
- How can the NOSB make binding recommendations to the USDA to exclude specific substances/inerts that it considers unnecessary or incompatible with OFPA if it delegates its rulemaking authority to EPA?
- Which lists are supposed to be used by Accredited Certifying Agents and Materials Review Organizations? Is it limited to only substances identified in 40 CFR 180, or does it include all substances on the InertsFinder Database?

Problems with Option 2

Option 2 also requires that the NOSB consider not only those substances currently in use, but also substances that: (1) are not permitted under the current regulation, (2) have no current applications in organic production, and (3) are often effective only when used in formulations that contain prohibited substances or excluded methods.

The principle of care (the precautionary principle) places the burden of proof on those who want to use a given technology, or those who seek to make a new technology available to organic producers. We believe that Option 2 unfairly places the burden on the public to show that a synthetic inert is incompatible with the OFPA. OFPA clearly states that to be on the National List, a synthetic substance is allowed only if it "is necessary to the production or handling of the

agricultural product because of the unavailability of wholly natural substitute products" [7 USC 6517(c)(1)(A)(ii)]. The burden therefore falls on the formulators to show why a substance is needed. Substances that are used only or primarily with prohibited active ingredients and are incompatible with those allowed for organic production have no business being on the National List, even if only by reference.

We also understand that every item on the National List is required to be evaluated using the criteria found at 7 USC 6518(m). While the criteria overlap with the models used by the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) as amended by the Food Quality Protection Act (FQPA), the 6518(m) criteria go beyond what is required by EPA.

Foremost, we think that the spirit and letter of the OFPA criteria for the National List requires approval of synthetic substances to go beyond what is required of EPA under FIFRA. Considering the "effects of the substance on human health" [6518(m)(4)], it is not enough to accept EPA's opinion on the toxicology of inerts because the EPA only evaluates generally short-term toxicology studies testing inerts in isolation, rather than as part of a formulated product. This approach ignores the well-known capacity of inerts to alter: (1) the environmental fate, and physical and chemical properties for formulations, (2) contact with target pests and other organisms, and (3) the metabolism in soil, plants, and mammals of the other ingredients in formulated pesticide products. Indeed, altering such properties is often an important part of why an inert is added to a formulated product.

Other health impacts need to be considered for organic food to remain ahead of the food-safety curve. While we currently consider the PCWO ingredients to meet the human health criterion in OFPA, we think the NOSB should subject PIWO ingredients to additional scrutiny and a higher standard than called for in FIFRA. Some substances exempt from EPA tolerance have limitations placed on them because of their potential adverse effects on human health. Consistent with our comments on pesticide residue tolerances, the NOSB may want to exclude such substances or provide an extra margin of safety when used on organic farms if they are found to be otherwise compatible with the OFPA criteria. We give examples below of EPA-approved inert ingredients that have known health effects besides the two included in the proposed Option 2. We do not claim that the list is exhaustive and assert that such an exhaustive list can be prepared only by evaluating every single substance that the EPA has approved for use as an inert.

The criteria requires that the NOSB consider "the potential for detrimental chemical interactions with other materials used in organic farming systems" [6518(m)(1)]. We can think of many such interactions with, for example, substances that are intended to act in as a synergist or enhance the toxicity of a given active ingredient.

The NOSB is also required to consider "the probability of environmental contamination during manufacture, use, misuse, or disposal" of a synthetic substance proposed for the National List [6518(m)(3)]. The bar to be allowed for organic was deliberately set higher than the risk-benefit balancing standard governing EPA approval of pesticide products.

Another criterion that is crucial to consider in many cases is "the effects of the substance on biological and chemical interactions in the ecosystem, including the physiological effects of the substance on soil organisms . . ." [6518(m)(5)]. Toxicity to earthworms and other soil organisms

should require greater scrutiny than what EPA carries out, given the critical importance of soil health to organic farming systems. The impacts on beneficial organisms also deserves special consideration, especially for persistent compounds.

Regarding the evaluation of alternatives [6518(m)(6)], if a PCWO is available that has comparable functionality and reduces human health and environmental risks, we believe that a PIWO should be deemed not necessary. We have seen such substitutions made in other contexts.

Finally, the NOSB is required to consider a synthetic substance's "compatibility with a system of sustainable agriculture [6518(m)(7)]. Such consideration would be unmanageable if it was extended to all substances that the EPA has approved for use in formulating pesticides, particularly those whose use is currently limited only to formulations with active ingredients prohibited for organic production. Evaluation of the criterion for PIWO substances makes sense only if that substance is claimed to be necessary for organic production. We give some examples below.

Under Option 2, the process of determining which substances are incompatible with OFPA will require evaluation of far more substances than those currently used in organic production. To exercise due diligence and meet the spirit and letter of the OFPA, Option 2 essentially requires all coformulants be evaluated, rather than only those that are necessary for use in organic production. Singling out two substances that are widely believed to be incompatible with the OFPA criteria is not particularly helpful or germane. Petroleum solvents have historically been rejected for use in organic production. It is not clear whether Option 2 will allow previously prohibited petroleum solvents and, if so, which ones.

Option 2 therefore requires that the NOSB consider even ***more*** ingredients than Option 1. Every substance approved by EPA—or at least every substance exempt from tolerance—will need to be re-reviewed and considered for the negative list at sunset, even if it is not used in a formulated product used for organic production. If the NOSB recommends Option 2, what is to prevent a petition from an interested party seeking review all inert ingredients approved by EPA? How will the NOSB and NOP address such a petition? If the rejection of such a petition is challenged in Federal Court, how will the matter be resolved? An approach like Option 2 could be embraced and emerge from the rulemaking process, only to be plagued by delays brought on by legal challenges.

Without full public disclosure of what ingredients are being used, the NOSB, certification agencies, materials review organizations, producers, handlers, scientists, and the public all lack the necessary information to determine whether pesticide products used in organic production meet the OFPA criteria. If a coformulant is added to a formulated product used in organic production that turns out not to be compatible with the criteria set forth in OFPA and organic principles, the damage to human health and the environment may not be easily undone.

The NOSB knows from experience that once a substance is added to the National List, it is difficult to remove. The NOSB should continue to take a precautionary approach when establishing what pesticides can be used for organic production. This is why the impacts of inerts on the properties and toxicity of formulated products must be addressed. To do so substantively and in meaningful ways, ***the identity and concentrations of inerts in formulated pesticides approved for use on organic operations must be public for a regulatory scheme grounded in transparency and public engagement to function as intended.***

If the NOSB is required to consider thousands more substances than are necessary for organic production, this will place a significant burden on the NOSB that will deliver modest, if any, benefits for the organic community. While EPA approval of coformulants and formulations should be a necessary condition for a coformulant to be added to the National List, it should not be regarded as sufficient since EPA reviews of inerts and decision processes do not take into account:

1. OFPA criteria that go beyond the requirements and considerations in the FIFRA statute.
2. The fact that the properties and toxicity of a given inert are tested as a standalone chemical, and hence
3. ***The way inert ingredients can markedly alter the Absorption, Distribution, Metabolism, and Excretion (ADME) of the active ingredient(s) in formulated pesticide products***.

It is not clear from the proposal who is responsible for petitioning substances to appear on such a negative list. What information would be required to support such a petition? Or, would a petitioner need to petition for each individual substance that was not on EPA List 4?

Several of the substances that appear on 40 CFR 180.910 and 180.920 are limited to use in herbicides, such as several of the alkyl amines. This family of chemistry includes many widely used inerts in herbicide formulations, including the surfactant alkyl polyethyl tallowamine (a polyethoxylated tallowamine [POEA], CAS #61791-26-2). POEA coformulants are the key surfactants in most glyphosate-based herbicides (GBHs) sold in the U.S. Like nonylphenol ethoxylate, some POEAs have appeared on EPA List 4B and are used in some products used in organic production. European regulators banned all GBHs that include a POEA as a coformulant in 2016 because of human health concerns (principally heightened genotoxicity). We believe that POEA and other alkyl amines should be viewed and managed in the same way as PFAS and alkylphenol ethoxylates, and not allowed under Option 2 if adopted.

While such surfactants are generally considered synergists and not herbicidal by themselves, there is evidence that many surfactants are phytotoxic, and hence are not truly inert chemically or biologically. There are hundreds of ingredients that appear on both InertFinder and the EPA's list of approved active ingredients and/or inert ingredients (and some both), which reinforce our case that few substances in a pesticide formulation are truly "inert". Some are non-synthetic, some appear on the National List, and some are low-risk. However, many EPA-approved inerts pose potential health and safety risks, including volatile inerts with chemical structures and properties similar to benzene and vinyl chloride.

Some inerts have the potential to circumvent organic standards. Several quaternary ammonia substances fall into this category. A creative formulator could conceivably add purportedly "inert" ingredients in a formulation that contribute to the desired pesticidal effect, creating in effect a "back door" active ingredient. It is often impossible to verify whether a given inert ingredient actually functions in a formulation as an active ingredient without full disclosure of all ingredients in pesticide products. The NOSB may see a need to recommend limitations on use of specific substances currently regarded as inert ingredients, and for reasons that go beyond the factors considered by the EPA in its assessment of inerts and their placement on various lists.

This is yet another example of a widespread, complex, and difficult-to-resolve policy issue that the organic community is struggling to deal with in a responsible way, while the EPA and conventional

farming community are content in letting the issues slide. Given all the problems with FIFRA and EPA regulation of pesticides, it is understandable that inert issues remain low on the pesticide policy list of priorities. But EPA's failure to address issues stemming from the presence of inerts in formulated products markedly enhances the cost and complexity facing the NOSB/NOP and organic community in crafting responsible inerts policy applicable to NOP-approved pesticides. In fact, we conclude that under current law (OFPA plus FIFRA) and EPA and NOP policy, fixing organic sector problems with how inert ingredients are evaluated, approved, or disallowed borders on mission impossible.

Aromatic petroleum solvents were historically prohibited as coformulants in pesticide products, even before the OFPA was passed. Certifiers had difficulty over years in getting disclosure of formulations. The status of such ingredients remains unclear. At least two appear in 40 CFR 180 (CAS #s 64742-95-6 & 64742-94-5) in §910 and §930, and several former List 2 inerts also remain in the EPA's InertsFinder database with unclear regulatory status. Does the NOP and NOSB really want to take responsibility for sorting out all the inert ingredient related conflicts and uncertainties lurking in EPA's weeds?

Another thing to consider is that California's Proposition 65 list requires a warning on certain consumer products known or suspected to cause cancer, birth defects, or other reproductive harm. Labels on such products are supposed to warn users in that state of such risks, making the presence of such risks known to those potentially impacted. At least one substance on that list appears to be non-synthetic and allowed by default, requiring NOSB action to prohibit it under either option. However, not all pesticides are registered to be sold in California. Ingredients found in both the EPA's Inerts Finder database and the Proposition 65 List appear in Table 1.

Table 1
Inert Ingredients on the California Proposition 65 List

Ingredient Name(s)	CAS #	40 CFR 180 §§
Butylated hydroxyanisole (BHA)	25013-16-5	910, 930
Carbon black	1333-86-4	920
Diethanolamine (DEA)	111-42-2	920
Ethylene glycol (1,2-Ethanediol)	107-21-1	910, 920, 1040
Methyl alcohol (Methanol)	67-56-1	910, 920, 930
Methyl isobutyl ketone (MIBK)	108-10-1	910, 920. 930
N-Methyl-2-pyrrolidinone (NMP)	872-50-4	920
MON 4660 (4-(Dichloroacetyl)-1-oxa-4-azaspiro[4.5]decane)	71526-07-3	465
Furilazole	121776-33-8	471
Magnesium aluminum silicate (Palygorskite)*	12174-11-7	910, 930
Sodium 2-phenylphenate (o-Phenylphenate, sodium)	132-27-4	920

*May be non-synthetic and would thus be allowed unless prohibited under §602 and §604.
Source: (Cal-EPA, 2023; US EPA, 2024).

If Option 2 is adopted, we believe and recommend that the substances in Table 2 should be added to the excluded list in the absence of a successful petition to add them to the National List. Note that several of these have closely related substances in the same family that also appear to be

incompatible with the OFPA. Various ketones, glycol ethers, and other families of substances may well fit into the same category.

Not all coformulants are exempt from the requirement of an EPA tolerance. Thus, every pesticide formulation will still need to be reviewed for organic compliance if only those exempt from a tolerance are allowed. For example, one inert ingredient (CAS #71526-07-3) has a very low tolerance of 0.005 ppm on corn [40 CFR 180.465]. Is this a reflection of its toxicity, or just the expected level in corn at harvest? Table 2 lists ingredients that appear in InertsFinder and have EPA tolerances. Tolerances are crop-specific and the range is reported.

Table 2
Formulants Not Exempt from EPA Tolerance

Ingredient Name(s)	CAS #	40 CFR 180 §§	Tolerances (ppm)
Benoxacor (4-(dichloroacetyl)-3,4-dihydro-3-methyl-2H-1,4-benzoxazine,	98730-04-2	460	0.01
MON 4660 (4-(dichloroacetyl)-1-oxa-4-azaspiro[4.5]decane)	71526-07-3	465	0.005
Dichlormid (2,2-dichloro-N,N-di-2-propenylacetamide	37764-25-3	469	0.05
Furilazole, (3-dichloroacetyl-5-(2-furanyl)-2, 2-dimethyloxazolidine) MON 13900	121776-33-8	471	0.01
Cloquintocet-mexyl, (acetic acid [(5-chloro-8-quinolinyl)oxy]-, 1-methylhexyl ester)	99607-70-2	560	0.1-0.5
isoxadifen-ethyl (ethyl 5,5-diphenyl-2-isoxazoline-3-carboxylate)	163520-33-0	570	0.04-0.5

Source: 40 CFR 180.

Regarding inert ingredients used coformulants in livestock external parasiticides, Option 1 should be limited to those inert ingredients that are currently used in organic livestock production. Option 2 should be limited only to those ingredients that are exempted from the requirement of a tolerance at 40 CFR 180.930.

To restate, the examples we give are not an exhaustive list. Due diligence requires evaluation of not just these few examples, but of all PIWO ingredients that could potentially be added to formulated pesticides applied by organic producers and handlers. We believe that collaboration with the EPA is essential to resolve what ingredients are allowed to be used in formulated pesticide products used in organic production. Option 1 does not involve consulting with EPA in determining what inert ingredients are used in formulated products approved for use in organic production, which was the intent of OFPA. Option 2 proposes to give EPA much greater authority over determining compatibility with organic production than was intended by OFPA, or likely possible under FIFRA. This is one of many obsolete provisions in the OFPA that Congress should modify and modernize in the upcoming farm bill.

Our Proposed Option 4

We propose a middle ground compromise. Coformulant substances that are currently permitted in pesticides should be grandfathered onto the National List and considered PCWO if they fit in any one of the following EPA categories:

- Exempt from registration under 25b of FIFRA; ,
- Considered minimum risk by EPA,
- Are used in a passive pheromone dispenser, or
- Classified by EPA as a polymer.

Those not categorized as such by EPA should be considered PIWO and will need to be petitioned and reviewed on a case-by-case basis. This proposed hybrid option retains the NOSB's and USDA's authority over the list of ingredients, while making the workload stemming from the need to review substances far more manageable. The number of substances in need of review will fall from hundreds under Option 1 and thousands under Option 2 to perhaps just a few dozen. An appropriate share of the burden in getting additional inerts onto the National List will fall upon those advocating future reliance on new inerts.

An Interim Path Forward

As an alternative to the two options presented in the discussion, we offer the following proposed amendments to the current USDA National Organic Program Rule as Option 3:

Option 3

Motion to sunset 7 CFR 601(m) and 7 CFR 601(e). If both motions fail, these substances will remain on the National List, at least until completion of the spring 2025 meeting of the NOSB.

We ask that the NOSB consider combining Options 1 and 2 into a viable option and work to build consensus in support of it across the organic community, including in the Congress. In our remaining comments, we offer draft model language and examples of ingredients currently in use. Specific ingredients may be added to or removed from the appropriate sections as needed, but it offers a point of departure that makes resolution of the issue feasible.

Option 4

We offer the model language below as an example of how the NOSB could possibly reach a consensus proposal that combines the positive attributes of both Option 1 and Option 2. We ask that the NOSB and the public focus on the process, and not on the specific regulatory sections that it considers to be PCWO or examples of specific PIWO substances that might meet the criteria for inclusion in the Tables below.

Because we don't have full public disclosure of inerts currently in use in organic production, our proposal includes only those that we are reasonably confident are being used. Some may need to be added. Such substances would need to be considered through the National List petition process that all other synthetic substances must undergo. Some advocates seeking to add a new inert to the National List may choose to petition the EPA to have a substance classified as PCWO by virtue of being added to one of those categories. We also understand that the NOSB may need to

remove some formulants in current use after reviewing them to the OFPA criteria. In any case, we respect the NOSB's statutory authority to determine what synthetics may be eligible for inclusion on the National List. We ask that the NOSB retain this authority and not delegate it to the USDA or EPA by requiring a positive list of exceptions and/or limitations in use of substances that lack community consensus for inclusion.

Motion to amend 205.601(m):

(m) As synthetic inert ingredients as classified by the Environmental Protection Agency (EPA), for use 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~~

~~(2) EPA List 3 Inerts of unknown toxicity for use only in passive pheromone dispensers.~~

(1) Ingredients determined by EPA to be eligible for use in minimum risk pesticide formulations [40 CFR 152.25(f)(2)].

(2) Ingredients that are exempted from the requirement of tolerance and determined by EPA to be of minimal risk [40 CFR 180.950].

(3) Ingredients that are exempted from the requirement of tolerance and determined by EPA to be low-risk polymers [40 CFR 180.960 & 723.250].

(4) Ingredients that are exempted from the requirement of a tolerance for use in semiochemical dispensers [40 CFR 180.1122].

(5) The following materials are exempted from the requirement of a tolerance by EPA when used in accordance with good agricultural practices, subject to the limitations established by EPA as inert (or occasionally active to some degree) ingredients in pesticide formulations applied to growing crops, or to raw agricultural commodities after harvest [40 CFR 180.910]:

Table 1 to §601(m)(5)

Chemical Name	CAS
1- Butanol	71-36-3
1- Hexanol	111-27-3
1- Hydroxyethylidene-1,1-diphosphonic acid	2809-21-4
1- Propanol	71-23-8
Acetic acid	64-19-7
Ammonium bisulfate	7803-63-6
Ammonium chloride	12125-02-9
Ammonium hydroxide	1336-21-6
Ammonium sulfate	7783-20-2
Benzoic acid	65-85-0
Benzopyran-6-ol,3,4-dihydro-2,5,7,8-2H-1-tetramethyl-2-(4,8,12-	10191-41-0
Butanedioic acid, dimethyl ester	106-65-0
Calcium chloride	10043-52-4

Chemical Name	CAS
Calcium hydroxide	1305-62-0
Carbonic acid, monoammonium	1066-33-7
Croscarmellose sodium	74811-65-7
d- Limonene	5989-27-5
Dimethyl ether	115-10-6
Diphosphoric acid, tetrasodium salt	7722-88-5
Disodium phosphate	7558-79-4
Dodecanol, ethoxylated, monoether with sulfuric acid, sodium salt	9004-82-4
Ethanol	64-17-5
Ethyl acetate	141-78-6
Ethylenediaminetetraacetic acid (EDTA)	60-00-4
Ethylenediaminetetraacetic acid (EDTA), tetrasodium salt	64-02-8
Fatty acids, C16-18 & C18-unsatd., Me esters	67762-38-3
Fatty acids, C16-18 and C18-unsatd	67701-08-0
Fatty acids, soya, Me esters	68919-53-9
FD&C Red No. 40	25956-17-6
Glycerides, C16-18 and C18-unsatd. mono- and di-	68424-61-3
Hydrogen chloride	7647-01-0
Lignosulfonic acid, calcium salt	8061-52-7
Naphthalenesulfonic acid, polymer with formaldehyde, sodium salt	9084-06-4
Oxirane, methyl-, polymer with oxirane, mono- 2-propenyl ether	9041-33-2
Phosphoric acid	7664-38-2
Poly(oxy-1,2-ethanediyl), .alpha.-hydro-. omega.-hydroxy-, mono-C10-12-alkyl	68908-64-5
Poly(oxy-1,2-ethanediyl), alpha-methyl-omega-[3-[1,3,3,3-tetramethyl-1-	27306-78-1
Poly(oxy-1,2-ethanediyl), alpha-methyl-omega-(2-propenyloxy)- (CA INDEX	27252-80-8
Poly(oxy-1,2-ethanediyl),.alpha.-2-propenyl-.omega.-hydroxy-	27274-31-3
Poly(oxy-1,2-ethanediyl),.alpha.-hydro-.omega.- hydroxy-, mono-C11-14-	78330-24-2
Polyethylene glycol mono(tristyrylphenyl)ether	99734-09-5
Polyoxyethylene monostearate	9004-99-3
Polyoxyethylene sorbitan trioleate	9005-70-3
Potassium hydroxide	1310-58-3
Propyl p-hydroxybenzoate	94-13-3
Propylene glycol	57-55-6
Rosin, maleated, polymer with pentaerythritol	68333-69-7
Silicic acid (H2SiO3), disodium salt	6834-92-0
Silicic acid, disodium salt, pentahydrate	10213-79-3
Silicic acid, sodium salt	1344-09-8
Siloxanes and silicones, 3-hydroxypropyl Me, ethers with polyethylene glycol	117272-76-1
Sodium hydroxide	1310-73-2
Sodium thiosulfate, pentahydrate	10102-17-7
Sodium tripolyphosphate	7758-29-4

Chemical Name	CAS
Sorbic acid	110-44-1
Sulfuric acid	7664-93-9
Sweet orange peel tincture	8028-48-6
Tricalcium phosphate	7758-87-4
Trisodium phosphate	7601-54-9

(6) The following materials that are exempt from the requirement of a tolerance by EPA when used in accordance with good agricultural practices, subject to the limitations established by EPA as inert (or active to some degree) ingredients in pesticide formulations applied to growing crops only [40 CFR 180.920):

Table 1 to §601(m)(6)

Chemical Name	CAS
Acetic acid, ammonium salt	631-61-8
Aluminum sulfate	10043-01-3
Ammonium chloride	12125-02-9
Carbonic acid, dipotassium salt	584-08-7
Copper phthalocyanine blue	147-14-8
Diammonium phosphate	7783-28-0
FD&C Red No. 40	25956-17-6
Magnesium nitrate	10377-60-3
Methyl oleate	112-62-9
Methyl p-hydroxybenzoate	99-76-3
N,N-Bis(2-hydroxyethyl)(coconut oil alkyl)amine	61791-31-9
Naphthalenesulfonic acid, polymer with formaldehyde, sodium salt	9084-06-4
Poly(oxy-1,2-ethanediyl), .alpha.-hydro-. omega.-hydroxy-, mono-C10-12-alkyl	68908-64-5
Poly(oxy-1,2-ethanediyl),.alpha.-hydro-.omega.- hydroxy-, mono-C11-14-	78330-24-2
Potassium phosphate (dibasic)	7758-11-4
Potassium phosphate, monobasic	7778-77-0
Sodium dihydrogen phosphate	7558-80-7
Sorbitan monostearate	1338-41-6
Tetrapotassium pyrophosphate	7320-34-5
Titanium dioxide	13463-67-7

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Motion to amend at 205.603(e)

(e) As synthetic inert ingredients as classified by the Environmental Protection Agency (EPA), for use 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~~

~~(2) EPA List 3-Inerts of unknown toxicity-for use only in passive pheromone dispensers~~

(1) Ingredients determined by EPA to be eligible for use in minimum risk pesticide formulations [40 CFR 152.25(f)(2)].

(2) Ingredients that are exempted from the requirement of tolerance and determined by EPA to be of minimal risk [40 CFR 180.950].

(3) Ingredients that are exempted from the requirement of tolerance and determined by EPA to be low-risk polymers [40 CFR 180.960 & 723.250].

(4) Ingredients that are exempted from the requirement of a tolerance for use in semiochemical dispensers [40 CFR 180.1122].

(5) The following substances that are exempted from the requirement of a tolerance by EPA when used in accordance with good agricultural practices as inert (or occasionally active) ingredients in pesticide formulations applied to animals [40 CFR 180.930]:

Table 1 to §603(e)(5)

Chemical Name	CAS
1- Butanol	71-36-3
1- Propanol	71-23-8
Acetic acid	64-19-7
Benzoic acid	65-85-0
Calcium chloride	10043-52-4
d- Limonene	5989-27-5
Dimethyl ether	115-10-6
Dodecanol, ethoxylated, monoether with sulfuric acid, sodium salt	9004-82-4
Ethanol	64-17-5
Fatty acids, soya, Me esters	68919-53-9
Lignosulfonic acid, calcium salt	8061-52-7
Methyl p-hydroxybenzoate	99-76-3
N,N-Bis(2-hydroxyethyl)(coconut oil alkyl)amine	61791-31-9
Oxirane, methyl-, polymer with oxirane, mono- 2-propenyl ether	9041-33-2
Poly(oxy-1,2-ethanediyl), .alpha.-3-[1,3,3,3-tetramethyl-1-	67674-67-3
Poly(oxy-1,2-ethanediyl), .alpha.-hydro-. omega.-hydroxy-, mono-C10-12-alkyl	68908-64-5
Poly(oxy-1,2-ethanediyl), alpha-methyl-omega-(2-propenyloxy)- (CA INDEX NAME)	27252-80-8
Poly(oxy-1,2-ethanediyl),.alpha.-2-propenyl-.omega.-hydroxy-	27274-31-3
Poly(oxy-1,2-ethanediyl),.alpha.-hydro-.omega.- hydroxy-, mono-C11-14-isoalkyl	78330-24-2
Polyoxyethylene monostearate	9004-99-3
Polyoxyethylene sorbitan trioleate	9005-70-3
Potassium hydroxide	1310-58-3
Propyl p-hydroxybenzoate	94-13-3
Propylene glycol	57-55-6

Chemical Name	CAS
Sodium hydroxide	1310-73-2
Titanium dioxide	13463-67-7
Trisodium phosphate	7601-54-9

Motion to Amend at 206.605(c):

(c) As synthetic inert ingredients as classified by the Environmental Protection Agency (EPA), for use 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~~

~~(2) EPA List 3-Inerts of unknown toxicity-for use only in passive pheromone dispensers~~

(1) Ingredients determined by EPA to be eligible for use in minimum risk pesticide formulations [40 CFR 152.25(f)(2)].

(2) Ingredients that are exempted from the requirement of tolerance and determined by EPA to be of minimal risk [40 CFR 180.950].

(3) Ingredients that are exempted from the requirement of tolerance and determined by EPA to be low-risk polymers [40 CFR 180.960 & 723.250].

(4) Ingredients that are exempted from the requirement of a tolerance for use in semiochemical dispensers [40 CFR 180.1122].

(5) The following synthetic chemical substances that are exempted from the requirement of a tolerance when used in accordance with good manufacturing practice as ingredients in an antimicrobial pesticide formulation, provided that the substance is applied on a semi-permanent or permanent food-contact surface (other than being applied on food packaging) with adequate draining before contact with food.

(a) The following chemical substances when used as ingredients in an antimicrobial pesticide formulation may be applied to: Food-contact surfaces in public eating places, dairy-processing equipment, and food-processing equipment and utensils:

Table 1 to §605(c)

Chemical Name	CAS
1- Butanol	71-36-3
1- Hexanol	111-27-3
1- Hydroxyethylidene-1,1-diphosphonic acid (HEDP)	2809-21-4
Acetic acid	64-19-7
Aluminum sulfate	10043-01-3
Ammonium bisulfate	7803-63-6
Ammonium chloride	12125-02-9
Calcium chloride	10043-52-4

Chemical Name	CAS
d- Limonene	5989-27-5
Dodecyl sulfate, sodium salt	151-21-3
Ethanol	64-17-5
Ethyl acetate	141-78-6
Ethylenediaminetetraacetatic acid (EDTA), disodium salt	139-33-3
Ethylenediaminetetraacetic acid (EDTA), tetrasodium salt	64-02-8
FD&C Red No. 40	25956-17-6
Gluconic acid, sodium salt	527-07-1
Nitric acid	7697-37-2
Octanoic acid	124-07-2
Polyoxyethylene sorbitan monooleate	9005-65-6
Potassium coconut oil soap	61789-30-8
Propanoic acid	79-09-4
Propylene glycol	57-55-6
Sodium bis(2-ethylhexyl) sulfosuccinate	577-11-7
Sodium dihydrogen phosphate	7558-80-7
Sodium dioctyl sulfosuccinate	1639-66-3
Sulfuric acid	7664-93-9
Trisodium phosphate	7601-54-9

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References

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US EPA. (2024). *Inert Use Information*. InertFinder. https://ordspub.epa.gov/ords/pesticides/f?p=INERTFINDER:1::::1::