BEYOND PESTICIDES
701 E Street, SE ■ Washington DC 20003
202-543-5450 phone ■ 202-543-4791 fax
info@beyondpesticides.org ■ www.beyondpesticides.org

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Ms. Michelle Arsenault
National Organic Standards Board
USDA-AMS-NOP
1400 Independence Ave. SW
Room 2648-S, Mail Stop 0268
Washington, DC 20250-0268

Docket ID # AMS-NOP-23-0075

Re. MS: "Inerts"

These comments to the National Organic Standards Board (NOSB) on its Spring 2024 agenda are submitted on behalf of Beyond Pesticides. Founded in 1981 as a national, grassroots, membership organization that represents community-based organizations and a range of people seeking to bridge the interests of consumers, farmers, and farmworkers, Beyond Pesticides advances improved protections from pesticides and alternative pest management strategies that eliminate a reliance on pesticides. Our membership and network span the 50 states and the world.

Introduction

We begin these comments with the observation that the evaluation of individual so-called "inert" synthetic ingredients in products used in organic production is not optional. It is required by law.[1] We are outraged by the continued failure of the NOSB and the National Organic Program (NOP) to move forward with the evaluation and listing of so-called "inert" ingredients used in organic production.

As the Federal Advisory Committee responsible for giving direction to NOP, this board—the National Organic Standards Board—has passed repeated recommendations instructing NOP, under the Agricultural Marketing Services (AMS), to replace the generic listings for U.S. Environmental Protection Agency (EPA) Lists 3, 4A, and 4B "inerts" with specific substances approved for the use. NOP must allocate resources for this project. Recent appropriations have increased for NOP, and some of this money must be used for the evaluation of "inert" ingredients to ensure compliance with the law and to maintain the integrity of the USDA organic label.

[1] The Organic Foods Production Act (OFPA), §6517 allows the use of a synthetic substance in organic production only if it is listed on the National List "by specific use or application" based on a recommendation by the NOSB, following procedures in OFPA.

In spite of the clearly stated intention of the NOSB to initiate steps to move forward with solutions, NOP persists in behaving as if the question is whether individual "inerts" should be evaluated, instead of the legally required question—how does the NOSB establish a process to move forward with the review of "inerts" under the National List of Allowed and Prohibited Substances. The failure of NOP/AMS to move efficiently and effectively on the "inerts" review of ingredients allowed in organic production and processing is a direct threat to the integrity of organic at a time when organic must grow exponentially to address the current and future health, biodiversity, and climate crises associated with synthetic pesticides and fertilizers used in chemical-intensive agriculture.

We are outraged that rather than leverage the incredible amount of important and effective work done by the NOSB and others to put in place an "inerts" review program, NOP/AMS misinforms and dissimulates in reciting the history and constructing a solution. We are extremely disturbed by the failure of NOP in its Advanced Notice of Proposed Rulemaking (ANPR) and response to comments to recognize and credit the work done by the NOSB and others in the organic community, going back to the 1990's, to ensure that organic producers and consumers are protected from hazardous chemicals misleadingly termed "inert" ingredients in pesticide products, even though they may be biologically and chemically active. NOP fails to take advantage of the experts in this field who served on the NOSB and repeatedly offered their services to minimize the "substantial work [required] by both the NOSB and AMS" in evaluating "inerts" for listing on the National List as overwhelmingly recommended by the NOSB.

The current "discussion document" continues this trend of inaction. Instead of actually analyzing and giving serious consideration to the comments offered in the Fall, the Materials Subcommittee (MS) has merely given a superficial overview of "themes" in those comments and offered an "analysis" of the List 4 "inerts" prepared by NOP—a spreadsheet that, although it must have required a great deal of time—is a totally inadequate starting point, as we discuss later in these comments. This discussion document is an insult to all of us who have provided detailed comments and suggestions.

The MS's discussion document, as well as previous documents created by AMS, reflect a lack of understanding or misdirection on the part of the authors of the character of so-called "inert" ingredients and the requirements of the Organic Foods Production Act (OFPA), as well as the history of efforts by the NOSB to address this issue. Therefore, we will address the questions posed by the MS only at the end of these comments. The substance of these comments is organized in the following subject areas:

1. Scope of the "inerts" requiring review.
2. Proposed NOSB Actions for Evaluating Former List 4 "Inerts"—in which we describe crucial next steps, including an approach to evaluating "inerts" that reflects NOSB recommendations.
3. Background Overview with:

a. Crucial Facts—important background about "inert" ingredients.
b. Crucial Elements of NOSB Recommendations—in which we pull out parts of past NOSB recommendations upon which we build.

1. Scope of the "inerts" requiring review.

In the Advanced Notice of Proposed Rulemaking (ANPR),[2] AMS is inconsistent and misleading in characterizing and estimating the number of "inert" ingredients used in organic production and therefore the time and process needed to complete a review. AMS says: "For organic crop and livestock production, current USDA organic regulations allow EPA List 3 and List 4 inert ingredients to be used in pesticide products when the product includes active ingredients permitted by the organic regulations. Together, EPA List 3 and List 4 include more than 2,700 inert ingredients. AMS does not know how many of these inert ingredients are included in products used in organic production, but it is likely a relatively small subset of these 2,700 ingredients. . . 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. . . Specifically, this option [listing former List 3 and List 4 "inerts" individually] would . . . [r]equire a sunset review of approximately 190 substances currently in use in organic-compliant pest control products every five years as required by OFPA at 7 U.S.C. 6517(e)."

In fact, as NOP/AMS is aware, the NOP's previously established Inerts Working Group (IWG), through queries to the Organic Materials Research Institute (OMRI) and the Washington Department of Agriculture (WDA), both of which conduct materials reviews of products used in organic production, compiled a list of such materials. That list is included in *"Inert" Ingredients in Organic Production*.[3] It contains 127 substances. In fact, AMS has included in the docket a spreadsheet developed by OMRI, which identifies 130 synthetic "inerts" in products used in organic production as of 2011. More may have been added during the time that AMS has delayed its review, but the total requiring review is certainly not "hundreds."

OMRI updated this list, including "inerts" in products allowed by Pennsylvania Certified Organic (PCO), and it was posted to the ANPR docket.[4] In Beyond Pesticides' review of the updated spreadsheet posted to the docket, we find the following:

- There are 301 "inerts" in products listed by OMRI and/or PCO.
- Of the 301, 128 are 25(b), leaving 173.

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[2] https://www.regulations.gov/document/AMS-NOP-21-0008-0001 and https://www.regulations.gov/document/AMS-NOP-21-0008-0016.
[3] Shistar, T., 2017. *"Inert" Ingredients in Organic Production.* https://www.beyondpesticides.org/assets/media/documents/Inert%20Ingredients%20in%20Organic%20Production.FULLreport.final.pdf.
[4] https://www.regulations.gov/document/AMS-NOP-21-0008-0013.

- Of the 173, 36 are “nonsynthetic,” "possibly nonsynthetic," or water. If these are classified nonsynthetic, it would leave 137 requiring review.

(Please see additional discussion on this in the background section of these comments. The spreadsheet in the current discussion document’s Appendix A fails to include the synthetic/nonsynthetic distinction, but other numbers are close, as discussed below.)

It should be noted that the exact number is not important to AMS’ statutory responsibility to review these synthetic ingredients allowed in organic production and processing. What is important is that AMS establish and carry out the required review, which is a manageable list of substances. It is **not** “hundreds” or thousands as intimated by AMS.

This list—or any update to it produced by AMS—must be published immediately in the Federal Register, with a request that registrants of products approved for use in organic production notify AMS of the “inert” ingredients contained in their products.

2. A Proposal for NOSB Action

In Beyond Pesticides’ 2017 report *“Inert” Ingredients in Organic Production*, we laid out in detail a process for evaluating former List 4 “inerts” that conforms to the 2015 NOSB recommendation. AMS insists that the procedure that relies on EPA’s Safer Choice Program [a voluntary partnership program that reviews all product ingredients for Safer Choice labeling] is not feasible, so the following suggestion is based on the 2012 NOSB recommendation.

It is important to recognize that the NOSB must evaluate for National List consideration only **synthetic** “inert” ingredients. Furthermore, the **immediate** need is to evaluate those synthetic “inert” ingredients in products currently used in organic production. There are approximately 137 (based on the spreadsheet posted in the docket) of these, which are identified by OMRI and contained in its 2022 spreadsheet. We understand a few more may be identified. In comments to the NOSB, we and the National Organic Coalition (NOC) have reiterated the proposal contained in our report. In the spirit of this discussion, we recommend a memorandum of understanding (MOU) between USDA and EPA be developed.

The memorandum of understanding (MOU) with EPA should finalize the agreement between NOP and EPA to spell out the details of how the recommendation would be implemented. The MOU should contain specific reviews required. The MOU should specify the NOSB materials review process and the analysis required for compliance with OFPA. Below is a description of the procedure for evaluating “inerts” that should be covered by the MOU, based on the NOSB recommendations made in Fall 2012.

Discussion of Procedure

Our proposal creates a five-year timeframe for evaluation of “inert” ingredients currently in use in organic agriculture that are not exempt from pesticide registration under

FIFRA section 25(b). This includes former EPA List 4 that were identified through information supplied by the Material Review Organizations (MROs) OMRI, PCO (Pennsylvania Certified Organic), and WSDA (Washington State Department of Agriculture). It also will include a call for other “inert” ingredients. This list so far is approximately 137 individual substances in 16 groups of chemicals.[5]

We propose review by classes or groups, rather than by individual substance. Allowing a class of substances to be evaluated by group will more efficiently allow the Board to individually review each substance previously allowed under the exemption for former List. For the purposes of these comments, only the group names are provided. However, the substances that are recommended by NOSB would be included by individual names and CAS numbers, entered as the class is reviewed, under 205.601(m) and 205.603(e) above. Below are the proposed groups, with approximate numbers of materials in each group:

1. Alkyl alcohols - 3
2. Alkyl alkoxylates - 4
3. Alkylphenol ethoxylates - 9
4. Dyes - 2
5. EDTA and salts - 2
6. Fatty acid ethoxylates - 4
7. Fatty acids esters and salts - 6
8. Low risk polymers, as defined under 40 CFR 180.960 - 8
9. Mineral acids, bases and their inorganic salts -22
10. Organic acids and salts - 3
11. Polyalkoxlylates and polyalkoxylated alkyl ethers - 5
12. Polysorbates - 5
13. Preservatives/antioxidants - 7
14. Tall oil and terpene derivatives - 5
15. Nonsynthetic - 14
16. Others - 27

A newly formed IWG should work in consultation with EPA and the NOSB to categorize some of the many substances in the "other" category into additional or existing groups. The proposal containing full group listing, including the list of chemicals, should be presented at the Fall 2024 NOSB meeting. Those substances identified as “nonsynthetic” or “possibly nonsynthetic” by OMRI or PCO should be removed from the list pending classification actions.

We expect that 4-6 groups of chemicals will be evaluated every year during the four-year period beginning in 2023. Should manufacturers identify ingredients in use that are not on the list for review, they will have time to come forward with a request for review. After this process is complete, manufacturers will be required to petition for the addition of new “other

[5] Previously, 126 substances, so some of the numbers in the categorized list below based on the 2012 numbers will be wrong.

ingredients" or "inerts," in pesticide formulations to the National List.

Given the scope of Technical Reviews (TRs) and NOSB evaluation of these materials, it is recognized that completion of this process will take substantial resources and time. NOP must devote adequate resources to this long-overdue project. The reviewers should be hired and overseen by the NOSB, as provided in OFPA §6518(j). The current projected timeline will involve NOSB completion of all reviews by its Fall 2026 public meeting to enable the NOP to complete rulemaking by April 2028, the sunset date for List 4 "inerts."

Because of the work associated with this review process, the NOSB may assess the viability of the timeline after it completes the recommendation on the first few groups of materials.

Proposed Procedure

A. The NOSB requests NOP to adopt within three months of the announcement of this proposal the appropriate mechanism for notifying manufacturers and the public regarding the "inerts" review process, including which "inerts" are under review and how to inform the newly appointed IWG of "inerts" that are in use, but not on the list under review.
B. The NOSB will work with the IWG to finalize groups and screening steps.
C. The NOSB will rely on the IWG to consult with MROs for updated "inerts" lists in case there are new "inerts" to add to the groups.
D. The NOSB requests NOP to commission one TR per group, except where noted, and coordinate review with the Board.
E. The NOSB requests NOP to determine an appropriate format and commission a special "inerts" TR for each group to contain the following:
    a. a chart of all substances in the group by CAS number with their chemical properties, uses, types of product categories in which they occur, EPA regulatory status, including data gaps.
    b. a description of how substances within group are related and how different, especially outliers that are significantly different from others.
    c. a chart that evaluates each substance in the group under the screening steps suggested by NOSB and any additional screening recommended by the NOSB, with input from the IWG.
F. Based on results of group TR, the NOSB Crops and/or Livestock Subcommittee accepts group to move forward to NOSB agenda, or singles out one or more for individual review. The group will then move forward without the singled out one and that one will be re-reviewed in more detail if necessary.
G. The NOSB, working with the IWG, will prioritize the order of reviews so that the most potentially problematic are reviewed first. The others can be done later and some may not need full TRs. Priority will also be given to fully disclosed ones that have been petitioned and may fall outside one of the groups. In setting priorities, there will be consideration of the amount used in organic production, if that can be determined.
H. The anticipated timeline will enable the NOSB to finalize the procedure by Fall 2024,

start reviews for Fall 2024 and to have as many reviews completed as possible by Fall 2025. The intention is to have an amendment to the National List in 2028, which will address the materials reviewed with an implementation period of 2 - 5 years, taking into account public comment and the need for additional reviews for reformulation and compliance.

I. By the time of the five-year sunset period the NOSB will approach a review of those "inert" substances permitted for use in minimal risk products exempt from pesticide registration under FIFRA section 25(b).

1. This timeframe is now delayed by 12 years since the 2012 NOSB recommendation—finalizing the procedure in 2024, resulting in completed reviews of all "inerts" in 2027.By July 1, 2024, NOP publishes in the *Federal Register* a list of "inert" ingredients known to be used in organic production, with a request that within 30 days, any manufacturer of a pesticide product used in organic production that wants to continue to use another "inert" not on the list notify NOP of the identity of that substance.
2. Replace the existing listings at §601(m) and §603(e) with the following:
   1) *Non-active ingredients exempt from the requirement of a tolerance under 40 CFR 180.1122 that were formerly on EPA List 3 in passive polymeric dispenser products: 2-(2-Hydroxy-3-tert-butyl-5-methylphenyl)-5-chlorobenzotriazole (CAS # 3896-11-5); 2, 2-Hydroxy-4-n-octyloxybenzophenone (CAS # 1843-05-6); Butylated hydroxytoluene (BHT) (CAS # 128-37-0); other such substance that may be revealed to the NOSB by [date]. The sunset date for these substances shall be the same as that currently set for List 3 "inert" ingredients.*
   2) *Non-active ingredients that are permitted in "minimum risk pesticide" products that are exempt from registration as described in the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and codified at 40 CFR 152.25(f)(2));*
   3) *As synthetic other ingredients not classified by the Environmental Protection Agency (EPA) as active ingredients, 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:*

      To sunset May 1, 2027 and every 5 years thereafter:

Alkyl alcohols
Hexanol (CAS# 111-27-3)
1-Butanol (CAS# 71-36-3)
Ethanol (CAS# 64-17-5)
Alkyl alkoxylates
Alcohols, C11-15-secondary, ethoxylated (CAS# 68131-40-8)
Alcohols, C12-15, ethoxylated propoxylated (CAS# 68551-13-3)
Alcohols, C12-18, ethoxylated propoxylated (CAS# 69227-21-0)
Alcohols, C9-16, ethoxylated (CAS# 97043-91-9)

Poly(oxy-1,2-ethanediyl), alpha.-hydro-.omega.-hydroxy-, mono-C11-14-isoalkyl ethers, C13-rich, phosphates (CAS# 78330-24-2)
Polyoxyethylene 2,6,8-trimethyl-4-nonyl ether (CAS# 60828-78-6)
Polyoxyethylene dodecyl mono ether (CAS# 9002-92-0)
Polyoxyethylene mono(cis-9-octadecenyl) (CAS# 9004-98-2)
Alkylphenol ethoxylates
p- Nonylphenol, ethoxylated (CAS# 26027-38-3)
Polyoxyethylene (1,1,3,3-tetramethylbutyl)phenyl ether (CAS# 9036-19-5)
Polyoxyethylene dodecylphenol (CAS# 9014-92-0)
Polyoxyethylene nonylphenol (CAS# 9016-45-9)
Fatty acid ethoxylates
Polyoxyethylene monolaurate (CAS# 9004-81-3)
Polyoxyethylene monooctadecyl ether (CAS# 9005-00-9)
Polyoxyethylene monooleate (CAS# 9004-96-0)
Polyoxyethylene monostearate (CAS# 9004-99-3)

To sunset May 1, 2028 and every 5 years thereafter:

Dyes
Copper phthalocyanine blue (CAS# 147-14-8)
FD&C Red No. 40 (CAS# 25956-17-6)
EDTA and salts
Ethylenediaminetetraacetic acid (EDTA) (CAS# 60-00-4)
Ethylenediaminetetraacetic acid (EDTA), tetrasodium (CAS# 64-02-8)
Fatty acids, esters and salts
Fatty acids, C16-18 & C18-unsatd., Me esters (CAS# 67762-38-3)
Fatty acids, C16-18 and C18-unsatd (CAS# 67701-08-0)
Methyl oleate (CAS# 112-62-9)
Polyglyceryl Phthalate Ester of Coconut Oil Fatty Acid (CAS# 66070-87-9)
Potassium coconut oil soap (CAS# 61789-30-8)
Potassium salts of fatty acids (C8-18 and C18 unsatd.) (CAS# 67701-09-1)

Low Risk Polymer as defined under 40 CFR 180.960
Acrylic acid polymer (CAS# 9003-01-4)
Acrylic acid polymer, sodium salt (CAS# 9003-04-7)
Dimethyl silicone polymer with silica (CAS# 67762-90-7)
Polyvinyl acetate (CAS# 9003-20-7)
Polyvinyl chloride resin (CAS# 9002-86-2)
Polyvinylpyrrolidone (CAS# 9003-39-8)
Rosin, maleated, polymer with pentaerythritol (CAS# 68333-69-7)
Vinyl alcohol-vinyl acetate copolymer (CAS# 25213-24-5)
Organic acids and salts
Acetic acid (CAS# 64-19-7)
Octanoic acid (CAS# 124-07-2)
Propanoic acid (CAS# 79-09-4)

To sunset May 1, 2029 and every 5 years thereafter:

Mineral acids, bases, and inorganic (their) salts
Acetic acid, ammonium salt (CAS# 631-61-8)
Ammonium chloride (CAS# 12125-02-9)
Ammonium hydroxide (CAS# 1336-21-6)
Ammonium phosphate (monobasic) (CAS# 7722-76-1)
Calcium chloride (CAS# 10043-52-4)
Calcium hydroxide (CAS# 1305-62-0)
Calcium oxide (CAS# 1305-78-8)
Carbonic acid, dipotassium salt (CAS# 584-08-7)
Carbonic acid, disodium salt (CAS# 497-19-8)
Diammonium phosphate (CAS# 7783-28-0)
Diphosphoric acid, tetrasodium salt (CAS# 7722-88-5)
Disodium phosphate (CAS# 7558-79-4)
Hydrogen chloride (CAS# 7647-01-0)
Phosphoric acid (CAS# 7664-38-2)
Potassium hydroxide (CAS# 1310-58-3)
Potassium phosphate (dibasic) (CAS# 7758-11-4)

Potassium phosphate, monobasic (CAS# 7778-77-0)
Silicic acid (H2SiO3), disodium salt (CAS# 6834-92-0)
Sodium acid pyrophosphate (CAS# 7758-16-9)
Sodium tripolyphosphate (CAS# 7758-29-4)
Sulfuric acid (CAS# 7664-93-9)
Tricalcium phosphate (CAS# 7758-87-4)

To sunset May 1, 2030 and every 5 years thereafter:

Organic acids and salts
Acetic acid (CAS# 64-19-7)
Octanoic acid (CAS# 124-07-2)
Propanoic acid (CAS# 79-09-4)
Polyalkoxylates and polyalkoxylated alkyl ethers
Oxirane, methyl-, polymer with oxirane, mono[2-(2-butoxyethoxy) ethyl] ether (CAS# 85637-75-8)
Polyethylene glycol (CAS# 25322-68-3)
Polyethylene glycol ether with 1,4-diisobutyl-1,4-dimethylbutynediol (2:1) (CAS# 9014-85-1)
Polyethylene-polypropylene glycol, monobutyl ether (CAS# 9038-95-3)
Polyoxyethylene-polyoxypropylene copolymer (CAS# 9003-11-6)
Polysorbates
Polyoxyethylene sorbitan monolaurate (CAS# 9005-64-5)
Polyoxyethylene sorbitan monooleate (CAS# 9005-65-6)
Polyoxyethylene sorbitan trioleate (CAS# 9005-70-3)
Polyoxyethylene sorbitan tristearate (CAS# 9005-71-4)
Polyoxyethylene sorbitol hexaoleate (CAS# 57171-56-9)
Preservatives / Antioxidants
Benzoic acid (CAS# 65-85-0)
Butylated hydroxytoluene (BHT) (CAS# 128-37-0)
Calcium propionate (CAS# 4075-81-4)
Ethoxyquin (CAS# 91-53-2)
Methyl p-hydroxybenzoate (CAS# 99-76-3)
Propyl p-hydroxybenzoate (CAS# 94-13-3)
Sorbic acid (CAS# 110-44-1)

Tall oil and terpene derivatives
Copolymer of alpha- and beta-pinene (CAS# 31393-98-3)
Homopolymer of alpha-pinene (CAS# 25766-18-1)
Homopolymer of beta-pinene (CAS# 25719-60-2)
Tall oil (CAS# 8002-26-4)
Terpenes and terpenoids, terpentine oil, alpha-pinene fraction polymerized (CAS# 70750-57-1)

To sunset May 1, 2031 and every 5 years thereafter:

Other
Hydroxyethylidene-1,1-diphosphonic acid (CAS# 2809-21-4)
1,1-difluoroethane (CAS# 75-37-6)
2-(2-hydroxy-3-tert-butyl-5-methylphenyl)-5-chlorobenzotriazole (CAS# 3896-11-5)
2,2-hydroxy-4-n-octyloxybenzophenone (CAS# 1843-05-6)
Aluminum sulfate (CAS# 10043-01-3)
Benzopyran-6-ol,3,4-dihydro-2,5,7,8-2H-1-tetramethyl-2-(4,8,12-trimethyltridecyl)- (CAS# 10191-41-0)
Castor oil, ethoxylated (CAS# 61791-12-6)
Chitosan (CAS# 9012-76-4)
Corn steep liquor (CAS# 66071-94-1)
Dodecyl sulfate, sodium salt (CAS# 151-21-3)
Ethylenediamine-N,N'-disuccinic acid (EDDS) (CAS# 20846-91-7)
Lignosulfonic acid, calcium salt (CAS# 8061-52-7)
Lignosulfonic acid, sodium salt (CAS# 8061-51-6)
Manganese sulfate monohydrate (CAS# 10034-96-5)
N,N-Bis(2-hydroxyethyl)(coconut oil alkyl)amine (CAS# 61791-31-9)
Naphthalenesulfonic acid, polymer with formaldehyde, sodium salt (CAS# 9084-06-4)
Oxirane, methyl-, polymer with oxirane, mono[3-[1,3,3,3-tetramethyl-1-[(trimethylsilyl)oxy]disiloxanyl]propyl] ether (CAS# 134180-76-0)

Oxirane, methyl-, polymer with oxirane, mono-2-propenyl ether (CAS# 9041-33-2)
Poly(oxy-1,2-ethanediyl),.alpha.-undecyl-.omega.-hydroxy-, branched and linear (CAS# 127036-24-2)
Poly(oxy-1,2-ethanediyloxycarbonyl-1,4-phenylenecarbonyl (CAS# 25038-59-9)
Polyoxyethylene tristyrylphenol phosphate, potassium salt (CAS# 163436-84-8)
Polypropylene glycol (CAS# 25322-69-4)
Propylene glycol (CAS# 57-55-6)
Silicones and siloxanes, dimethyl (CAS# 63148-62-9)
Sodium bis(2-ethylhexyl) sulfosuccinate (CAS# 577-11-7)
Sorbitan monostearate (CAS# 1338-41-6)
Titanium dioxide (CAS# 13463-67-7)
Tridecanol, ethoxylated, phosphate ester (CAS# 26915-70-8)
Triethanolamine, compd. with poly(oxyethylene) tristyrylphenyl ether (CAS# 105362-40-1)
Tannic Acid (Tannin) (CAS# 1401-55-4)
[Others as revealed in response to Federal Register notice.]

The exact assignment of "inert" ingredients to the review groups can, of course, be adjusted to meet the convenience of the NOSB and contracted reviewers. However, we feel it necessary to lay out a workable possibility in order to get started.

3. Background Overview: a. Crucial Facts

"Inert" ingredients are not necessarily chemically or biologically inert.

In fact, the same chemical may be used as an "active" ingredient in one formulation and an "inert" ingredient in another. The Beyond Pesticides "Inerts" Report[6] compares toxicological

[6] Shistar, T., 2017. *"Inert" Ingredients in Organic Production.* https://www.beyondpesticides.org/assets/media/documents/Inert%20Ingredients%20in%20Organic%20Production.FULLreport.final.pdf.

characteristics of "inert" and "active" ingredients found in pesticides used in organic production. The table below is taken from that report and summarizes hazards of "inerts" and synthetic active ingredients used in organic production. From this summary, it is clear that so-called "inert" ingredient review and assessment to organic standards are seriously overdue and cannot continue to be ignored.

Table 4. Total Number of Synthetic Active and "Inert" Ingredients Used in Organic Production by Categories of Harm

	Acute toxicity	Neurotoxic	Carcinogenic	Developmental / Reproductive	Kidney/Liver Damage	Sensitizer	Endocrine Disruption	Soil Mobility	Toxic to Birds	Aquatic toxicity	Toxic to bees
Number of actives	8	1	2	6	2	8	1	1	1	19	5
Number of "inerts"	20	4	4	5	4	15	4	1	0	65	4

Secrecy and "inerts"

In general, "inert" ingredients are not listed by name on pesticide labels. Labels contain a categorical statement of the percentage of "inert" or "other" ingredients. The exceptions are the most toxic (former List 1) and those products allowed under Section 25(b) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)–minimum risk pesticides, which require full disclosure of all product ingredients. The 25(b) minimum risk pesticides "have been determined to be of a character not requiring regulation under FIFRA and are therefore exempt from all provisions of FIFRA when intended for use, and used, only in the manner specified." All ingredients, including "inert" ingredients, used in minimum risk pesticide products must be listed on the label.

"Inert" Ingredients Comprise the Largest Part of Pesticide Products

NOP and the NOSB cannot continue to ignore the fact that when a substance is added to the National List, it is not used in organic production by itself, but is a (usually minor) ingredient in a formulation. Since, as shown above, the "inert" ingredients may be more toxic than the approved active ingredients, **NOP and the NOSB have been allowing unknown toxic mixtures to be applied to organic crops and livestock**. They are applied not only in products containing approved National List materials, but also in products in which the active ingredient is nonsynthetic, which require no NOSB review. For example, we looked at a few randomly-selected labels of Organic Materials Review Institute (OMRI)-approved products in which the percentage of "inert" ingredients is shown in Table 1.

Table 1	
Product	**Percent "inerts" on label**
Azera	97.4
Brandt Lime Sulfur	71.0
GreenClean Pro	15.0
Safer Soaps	50.48
Thuricide	30.0

Background Overview: b. Crucial Elements of NOSB Recommendations

NOSB recommendations on "inert" ingredient review have been amplified over the years, as the Board tried to respond to reluctance by NOP/AMS to undertake the necessary review. However, there are some important elements that have not changed.

NOP and the NOSB must, as soon as possible, compile and publish a list of all "inerts" used in organic production.

NOSB minutes of the February 11, 1999 meeting record the following:

> Motion: Joint Crops and Materials Committees– Eric Sideman moves that the NOSB/NOP send a letter to be modified as needed by NOP to manufacturers of pesticides formulations used in organic production requesting lists of ingredients, including inert ingredients.
>
> Second: Rod Cossley
>
> Discussion: USDA will create/finesse a new draft, and clear it through the NOSB. Call for the vote
>
> Vote:
> Those In Favor: Unanimous

This has so clearly been the obvious first step to evaluating "inerts" that in its response to the Fall 2012 NOSB meeting, NOP in the past has said that it intended to conduct a public notification and comment process, including notification to the public of "inert" ingredients known to be used in organic production and NOSB's review plan. As a part of this, NOP has said it would issue a request for public comments regarding any other "inert" ingredients that at the time were used in organic production but were not identified on the list provided by NOP. It said that changes to the National List would be considered after NOSB completion of "inerts" review. In the Spring of 2012, NOP reiterated its intention and said that a Federal Register notice to this effect was in review. Nevertheless, NOP has failed to take this first step and omits any mention of it in the ANPR or the current request for comments.

"Inerts" formerly on List 3 should be addressed separately from those formerly on List 4.

As NOP/AMS knows, the "inerts" formerly on List 3 used in organic production have been identified in a discussion document by the IWG, submitted to the NOSB by the Crops Subcommittee.[7] EPA's former List 3, "Inerts of Unknown Toxicity," contains many substances, but their use in organic production was always limited, and the regulations state, "EPA List 3 - Inerts of unknown toxicity - for use only in passive pheromone dispensers." According to the IWG, there appear to be only four of these. These List 3 "inerts" were all reclassified by the time the IWG was examining them. This makes AMS's estimate of the number of affected chemicals particularly misleading and disingenuous.

The IWG discussion document said:

> At this time the Working Group (including EPA) is only aware of 4 List [3] inerts that are currently in use in pheromone dispensers used in organic production, three of them have been disclosed via petition to the NOSB:
> - 2-(2-Hydroxy-3-tert-butyl-5-methylphenyl)-5-chlorobenzotriazole (CAS # 3896-11-5)
> - 2, 2-Hydroxy-4-n-octyloxybenzophenone (CAS # 1843-05-6)
> - Butylated hydroxytoluene (BHT) (CAS # 128-37-0)
> - one other surfactant.

Of these, the first is now approved for nonfood use only, so it should not be in pheromone dispensers used in food production. EPA defines **"Nonfood Use Only"** as "Permitted solely for use in pesticide products applied to nonfood use sites, such as ornamental plants, highway right-of-ways [sic], rodent control, etc. Food use is not permitted." The second is a light stabilizer approved for food and nonfood use and is subject to restrictions applying to fragrances in nonfood uses (not more than 0.2% of formulation).[8] The third is an antioxidant approved for food and nonfood use and is subject to restrictions applying to fragrances in nonfood uses.[9]

> At the Spring 2012 meeting, the NOSB adopted a four-part recommendation:
> Statement of the Recommendation (Including Recount of Vote):
> First Motion:
> Be it Resolved,
> It is the understanding of the NOSB that the NOP is committed to expediting the review of all inert ingredients as soon as possible and will support the NOSB in creating a plan for inerts review and accompanying workplan for the crops committee to complete this work.
> Committee Vote
> Moved: Jay Feldman Second: Zea Sonnabend
> Yes 15 No 0 Abstain 0 Absent 0 Recuse 0

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[77] "Inert Ingredients Discussion Document," October 11, 2011.
[8] 40 CFR 180.920.
[9] 40 CFR 180.910 (crops) and 40 CFR 180.930 (animals).

Second Motion:
[The italicized text indicates amendments to the regulatory language. Deleted text is indicated with a strike-through line.]
List: 205.601 Synthetic substances allowed for use in organic crop production.
(m) As synthetic ~~inert~~ *other* ingredients *not* ~~as~~ classified by the Environmental Protection Agency (EPA) *as active ingredients*, 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.
2) *Inert ingredients exempt from the requirement of a tolerance under 40 CFR 180.1122 that were formerly on EPA List 3 in passive polymeric dispenser products may be used until October 21, 2017.*
Committee Vote
Moved: Jay Feldman Second: Zea Sonnabend
Yes 15 No 0 Abstain 0 Absent 0 Recuse 0

Third Motion:
§ 205.2 Terms defined.
Passive polymeric dispenser products. *Solid matrix dispensers delivering pheromones through volatilization only at rates less than or equal to 150 grams active ingredient (AI)/acre/year that are placed by hand in the field and are of such size and construction that it is readily recognized and retrievable. [59 FR 7368, March 30, 1994.] To be removed as a definition when 205.601(m)2(a) and (b) expire.]*
Committee Vote
Moved: Jay Feldman Second: Harold Austin
Yes 15 No 0 Abstain 0 Absent 0 Recuse 0

Fourth Motion:
Committee Backup Vote to Relist:
List: 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 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.
(2) EPA List 3—Inerts of unknown toxicity—for use only in passive pheromone dispensers.
Committee Vote
Moved: Jay Feldman Second: Zea Sonnabend
Yes 15 No 0 Abstain 0 Absent 0 Recuse 0

This recommendation was adopted during the consideration of the sunset of List 3 "inerts" at a time when the NOSB's Policy and Procedure Manual allowed annotations at sunset with the inclusion of a backup relisting motion that would give USDA time to move the

recommended change through the regulatory system. NOP violated the procedure established with the NOSB and chose to only adopt the backup motion. This violation of trust between the NOSB and NOP/AMS only served to weaken public trust in the organic label and the underlying stakeholder process that is foundational to the organic market and its growth.

Along with the IWG discussion document, this recommendation sets a clear course of action for resolving the listing of List 3 "inerts." Therefore, further discussion should be limited to those "inerts" formerly on List 4.

The listings for List 3 "inerts" in §601 and §603 should be replaced with the following:

(m) 2) Inert ingredients used in passive polymeric dispenser products:

(i) 2, 2-Hydroxy-4-n-octyloxybenzophenone (CAS # 1843-05-6)

(ii) Butylated hydroxytoluene (BHT) (CAS # 128-37-0)

(iii) [others as revealed in response to AMS FR notice].

§ 205.2 Terms defined.

Passive polymeric dispenser products. Solid matrix dispensers delivering pheromones through volatilization only at rates less than or equal to 150 grams active ingredient (AI)/acre/year that are placed by hand in the field and are of such size and construction that it is readily recognized and retrievable.[10]

Since the listings on the National List are subject to sunset review, they will be reviewed after five years. Any new chemicals approved by EPA for food use and exempt from the requirement of tolerance may be petitioned for the use through the NOSB's petition process. As stated above, this action will resolve the listing of List 3 "inerts." Therefore, further focus on resolving the serious "inerts" review problem should be limited to those "inerts" formerly on Lists 4A and 4B.

"Inerts" formerly on Lists 4A and 4B must be addressed as individual substances.

The NOSB has sought, over the past 24 years, to establish a process for evaluating individual "inert" materials. In 1999, the NOSB identified the first step as "requesting lists of ingredients, including inert ingredients" used in organic production. The IWG compiled a list of such "inert" ingredients and suggested that it be separated into groups of similar chemicals for review. Subsequent recommendations by the NOSB have sought ways to facilitate review of those materials. The requirement goes back to the Senate Report accompanying OFPA, which says,

> Until such time as FIFRA is altered to require the full disclosure of inert ingredients, organic farmers should be allowed to continue using compounded substances if the active ingredient is natural and if use of the substance is recommended by the National Organic Standards Board and approved by the Secretary

[10] 59 FR 7368, March 30, 1994.

for inclusion on the National List. However, in order for the National Organic Standards Board to evaluate whether certain compounds should be listed, the Board will need some information about the inert ingredients in question. The Committee directs the Board to seek the advice of the Administrator of the EPA, who has information on inert ingredients submitted as part of registration, as to whether such inert material would be appropriate for organic production. EPA's response will not limit its regulatory responsibility for material.

Thus, Congress directs the NOSB and USDA to seek information from EPA on individual "inert" ingredients and evaluate their consistency with the standards of organic production, as required by law.

Resource Issues

It must be reemphasized that the evaluation of so-called "inert" synthetic ingredients in products used in organic production is not optional. It is required by law.[11] NOP must allocate resources for this project. Recent appropriations have increased for NOP, and some of this money must be used for the evaluation of "inert" ingredients, which may be the most hazardous ingredients and make up the largest part of a pesticide product. Staff must be hired or contracted to perform reviews of "inert" ingredients, and those staff must be under the direct control of the NOSB.[12]

Questions posed by the MS:

1. **Please provide feedback on the format and analysis of Appendix A. The Board will use this to comprehend the practical impact the various options will have on the number of substances that would need to be added to the National List based on the corresponding option (e.g. if all inerts are listed individually or that would be allowed under various subsets of EPA regulations depending on the option)?**

   The spreadsheet is not an analysis. An analysis would have posed questions that are meaningful to the evaluation of the materials. It provides some of the information needed for an analysis, but fails to ask the most important question. The question that should have been asked first and included in the spreadsheet is, "Is the substance synthetic or nonsynthetic?" This question, along with the question that <u>was</u> asked, "Is it used in organic production?" would reduce the universe of "inerts" to be evaluated to approximately 137, according to our analysis of the spreadsheet included in the ANPR docket. The column for 40 CFR 152.25, or "inerts" eligible for use in minimum risk pesticides, is also helpful in

[11] The Organic Foods Production Act (OFPA), §6517 allows the use of a synthetic substance in organic production only if it is listed on the National List "by specific use or application" based on a recommendation by the NOSB, following procedures in OFPA.

[12] See OFPA §6518(j) "The Secretary shall authorize the Board to hire a staff director and shall detail staff of the Department of Agriculture or allow for the hiring of staff and may, subject to necessary appropriations, pay necessary expenses incurred by such Board in carrying out the provisions of this chapter, as determined appropriate by the Secretary."

evaluating the materials. If a substance is not found in any reference in EPA's regulations, the researchers should determine whether it is allowed in pesticide products.

2. **What areas of expertise should the MS consider when inviting speakers to subcommittee meetings in order to obtain the fullest and most accurate understanding of this topic?**

   The MS should attempt to get the input of the EPA staff who participated in the Inerts Working Group, since they could answer questions about which "inerts" are currently allowed, as well as how EPA's standards differ from those of OFPA. There have been NOSB members in the past who had relevant expertise and the desire to solve this problem—including Jay Feldman and Asa Bradman. The MS should also look for those who have experience with pesticides and "inert" ingredients—including Caroline Cox, who studied "inerts" extensively while at the Northwest Center for Alternatives to Pesticides and the Center for Environmental Health, and Bill Freese of Center for Food Safety. The identified experts should make up a revitalized IWG that can be overseen by the NOSB as it does its work—rather than simply providing one-time input.

3. **Please provide feedback on whether the list of inert ingredients currently in use (see Appendix A), is accurate.**

   We have no information about "inerts" in use in organic production other than that presented in Appendix A or the spreadsheet posted to the ANPR docket.

4. **Does the potential reduction in the number of substances the Board must review outweigh the inflexibility associated with the option to develop a single, external list of allowed inert ingredients?**

   All synthetic substances used in organic production must be reviewed according to OFPA criteria, included on the National List, and subject to regular sunset review.

5. **Would designation of a specific entity responsible for maintaining the single external list of allowed inert ingredients change stakeholder's opinions of this option?**

   All synthetic substances used in organic production must be reviewed according to OFPA criteria, included on the National List, and subject to regular sunset review.

Thank you for your consideration of these comments.

Sincerely,

Terry Shistar, Ph.D.
Board of Directors