

NOTE

This Discussion Document is presented by the **National Organic Standards Board Crops Committee** on behalf of the **NOSB-NOP-EPA Working Group on Inert Ingredients**. This document has not been approved by the Crops Committee, but comments on this document are welcomed, and will be supplied to the Working Group as they develop a final recommendation. The Crops Committee also seeks comments in particular on the status of former List 3 inert ingredients, which are currently permitted only in passive pheromone dispensers (§ 205.601(m)(2)). The allowance for former List 3 inert ingredients is scheduled to sunset on November 3, 2013; a vote to determine renewal is scheduled for the May 21-24, 2012 NOSB Meeting.

Inert Ingredients Discussion Document October 11, 2011

Background

Inert ingredients are defined in the National Organic Program (NOP) regulations, with reference to the Environmental Protection Agency (EPA) definition, to include any ingredient other than active ingredients used in pesticide products. The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) provides that inert ingredients used in pesticides do not need to be disclosed on product labels.

NOP 7 CFR §205.2 Terms Defined

Inert ingredient. Any substance (or group of substances with similar chemical structures if designated by the Environmental Protection Agency) other than an active ingredient which is intentionally included in any pesticide product (40 CFR 152.3(m)).

EPA 40 CFR 152.3 Definitions

Active ingredient means any substance (or group of structurally similar substances if specified by the Agency) that will prevent, destroy, repel or mitigate any pest, or that functions as a plant regulator, desiccant, or defoliant within the meaning of FIFRA sec. 2(a), except as provided in §174.3 of this chapter

Section 6517(c)(1)(B)(ii) of the Organic Foods Production Act of 1990 (OFPA) authorizes the National Organic Standards Board (NOSB) to establish a National List of approved and prohibited substances that may include synthetic inert ingredients that are not classified by the Administrator of the EPA as “inerts of toxicological concern.”

OFPA

7 USC 6517(c)(1) Exemption for Prohibited Substances.

The National List may provide for the use of substances in an organic farming or handling operation that are otherwise prohibited under this chapter only if
...(B) the substance

... (ii) is used in production and contains synthetic inert ingredients that are not classified by the Administrator of the Environmental Protection Agency as inerts of toxicological concern;

The NOSB, in conjunction with USDA, consulted with EPA during the development and subsequent amendments of the National List. The NOSB recommended in 1999 prohibiting List 1 and 2 inerts, and List 3 inerts that are not specifically approved by the NOSB. In 1999, the NOSB recommended that “inerts on List 4 generally be allowed unless explicitly recommended for prohibition.”¹ in spite of the fact that the EPA had by that time distinguished Lists 4A and 4B as those ingredients that were not of toxicological concern (4A), and those regarded as not causing adverse effects based on their use patterns (4B)². In 2002, the NOSB recommended that the Secretary of Agriculture allow the use of certain EPA List 3 inert pesticide ingredients in certain pheromone products.³ The Secretary accepted and codified the NOSB recommendations accordingly.

NOP regulation

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

In accordance with restrictions specified in this section, the following synthetic substances may be used 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.

(1) EPA List 4—Inerts of Minimal Concern.

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

In 2006, EPA reassessed all inert ingredients used in pesticide formulations allowed on food crops, including former Lists 3, 4A, and 4B inerts, to ensure that they met the requirements of the Food Quality Protection Act. Inerts allowed for use in EPA registered pesticides applied to food now must either have a residue tolerance level or an exemption from tolerance level codified at 40 CFR Part 180. As a result of this

¹ 1999 NOSB Recommendation available at <http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=stelprdc5058968>

² In the notice 54 FR 48314 (11/22/89), EPA said (emphasis added), “To accommodate revision of the lists, EPA has decided to subdivide List 4 into two parts. The previous list 4, representing inerts generally recorded as safe, has become List 4A, and a new List 4B has been created. List 4B is composed of inerts for which EPA has sufficient information to reasonably conclude that *the current use patterns* in pesticide products will not adversely affect public health and the environment. List 4B inerts in formulations proposed for new use patterns which cause significant increases in exposure will receive further scrutiny.” In notice 59 FR 49400 (6/28/94), EPA said, “In reviewing List 4 inert ingredients for the proposed section 25(b) rule, many inerts on the original List 4 were moved from List 4A to List 4B. In particular, acutely toxic inerts were moved to 4B because, although the testing of products for acute toxicity ensures low concern for these inerts in registered products, without such regulatory oversight there may be unacceptable acute risks.”

³ October 19–20, 2002 NOSB Meeting minutes available at <http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5057498>

reclassification, the NOP regulations concerning allowed inert ingredients are out of date when compared with current EPA regulations. The NOSB recommended in April 2010 that NOP establish a task force in collaboration with EPA to examine this problem and provide a recommendation to the board for re-evaluation of former List 3 and List 4 inerts. In October 2010, the NOSB recommended that the current exemption on the National List that permits former List 4 inerts through October 2012 should be renewed “pending review by the program of inerts individually and as a class of materials”.⁴ The current exemption that permits former List 3 inerts in passive pheromone dispensers only is scheduled to sunset November 3, 2013 and will be voted on at the May 21-24, 2012 NOSB meeting.

A NOSB-NOP-EPA working group was established in June 2010. Members include: Jay Feldman (NOSB), Tracy Miedema (NOSB), Jeff Moyers (former NOSB), Chris Pfeifer (EPA Biopesticides and Pollution Prevention Division), Kerry Leifer (EPA Registration Division), Emily Brown Rosen (NOP), Lisa Brines (NOP), and John Punzi (NOP, on detail from AMS Pesticide Data Program). The group has collected information regarding current classification of the former List 3 and 4 inerts and gave a brief presentation at the April 2011 NOSB meeting.⁵

At this point, the Working Group has developed a few options for consideration and is requesting public comment.

I. Some initial considerations for review of inert ingredients

- a. NOSB must be able to review any substance recommended for the National List according to OFPA criteria, section 6518 (m):

“Evaluation. In evaluating substances considered for inclusion in the proposed National List or proposed amendment to the National List, the Board shall consider:

1. The potential of such substances for detrimental chemical interactions with other materials used in organic farming systems;
2. The toxicity and mode of action of the substance and of its breakdown products or any contaminants, and their persistence and areas of concentration in the environment;
3. The probability of environmental contamination during manufacture, use, misuse or disposal of such substance;
4. The effect of the substance on human health;
5. The effects of the substance on biological and chemical interactions in the agroecosystem, including the physiological effects of the substance on soil organisms (including the salt index and solubility of the soil), crops and livestock;
6. The alternatives to using the substance in terms of practices or other available materials; and
7. Its compatibility with a system of sustainable agriculture.”

⁴ October 28, 2010 recommendation available at

<http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5087999&acct=nosb>

⁵ Available at <http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5090591&acct=nosb>

- b. This means that any EPA permitted category of “inerts” used in organic formulations would need to be reviewed. The OFPA criteria include need for use (i.e. the absence of natural alternatives) and cradle-to-grave considerations, which are not FIFRA criteria, so no list adopted under FIFRA would be satisfactory without additional consideration.
- c. In the interim, the NOSB could accept an EPA list (or lists) aligned with some of the OFPA criteria related to the potential for hazardous effects associated with use. The working group notes that the EPA’s criteria do not include need, manufacture, misuse, or disposal issues.
- d. If a baseline EPA category is accepted, the NOSB will need to provide other options for substances not covered by this list (e.g., applying OFPA criteria for review of petitioned inert ingredients).
- e. The NOSB may need to separately consider the few former List 3 chemicals that are currently in use.
- f. The WG on Inerts believes there are at least 120 substances in current use in organic production as inert ingredients that are not included in EPA’s current 25(b) list (Inerts of Minimal Concern). Most of these substances would be classified as synthetic and appear on the former EPA List 4B.

II. Proposals Under Consideration by WG-Inerts

1. Relist the allowance for former List 3 inerts “as is” for use in passive pheromone dispensers only during the 2013 Sunset review

The NOSB could renew the current exemption for former List 3 inerts for the next sunset period (i.e. through 2018). In the interim, the Working Group will continue to determine how to apply the OFPA criteria for evaluation of individual inert ingredients or categories of inerts, and provide a recommendation to NOSB for implementation by 2017, when the exemption (allowance) for former List 4 inert ingredients expires.

2. Allow the List 3 listing to sunset; former List 3 inert ingredients would need to be individually petitioned to be allowed for continued use

Guidelines for applying OFPA criteria for review of inert ingredients are still in development within the working group.

The WGI is unclear of essentiality of the approximately four former List 3 materials known to be in use. There may be alternatives to the use of these substances. This option would mean that manufacturers would need to bring forward information on lack of alternatives, safety, and environmental impacts.

The working group notes that it would be difficult for the board to review petitions in time for them to be reviewed before the November 3, 2013 sunset date for List 3 inerts. At a minimum, the NOSB may need to extend expiration date to allow

additional time for petitions and rulemaking. A channel of trade provision would also be needed.

3. Replace/amend the current listing for former List 3 inert ingredients, limiting to pheromone products.

Replacement options under consideration include the following:

- a) Inert ingredients of semiochemical dispenser products that are exempt from the requirement of a tolerance under 40 CFR 180.1122.⁶
- b) Inert ingredients for use in retrievable polymeric pheromone dispensers:⁷
 - a. Butylated hydroxytoluene (CAS # 128-37-0)
 - b. 2-Hydroxy-4-n-octyloxybenzophenone (CAS # 1843-05-6)
 - c. 2-(2-Hydroxy-3-tert-butyl-5-methylphenyl)-chlorobenzotriazole (CAS #3896-11-5)
- c) Inert ingredients for use in passive pheromone dispensers
- d) Inert ingredients for use in retrievable polymeric pheromone dispensers⁸.

4. Replace both former List 4 and List 3 references:⁹

- a) Inert ingredients eligible for FIFRA 25(b) Pesticide Products.^{10,11}

⁶ eCFR available at <http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=8e1e539122b1034803f22bdbdc391ecc&rgn=div8&view=text&node=40:24.0.1.1.28.4.19.70&idno=40>

⁷ Or, alternatively, “Inert ingredients for use in for use in passive pheromone dispensers.”

⁸ Defined as a “solid matrix dispenser” delivering pheromones “at rates less than or equal to 150 grams active ingredient (AI)/acre/year” that is “placed by hand in the field and is of such size and construction that it is readily recognized and retrievable.” 59 FR 7368, March 30, 1994. (<http://frwebgate2.access.gpo.gov/cgi-bin/TEXTgate.cgi?WAISdocID=9xi50t/3/1/0&WAISaction=retrieve>) The notice says, “First, the proposal incorporates features that would limit the direct dietary exposure to the arthropod pheromones used as pesticides by requiring the formulation to be restricted to larger dispensers. This formulation restriction will limit exposure to an active ingredient resulting from the small amount that volatilizes from the dispenser and subsequently may deposit on food crops. Due to its size, the dispenser itself, with or without any remaining active ingredient, is not likely to become incorporated into food. Second, the Agency believes that an annual rate limitation of 150 grams AI/acre and a restriction to retrievably sized dispensers are likely to limit the dietary exposure to what is no greater than that found naturally in food as a result of heavy infestations of the pest arthropods. An arthropod species becomes a pest only if its populations reach levels that impede economic returns. The Agency believes there already has been dietary exposure to the arthropod pheromones deposited after volatilization from natural heavy pest infestations that could be shown to control such pest species.”

⁹ Inert ingredients not included would need to be individual petitioned, pending additional criteria adopted by NOSB.

¹⁰ http://www.epa.gov/opprd001/inerts/section25b_inerts.pdf

¹¹ Does not include synthetic former List 3 inerts known to be in use in pheromone products.

- b) Inert ingredients exempt from the requirement of a tolerance under 40 CFR 180.910, 180.920, 180.930, 180.940, 180.950, 180.960 and/or 180.1122.¹²
- c) Individual listings of inerts.
- d) Inert ingredients as permitted by the Environmental Protection Agency.¹³
- e) Hybrid approach – Class(es) of inerts plus individual listings.
- f) Classes of inerts, minus specific ones.

III. Issues and Discussion

1. Consider inert ingredients eligible for use in minimal risk pesticide products under FIFRA Section 25(b)

Under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) 25(b)(2), EPA may exempt from the requirements of FIFRA any pesticide that is “of a character unnecessary to be subject to [FIFRA]”. Regulations at §152.25(f) implement 25(b).

Restrictions on which ingredients may be used in minimum risk pesticide products are key aspects of the exemption, since the properties of these specific ingredients are the reason EPA exempted minimum risk pesticide products from FIFRA regulatory requirements.

The federal register notice establishing this list (61 FR 8876; Mar. 6, 1996) also noted the following:

In developing its list of exempted substances, EPA applied certain factors. Consideration was given to such factors as, (1) whether the pesticidal substance is widely available to the general public for other uses; (2) if it is a common food or constituent of a common food; (3) if it has a nontoxic mode of action; (4) if it is recognized by the Food and Drug Administration (FDA) as safe; (5) if there is no information showing significant adverse effects; (6) if its use pattern will result in significant exposure, and (7) if it is likely to be persistent in the environment.

In 2006, EPA classified 13 additional substances having tolerance exemptions under 40 CFR 180.910 and/or 180.920 as minimal risk under 40 CFR 180.950(e). The proposed rule also clarified that EPA was shifting existing tolerance exemptions for the “inert” ingredients that appear on former List 4A

¹² Includes all inert ingredients allowed for food use which are exempt from tolerance by EPA.

¹³ Would include inert ingredients for both food use and non-food use.

from that list to 40 CFR 180.950(e). 40 CFR 180.950 also includes exemptions from tolerance for certain foods, animal foods, and edible fats and oils. The current compiled list of all inerts that qualify for 25(b) exemption may be found at: http://www.epa.gov/opprd001/inerts/section25b_inerts.pdf.

The working group is aware of at least 120 inerts allowed for use in organic products that are former EPA List 4B substances that are currently in use and are not included on the 25(b) list. The majority of these substances would be classified as synthetic. If the baseline for allowance in organic products is limited to 25(b) substances, there will need to be development of an approach to apply the OFPA criteria to inert ingredients, and a phase in time to allow for reformulation and for review of petitions for substances currently allowed under the exemption for former EPA List 3 and List 4 inert ingredients.

2. Other lists of substances exempt from tolerance have been considered.

- a. EPA residue tolerance exemptions under 40 CFR 180.910 and 180.920 are established for “inert” ingredients used pre-harvest or post-harvest on crops. Exemptions under 180.930 are established for inert ingredients applied to animals. Exemptions provided under 180.940 are established for active and inert ingredients used in food-contact surface sanitizing for processing equipment solutions.
- b. 40 CFR 180.950 lists the pesticide chemicals that are exempted from the requirement of a tolerance based on the Agency's determination that these chemicals are of “minimal risk.” The pesticide chemicals listed include both active and inert ingredients.
- c. 40 CFR 180.960 lists the pesticide chemicals that are exempt from the requirement of a tolerance because they meet the criteria established by the Agency to identify certain polymers that are of low risk. This section contains those polymers whose tolerance exemptions were established post-Food Quality Protection Act (FQPA) of 1996 and are based on the polymer's meeting the criteria described in 40 CFR 723.250. These compounds have been determined to present little risk to the environment because of their size, they are too large to be active in biological systems.
- d. Inerts used in Pheromones – 40 CFR 180.1122 indicates the following:
 - i. All inert ingredients of semiochemical dispenser products formulated with, and/or contained in, dispensers made of polymeric matrix materials (the monomers, plasticizers, dispersing agents, antioxidants, UV protectants, stabilizers, and other inert ingredients) are exempted from the requirement of a tolerance when used as carriers in pesticide formulations for application to growing crops only.

3. List 3 Inerts permitted for use in passive pheromone products.

NOP regulation:

§ 205.601(m)(2) EPA List 3—Inerts of unknown toxicity—for use only in passive pheromone dispensers.

The NOSB received petitions for several List 3 specific inerts for use in pheromones and voted in 2002 to add a general allowance for List 3 substances, only in passive dispensers, rather than add these specific chemicals to the National List. At this time the Working Group (including EPA) is only aware of 4 List 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-chlorobenzotriazole¹⁴ (CAS # 3896-11-5)
- 2, 2-Hydroxy-4-n-octyloxybenzophenone (CAS # 1843-05-6)
- Butylated hydroxytoluene (BHT)¹⁵ (CAS # 128-37-0)
- one other surfactant

At this time the Working Group invites manufacturers to provide information on additional substances that may be used in passive pheromone dispensers, particularly any inert ingredients that are not specifically listed above, or that are not included on the EPA 25(b) list for inerts of minimal risk.

IV. Comments Requested

The NOSB Crops Committee and NOSB-NOP-EPA Working Group on Inerts specifically invite comments on the following topics at this time:

- What are the preferred options for replacing / amending the current allowance for List 3 inert ingredients in pheromone products?
- Is the list of former List 3 inert ingredients that are currently used in NOP-compliant pheromone products accurate, or are there others in use?
- The NOP regulation uses the term “passive pheromone dispensers.” Has this terminology been problematic? Is the term “retrievable polymeric pheromone dispensers” a better fit?
- Provide suggestions regarding the process by which alternatives to the use of synthetic inert ingredients may be considered and implemented.
- What are the barriers to the development or use of alternative natural inert ingredients for use in pesticide formulations?
- What timelines for implementation are appropriate?
- What are preferred replacement options for both List 3 and List 4 references? Include any that may not have been discussed above.

¹⁴ TAP review available at <http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5094039>

¹⁵ TAP review available at <http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5057586>