

**National Organic Standards Board  
Crops Committee  
2012 Sunset Recommendation  
List 3 Inert Ingredients in Passive Pheromone Dispensers  
March 20, 2012**

**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.

**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 require disclosure 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;

## Summary

### OFPA, Regulations, and Previous NOSB Action

OFPA, in establishing the National List (§2118, 7 U.S.C. 6517), creates a list of exemptions for prohibited substances in organic production and handling and in so doing lists the categories of substances that must be reviewed by the NOSB if they are to be listed: “(B) the substance (i) is used in production and contains an active synthetic ingredient in the following categories: .....; (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; or...” Tracking the U.S. Environmental Protection Agency (EPA) categorization of active and inert ingredients in pesticide formulations, OFPA subjects all allowed substances to the underlying statutory standards of health and safety, essentiality, and compatibility in this section of the law. Section 2118(c)(1)(B)(i) creates a category of **active ingredients** that may be allowed, which is parallel to Section 2118(c)(1)(B)(ii) creating the category of **inerts** that may be allowed --those found by EPA to not be “inerts of toxicological concern.” In summary, the categories of active and inert ingredients in Section 2118 establish an NOSB duty to review these substances.

The fact that OFPA uses the language the “substance...contains synthetic inert ingredients...” is somewhat confusing. The confusion is amplified by the fact that inert ingredients are themselves “substances.”<sup>1</sup> The language in OFPA is clarified in the Conference Report, which states: “The Conference substitute adopts the House provision with an amendment that adds production aids to the category of synthetic active ingredients and the category of synthetic inert ingredients not of toxicological concern to the Administrator of EPA *as possible exemptions* on the National List.” [Emphasis added.]

The language of the Conference Report thus makes it clear that “synthetic inert ingredients not of toxicological concern to the Administrator of EPA” is a category of substances that may be considered for listing on the National List.

<sup>1</sup> §205.2

*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)).

Classification of Materials November 2009: “*Substance*”: “An element, molecular species, or chemical compound that possesses a distinct identity (For example, a distinct identity may be demonstrated through the material having a separate Chemical Abstract Service (CAS) number (in some cases the same material may have multiple CAS numbers), Codex International Numbering System (INS) number, or FDA or other agency standard of identity).”

However, even if we take the interpretation that it is “substances *containing* synthetic inert ingredients not of toxicological concern to the Administrator of EPA” that may be listed on the National List, §6517(c)(1)(B) only allows such substances to be listed on the National List if the requirements of §6517(b), §6517(c)(1)(A), and §6517(d) are met. This requires that the “substance” undergo review according to the criteria of OFPA. If the inert is regarded as a component of the substance and not a substance itself, it still must be reviewed as part of the review of the substance.

The NOSB responsibility has its roots in both the Senate Report and the Preamble to OFPA and the subsequent action by the NOSB.

The Senate Report makes it clear that inert ingredient review was to be subject to the National List process:

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 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 such material.

In the Preamble to the Final Rule, December 21, 2000, USDA said,

In this final rule, only EPA List 4 Inerts are allowed as ingredients in formulated pesticide products used in organic crop and livestock production. The allowance for EPA List 4 Inerts only applies to pesticide formulations. Synthetic ingredients in any formulated products used as organic production inputs, including pesticides, fertilizers, animal drugs, and feeds, must be included on the National List. As sanctioned by OFPA, synthetic substances can be used in organic production and handling as long as they appear on the National List. The organic industry should clearly understand that NOSB evaluation of the wide variety of inert ingredients and other nonactive substances will require considerable coordination between the NOP, the NOSB, and industry.

In February, 1999, the NOSB recommended:

Inert ingredients on EPA Lists 1 and 2 shall be prohibited for use in organic production and handling effective on the date of implementation of the final rule of NOP. Synthetic inerts on EPA List 3 shall be prohibited if not specifically approved by the NOSB. This approval process will be completed and published

by January 1, 2002. Any inert currently in use in organic production that is not approved by the NOSB will be banned within 18 months after the review is completed and published. To that goal, inerts on EPA List 3 used in products that have active ingredients approved for organic production shall be reviewed by the NOSB on a case-by-case basis for possible inclusion on the National List.

Thus, the board voted that the consideration of individual List 3 materials was to be completed by January 1, 2002 –more than 10 years ago.

In October 2002, the Board passed the motion to list pheromones, which resulted in the current listing for List 3 inerts.

Pheromones—includes only EPA-exempt pheromone products, EPA registered pheromone products with no additional synthetic toxicants unless listed in this section and any inert ingredients used in such pheromone formulations that are not on EPA List 1, that is inerts of toxicological concern or EPA List 2, that is potentially toxic inerts, provided the pheromone products are limited to passive dispensers, pheromone products containing only pheromone active ingredients listed in this section and List 4 inerts may be applied without restriction.

At the same meeting, the Board also passed a motion *temporarily* allowing the continued listing of certain List 3 inerts:

The NOSB recommends that any list 3 inert material forwarded for a technical review be allowed for use until that material is approved or prohibited by the Secretary of Agriculture.

When the List 3 inerts came up for sunset in November 2007, the summary of the recommendation said,

Future petitions to add, remove or renew an inert ingredient to the National List will need to reference a specific inert ingredient. A petition may be submitted to the NOSB using the National List petition procedures. Individually petitioned substances must be recommended by the NOSB and added to the National List through notice and comment rulemaking before use in organic agriculture.

That recommendation was reaffirmed in February 2008. And, in presenting the discussion paper on List 4 inerts in November 2008, Gerald Davis said, “[Discussion paper point number] Five concerns the list 3 inerts currently used in passive pheromone dispensers. The current policy is that they need to be petitioned individually and are subject to regular sunset reevaluations, that that has already been in place as an NOP policy for a couple years now, since we were first notified about the EPA change.”

### **Consultations with USDA and EPA**

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 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).<sup>2</sup>

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 tolerance reassessment 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 reclassification, NOP regulations concerning allowed inert ingredients are out-of-date when compared with current EPA regulations, since EPA eliminated its list categories when it completed its tolerance reassessment. 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”.<sup>3</sup> The current exemption that permits former List 3 inerts in passive pheromone dispensers only is scheduled to sunset November 3, 2013.

An NOSB-NOP-EPA working group was established in June 2010. Current members include: Jay Feldman (NOSB), Zea Sonnabend (NOSB), Chris Pfeifer (EPA Biopesticides and Pollution Prevention Division), Kerry Leifer (EPA Registration Division), Emily Brown Rosen (NOP), and Lisa Brines (NOP). The group has collected information regarding current classification of the former List 3 and 4 inerts and presented a discussion document at the November 2011 NOSB meeting.<sup>4</sup>

This NOSB policy recommendation phases out former EPA List 3 inerts in passive pheromone dispensers from a general approval provision to full review under the National List standards. Currently, based on information from EPA, OMRI, and WSDA, we believe that there are three formerly List 3 inerts in use under this provision, three of which were the subject of petitions filed to the NOSB. It is understood that the former List 3 inerts requiring review are limited to the following substances: (i) Butylated

<sup>2</sup> 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.”

<sup>3</sup> October 28, 2010 recommendation available at <http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5087999&acct=nosb>

<sup>4</sup> Available at <http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5094901&acct=nosb>

hydroxytoluene (CAS # 128-37-0); (ii) 2-Hydroxy-4-n-octyloxybenzophenone (CAS # 1843-05-6); (iii) 2-(2-Hydroxy-3-tert-butyl-5-methylphenyl)-chlorobenzotriazole (CAS #3896-11-5)]. It is also understood that there may be a fourth inert in this category that has been identified by the Washington State Department of Agriculture.

The proposed annotation creates a timeframe for evaluation of these formerly List 3 inerts in passive pheromone dispensers: a review and board action is set for Dec. 31, 2015. This gives the board two years to review the petitions and act, and it provides the NOP a year to go to rulemaking. If for some reason the timeframes are delayed, the backup sunset provision allows the former List 3 uses to continue until Board action and rulemaking are complete. If the NOP adopts a policy by December 31, 2015 that covers former List 3 as well as other inerts, then that policy will prevail.

### Committee Recommendation

The italicized text is new proposed 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 December 31, 2015, after which point they are subject to individual review under 205.601, unless already covered by a policy adopted by the NOP for all other inert ingredients.*

### Committee Vote

Moved: Jay Feldman                      Second: Nick Maravell  
Yes 8                      No 0                      Abstain 0                      Absent 0                      Recuse 0

### Committee Backup Vote to Relist:

**List: 205.601 Synthetic substances allowed for use in organic crop production.**

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

**Committee Vote:**

Moved: Zea Sonnabend

Second: Jay Feldman

Yes 8

No 0

Abstain 0

Absent 0

Recuse 0

**§ 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 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.] To be removed as a definition when 205.601(m)2(a) and (b) expire.]*

Moved: Jay Feldman

Second: Zea Sonnabend

Yes 8

No 0

Abstain 0

Absent 0

Recuse 0