



# BEYOND PESTICIDES

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National Organic Standards Board  
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Savannah, GA

## Comments on Inerts Discussion Document

Dear Board Members:

Below we present our thinking on the inert ingredients in substances allowed in organic production.

### I. Framework

#### A. All materials must be reviewed by the NOSB

So-called “inert” ingredients should not have special standing. Like any other material used in organic production, “inert” ingredients should be evaluated against the criteria in OFPA.

#### B. “Inert ingredient” is a misleading term.

##### 1. List reasons that “inerts” are added.

Surfactant, solvent, diluent, synergist, emulsifier, propellant, sticker, dispersant, wetting agent, defoamer, stabilizer, anti-microbial, antifreeze, colorant, penetrator, safener, carrier.

##### 2. List ways in which “inerts” may be biologically active.

###### a) Purposeful biological activity

In a sense, all “inert” ingredients are synergists, since their purpose is to increase the effectiveness of the active ingredients. Although some of these ingredients are just designed to be vehicles for moving the product (diluent, carriers, propellants), many increase the toxicity to the target or nontarget organism by allowing more penetration through the skin or cuticle or by interfering with detoxification processes. An antimicrobial added to prevent the product from being broken down by microorganisms may have an impact on other microbes as well.

###### b) Incidental biological activity

“Inert” ingredients have many toxicological effects, including acute and chronic effects. Exposure to so-called “inert” ingredients may result in carcinogenicity, adverse reproductive effects, neurotoxicity or other chronic effects, developmental effects, as well as ecological effects or the potential for bioaccumulation. Those “inert” ingredients formerly listed on List 4A

were considered by EPA to be “minimal risk inert ingredients.” EPA said of List 4A, “The determination that a chemical is minimal risk would be based on a recognition of the overall safety of the chemical (such as very low toxicity or practically non-toxic) considering the widely available information on the chemical's known properties, and a history of safe use under reasonable circumstances.”<sup>1</sup> On the other hand, List 4B included chemicals that are acutely toxic, but limited by EPA to uses in which exposure would be lower. They may have other toxicological effects, and some are endocrine disruptors. List 3 was made up of chemicals about which EPA had insufficient information to put on another list.

### **C. We should be talking about/reviewing *all* “ingredients”**

#### **1. EPA now recognizes that “inert ingredient” is an inappropriate term. They say,**

In September 1997, the Environmental Protection Agency (EPA) issued [Pesticide Regulation Notice 97-6](#) which encourages manufacturers, formulators, producers, and registrants of pesticide products to voluntarily substitute the term "other ingredients" as a heading for the "inert" ingredients in the ingredient statement on the label of the pesticide product. EPA made this change after learning the results of a consumer survey on the use of household pesticides. Many comments from the public and the consumer interviews prompted EPA to discontinue the use of the term "inert." Many consumers are misled by the term "inert ingredient," believing it to mean "harmless." Since neither federal law nor the regulations define the term "inert" on the basis of toxicity, hazard or risk to humans, non-target species, or the environment, it should not be assumed that all inert ingredients are non-toxic.<sup>2</sup>

#### **2. Active/inert in OFPA?**

OFPA does not define “inert ingredient,” but allows for the use of certain synthetic “inert” ingredients that meet other criteria for listing on the National List.

#### **3. List of allowable categories of synthetic inputs**

7 U.S.C. § 6517 : US Code - Section 6517: National List

(a) In general

The Secretary shall establish a National List of approved and prohibited substances that shall be included in the standards for organic production and handling established under this chapter in order for such products to be sold or labeled as organically produced under this chapter.

(b) Content of list

The list established under subsection (a) of this section shall contain an itemization, by specific use or application, of each synthetic substance permitted under subsection (c)(1) of this section or each natural substance prohibited under subsection.

(c)(2) of this section.

(c) Guidelines for prohibitions or exemptions.

(1) Exemption for prohibited substances in organic production and handling operations

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 –

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<sup>1</sup> <http://www.epa.gov/opprd001/inerts/oldlists.html>

<sup>2</sup> <http://www.epa.gov/opprd001/inerts/notices.htm>

(A) the Secretary determines, in consultation with the Secretary of Health and Human Services and the Administrator of the Environmental Protection Agency, that the use of such substances

- (i) would not be harmful to human health or the environment;
- (ii) is necessary to the production or handling of the agricultural product because of the unavailability of wholly natural substitute products; and
- (iii) is consistent with organic farming and handling;

(B) the substance -

- (i) is used in production and contains an active synthetic ingredient in the following categories: copper and sulfur compounds; toxins derived from bacteria; pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals; livestock parasiticides and medicines and production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleansers; or
- (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; and

(C) the specific exemption is developed using the procedures described in subsection (d) of this section.

#### **D. Everything we do now is part of a transition**

With even EPA (possibly) moving away from the use of the term “inert ingredient,” it is time for the NOSB to incorporate the evaluation of synthetic “inerts” into the overall materials evaluation process. The term “inert ingredient” creates a false distinction among the synthetic substances evaluated as inputs. The NOSB needs to adopt a policy that facilitates a transition to a more rational materials policy.

#### **E. All materials must meet OFPA criteria**

All materials must meet all the criteria of OFPA, which requires that substances not be harmful to human health or the environment; be necessary to the production or handling of the agricultural product because of the unavailability of wholly natural substitute products; and be consistent with organic farming and handling. Therefore, we foresee that those ingredients now classified as “inert” would go through the same process as any other materials being reviewed for inclusion on the National List.

## **II. Questions posed in discussion paper**

### **A. What are preferred replacement options for both List 3 and List 4 references?**

As noted above, all references to “inert ingredients” should eventually be eliminated, and all materials should be judged against OFPA criteria. The first criterion for moving in that direction is that all ingredients be disclosed. All ingredients that are eligible for listing as 25(b) “minimal risk” pesticide ingredient must be disclosed. In addition, the other 25(b) criteria are consistent with OFPA criteria. As noted in the issue paper, the 25(b) criteria do not include the OFPA criteria of need or cradle-to-grave impacts, so those additional criteria would eventually need to be considered, as would the criterion of compatibility with organic and sustainable agriculture.

**B. What are the preferred options for replacing / amending the current allowance for List 3 inert ingredients in pheromone products?**

Since there are only four materials that fit into this classification, there is no reason not to address them individually. Two of the four have already been reviewed, and TAP reviews have been produced. These four materials are up for Sunset review, so the board should do a sunset review. It should be considerably easier to review four specific chemicals than a poorly-defined class of chemicals of unknown size.

**C. The NOP regulation uses the term “passive pheromone dispensers”. Has this terminology been problematic? Is the term “retrievable polymeric pheromone dispensers” a better fit?**

It is problematic to have undefined terms in regulations. The term “retrievable polymeric pheromone dispensers” has been defined. Any defined term is better than an undefined term. It is possible that if “passive pheromone dispenser” were defined, that it would fit our idea of what should be allowed better than “retrievable polymeric pheromone dispenser,” but it makes much more sense to drop both terms and review the four chemicals at issue.

**D. Provide suggestions regarding the process by which alternatives to the use of synthetic inert ingredients may be considered and implemented.**

The NOSB has a process for considering alternatives to materials, and this should be applied to alternatives to synthetic “inert” ingredients. As we have been at pains to stress in these comments, “inert” ingredients are not “inert” and should have no special standing among materials. They are materials with certain uses and certain properties, and the board should evaluate them and their alternatives as they would any other materials.

**E. What timelines for implementation are appropriate?**

The four former List 3 chemicals should be reviewed within the timeline of their Sunset.

The NOSB voted to relist the former List 4 chemicals last year, so there is a four-year window in which to:

- 1. Adopt a general approach to “inerts”—for example, the approach of temporarily allowing chemicals qualifying for 25(b), as we suggest;**
- 2. Develop a list of former “inerts” used in products approved for organic production not meeting 25(b) criteria;**
- 3. Set deadlines for the removal of those synthetics not meeting 24(b) criteria;**
- 4. Consider any petitions for those materials not meeting 25(b) criteria that remain—that is, for which no replacements have been found.**

According to the issue paper, there are 120 chemicals that might need to be petitioned. We believe that steps 1-3 can be completed by the Spring or possibly Fall 2012 meeting, allowing three more years before a Sunset decision must be made concerning the remaining former List four chemicals. If there are truly 120 chemicals left, then the board may need to figure out how to stagger Sunset dates for them, but we believe that if the Board is clear in promoting a policy that requires transparent and complete evaluation according to OFPA criteria, that alternatives will be found for most that meet those criteria. Finally, the process will only be complete when all ingredients are individually weighed against OFPA criteria, and the completion of the process may again require a staggering of Sunset dates.

Thank you for your attention to this important issue.

Sincerely,

A handwritten signature in cursive script, appearing to read "Terry Shistar".

Terry Shistar, Ph. D.  
Board of Directors