

## **NOSB Materials and Crops Committees Working Draft Guidance on Inert Ingredients in Pesticide Formulations**

### **Introduction**

This a working draft submitted by the Materials and Crops Committees concerning the status of inert ingredients used in pesticide formulations for consideration by the full Board.

### **Background**

On April 23, 2004, the USDA National Organic Program issued a directive on inert ingredients used in pesticide formulations (NOP C&E #04.01 “Pesticide Use”). The directive stated, “If the certifying agent and producer, after reasonable effort (contacting the manufacturer, EPA, and other USDA accredited certifying agents) are unable to ascertain whether inerts in a pesticide are allowed under the NOP, the certifying agent will approve that part of the organic production system plan. The certifying agent will inform the producer of the requirement to immediately stop use of the pesticide upon determination that the pesticide contains a prohibited inert. This notification must be documented. There will be no adverse impact on the operation’s certification until such notification is received by the producer. If the producer uses the pesticide after receiving this notification, the certifying agent will initiate revocation enforcement action.”

Members of the NOSB and the public objected to the directive because it allowed the use of pesticides containing undisclosed inert ingredients, including EPA List 2 or List 3 inert ingredients, which are prohibited by §205.105(a) and §205.601(m). It was also observed that the policy was a disincentive for pesticide companies to re-formulate using allowed List 4 inert ingredients. The directive failed to acknowledge and reward the companies that have reformulated their products to meet the NOP standards. There were also concerns that the directive was developed with little or no consultation of the EPA or NOSB.

On May 26, 2004, USDA Sec. Ann Veneman ordered that the pesticide directive and three other directives issued by the NOP be rescinded and that the NOP work with the NOSB and organic industry in the development of future directives and policy statements. NOP has solicited the input of the NOSB concerning the use of inert ingredients in pesticides allowed for use in organic production.

### **Statutory Background**

The Organic Foods Production Act makes two references to inert ingredients.

#### **6517(c) Guidelines for Prohibitions or Exemptions.**

(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;

**6518 (l) Requirements.** In establishing the proposed National List or proposed amendments to the National List, the Board shall

(2) work with manufacturers of substances considered for inclusion in the proposed National List to obtain a complete list of ingredients and determine whether such substances contain inert materials that are synthetically produced;

### **Regulatory Background**

The National Organic Program Final Rule, as amended, makes the following references to inert ingredients:

#### **§ 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)).

#### **§ 205.105 Allowed and prohibited substances, methods, and ingredients in organic production and handling.**

To be sold or labeled as “100 percent organic,” “organic,” or “made with organic (specified ingredients or food group(s)),” the product must be produced and handled without the use of:

(a) Synthetic substances and ingredients, except as provided in § 205.601 or § 205.603;

#### **§ 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.

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

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

#### **§205.603 Synthetic substances allowed for use in organic livestock production.**

(e) As synthetic inert ingredients as classified by the Environmental Protection Agency (EPA), for use with nonsynthetic substances or a 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.

**Preamble to NOP Final Rule, Federal Register, December 21, 2000 says:**

**Page 80612** - The NOSB has also provided recommendations for the use of synthetic inert ingredients in formulated pesticide products used as production inputs in organic crop or livestock operations. The Environmental Protection Agency (EPA) regulates and maintains the EPA Lists of Inert ingredients used for pesticide. In this final rule, EPA Inerts List 1 and 2 are prohibited, EPA List 3 is also prohibited unless specifically recommended as allowed by the NOSB, and EPA List 4 Inerts are allowed unless specifically prohibited. 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.

**Page 80615** - Commenters expressed concern that the prohibition on the use of EPA List 3 inerts would prevent organic producers from using certain botanical or microbial formulated products that are currently allowed under some certification programs. These commenters requested that the NOP and the NOSB expedite the evaluation of List 3 inerts used in nonsynthetic formulated products to prevent the loss of certain formulated products. The prohibition of List 3 inerts was based on the recommendation of the NOSB to add only those substances from List 4 to the National List. The NOSB also recommended that individual inert substances included on List 3 could be petitioned for addition to the National List. The NOP has requested that the NOSB identify for expedited review those List 3 inerts that are most important in formulated products used in organic production. Individuals may petition to have these inerts considered for inclusion on the National List. Additionally, the NOP will work with the EPA and the registrants of formulated products to expedite review of List 3 inerts currently included in formulated products used in organic production. Unless List 3 inerts are moved to List 4 or individually added to the National List, they are prohibited for use in organic production.

**Preamble to Second Proposed Rule, March 13, 2000 says:**

**Pages 13589-90:** We recognize that inert ingredients in pesticides and similar substances in other formulated products pose one of the most problematic examples of the use of synthetic materials in organic production. For example, verifying the use of inerts and similar substances such as fillers, carriers, additives, and excipients has been difficult because they are not required to appear on ingredient labels, and formulators typically treat product formulas as confidential information. At times, certifying agents have been unable to determine the exact composition of formulated products proposed for use in organic production. In other instances, organic producers have applied formulated products containing inert ingredients and similar substances that are not specifically allowed. We are challenged with balancing standard practice with the strict statutory requirement that producers and handlers apply only those synthetic substances added to the National List. As sanctioned by OFPA, synthetic substances can be used in organic production as long as they appear on the National List.

The development and maintenance of the National List has been and will be designed

to allow the use of a minimal number of synthetic substances that are acceptable to the organic industry and meet the OFPA criteria.

Two principles will be essential for responding to this challenge: greater disclosure of the contents of formulated products and an expedited review of inert ingredients and other nonactive substances. The OFPA recognized the need for disclosure by requiring the NOSB to work with formulators to obtain a complete list of ingredients in their products. The NOSB has initiated this work, and its effort is ongoing as of the date of this publication. It is our understanding from the comments, hearings, and information considered by the NOSB that the organic industry has made considerable progress on disclosure of inert ingredients since the passage of OFPA. Formulators have responded to the incentive to provide products using EPA List 4 inert ingredients, and certifying agents have gained greater access to information on product composition. EPA has expressed its willingness to expedite the review of its List 2 and 3 inerts, which the NOSB identifies as particularly important in formulated products widely used in organic operations. 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. Materials review can be anticipated as the NOSB's primary activity during NOP implementation. Considering the critical nature of this task, the organic industry should make a collaborative effort to prioritize for NOSB review those substances which are essential to organic production and handling.

We are sensitive that an abrupt prohibition on synthetic substances which may have knowingly or unknowingly been used in the past but which are not added to the National List may disrupt many well-established and accepted production systems. However, our assessment is that the benefits of a clear policy consistent with the OFPA, NOSB recommendations, and public comment outweigh the costs. The net effect will be greater consumer confidence in USDA's organic label and more products that are tailored to the needs of organic producers.

**EPA PR Notice 2003-1: Labeling of Pesticide Products under the National Organic Program.** ([http://www.epa.gov/opppmsd1/PR\\_Notices/pr2003-1.pdf](http://www.epa.gov/opppmsd1/PR_Notices/pr2003-1.pdf))

This notice describes how registrants can obtain Environmental Protection Agency (EPA) approval of label language indicating that all ingredients (active and inert) in a pesticide product and all uses of that pesticide meet the criteria defined in the United States Department of Agriculture's (USDA) National Organic Program (NOP) Rule. This PR Notice provides an example of acceptable label language and the procedures for adding such identification to product labels. The information on the pesticide label will assist organic growers and those persons certifying organic production methods in knowing which pesticide products meet the requirements of the NOP Rule for use in organic agriculture.

According to USDA's rules, organic growers are required to rely on their certifier for

compliance with the NOP (7 CFR Sections 205.400 - 406). Any label language on a pesticide product as described in this notice is to assist the grower and certifier. Label language on a pesticide product stating that the pesticide meets the NOP Rule criteria is not required for an organic producer to utilize a pesticide product which the producer and/or certifier ascertains meets the requirements of the NOP. Registrants of pesticide products are not required to add such NOP language to their products for the products to be used in organic agriculture. Use of products with NOP language does not modify the requirement that growers rely on their certifier for compliance with the NOP.

This notice provides guidance to pesticide registrants who may consider participation in this voluntary program.

In order for a product to meet the requirements of the NOP, each ingredient in the product, including active and inert ingredients, must be allowable under The National List of Allowed and Prohibited Substances (National List) contained in 7 CFR part 205.

We encourage registrants who want their pesticide products to be marketed for organic production to list all product ingredients on the pesticide label, including inert or other ingredients. This will make it easier for an organic farmer or the farmer's certifier to verify that the product is allowable for use in organic production, especially where changes to the NOP are made.

## **Discussion**

The consideration of inert ingredients and other non-active ingredients in fertilizers and feed has been thoroughly debated by NOSB, commented on by the public, and referenced by the NOP in the regulation and preamble to both the March and Dec. 2000 rule. The regulation and preamble make it clear that all synthetic ingredients, whether active, inactive, or inert must appear on the National List in order to be used in crop or livestock production.

Since the NOP rule was published in December, 2000 considerable progress has been made in the review and reformulation of pesticide products to meet NOP requirements.

The EPA labeling program implemented in May, 2003 provides a federal process for manufacturers to have product formulations verified as NOP compliant at no additional cost, and without additional disclosure.

Progress is being made moving substances from EPA list 3 to list 4. The EPA is undergoing a review of active and inert ingredients mandated by the Food Quality Protection Act of 1996. This requires re-assessment of older pesticides and inert ingredients by August 2006. Robert Torla of the EPA Biopesticides Division reports that the EPA has moved more than 50 inerts to list 4 in recent years. EPA has a schedule for the remaining List 3 inerts that have tolerances (maximum residue limits permitted, or

exemption from residue limits) for use on food crops. Those without food tolerances may not be reassessed by August 3, 2006. Inerts that do not have an established tolerance for food crops cannot be used in agricultural crops. Mr. Torla stated that according to the inerts program staff, the reassessment of inerts for which sufficient information exists will be completed by Aug. 3, 2006. Some inerts will likely not be re-categorized due to lack of information needed to make the required safety finding.

Two existing brand name product review programs require complete disclosure of inert ingredients in pesticides: the Organic Materials Review Institute and Washington State Department of Agriculture. In January 1999, the OMRI Brand Name Product List included approximately 60 pesticides. WSDA and OMRI now list over 200 registered and exempt pesticides that meet NOP requirements for inert ingredients.

The organic industry has experienced continual, strong growth since the passing of OFPA and the subsequent development of the National Organic Standards. Many organizations both public and private have directed much of their time and resources to assisting growers in obtaining information about the Standards. The NOP and SARE program has funded the Appropriate Technology Transfer for Rural Areas (ATTRA) organization to write outreach materials and check sheet tools designed to help farmers with all aspects of certification including what materials are allowed and prohibited in organic production. Many Land Grant Institutions have hired individuals with expertise in organic agriculture to assist growers in decision making and providing them with answers to the questions regarding materials. This private and public support shall assist growers in obtaining the information they need regarding pesticide formulations that are compliant with the NOP regulation.

Any directive or policy statement that allows acceptance of unknown inert ingredients is counter to the requirements of OFPA and the Final Rule. Such a policy undermines the EPA labeling program and brand name product reviews by rewarding non-disclosure. There is no need for NOP to issue a directive weakening enforcement of existing requirements.

## **Recommendation**

The NOSB Materials and Crops Committees recommend the following:

1. The NOSB encourages pesticide manufacturers who want to market their products for organic production to take advantage of the EPA organic labeling program. They are also be encouraged to disclose all product ingredients on the pesticide label, including inert or other ingredients, as advised by the EPA.
2. Pesticide manufacturers with products that contain allowed active ingredients and List 3 inert ingredients are encouraged to reformulate to comply with the existing regulation. Other options are to notify EPA of a need for expedited review, and to petition the NOSB for review of the specific List 3 inert. (Note that petitions to the NOSB may take up to three years for regulatory action.)

3. Since the EPA regulates the use claims, directions for use, and composition of a pesticide product as a pre-market condition, the NOP should establish functional lines of communication with EPA in order to provide EPA consistent information about organic standards and updates to the National List, and to obtain advice from EPA on the status of petitioned materials.
4. Certification agents who find that producers are reporting use of pesticide products with unknown inert ingredients should instruct producers to discontinue use immediately unless the ingredients can be verified as compliant with the NOP regulation. Discontinuation of use will be considered sufficient corrective action for use of pesticide products with approved active and unknown inert ingredients.

**Committee vote**

**Minority opinion**

**Conclusion**