

**FORMAL RECOMMENDATION BY THE
NATIONAL ORGANIC STANDARDS BOARD (NOSB)
TO THE NATIONAL ORGANIC PROGRAM (NOP)**

Date: April 29, 2010

Subject: Inerts in Pesticides Allowed for use in Organic Production

Chair: Daniel G. Giacomini

Recommendation

The NOSB hereby recommends to the NOP the following:

Rulemaking Action:

Guidance Statement: X

Other:

Summary Statement of the Recommendation (including Recount of Vote): The NOSB voted 13 yes to 1 no with one member absent to submit to the NOP a guidance recommendation on inerts in pesticides allowed for use in organic production. The NOSB is suggesting 6 steps to accomplish the changes in regulation that would allow materials on the now obsolete EPA List 3 and 4 Inerts currently on the National List to be looked at by the NOSB, NOP, and EPA to determine how best to evaluate these materials for listing, maintain the list, and continue to evaluate new inert materials for inclusion on the List.

NOSB Vote: **Motion:** Jeff Moyer **Second:** Jay Feldman

Board vote: Yes - 13 No- 1 Abstain- 0 Absent - 1

Summary Rationale Supporting Recommendation (including consistency with OFPA and NOP): OFPA Section 6517(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). The NOP currently maintains an outdated classification listing for inerts used in pesticides under the old EPA list 4 and list 3 classifications. As of 2006 this EPA classification no longer exists and has been replaced by the new EPA classification lists 40CFR 180. EPA has reassessed a number of List 4 Inert ingredients and these reassessments have resulted in a number of revocations. Assessments have also resulted in a number of reclassifications of List 3 inert ingredients to List 4 Inert ingredients. As a result, the NOP regulations must be amended to acknowledge the inert tolerance reassessments conducted by EPA. This recommendation is meant to help determine the most effective and efficient way to amend the regulations with the collaboration of the NOSB, NOP, and the EPA.

Response by the NOP:

National Organic Standards Board (NOSB)
Crops Committee
Guidance Recommendation on
Inerts in Pesticides Allowed for use in Organic Production
March 1, 2010

Introduction

This document discusses the Crops Committee proposed guidance to the program (NOP) regarding the need for clarification on materials listed as inerts under the old EPA List 4 and List 3 classifications.

The ORGANIC FOODS PRODUCTION ACT OF 1990 states:

Sec. 2119

- (1) REQUIREMENTS. In establishing the proposed National List or proposed amendments to the National List, the Board shall-
- (1) review available information from the Environmental Protection Agency, the National Institute of Environmental Health Studies, and such other sources as appropriate, concerning the potential for adverse human and environmental effects of substances considered for inclusion in the proposed National List;
 - (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; and

Background

The NOP currently maintains an outdated classification listing for inerts used in pesticides under the old EPA list 4 and list 3 classifications. As of 2006 this EPA classification no longer exists and has been replaced by the new EPA classification lists 40CFR 180. The NOP issued the following statement on September 6, 2007 documenting the position of the program regarding the changes made by EPA to their List 3 and 4 inerts.

The National Organic Program (NOP) regulations currently allow inert ingredients which appear on the Environmental Protection Agency (EPA) List 4A – Minimal Risk Inert Ingredients and List 4B – Other ingredients for which EPA has sufficient information to reasonably conclude that the current use pattern in pesticide products will not adversely affect the public health or the environment – as ingredients in pesticides allowed in organic production operations. These lists were maintained and managed by EPA.

EPA has been reassessing exemptions from tolerances for inert ingredients in pesticide products to ensure that they meet the safety standard established by the Food Quality Protection Act (FQPA). FQPA requires the reassessment of inert ingredient tolerances and tolerance exemptions that were in place prior to August 3, 1996. EPA completed their reassessments in 2006.

EPA reassessments resulted in the revocation of a few List 4 inert ingredients, and they are therefore prohibited under NOP. List 4 inert ingredients that have been revoked for use in pesticide formulations and are now prohibited under NOP are as follows:

- Acetylated lanolin alcohol (CAS Reg. No. 91994-94-4); Revoked in 70 FR 31401, June 1, 2005.
- Acrylic acid methyl ester, polymer with acrylonitrile and 1,3-butadiene (CAS Reg. No. 27012-62-0); Revoked in 71 FR 14411, March 22, 2006; the tolerance exemption is called "Nitrile rubber modified acrylonitrile methylacrylate conforming to 21 CFR 177.1480.
- Coumarone – indene resin (CAS Reg. No. 63393-89-5); Revoked in 71 FR 14411, March 22, 2006.
- Manganous oxide (CAS Reg. No. 1344-43-0); Revoked in 71 FR 45415, August 9, 2006.
- Pentaerythritol monostearate (CAS Reg. No. 78–23–9); Revoked in 71 FR 14411, March 22, 2006.
- Pentaerythritol tetrastearate CAS Reg. No. 115–83–3); Revoked in 71 FR 14411, March 22, 2006.
- Polyglyceryl phthalate ester of coconut oil fatty acid (CAS Reg. No. 66070-87-9); Revoked in 71 FR 45415, August 9, 2006.
- Sodium fluoride (CAS Reg. No. 7681-49-4); Revoked in 70 FR 31401, June 1, 2005.

EPA has also reclassified a number of List 3 inert ingredients (inerts of unknown toxicity) as List 4 inert ingredients. Those materials have not been added to EPA's published List 4 documents but appear through individual approvals issued by EPA and posted on their website. EPA has informed USDA that the "Inerts List" system may no longer be effective or available for the NOP to reference in the Regulations. Also impacted is the EPA review and labeling program for determining the compatibility of pesticides with the Regulations.

As a result, the NOP regulations must be amended to acknowledge the inert tolerance reassessments conducted by EPA. NOP will collaborate with EPA and the National Organic Standards Board (NOSB) to determine the most effective and efficient way to amend the regulations.

On September 30, 2009, EPA issued a statement that said the agency will seek to disclose hazardous pesticide inert ingredients (See http://epa.gov/oppfead1/cb/csb_page/updates/2009/disclose-inerts.html). In a letter responding to

petitions before the agency, EPA said that it is "initiating rulemaking to increase public availability of hazardous inert ingredient identities for specific formulations." EPA continues, "In connection with the rulemaking, EPA will also be discussing ideas to increase the disclosure of inert ingredients to an even greater degree than requested by petitioners, for example, by requiring disclosure of all inert ingredients, including ingredients not deemed hazardous." (See entire letter at <http://www.epa.gov/opprd001/inerts/petitionresponse.pdf>)

NOP Policy

Parties reviewing pesticide product ingredients for compliance with the NOP are advised to use EPA's August 2004 lists of approved List 4 inert ingredients, minus the revoked inert ingredients. These lists are provided at the end of this document as attachments:

- -Inert Ingredients Ordered Alphabetically by Chemical Name - List 4A (Attachment 1)
- -Inert Ingredients Ordered Alphabetically by Chemical Name - List 4B (Attachment 2)

The NOSB has requested that inert ingredients reassessed by EPA, but not previously authorized for use under the NOP remain prohibited in organic agriculture. Until the NOP and NOSB can determine the best course to take in response to EPA's reassessment decisions, NOP will concur with the NOSB's request and grant that use of such ingredients must be petitioned. A petition may be submitted to the NOSB using the National List petition procedures. Petitioned substances must be recommended by the NOSB and added to the National List through notice and comment rulemaking before use in organic agriculture.

This policy will remain in effect until superseded by regulatory changes or new guidance. Certifiers and other affected parties should consult the NOP Document Control Masterlist for the most current guidance on this topic.

Definitions:

EPA Inert (other) Ingredients in Pesticide Products

Pesticide products contain both "active" and "inert" ingredients. The terms "active ingredient" and "inert ingredient" have been defined by Federal law, the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), since 1947.

An active ingredient is one that prevents, destroys, repels or mitigates a pest, or is a plant regulator, defoliant, desiccant or nitrogen stabilizer. By law, the active ingredient must be identified by name on the label together with its percentage by weight.

An inert ingredient means any substance (or group of structurally similar substances if designated by the Agency), other than an active ingredient, which is intentionally included in a pesticide product. Inert ingredients play a key role in the effectiveness of a pesticidal product. For example, inert ingredients may serve as a solvent, allowing the pesticide's active ingredient to penetrate a plant's outer surface. In some instances, inert ingredients are added to extend the pesticide product's shelf-life or to protect the pesticide from degradation due to exposure to sunlight. "Inert" ingredients can be and are frequently chemically and biologically active substances, as well as hazardous and toxic to the environment and humans.

Pesticide products can contain more than one inert ingredient, but federal law does not require that these ingredients be identified by name or percentage on the label. Only the total percentage of inert ingredients is required to be on the pesticide product label.

**EPA Regulatory Statement:
EPA's National Organic Program Guidance
December 20, 2007**

- The National Organic Program (NOP) is a USDA program. All matters of policy concerning the eligibility of Inert Ingredients for use in the NOP are determined by USDA. EPA's role is to assist USDA by assuring that USDA's policies are implemented with regard to organic claims made by registered pesticide products.
- USDA policy regarding Inert Ingredients and List 4 is summarized in the following USDA document: [Instructions to Certifiers for Use of EPA List 4 Inert Ingredients](#)
- If an applicant has questions with regard to the policy outlined in the above link, or wishes to petition USDA for the addition of another Inert Ingredient, EPA refers the applicant to USDA's NOP office. Program and contact information can be found through the following link: <http://www.ams.usda.gov/nop/indexIE.htm>
- Per USDA, any applicants seeking organic designation must assure that their inert ingredients can be found on this posted List 4, dated August 2004. No other Inert Ingredients (i.e. reassessed inert ingredients) will be considered for organic designation at this time. (Ingredients approved by 7 CFR part 205 excepted.)
- NOP applicants should be aware that the tolerance exemptions for the following ingredients still found in the above List 4 have since been revoked and are no longer approved for use in pesticide products under USDA's NOP: manganous oxide; polyglyceryl phthalate ester of coconut

oil fatty acid; coumarone - indene resin; pentaerythritol monostearate; pentaerythritol tetrastearate; acrylic acid methyl ester, polymer with acrylonitrile and 1,3-butadiene (tolerance exemption is called "Nitrile rubber modified acrylonitrile methylacrylate [CAS Reg. No. 27012-62-0] conforming to 21 CFR 177.1480"); sodium fluoride; and acetylated lanolin alcohol.

- For food uses, NOP applicants should cross-check their inert ingredients against the electronic Code of Federal Regulations (e-CFR) (40 CFR Part 180) to assure that their proposed uses remain covered by an appropriate tolerance exemption. The e-CFR can be found through the following link: <http://www.gpoaccess.gov/ecfr/> (Select Title 40, Volume 23 (parts 150-189), and then part 180. The majority of inert ingredient tolerance exemptions are found in 180.910 – 160.)
- NOP applicants are responsible for providing sufficient information on their inert ingredients for EPA to make an NOP determination. Simply noting an ingredient as List 4 is often not sufficient. The NOP has many additional requirements for ingredients, which are intended to assure organic compatibility of the formulation. EPA suggests applicants submit Manufacturing Process data for their product and technical data sheets and MSDS for their inert ingredients.
- NOP applicants using proprietary blends in their formulations should check with their suppliers to assure that all the constituent ingredients in their blend can be found on this posted List 4, dated August 2004. The owner of the propriety blend must submit to EPA a complete description of the blend's composition (trade name, chemical names, CAS Reg. No.s, and amount of each component the total of which must equal 100%).

NOP Regulatory Citation: (This is the current listing regarding inerts under the NOP rule)

§ 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: Provided, That, use of such substances do not contribute to contamination of crops, soil, or water.

Substances allowed by this section, except disinfectants and sanitizers in paragraph (a) and those substances in paragraphs (c), (j), (k), and (l) of this section, may only be used when the provisions set forth in §205.206(a) through (d) prove insufficient to prevent or control the target pest

- (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 allowed:
 - (i) Glycerine Oleate (Glycerol monooleate) (CAS #s 37220–82–9)—for use only until December 31, 2006.
 - (ii) Inerts used in passive pheromone dispensers

Discussion

The Crops Committee, with the input of many individuals and organizations has been working through the historic and current perspectives regarding the updating of the NOP's classification of the inert materials. It is clear to this committee that the EPA definitions of inerts do not preclude them from actually functioning as active ingredients depending on the formulation used. We, as a committee, are extremely reluctant to assimilate the new 40 CFR 180 listings for these materials in mass into the organic materials use list thereby bringing in hundreds of un-reviewed materials. We also recognize that both dollars and time preclude individual examination of the hundreds of materials found on these lists.

The NOSB needs to review all inert ingredient components used in current NOP compliant pesticide formulations for consideration for inclusion on the National List of Allowed Materials on 205.601.

Proposed Guidance to the NOP: The Crops Committee is making the following recommendation to the NOSB:

The NOSB requests that the NOP create and enter into a Memorandum Of Understanding (MOU) with the EPA to assist in the evaluation of the materials previously known as both EPA List 4, inerts of minimal concern and EPA List 3, inerts of unknown toxicity allowed. This MOU should serve as the platform for an implementation strategy that may include an official task force or some other structure to achieve the following objectives.

From the date of public notice of the approval of this recommendation:

1) Working with the EPA, the NOSB will create a sub-list from the previous list of inert materials used in organic pesticide formulation known as list 3 and list 4 inerts that meet the NOSB established review criteria for non-synthetic "natural" materials. Nonsynthetic substances are not required to be listed on the National List on 205.601 or 205.603 for use in organic production and will not require further review in order to be allowed for use in the manufacturing of pest management materials. Manufacturers of organic pesticides will be directed to

this “list” of materials as their first choice for ingredients used in the formulation of their products.

2) If unable to formulate pesticide products for use in organic production relying on these non-synthetic “natural” ingredients, the manufacturers of pesticides currently allowed for use and in organic production must provide the NOP with the names and CAS numbers for all their product ingredients currently listed as inert that they intend to defend for continued use, for review by the NOSB under the existing petition process. Product status will remain unchanged during the petition process. Any ingredients not introduced for review within an established time frame will not be considered for inclusion on the National List of Allowed Materials and will Not Be Allowed for use in pesticide formulations in organic production.

3) The inert materials submitted to the NOSB as a petitioned substance will receive priority review by the board to determine compliance with the standards of OFPA under the general materials review procedures. Upon receipt of the petitioned product ingredients, the crops committee will solicit a technical review (TR) of each material. Materials not submitted for review will have a designated grace period, after which they will no longer be allowed.

4) Following the petition process and the committee recommendation, any material or substance found to be incompatible with organic production will be given an established time period in which to reformulate or lose approved status and be prohibited from further use.) Submitted materials rejected during NOSB review process will be prohibited after a designated grace period, unless health and environmental risks dictate an expedited termination of use

5) Items:

1) EPA List 4 Inerts of Minimal Concern
2) EPA List 3 Inerts of Unknown Toxicity allowed:
under 205.601(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, will remain in the rule as a static list until recommendations from the Task Force indicate change.

6) Based on the results of the MOU established task force the NOSB will either list the specific inert ingredient components recommended for inclusion on 205.601 (m) by the NOSB subject to the current sunset process or post the list as a single material listing as a subset list managed by the EPA as a “List of inerts suitable for organic production” or other delineation. Which ever listing format is utilized individual materials will be subject to the sunset process already established under the NOSB policy manual.

Committee Vote to recommend this document:

Motion: Barry Flamm ; Second: Tina Ellor ;

Yes: 6 No: 0 Absent: 1 Abstain: 0

Respectfully submitted:

Tina Ellor

Crops Committee Chair

March 1st, 2010

Addendum

Screen for Allowable Inerts

[Note: This type of screen would take about ½ hour to run a chemical through. It would confirm that those remaining on the allowable list do not raise any red flags. If the ingredient turns up on one of these lists, then it would trigger a more indepth review.]

- (1) Toxicity Category I or II by the United States Environmental Protection Agency (EPA). These pesticides are identified by the words “DANGER” or “WARNING” on the label.
- (2) A developmental or reproductive toxicant as defined by the State of California Proposition 65 Chemicals Known to Developmental or Reproductive Harm.
- (3) A carcinogen, as designated by EPA's List of Chemicals Evaluated for Carcinogenic Potential (chemicals classified as a human carcinogen, likely to be carcinogenic to humans, a known/likely carcinogen, a probable human carcinogen, or a possible human carcinogen), the International Agency for Research on Cancer (IARC), U.S. National Toxicology Program (NTP), and the state of California's Proposition 65 list. Any of the following classifications shall deem the chemical a carcinogen and unacceptable:
 - Known to the State of California to Cause Cancer (California)
 - Group A: Human Carcinogen (US EPA 1986 category)
 - Group B: Probably Human Carcinogen (US EPA 1986 category)
 - Group C: Possible Human Carcinogen (US EPA 1986 category)
 - Known Carcinogen (US EPA 1996 category)
 - Likely Carcinogen (US EPA 1996 category)
 - Carcinogenic to Humans (US EPA 1999 category)
 - Likely to be Carcinogenic to Humans (US EPA 1999 category)
 - Suggestive Evidence of Carcinogenicity (US EPA 1999 category)
 - Known to be Human Carcinogens (NTP)
 - Reasonably Anticipated to be Human Carcinogens (NTP)
 - Group 1: Carcinogenic to Humans (IARC)
 - Group 2A: Probably Carcinogenic to Humans (IARC)
 - Group 2B: Possibly Carcinogenic to Humans (IARC)
- (4) Neurotoxic cholinesterase inhibitors, as designated by California Department of Pesticide Regulation or the Materials Safety Data Sheet (MSDS) for the particular chemical,
- (5) (5). Known groundwater contaminants, as designated by the state of California (for actively registered pesticides) or from historic groundwater monitoring records (for banned pesticides).

- (6) Pesticides formulated as dusts, powder or aerosols, unless used in a way that virtually eliminates inhalation hazard (for example, applied to cracks or crevices and sealed after the application, or as a directed spray into the entrance of an insect nest).
- (7) Nervous system toxicants, including chemicals such as cholinesterase inhibitors or chemicals associated with neurotoxicity by a mechanism other than cholinesterase inhibition, or listed on:
- Toxics Release Inventory (TRI), EPA EPCRA Section 313 (Identified as "NEUR" on Table 1)
 - EPA Reregistration Eligibility Decisions (RED)
 - Insecticide Resistance Action Committee (IRAC) Mode of Action Classification:
 - Acetylcholine esterase inhibitors;
 - GABA-gated chloride channel antagonists;
 - Sodium channel modulators;
 - Nicotinic Acetylcholine receptor agonists /antagonists;
 - Nicotinic Acetylcholine receptor agonists;
 - Chloride channel activators;
 - Octopaminergic agonists;
 - Voltage-dependent sodium channel blockers; or
 - Neuronal inhibitors (unknown mode of action).
- (8) Endocrine disruptors, which include chemicals that are known to or likely to interfere with the endocrine system in humans or wildlife, based on the European Commission (EC) List of 146 substances with endocrine disruption classifications, Annex 13 (and/or any subsequent lists issued as follow-up, revisions, or extensions).
- (9) (Regarding outdoor use) Adversely affects the environment/wildlife, based on:
- a. Label precautionary statements including "toxic" or "extremely toxic" to bees, birds, fish, aquatic invertebrates, wildlife or other non-target organisms, unless these organisms are the target pest and/or environmental exposure can be virtually eliminated.
 - b. Pesticides with ingredients with moderate or high mobility in soil, according to the Groundwater Ubiquity Score (GUS), or with a soil half-life of 30 days or more (except for mineral products). Persistence and Soil Mobility procedures appear below.
 - i. If GUS (Groundwater Ubiquity Score) cannot be found, we search for the aerobic soil half-life and soil-binding coefficient Koc. GUS is then calculated from the formula: $GUS = \log_{10}(\text{half-life}) * (4 - \log_{10}(Koc))$.
- (10) Has data gap or missing information in EPA registration documents, including pesticide fact sheets, or EPA reregistration eligibility decisions, which EPA is requiring the registrant to fulfill.

- (11) Contaminants and metabolites recognized by EPA that violate any of the above criteria.
- (12) Inert or active ingredients that are Chemicals Included on EPA's List 1 (Inerts of Toxicological Concern) or EPA List 2: (Potentially Toxic, High Priority for Testing).