

Formal Recommendation
From: National Organic Standards Board (NOSB)
To: the National Organic Program (NOP)

Date:

Subject:

Chair:

The NOSB hereby recommends to the NOP the following:

Rulemaking Action:

Guidance Statement:

Other:

Statement of Recommendation: (Motion # 1)

Replace the language at sections 205.601(m) and 205.603(e) with the following language (see attached Statement of Recommendation Motion # 1), including the listing of any approved (inert) ingredients, to be completed prior to the October 21, 2017 sunset date for List 4 inerts.

Rationale Supporting Recommendation (including consistency with OFPA and NOP):

The recommendation for review of other (“inert”) Ingredients in pesticide formulations on the National List addresses the many recommendations of the NOSB and concerns of the public about the crop production materials that are allowed for use in certified organic production under the National List section of OFPA (7 USC 6517). See attached rationale supporting recommendation for further explanation.

Committee Vote:

Moved:

Seconded:

Yes:

No:

Abstain:

Absent:

Recuse:

Statement of the Recommendation: Motion 1

Replace the language at sections 205.601(m) and 205.603(e) with the text below, including the listings of any approved (inert) ingredients, to be completed prior to the October 21, 2017 sunset date for List 4 inerts:

“As synthetic other (“inert”) ingredients in pesticide formulations as classified by the Environmental Protection Agency (EPA) for use with nonsynthetic substances or synthetic substances listed in this section that are used as an active pesticide ingredient in accordance with any limitations on the use of such substances.

(i) Substances permitted for use in minimal risk products exempt from pesticide registration under FIFRA section 25(b);

(ii) Reserved (for list of approved other (“inert”) ingredients)”

Procedure for initiating the review of these substances:

A. The NOSB will work with the Inerts Working Group (IWG) to finalize groups and screening steps.

B. The NOSB will rely on the IWG to consult with Organic Materials Review Institute (OMRI) and the Washington State Department of Agriculture (WSDA) for updated inerts lists in case there are new inerts to add to the groups.

C. The NOSB requests NOP to investigate and adopt within six months of the announcement of this proposal (Spring 2013) the appropriate mechanism for notifying manufacturers and the public regarding the inerts review process, including which inerts are under review and how to inform the IWG of inerts that are in use, but not on the list under review. .

D. The NOSB requests NOP to commission one TER per group, except where noted, and coordinate review with the Board.

E. The NOSB requests NOP to determine an appropriate format and commission a special inerts TER for each group to contain the following:

1. a chart of all inerts in the groups by CAS number with their chemical properties, uses, types of product categories in which they occur, EPA regulatory status, including data gaps.
2. a description of how inerts within group are related and how different, especially outliers that are significantly different from others.
3. a chart that evaluates each inert in the group under the screening steps suggested by NOSB (Appendix 1) and any additional screening recommended by the NOSB, with input from the IWG.
4. OFPA criteria will be addressed that are not covered in the EPA review (environment, interactions, and alternatives or essentiality)

F. Based on results of group TER, the NOSB Crops Subcommittee accepts group to move forward to NOSB agenda, or singles out one or more for individual review. The group will then

move forward without the singled out one and that one will be re-reviewed in more detail if necessary.

G. The NOSB, working with the IWG, will prioritize the order of reviews so that the most potentially problematic are reviewed first. The others can be done later and some may not need full TERs. Priority also given to fully disclosed ones that have been petitioned and may fall outside one of the groups. In setting priorities, there will be consideration of the amount used in organic production if that can be determined.

H. The anticipated timeline will enable the NOSB to finalize the procedure by spring 2013, start reviews for fall 2013 and to have as many reviews completed as possible by spring 2015. The intention is to have an amendment to the National List in 2017, which will address the materials reviewed with an implementation period of 2 - 5 years, taking into account public comment and the need for additional reviews for reformulation and compliance.

I. By the time of the five-year sunset period the NOSB will approach a review of those inert substances permitted for use in minimal risk products exempt from pesticide registration under FIFRA section 25(b).

Rationale Supporting Recommendation:

This Policy and Procedure Recommendation for review of other (“inert”) Ingredients in pesticide formulations on the National List addresses the many recommendations of the NOSB and concerns of the public about the crop production materials that are allowed for use in certified organic production under the National List section of OFPA (7 USC 6517).

This recommendation (as described in the subcommittee proposal) consists of a roadmap for initiating the review of these substances in groups over a four-year timespan, with the goal of completing the majority of the reviews by the end of the current sunset period for §205.601(m) and §205.603(e) (the sections in 7 CFR 205 that list inert ingredients) in October of 2017. The recommendation contains new regulatory language, a series of steps to use in preparing for inerts review, screening guidelines that the Technical Evaluation Reports (TERs) will address, a tentative list of the proposed groups, and a rough timeline for review and completion. The NOSB will assess the viability of the timeline after it completes the recommendation on the first few groups of materials.

NOSB Committee Vote:

Moved: Zea Sonnabend

Seconded: Jay Feldman

Yes: 15 **No:** 0 **Abstain:** 0 **Absent:** 0 **Recusal:** 0

**National Organic Standards Board
Crops Subcommittee
Policy and Procedure Proposal
Other (“Inert”) Ingredients in Pesticide Formulations on the National List**

August 22, 2012

Introduction

This Policy and Procedure Proposal for review of other (“inert”) Ingredients in pesticide formulations on the National List addresses the many recommendations of the NOSB and concerns of the public about the crop production materials that are allowed for use in certified organic production under the National List section of OFPA (7 USC 6517).

This proposal consists of a roadmap for initiating the review of these substances in groups over a four year timespan, with the goal of completing the majority of the reviews by the end of the current sunset period for §205.601(m) and §205.603(e) (the sections in 7 CFR 205 that list inert ingredients) in October of 2017. This document contains a proposal for new regulatory language, a series of steps to use in preparing for inerts review, screening guidelines that the Technical Evaluation Reports (TERs) will address, a tentative list of the proposed groups, and a rough timeline for review and completion.

In order to initiate development of the necessary TERs by 2013, a vote on moving forward at the Fall 2012 NOSB meeting will be followed by additional details on the procedure, which will be finalized at the Spring 2013 meeting of the Board. Though it is recognized that many of these substances are not truly “inert,” this proposal retains use of the word inert in the regulatory language “inert (other) ingredients,” as that is the terminology used in Environmental Protection Agency (EPA) regulations and the Organic Foods Production Act of 1990 (OFPA). However, like EPA, the NOSB encourages the labeling of products permitted in certified organic production with the phrase “other ingredients” per EPA’s finding, “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.”¹

Background

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,

¹See EPA, Inert (other) Pesticide Ingredients in Pesticide Products - Federal Register and Pesticide Registration Notices on Other (Inert) Pesticide Ingredients, “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.”

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 and the NOSB 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 the renewal until October 21, 2017 of the current exemption on the National List permitting former List 4 inerts “pending review by the program of inerts individually and as a class of materials”.² In May 2012, the NOSB recommended an expiration date of October 21, 2017 for the current exemption that permits former List 3 inerts in passive pheromone dispensers, to coincide with the sunset date for List 4 inerts.

The NOSB-NOP-EPA working group was established in June 2010, known as the Inerts Working Group (IWG). 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.³

For more detail on the background of inerts discussions among the NOSB and references in OFPA and the USDA organic regulations, please see the above referenced documents.

Regulatory Language Proposal

The NOSB proposes this language to replace the current listing at section 205.601(m) and 205.603(e). The NOSB recommends that this change, including the listing of any approved (inert) ingredients, be completed prior to the October 21, 2017 sunset date for List 4 inerts:

Current language at sections 205.601(m) and 205.603(e):

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.

Replace the language at sections 205.601(m) and 205.603(e) with:

As synthetic other (“inert”) ingredients in pesticide formulations as classified by the Environmental Protection Agency (EPA) for use with nonsynthetic substances or synthetic substances listed in this section that are used as an active pesticide ingredient in accordance with any limitations on the use of such substances.

- (i) *Substances permitted for use in minimal risk products exempt from pesticide registration under FIFRA section 25(b);*
- (ii) *Reserved (for list of approved other (“inert”) ingredients)*

Discussion of Procedure

² October 28, 2010 recommendation available at <http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5087999&acct=nosb>

³ Available at <http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5094901&acct=nosb>

The policy proposal creates a four-year timeframe for evaluation of inert ingredients currently in use in organic agriculture that are not exempt from pesticide registration under FIFRA section 25(b). This includes former EPA List 4b and List 3 inerts in pheromones that were identified through information supplied by the Material Review Organizations OMRI (Organic Materials Review Institute) and WSDA (Washington State Department of Agriculture). It also will include inert ingredients that have previously petitioned, and a call for other (inert) ingredients. This list so far is 126 individual substances.

The NOSB proposes review of inerts by classes or groups, rather than by individual substance. The NOSB believes that allowing a class of substance by group will reduce the burden of the Board to individually review each substance previously allowed under the exemption for former List 4 or former List 3 for pheromone dispensers. For the purposes of this recommendation only the group names are provided. However, the substances that are recommended by NOSB would be included by individual names and CAS numbers, entered as the class is reviewed, under 205.601(m) and 205.603(e) above. Below are the proposed groups, with approximate numbers of materials in each group:

1. Alkyl alcohols - 3
2. Alkyl alkoxyates - 4
3. Alkylphenol ethoxyates - 9
4. Dyes - 2
5. EDTA and salts - 2
6. Fatty acid ethoxyates - 4
7. Fatty acids esters and salts - 6
8. Low risk polymers, as defined under 40 CFR 180.960 - 8
9. Mineral acids, bases and their inorganic salts -22
10. Organic acids and salts - 3
11. Polyalkoxyates and polyalkoxylated alkyl ethers - 5
12. Polysorbates - 5
13. Preservatives/antioxidants - 7
14. Tall oil and terpene derivatives - 5
15. Nonsynthetic - 14
16. Others - 27

The IWG is continuing to work in consultation with the EPA and the NOSB to categorize some of the many substances in the "other" category into additional or existing groups. The full group listing, including the list of chemicals, will be presented at the Spring 2013 NOSB meeting.

It is expected that 4-6 groups of chemicals will be evaluated every year during the four year period beginning in 2013. Should manufacturers identify ingredients in use that are not on the list for review, they will have time to come forward with a request for review. After this process is complete, manufacturers will be required to petition for the addition of new other ingredients, or "inerts," in pesticide formulations to the National List.

Given the scope of TERs and NOSB evaluation of these materials, it is recognized that completion of this process will take substantial resources and time. The current projected timeline will involve NOSB completion of all reviews by its Spring 2015 public meeting to enable the NOP to complete rulemaking by October 2017, the sunset date for List 4 inerts.

Because of the challenge that this presents, the NOSB will assess the viability of the timeline after it completes the recommendation on the first few groups of materials.

Proposed Procedure

- A. The NOSB will work with the IWG to finalize groups and screening steps.
- B. The NOSB will rely on the IWG to consult with OMRI and WSDA for updated inerts lists in case there are new inerts to add to the groups.
- C. The NOSB requests NOP to investigate and adopt within six months of the announcement of this proposal (Spring 2013) the appropriate mechanism for notifying manufacturers and the public regarding the inerts review process, including which inerts are under review and how to inform the IWG of inerts that are in use, but not on the list under review. .
- D. The NOSB requests NOP to commission one TER per group, except where noted, and coordinate review with the Board.
- E. The NOSB requests NOP to determine an appropriate format and commission a special inerts TER for each group to contain the following:
 - a. a chart of all inerts in the groups by CAS number with their chemical properties, uses, types of product categories in which they occur, EPA regulatory status, including data gaps.
 - b. a description of how inerts within group are related and how different, especially outliers that are significantly different from others.
 - c. a chart that evaluates each inert in the group under the screening steps suggested by NOSB (Appendix 1) and any additional screening recommended by the NOSB, with input from the IWG.
 - d. OFPA criteria will be addressed that are not covered in the EPA review (environment, interactions, and alternatives or essentiality)
- F. Based on results of group TER, the NOSB Crops Subcommittee accepts group to move forward to NOSB agenda, or singles out one or more for individual review. The group will then move forward without the singled out one and that one will be re-reviewed in more detail if necessary.
- G. The NOSB, working with the IWG, will prioritize the order of reviews so that the most potentially problematic are reviewed first. The others can be done later and some may not need full TERs. Priority also given to fully disclosed ones that have been petitioned and may fall outside one of the groups. In setting priorities, there will be consideration of the amount used in organic production if that can be determined.
- H. The anticipated timeline will enable the NOSB to finalize the procedure by Spring 2013, start reviews for fall 2013 and to have as many reviews completed as possible by Spring 2015. The intention is to have an amendment to the National List in 2017, which will address the materials reviewed with an implementation period of 2 - 5 years, taking into account public comment and the need for additional reviews for reformulation and compliance.

- I. By the time of the five-year sunset period, the NOSB will approach a review of those on the 25b list.

Recommended Subcommittee Action & Vote (state actual motion):

Motion:

To adopt the proposed Policy and Procedure Proposal on Other (“Inert”) Ingredients in Pesticide Formulations on the National List.

Motion by: Colehour Bondera Second: Jay Feldman
Yes 8 No 0 Abstain 0 Absent 0 Recuse 0

Approved by Subcommittee Chair to Transmit to NOSB

Jay Feldman, Subcommittee Chair

August 22, 2012

Appendix A – Inerts Screen

(modified from NOSB proposal of 2010)

(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)

http://www.oehha.org/prop65/prop65_list/Newlist.html

Group A: Human Carcinogen (US EPA 1986 category)

http://npic.orst.edu/chemicals_evaluated.pdf :

<http://iaspub.epa.gov/apex/pesticides/f?p=chemicalsearch:1:613774867565701>

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) <http://ntp.niehs.nih.gov/?objectid=03C9F0A4-B1C2-31DE-ABA8508AE9949C57>

Reasonably Anticipated to be Human Carcinogens (NTP)

Group 1: Carcinogenic to Humans (IARC)
<http://monographs.iarc.fr/ENG/Classification/index.php>
Group 2A: Probably Carcinogenic to Humans (IARC)
Group 2B: Possibly Carcinogenic to Humans (IARC)

(4) 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) http://www.epa.gov/tri/trichemicals/hazardinfo/hazard_chronic_non-cancer95.pdf

EPA Reregistration Eligibility Decisions (RED)

<http://iaspub.epa.gov/apex/pesticides/f?p=chemicalsearch:1:613774867565701>

Insecticide Resistance Action Committee (IRAC) Mode of Action Classification:

<http://www.irac-online.org/eClassification/>

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).

California Department of Pesticide Regulation or the Materials Safety Data Sheet (MSDS) designations for cholinesterase inhibitors

(5) 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).

http://ec.europa.eu/environment/docum/pdf/bkh_annex_13.pdf or

http://ec.europa.eu/environment/endocrine/strategy/substances_en.htm#report2

(6) (Regarding outdoor use) Adversely affects the environment/wildlife, based on:

1. 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.
2. 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.
 - a) 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: $GUS = \log_{10}(\text{half-life}) * (4 - \log_{10}(Koc))$.

(7) 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.

(8) Contaminants and metabolites recognized by EPA that violate any of the above criteria.

(9) Known groundwater contaminants, as designated by the state of California (for actively registered pesticides) or from historic groundwater monitoring records.