

Formal Recommendation

From: National Organic Standards Board (NOSB)

To: the National Organic Program (NOP)

Date: October 16, 2012

Subject: Policy and Procedure on Other (“Inert”) Ingredients in Pesticide Formulations on the National List

Chair: Barry Flamm

The NOSB hereby recommends to the NOP the following:

Rulemaking Action: X

Guidance Statement:

Other:

Statement of the Recommendation: Motion 1

Replace the language at sections 205.601(m) and 205.603(e) with the following (with the change, including the listing 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

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:

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.

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 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 recommendation initiates additional details on the procedure for inerts review, which will be finalized at the Spring 2013 meeting of the NOSB. Though it is recognized that many of the substances to be reviewed are not truly “inert,” the recommendation 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.”

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 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”. 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 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 reviewing a class of substances 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.

NOSB Committee Vote:

Moved: Zea Sonnabend

Seconded: Jay Feldman

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