



# BEYOND PESTICIDES

701 E Street, SE ■ Washington DC 20003  
202-543-5450 phone ■ 202-543-4791 fax  
info@beyondpesticides.org ■ www.beyondpesticides.org

October 2, 2015

Ms. Michelle Arsenault  
National Organic Standards Board  
USDA-AMS-NOP  
1400 Independence Ave. SW.,  
Room 2648-S, Mail Stop 0268  
Washington, DC 20250-0268

## Re. CS, LS: List 4 “inerts” annotation change

These comments to the National Organic Standards Board (NOSB) on its Fall 2015 agenda are submitted on behalf of Beyond Pesticides. Founded in 1981 as a national, grassroots, membership organization that represents community-based organizations and a range of people seeking to bridge the interests of consumers, farmers and farmworkers, Beyond Pesticides advances improved protections from pesticides and alternative pest management strategies that reduce or eliminate a reliance on pesticides. Our membership and network span the 50 states and the world.

## Annotations at Sunset

It should be noted that the National Organic Program (NOP) in September of 2013 issued a rule<sup>1</sup> that reversed the NOSB’s annotation policy and has since that time prohibited the board from adopting recommendations for annotation changes to sunset materials without a petition.

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<sup>1</sup>AMS/NOP issued a rule in 78 FR 56811 (September 16, 2013), stating, in part: “**Can NOSB recommend a change to or addition of an annotation to a substance during Sunset Review? Can the NOSB recommend moving a substance to a different section of the National List during the Sunset Review?**”

No. For substances already on the National List, changes to or addition of annotations, or changes to the location of a substance on the National List (e.g., agricultural versus nonagricultural), cannot be proposed during the Sunset Process. In the past, NOSB made recommendations to further restrict the use of substances during Sunset Review. At times, these recommendations have not been exposed to robust public comment and have been difficult for AMS to implement through rulemaking actions by the sunset date. The difficulties with implementing these recommendations include the level of analysis required to assess how organic stakeholders may be affected by the recommendation and the deadline for completion of the Sunset Process. If the NOSB identifies new information that it believes merits reconsideration of a use restriction on a substance (e.g., to expand its use, further restrict its use, or correct its restrictive annotation) or the location of a substance on the National List, then a member of the NOSB or a member of the public can file a petition for changes to the use or classification of a substance through the National List Petition Process ([www.ams.usda.gov/nop](http://www.ams.usda.gov/nop)).” *National Organic Program –Sunset Process*. 78 FR 56811. See <http://www.gpo.gov/fdsys/pkg/FR-2013-09-16/pdf/2013-22388.pdf>.

Since the September 2013 notice and resulting final rule, NOP has prohibited the board from proposing annotations at sunset. The NOP rule allowing uses that were restricted by board-adopted annotation recommendations reversed procedures and policy adopted by the NOSB in October 2010, after public hearing and comment, to permit the board to annotate National List materials in sunset review, as long as the annotations are not more permissive than the existing listing. While we support annotations at sunset as a mechanism that improves the ability of the NOSB to respond to new science and information on practices, we do not support the Agricultural Marketing Service and NOP of the USDA issuing changes in policies and procedures without subjecting those changes to public review and comment, which is required by law. Therefore, we submit these comments in protest of a procedure that we deeply believe not only violates proper procedure and policy but undermines the integrity of the organic label.

### Beyond Pesticides strongly opposes the proposed annotation change on synthetic “inert” ingredients in substances, or materials, allowed in organic production.

In failing to set forth a process to fully and specifically review synthetic materials identified as “inert” or other ingredients, the Crops Subcommittee (CS) is proposing to abdicate NOSB’s statutory responsibility to determine whether these synthetic materials contained in allowed materials comply with criteria established by the Organic Foods Production Act (OFPA) and subsequent regulations. As we have said to the NOSB and the NOP, it is simply inadequate and not compliant with organic law to reference allowances of synthetic materials under other statutes that do not contain the same or equivalent review criteria established by OFPA. The NOSB, in so doing, is giving the authority to decide which “inerts” are suitable for use in organic production to an agency—the U.S. Environmental Protection Agency (EPA), in the inerts proposal—for which there is a documented failure to regulate these ingredients in pesticide products and which has no guidance for determining whether the materials meet the listing criteria of OFPA. Furthermore, the NOSB proposal eliminates all transparency, including required opportunities for public comment on the inclusion of these synthetic materials in organic production or processing. Under the CS proposal, the chemicals will not be considered, as required by OFPA, “by specific use or application.” Nor would the identity of the “inert” ingredients be revealed. As you know, the identity of inert ingredients in pesticides generally is public information and routinely disclosed by EPA, though EPA has chosen not to require that they be disclosed on pesticide labels. Through its previous proposals, the NOSB, similar to EPA, sought to disclose inert ingredients used generally in organic production without association to specific products.

In stark contrast to previous recommendations of the NOSB that were adopted in April 2010 and at subsequent meetings, the CS is now proposing a path forward with the review of previous (no longer used by EPA) List 4 “inerts” that betrays a board-adopted plan and the underlying statute. Finally, the CS is offering the public neither a specific explanation for the dramatic departure from a previous board proposal nor an assessment of how its changed proposal to utilize determinations by EPA meets the standards and criteria of OFPA.

While we believe that any process that is adopted by the NOSB should not be disruptive of product availability in organic production, the established review process must not undermine the credibility of the NOSB's assessment and technical review, the integrity of the organic food label, and public trust. When NOSB cites the actions of agencies of the federal government, it is critical that it not wholly relinquish its review responsibility. The board's previous wholesale reliance on EPA's "List 4" exemplifies the problem with relying on other federal agency standards, which may be eliminated or changed. EPA's List 4 does not meet the standards of OFPA, especially as it relates to potential environmental and biodiversity impacts of the chemicals listed, and especially List 4B, which relies on exposure assumptions. In the proposed annotation change to the inerts listing, the reference to FIFRA Section 25(b) and the Safer Chemical Ingredient List, while helpful in guiding the NOSB's decision making, does not allow the board to forego a review process to ensure compliance with OFPA criteria. Therefore, the annotation may cite other governmental review programs, but it must ensure ongoing review of individual materials or classes of materials, in compliance with OFPA. This type of review by individual material or group of materials must occur and therefore this review must be included in the annotation language. By reversing a previous board decision and adding a blanket allowance of "Inert ingredients that are exempt from the requirement of a tolerance under 40 CFR 180.1122 – for use only in passive pheromone dispensers," the board is violating its legal responsibility to ensure review of all synthetic materials for their impact on the environment and biodiversity. Remember that clear restrictive language governing inerts review does not eliminate the inerts from use in organic; it simply ensures that the NOSB carries out its responsibility for proper materials oversight and review in issuing its recommendations.

To ensure proper oversight by the NOSB, the proposal should be amended to read,

205.601(m) and 205.603(e) – As synthetic inert or other 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.

- ~~(i) Substances permitted for use in minimal risk products exempt from pesticide registration under FIFRA section 25(b).~~ on EPA's former List 4A or 4B that have been reviewed according to OFPA criteria: [List]; and
- ~~(ii) Substances included on the EPA's Safer Chemical Ingredient List.~~
- ~~(iii) Inert ingredients that are exempt from the requirement of a tolerance under 40 CFR 180.1122 – for use only in passive pheromone dispensers.~~
- ~~(iv)~~ [Reserved] (for any other inerts individually petitioned and reviewed)]

## **Previous NOSB recommendations gave direction to the NOP and NOSB.**

A short history was presented in the Fall 2012 Crops Subcommittee proposal:

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 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.

At the fall 2012 NOSB meeting, following up on the NOSB recommendation of spring 2010, the board unanimously passed a recommendation that was to put in motion the long-anticipated review of “inert” or “other” ingredients in pesticide products used in organic with the following language:

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)

And now, as “List 4 inerts” are up for sunset review, the only progress that has been made is a discussion concerning nonylphenol ethoxylates –that will not be considered at this meeting— and this proposal, which we believe does not meet the NOSB’s responsibility to issue recommendations in accordance with OFPA criteria. NOP and the Agricultural Marketing Service (AMS) have still not issued a notification, as it told the board and public it would do nearly five years ago, to manufacturers and users of products with a request for information on current inert ingredients in use. This ‘data call-in notice’ was intended to capture inert ingredients that may not be on the comprehensive list of 126 priority “inert” ingredients and 87 “minimal risk” substances eligible for registration under FIFRA section 25(b) used in formulations allowed in organic production, which was generated by the Inerts Working Group based on data from Material Review Organizations and the Washington State Department of Agriculture and provided to the public as categories of common chemicals at the fall 2012 meeting of the NOSB. NOP’s failure to publish a notice impedes the program from moving ahead on this critical matter of agency noncompliance with the law. **The inerts notice by NOP/AMS is woefully overdue and should be issued without further delay.**

### **The current proposal is inadequate.**

The proposal would allow EPA’s Safer Choice Program full control over the listing of “inert” ingredients for use in organic production by allowing anything listed by EPA on its Safer Chemical Ingredient List (SCIL) to be used. The SCIL is compiled without reference to use in products approved for use in organic production, which is contrary to OFPA §6517(b). This provision requires that, “The list established under subsection (a) shall contain an itemization, by specific use or application, of each synthetic substance permitted under subsection (c)(1) or each natural substance prohibited under subsection (c)(2).” The CS acknowledges in its appendix that the materials are on SCIL without being evaluated for agroecosystem effects unless data is provided and proposes no uniform production or evaluation of such data. Issues like this could easily be resolved with information provided by a Technical Review document.

The proposal lists factors required to be taken into account under OFPA and compares them to factors considered by EPA in creating the SCIL. The list of factors to consider is fine, but it does not constitute and are not equivalent in major ways to criteria for listing. Those criteria are established in OFPA §6517(c)(1):

- (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—
  - (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;

Unless the NOSB subjects “inerts” to a decision-making process incorporating these decision criteria, it is not fulfilling its statutory responsibility as gatekeeper to the National List.

### **The Safer Choice Program should play a role, but requires better direction from the NOSB.**

The Safer Choice Program (SCP, formerly Design for the Environment (DfE)) is a valuable resource. We have suggested, for example, that the NOSB use information about alternative sanitizers in its review of sanitizers on the National List. The SCP could through a collaborative process or Memorandum of Understanding review chemicals to OFPA criteria, and this was the original plan in working with DfE. However, the approach as proposed by the CS triggers an allowance without the legally required review by the board accompanied by public notice and comment.

We suggest that correct, legal use of SCP should proceed as follows:

1. The SCP reviews “inerts” according to OFPA criteria, using the factors of OFPA §6518(m), as listed in the proposal, producing a familiar material evaluation checklist and a proposed verdict concerning whether the material meets the three criteria listed in OFPA §6517(c)(1) (which are also on the cover sheet of the materials evaluation checklist).
2. The CS or LS proposes listing/delisting the materials based on whether they meet OFPA criteria. This proposal, like all NOSB proposals, would be subject to public comment as a subcommittee proposal and later as a proposal by the NOP for amending the National List.
3. The NOSB votes on the listing of the materials.
4. The NOP proposes additions to the National List as appropriate.

As indicated by the NOSB recommendation passed unanimously by the board in the fall of 2012, the review and proposals for listing can proceed in groups of related chemicals.

### **“Inerts” in pheromone products should be subject to the same criteria as other “inerts.”**

The current proposal includes a separate listing for “Inert ingredients that are exempt from the requirement of a tolerance under 40 CFR 180.1122 –or use only in passive pheromone dispensers.” Why should the NOSB not subject all “inert” ingredients to the same degree of scrutiny? All “inerts” should be subject to review in accordance with OFPA criteria.

## **NOP currently allows toxic chemicals –“inerts” of toxicological concern—to be used in organic production.**

OFPA prohibits “inerts of toxicological concern,” which has been improperly defined as those on the former Lists 1, 2, and 3, given that the scope of EPA’s review under the Federal Insecticide, Fungicide and Rodenticide Act is narrower than the review required under OFPA. By defining the allowed “inert” ingredients in products used in organic production to include List 4B as well as List 4A, the NOSB and NOP have allowed chemicals known to be toxic, but judged to be low-risk by EPA’s pesticide program based only on dietary exposure. This is insupportable because OFPA criteria are broader than those considered by EPA in conducting a food-use exposure assessment and making a determination to exempt a material from tolerance.

Active ingredients in pesticide products permitted under organic standards have been carefully screened to ensure that they meet the requirements of OFPA. Because of the thorough investigation by the NOSB and the additional scrutiny given by the public in written and oral comments, the active ingredients that are allowed in organic agriculture present little hazard to people and ecosystems, from their manufacture through their use and disposal.

So-called “inert” ingredients, on the other hand, have not received –and will not receive under this proposal—the same level of scrutiny as active ingredients to ensure that they meet OFPA standards. It should be noted that “inert” ingredients often comprise the majority of the pesticide product formulation. As a result, the most hazardous part of pesticide products used in organic production may actually be the so-called “inert” ingredients.

Our review of “inerts” known to be used in organic production has revealed a number of toxic chemicals, including the nonylphenol ethoxylates that are being considered for exclusion by the CS. Other groups of potential problem chemicals that we have investigated are EDTA and its salts and those formerly on EPA’s list 3 and used in pheromone products.

## **NOP has broken faith with the organic community in failing to follow through with NOSB recommendations and should take immediate steps to eliminate “inerts” of toxicological concern from products used in organic production.**

The NOP should:

- Immediately issue a notification to manufacturers and users of products used in organic production with a request for information on current inert ingredients in use.
- 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, with expiration dates until reviewed individually.)

The NOSB must:

- Immediately begin reviews of “inerts” used in organic production, proposing listing/delisting based on OFPA criteria.

In addition, if any change is to be made to the listing as previously recommended by the NOSB, then it must move the process along. Therefore, we recommend the following instead of the CS proposal:

205.601(m) and 205.603(e) – As synthetic inert or other 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:

- (i) substances formerly on EPA List 4A or 4B that have been reviewed according to OFPA criteria: [List]; and
- (ii) [Reserved] (for any other inerts individually petitioned and reviewed)]

This is what would ultimately result from adoption of the procedure in the fall 2012 recommendation.

We look forward to working with the NOSB and NOP to resolve these critical issues that go to the heart of synthetic materials used in organic production and the protection of farmers, consumers, and the environment. If we are to see the growth that we all want to see in the organic sector, we will need to get the inerts issue right, lest we risk undermining the meaning of the organic label.

Thank you for your consideration of these comments.

Sincerely,



Terry Shistar, Ph.D.  
Board of Directors