



# BEYOND PESTICIDES

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April 3, 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. NOP Policy on Nanotechnology (Policy Memo 15-2)**

These comments to the National Organic Standards Board (NOSB) 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 groups around the world.

We urge the NOSB to make a strong statement protesting the nanotechnology policy memo issued by the National Organic Program (NOP). The policy articulated in Policy Memo 15-2 is at odds with the policy passed by the NOSB and would allow materials to be listed on the National List that would not be allowed according to the policy adopted by the NOSB.

In the fall of 2010, the NOSB adopted a policy that defined “engineered nanomaterials” and recommended that the NOP prohibit engineered nanomaterials in organic products and take steps to avoid their accidental or incidental presence.

### **Definition is essential.**

The NOSB realized that size is not the sole determining factor in defining the object of its concern, and defined “engineered nanomaterials” as follows:

Engineered nanomaterials: substances deliberately designed, engineered and produced by human activity to be in the nanoscale range (approx 1-300 nm) because of very specific properties or compositions (eg. shape, surface properties, or chemistry) that result only in that nanoscale. Incidental particles in the nanoscale range created during traditional food processing such as homogenization, milling, churning, and freezing, and naturally occurring particles in the nanoscale range are not intended to be included in this definition. All nanomaterials (without exception) containing capping reagents or other synthetic components are intended to be included in this definition.

The NOSB requested that “the NOP work with the NOSB on the adequacy of the definition, any potential areas of concern that may not be included in this definition, parts of this definition that are not workable within enforcement, and possible adjustments to the approximate size constraints that may be needed.” Instead, the NOP unilaterally refused to define the subject of its notice, saying:

To avoid conflicts about the presence of nanomaterials in substances regulated by other Federal agencies, the NOP is not establishing a separate definition for engineered nanomaterials, such as the definition recommended by the NOSB. The descriptions in the U.S. Food and Drug Administration’s Guidance for Industry Considering Whether an FDA-Regulated Product Involves the Application of Nanotechnology and the U.S. Environmental Protection Agency’s policies on Regulating Pesticides that Use Nanotechnology and Control of Nanoscale Materials Under the Toxic Substances Control Act should be used as applicable.

The three sources cited by NOP do not agree on a definition. The two EPA documents cited state that nanomaterials are in the size range of approximately 1-100 nm. On the other hand, the FDA document is more consistent with the NOSB recommendation, considering also “[w]hether a material or end product is engineered to exhibit properties or phenomena, including physical or chemical properties or biological effects, that are attributable to its dimension(s), even if these dimensions fall outside the nanoscale range, up to one micrometer (1,000 nm).” NOP must act to protect organic products and production. Its mission is not necessarily in alignment with other agencies, and the agency must not depend on other agencies with less protective standards to take the lead in preventing the intrusion of unwanted technology into organic products and production.

Regulation depends on clear definitions, and NOP’s policy is meaningless without a definition of “engineered nanomaterial.” NOP has clarified this reliance on contradictory definitions by saying that the EPA definition would be used when looking at pesticides and the FDA definition would be used when looking at food additives. This inconsistency requires further clarification since some pesticide uses result in food additives.

Furthermore, the policy cannot be implemented without questions in the petition form that elicit the relevant information. We challenge NOP to devise questions for the petition form that will tell NOP and NOSB whether the petitioned substance meets its vague criteria for nanomaterials. The NOSB is charged with creating the petition process, so the board should have been consulted before announcing this policy.

**The NOSB’s policy prohibited all use of engineered nanotechnology in organic.**

While the NOP policy takes a neutral stance towards nanotechnology –“The NOP does not consider nanotechnology to be intrinsically benign or harmful.”—the NOSB said, “There is overwhelming agreement within the organic industry to prohibit nanotechnology in organic production and processing at this time.” The NOSB policy asked that the NOP “accept the definition listed above as synthetic substances, that they may have unique properties that distinguish them from all listings of these substances in a bulk form, and that they are not allowed by a listing of the bulk form of the substance on the NL, or otherwise allowed in organic

production, pending a further recommendation from the NOSB, and implementation thereof by the NOP, on the use, or prohibition, of engineered nanomaterials in organic production processing and packaging.” [Emphasis added.]

The NOSB recommendation could have been codified in the regulations by adding the NOSB definition at §205.2 and the prohibition at §205.105, Allowed and prohibited substances, methods, and ingredients in organic production and handling, by adding (h) engineered nanomaterials.

Instead of the clarity recommended by the NOSB, the NOP invites petitions for nanomaterials: As with other substances, no engineered nanomaterial will be allowed for use in organic production and handling unless the substance has been: 1) petitioned for use; 2) reviewed and recommended by the NOSB; and 3) added to the National List through notice and comment rulemaking. The OFPA provides criteria that the NOSB must use to evaluate substances requested for use in organic production and handling. Individuals or organizations petitioning to add an engineered nanomaterial to the National List must provide information to address the OFPA criteria.

Moreover, this statement is false, since there are “other substances” –such as nonsynthetic materials used in organic crop and livestock production—that do not require these steps. So which is it? Do nanomaterials need to comply with the requirements for “other substances,” or with those for synthetic substances?

The NOSB further expressed concerns about contamination of organic products from packaging, food contact surfaces, and water sources. The NOP has failed not only to address these concerns, but to recognize their implications for the extent of concern regarding engineered nanomaterials in general.

### **NOP may not legislate through policy memos.**

It is reasonable to classify engineered nanomaterials as synthetic. In fact, the NOSB argues they should be considered synthetic under the current definition. Comments from Consumers Union on a 2009 proposal by the Materials Committee addressed the issue directly:<sup>1</sup>

The critical question is what constitutes a “synthetic” substance. Normally to be considered synthetic a substance has to be changed chemically in the lab. We would argue that the production of a nano-scale material would constitute a chemical change that would make it “synthetic.” Indeed, experts on nanotechnology are virtually unanimous that nano-scale materials have the potential for structure-dependent health effects that are uniquely different than their larger counterparts.

However, the NOP memo does not try to justify that classification. In fact, NOP argued that the fact that many or most nanomaterials would be classified as nonsynthetic under the current regulations is one reason for issuing the policy memo.<sup>2</sup>

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<sup>1</sup> Comments of Consumers Union on Agricultural Marketing Service, Notice of the Meeting of the National Organics Standards Board (Docket No. AMS-TM-09-0014). Prepared by Michael Hansen, Ph.D. Senior Scientist April 20, 2009.

Nevertheless, the policy memo never states that engineered nanomaterials are synthetic or that NOP will treat them as such. Through this policy memo, NOP seeks to subject nanomaterials, many of which may meet the definition of “nonsynthetic” under the regulations,<sup>3</sup> to the procedures (petition, etc.) required of synthetic materials (and nonsynthetic, nonorganic materials used in processing.) It has not proposed a new definition of “synthetic” or “nonsynthetic” in the regulations that supports this interpretation, nor has it given a justification for including it under the current definition of synthetic. NOP refers to a recommendation of the NOSB, but is not implementing that recommendation. The recommendation asks NOP “to accept the definition listed above as synthetic substances, that they may have unique properties that distinguish them from all listings of these substances in a bulk form, and that they are not allowed by a listing of the bulk form of the substance on the NL, or otherwise allowed in organic production, pending a further recommendation from the NOSB, and implementation thereof by the NOP, on the use, or prohibition, of engineered nanomaterials in organic production processing and packaging. NOP has not defined “engineered nanomaterials” as the NOSB recommended, or otherwise. The NOSB recommendation called for implementation using guidance, which would require a public comment period. Instead, NOP has chosen a policy memo as a vehicle for the statement, which NOP considers to be more enforceable, but without a requirement for public notice and comment.<sup>4</sup> We question its enforceability because we question whether it can actually do what NOP claims.

### **The NOSB must exercise enough control over its agenda to respond to such actions by the NOP.**

The NOP has taken control of the NOSB to the extent that the Board is not permitted to set its own agenda. However, if it does not respond to NOP actions that are inconsistent with NOSB, recommendations, especially when those actions may permit the listing (through ignorance of a material’s properties) of a material specifically prohibited by prior action, it will not meet its obligation under OFPA “to assist in the development of standards for substances to be used in organic production and to advise the Secretary on any other aspects of the implementation of this chapter.”

With regard to engineered nanomaterials in particular, having seen the ineffective response of NOP to the recommendation to address nanotechnology through guidance, the NOSB should propose more effective measures:

1. NOP must define “engineered nanomaterials.”
2. NOP must state and support its conclusion that engineered nanomaterials as defined are synthetic.
3. NOP must state that engineered nanomaterials are not permitted in organic production and handling, including packaging, based on the NOSB recommendation. The NOSB recommendation could have been codified in the regulations by adding the NOSB definition at §205.2 and the prohibition at §205.105, Allowed and prohibited

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<sup>2</sup> Statement by Miles McEvoy in conference call with members of the National Organic Coalition, 4/2/2015.

<sup>3</sup> Statement by Miles McEvoy in conference call with members of the National Organic Coalition, 4/2/2015.

<sup>4</sup> Statement by Miles McEvoy in conference call with members of the National Organic Coalition, 4/2/2015.

substances, methods, and ingredients in organic production and handling, by adding (h) engineered nanomaterials.

Thank you for your consideration of these comments.

Sincerely,

A handwritten signature in black ink, appearing to read "Terry Shistar". The signature is fluid and cursive, with a long horizontal stroke at the end.

Terry Shistar, Ph.D.  
Board of Directors