

**Formal Recommendation by the
National Organic Standards Board (NOSB)
to the National Organic Program (NOP)**

Date: **October 28, 2010**

Subject: **Guidance Document -- Engineered Nanomaterials in Organic
Production, Processing and Packaging**

Chair: **Daniel G. Giacomini**

The NOSB hereby recommends to the NOP the following:

Rulemaking Action
Guidance Statement X
Other

Statement of the Recommendation (Including Recount of Vote):

There is overwhelming agreement within the organic industry to prohibit nanotechnology in organic production and processing at this time. The Materials committee recommended a guidance document that included a definition of engineered nanomaterials and asked the National Organic Program to recognize materials that met the definition as synthetic and prohibited. Additionally, the document asks the NOP to work with NOSB to determine whether enforcement of restrictions in primary packaging and food contact surfaces is possible, practical, and legal and to schedule a symposium on the topic of engineered nanomaterials to aid in evaluating a several topics related to the guidance document and further rulemaking. The recommended guidance document is attached.

Public comment in response to the recommended guidance document was mixed with all of those providing comment agreeing that consumers of organic products did not want nanotechnology in their products. Many comments were received saying the recommendation did not go far enough because it did not prohibit engineered nanomaterials immediately. Two comments asked that any action be deferred until more some of the areas in question could be explored at a symposium. Several comments supported the recommended guidance document in full.

The Materials committee met during the October 2010 NOSB meeting to make changes to the recommended guidance document in reaction to public comment received. Specifically the committee added language to make it clearer that the intention was to prohibit engineered nanomaterials immediately pending further study during a symposium. Language was also added, in

response to one public comment, asking for clarification for how §205.272(b)(1) and OFPA 2111.a.5 prohibit use of engineered nanomaterials in packaging.

The NOSB voted to accept the recommended guidance document on engineered nanomaterials with 14 voting yes and 0 no votes.

NOSB Vote:

Moved: Katrina Heinze		Second: Joe Smillie		
Yes: 14	No: 0	Abstain: 0	Absent: 0	Recusal: 0

**National Organic Standards Board
Materials Committee
Guidance Document -- Engineered Nanomaterials in
Organic Production, Processing and Packaging**

October 28, 2010

The National Organic Standards Board proposes that Engineered Nanomaterials be prohibited from certified organic products as expeditiously as possible. We respectfully request that the National Organic Program take immediate actions to implement this document.

Introduction

There is overwhelming agreement within the organic industry to prohibit nanotechnology in organic production and processing at this time. However, there is confusion over the definition of what exactly should be prohibited. Additionally, there is disagreement over how to prohibit the products of this technology in the organic industry. Everyone shares a concern about the contamination by products of nanotechnology. This concern includes the ability of the regulatory agency, the National Organic Program (NOP), to fully control two of the major sources of contamination in final organic food products: food contact surfaces and primary packaging. This subject is further complicated since nanotechnology is a new and developing technology. This document offers guidance to the NOP on how the National Organic Standards Board (NOSB) believes the area of most concern about this technology can be regulated within the current rules and regulations already in place. This guidance document requests cooperation with the NOP to help the NOSB make further recommendations to more clearly regulate this developing technology within the organic industry. Finally, this document requests the NOP allow the NOSB to host a symposium at one of its upcoming meetings to better understand this technology.

Background and Discussion

The potential contamination by extremely small particles of a substance that may exhibit characteristics distinct from the bulk products is of great concern to the organic industry and consumer. As with all materials that are not naturally occurring, the Organic Foods Production Act (OFPA) requires us to question the impacts on health and safety to humans, animals, and the environment of these extremely small synthetic particles with unique properties in determining whether these substances are safe and advantageous. The determination of whether these materials should be allowed in organic production and processing should be made separately from the allowance and consideration of the same substance in its bulk form.

Defining area of concern

The NOSB received public comment via previous documents from the Materials Committee (MC) related to nanotechnology and the products of nanotechnology. Public comment overwhelmingly agrees that nanotechnology in organic production and processing be prohibited at this time. However, there is considerable debate and disagreement on what exactly nanotechnology is and what products of nanotechnology should be prohibited.

A Technical Review (TR) was requested to aid the MC, and the Board has utilized this TR, dated June 28, 2010, and other supporting materials to develop a definition of the area of concern within the larger term of nanosized materials and products of nanotechnology. The TR identifies three sources of nanosized materials: natural, incidental and engineered. Natural nanosized products such as corrosion particles and sea spray are not practical to prohibit. Incidentally produced nanosized particles, such as those created in traditional production methods such as grain milling and milk homogenization have been present in materials utilized within the crops, livestock, and food industries for decades and are not the areas of concern.

The MC proposes a definition for Engineered Nanomaterials. The MC believes all substances that would fall under this definition are synthetic and therefore are prohibited in organic production and processing unless specifically allowed on the National List of Allowed and Prohibited Substances (NL). Further, the MC believes that these items may have unique properties that distinguish them from their bulk-sized counterparts and that no listings on the NL were intended at the time of listing to include the engineered nanomaterial form. The MC firmly believes that nothing currently on the NL has been reviewed or a TR performed that included any aspect of the manufacture, use and disposal of that substance in a nanomaterial form, and that nothing on the list should currently be allowed in this form.

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.

There was extensive debate within the MC regarding the size range included in the definition. The TR specifically states that the classic definition of nanotechnology is within the 1-100 nm range. However, the TR specifically states that size is not the best determinant for the items of concern. Better determinants would include size to mass ratio or specific reference to unique characteristics. The main concerns leading us to restrict these materials are unique properties or functions that could be harmful to the animal, human or the environment and the potential for contamination by these small particles within organic production and processing. The MC recognizes that there may be substances less than 100 nm in size that offer no unique properties or functions and offer no potential problems with their use or contamination. Conversely, it is recognized that small particles, larger than the 100 nm limit, can offer very unique properties and a great potential for contamination. Substances larger than 300 nm also could exhibit unique properties than those of their bulk counterparts as well. The main issue of concern is the potential contamination from these very small materials that are poorly studied in regard to being harmful to animals, humans and the environment. Public comment with scientific citations from consumer and environmental groups received during the November 2009 and April 2010 meetings of the NOSB requested the inclusion of a size range up to 300 nm within the definition of materials of concern. The MC has chosen to include that size range in this definition, with the qualifier that this size restriction is an approximate. The more important issue is the unique properties that occur with the small sized particle.

The MC requests the 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. Furthermore, the Board requests 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.

Extent of enforcement

Again, the concern with these substances is not only their intentional use in organic production and processing but also the contamination from these substances during production and processing.

The MC would support the application of these restrictions to primary packaging and food contact surfaces as well as the normal management of organic crops and livestock and processing of final retail products. There is great concern for contamination that could occur from the primary packaging (i.e., packaging materials in physical contact with the certified organic product) and via food contact surfaces that the organic product comes in contact with during production and processing. The MC requests that the NOP work with the NOSB during the time this guidance document is in place to determine whether enforcement of restrictions in these two areas is possible, practical, and legal. We seek clarification for how §205.272(b)(1)

and OFPA 2111.a.5 prohibits use of engineered nanomaterials in packaging. The MC is interested in restricting as much as possible the potential for contamination by these substances, while recognizing the problems and potential harm to the NOP and the industry of requesting a level of enforcement that is not practical, possible or legal.

Additional concern exists over the inadvertent contamination that could occur out of the control of the production or processing management. Such sources could include, but certainly are not limited to, the use of a nanotechnology filter in a municipal or other water supply that contaminates the water used in the facility even at very low levels. In cases, where there is inadvertent contamination from a source out of the organic facility's control and where no alternatives exist, the MC does not believe this restriction should force the facility to move to a new location or be forced out of organic production. The MC requests the NOP work with the Board to clarify such situations.

The MC recognizes that these restrictions could not apply in cases where the use of materials covered within the definition is required by law. A potential example of this would be a requirement to place a nanosensor in contact with a perishable product, such as raw meat, that would detect bacterial growth, toxin production, or other spoilage.

Request for a Symposium

The MC requests the NOP allow the NOSB to call for a symposium on this topic. This field of science is very complex and complicated. It is a new science that is still developing rapidly. Board members have studied this science in the preparation of four related documents. There is still much confusion. The MC believes a face-to-face symposium to discuss the issues related to the human-engineered portion of this science would help to clarify these confusing issues, and serve to educate both the Board and the NOP on this topic.

The Symposium would need to be specific to the areas of concern within the science of nanotechnology in order to more clearly define the term used to enforce a prohibition. It should include the areas described above regarding the potential for contamination in areas such as primary packaging and food contact surfaces. Other areas of interest regarding this topic could be included to help educate the NOSB members. The selection of speakers for the symposium should focus on education for the members of the Board and fairness to as many sides of the debate as possible.

The NOSB recognizes that it may take some time to organize and schedule such a symposium. The NOSB requests cooperation with the NOP to work with the NOSB on this matter. The NOSB hopes that this matter will be a high enough priority to allow for some budget consideration for this topic. The NOSB recognizes that there may be budgetary matters involved in conducting such a symposium that are beyond its influence or control.

Future developments

At some point in time in the future, after working with the NOP according to the terms of this guidance document, the MC will return to this topic to propose further recommendations.

Such a recommendation could include fine-tuning and greater clarity regarding the definition of the sector of this technology being prohibited, a more definitive statement on the extent of the prohibition of the substances within the definition, potentially recommending a complete §205.105 prohibition, a §205.105 prohibition unless as provided in the NL, or a statement that these substance are synthetic and all the prohibitions regarding that policy would be in place. As a result, future Boards are requested to be very diligent and cautious in their consideration for adding annotations to substances already on the NL or to be added to the NL that would allow the engineered nanomaterial form of a substance in organic production or processing.

A future recommendation could include considerations determined after working in cooperation with the NOP on the legality and ability to restrict and enforce the use of such substances in primary packaging, food contact surfaces, or other areas of potential contamination. The Board recognizes that since contamination from these substances is a primary concern, a future Board could be influenced by a limitation of its ability to prevent contamination in final processing and how that could impact the extent of prohibition it imposes on other aspects of production and processing within the industry.

A more specific recommendation or rule change may come after the Board becomes better informed on this subject from information learned in the symposium that is being requested.

Committee Vote:

The MC moves to accept this document as a guidance recommendation specifically asking the NOP to:

- accept as a working definition:
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
- disallow the engineered nanomaterial form of substances currently on the NL since nothing on the NL has been reviewed or a TR performed that included any aspect of the manufacture, use and disposal of the listed substances in a nanomaterial form.
- accept materials that meet the working definition of engineered nanomaterials as synthetic substances even when those same materials in bulk form are nonsynthetic.
- accept that engineered nanomaterials 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, 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.

- work with the NOSB to determine whether enforcement of restrictions in primary packaging and food contact surfaces is possible, practical, and legal.
- work with the NOSB to schedule a symposium on the topic of engineered nanomaterials to aid in evaluating (i) the adequacy of the definition, (ii) any potential areas of concern that may not be included in this definition, (iii) the enforceability of the various parts of the definition, (iv) possible adjustments to the approximate size constraints that may be needed, and (v) the effect of different regulatory approaches, including, but not limited to a complete §205.105 prohibition, a §205.105 prohibition unless as provided in the NL, or a statement that these substance are synthetic and all the prohibitions regarding that policy would be in place; all for the purpose of considering the development of a rule change on their use or prohibition.

Committee Vote:

Motion: Dan Giacomini Second: Wendy Fulwider
Yes: 6 No: 0 Abstain: 0 Absent: 0