National Organic Standards Board
Materials Committee
Nanotechnology in Organic Production, Processing, and Packaging
Request for information for developing a usable definition of the term in Organics

February 25, 2010

Introduction

In response to two separate NOSB Materials Committee documents related to restricting the use of Nanotechnology in organic production, processing, handling, and primary packaging, public comment has clearly supported the prohibition of most, if not all types of products of nanotechnology. However, a difficulty in developing a definition for the term "Nanotechnology" has prevented the committee from completing a final recommendation on this important issue. This document requests a technical and scientific review of this issue to aid the committee in clearly identifying the term "nanotechnology" so that it does not include products of technologies that have been allowed in organic production and processing since the passage of the Organic Foods Production Act of 1990 but that does include the intentionally engineered substances produced for their unique and specific properties that result only when these substances are in the nanoscale size range.

This document also serves as a posting notice to the public that the Materials Committee of the NOSB is taking this action as we work to resolve this issue.

Background

Nanotechnology is the science of engineering and the control of matter on an almost molecular scale. This technology is being used increasingly in numerous areas of agricultural production and food production and handling. Portions of the organic industry call for the total prohibition of nanotechnology in certified organic products. However, other individuals within the organic community have concerns with possible future implications from a complete prohibition on products of this technology.

In either case, the first step in this process must be a clear definition of what the term "nanotechnology" means. It is only with a clear description of what "nanotechnology" is can the differing points of view be clearly debated and a recommendation crafted for the industry to properly prohibit products of nanotechnology from being used in organic production and processing.

In the strictest sense, the term nanotechnology is the science of matter on the nano-size scale. The term is used also to describe the products of this science. Since size is a major part of the term itself, the term tends to include naturally-occurring substances such as sea-foam, colloidal minerals, and some particles created during corrosion whether they have a 'technology" factor or not, as well as nanoscale particles created during traditional manufacturing or food processing processes such as grain milling or milk homogenization even though the nano-sized particle created in these processes are byproducts of the process and not the means of the process itself.

The definitions proposed by the Materials Committee in the past have been criticized as including a description of nanotechnology that does not define, with enough clarity, the types of materials that are prohibited, and, as a consequence, includes small nanoscale particles inadvertently created during some typical food processing techniques.

The Materials Committee does not intend to include in the category of nanotechnology those naturally-occurring substances or substances caused as a result of traditional food processing techniques . Products such as, but not limited to, wheat flour dust, homogenized milk, or even colloidal minerals as they have been marketed for decades, are not intended to be included in this definition.

It is important to understand in this discussion that the debate includes substances that could be introduced into the soil, fed to or placed on the animal, included in the direct processing of organic products or that could come in contact with soil, animal or products including, but not limited to, paint and other surface coatings, water, or food contact surfaces and primary packaging.

Definitions Considered in MC Discussions

In our Nov 2009 recommendation the Materials Committee included the following definition: *Nanotechnology. Technology and the result of that technology that is intent on a) creating and using structures, devices, and systems that have novel properties and functions because of their small size, b) maintaining the ability to control or manipulate on the atomic scale, and c) researching and developing technology at the atomic, molecular or macromolecular level, typically in the size scale of approximately 1-100 nanometer range.*

At the public NOSB meeting the board considered modifying the definition by adding the following to the above definition:

Nanotechnology does not include particles created naturally or inadvertently in processes allowed in organic production or handling. All particles created via nanotechnology are considered nonagricultural and synthetic for the purposes of this chapter. Products of nanotechnology do not qualify as processing aids, adjuvant, excipients, solvents or other inert of minor ingredient substances for the purposes of this chapter even when present in insignificant amounts in the final product.

An alternative definition informally presented to the committee was:

Substances engineered to be in the nanoscale size range because of specifically unique properties that result only in that nanoscale. Traditional food processing such as homogenization and milling is not intended to be included in this definition.

Request of input from scientific experts

The Material Committee requests input from technical and scientific experts to help us develop a definition for the term “nanotechnology” that works for the organic community and in federal organic regulations. The committee is interested in a review of scientific papers, as well as domestic and international governmental and nongovernmental agencies overseeing or regulating the development and use of nanotechnology and its resulting products.

Size: We request clarity as to the proper size limits needed in the definition, if needed at all. Our need for a size limit in the definition is not limited to a strict definition of nanoparticle, nanosize, or nanoscale. The size limit cannot be so restrictive as to limit the ability of the definition to include slightly larger particles that are created and exhibit characteristics that are covered in other sections of the definition. While 1-100 nanometers is typically considered nanoscale, for the sake of defining nanotechnology usually 1-300 (or 350) nanometers is used. Some believe that as the technology

develops even this range may need to be larger. Additional confusion exists when small nano-sized particles are included into larger structures such as long nanotubes or films.

Techniques: We request advice on language that will clarify between naturally-occurring and man-made particles as well as man-made particles created via traditional food processing technology such as grain milling, milk homogenization, and freezing.

Intent and control: We request clarity for language that can describe the intent of creating and controlling the small particles that are created. Many discussions of nanotechnology focus on the technology that allows for the examination and measurement of the properties of this technology such as analytical electron microscopes, scanning tunneling microscopes, and atomic force microscopes. While a list of technology is limiting in itself as new technology develops, can consideration for the need for this technology in the development of the products of this technology be included in the definition to add clarity to the term?

Unique properties: Unique and often unknown and unresearched properties of these small engineered substances is a major factor influencing the concern to prohibit nanotechnology from organic production, processing and via contamination from primary packaging. Some unique properties such as change in reflection of light waves would seem to carry few health or environmental risks; however, potential risk in the manufacture, use, misuse and disposal carry greater concern. Concerns include, but are not limited to: the ability of these small particles to bypass most breathing-filter devices in workers; increased absorption through the skin; direct uptake of products by plants or animals with unknown human, animal, or environmental effects; increased passage through traditional cell barriers in the human or animal such as the blood-brain barrier or into the milk supply; and significant changes in biodegradability of the substances during use and at disposal. There are at least five areas of current scientific knowledge regarding nanoparticles in general and products of nanotechnology specifically in which we request clarification from technical and scientific experts to enable the committee to craft a definition and position: environmental fate; environmental detection and analysis; potential releases and human exposures; human health effects assessment, and; ecological effects assessment.

It can be argued that man-made particles which we identify above as not wanting to include in this definition, such as grain dust and nanosized milkfat particles created in the process of homogenization, develop unique properties as well. Input to help the committee bring out a difference between these types of unique properties developed would be helpful.

Synthetic classification: The organic final rule defines synthetic as "*a substance that is formulated or manufactured by a chemical process or a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral sources, except that such term shall not apply to substances created by naturally occurring biological processes*" (§205.2). The committee requests input concerning the nature of the chemical change, or change in the chemical nature, of these synthesized nanoparticles, including both the substance considered to be the "active" substance as well as the transport or storage systems of nanotechnology products including, but not limited to, carbon nanotubes and structural films. This input is requested so that a determination of the appropriateness of classifying products of nanotechnology as synthetic can be made. The committee is interested especially in structure-dependent health and environmental effects that are unique from their larger counterparts.

Conclusion

The Materials Committee of the National Organic Standard Board requests technical and scientific input to aid in our discussion to define the term “Nanotechnology”. Standard definitions in the public and scientific press have not been satisfactory to provide us information for the proper clarity and specific parameters we are trying to include in our discussions. From this discussion and determination of a definition a discussion of the best method to restrict the use of nanotechnology and the products of nanotechnology in organic production and processing will occur.

Committee Vote:

The Materials Committee moves to accept this document to serve as a request for a Technical Review on the term “nanotechnology” and to notify the public and National Organic Standard Board of the direction and progress of the committee on this matter.

Moved: Daniel Giacomini Second: Katrina Heinze

Yes: 6 No: 0 Absent: 0 Abstain: 0 Recuse: 0