National Organic Standards Board Materials Committee

Nanotechnology in Organic Production and Processing Discussion Document

March 17, 2009

Introduction

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. The Materials Committee seeks discussion and public comment related to the use and compatibility of nanotechnology in the certified organic industry.

Background

Nanotechnology is a science with many different definitions. Some of these definitions deal with particle size, formation of the particles and some with end use. Conflictbetween various definitions have made it difficult for one universal definition to be accepted.

The National Nanotechnology Initiative (NNI) says that something is "nanotechnology" only if it involves all of the following:

- research and technology development at the atomic, molecular, or macromolecular level, in the length scale of approximately 1-100 nanometer (nm) range,
- creating and using structures, devices, and systems that have novel properties and functions because of their small or intermediate size, and
- ability to control or manipulate on the atomic scale.

Objects with dimensions on the order of 1-100 nm are considered to be "nanoscale". Individual or combined groups of nanoscale particles are called "nanoparticles".

A nanometer is one billionth (10^{-9}) of a meter, or ten Ångström. As a matter of reference, a sheet of paper is about 100,000 nm thick; a single gold atom is about a third of a nm in diameter.

The sources of nanoparticles vary. Nanoparticles can be specifically engineered, byproducts of various activities such as combustion or industrial manufacturing, or they can occur naturally, as in sea spray or erosion. Some nanoparticles are created in normal food processing technologies as homogenization of milk. Technology is being developed to manufacture nanoparticles from microscopic machines composed of other nanoparticles. Structurally, nanoparticles can exist as individual particles or be combined together into larger structures such as tubes or films.

While the FDA says that there must be a "reasonable certainty of no harm" from the use of nanotechnology in food, the companies producing these products conduct the safety testing and most of the data is confidential. Generally, the FDA does not treat nanoscale particles of a substance differently than the naturally occurring bulk forms of the same material. However, the NNI notes that "unusual physical, chemical and biological properties can emerge in materials at a nanoscale" and includes "novel properties and functions because of their small . . size" as part of the definition of nanotechnology.

Uses of Nanotechnology

Nanotechnology is in use today and has many possible future uses. Current uses include coatings for eye glasses, food packaging to improve gas barrier properties and ingredients in foods to improve nutritional benefits, anti-bacterial properties, and improved mouth-feel. They are also being used in personal health care and clothing as well as industrial settings as material coatings and ingredients in paint. Future uses of nanotechnology that are being explored include altering bioavailability of nutrients and targeted delivery of nutrients, nanosensors to provide improved sensitivity and speed for chemical and biological analysis, and packaging materials that detect and communicate changes in food quality and safety.

The development and use of nanotechnology creates unique safety and regulatory questions because below 100 nm particles have the potential to behave differently than larger sized particles. They may be more reactive, conductive, and stronger than larger particles of the same material. Concern for these changes include but are not limited to, changes in intake via dermal, respiratory, or oral routes, the ability of the particle to cross biological membranes of individual cells and potentially the blood-brain barrier, increased occupational exposure regarding worker safety, increased risk to the environment via multiple pathways of entry during manufacturing, transport, use or disposal, and decreases in the rate of biodegradation. These same changes offer great potential advantages in other areas including but not limited to medicine and food safety. In the future, it is likely that some product of nanotechnology could be required by law to be added to some types of food products.

Regulatory Framework

There is no mention of nanotechnology in the Organic Foods Production Act of 1990, as amended (OFPA), nor in the National Organic Program (NOP) Rule.

The Rule does prohibit Excluded Methods.

Excluded Methods are defined as "[a] variety of methods used to genetically modify organisms or influence their growth and development by means that are not possible under natural conditions or processes and are not considered compatible with organic production. Such methods include cell fusion, microencapsulation and macroencapsulation, and recombinant DNA technology (including gene deletion, gene doubling, introducing a foreign gene, and changing the position of genes when achieved by recombinant DNA technology). Such methods do not include the use of traditional breeding, conjugation, fermentation, hybridization, in vitro fertilization or tissue culture" (§205.2). Excluded methods are prohibited in substances, methods, and ingredients in organic production and handling for products to be sold or labeled as "100 percent organic", "organic", or "made with organic…" (§205.105(e))

Under the current definition, most nanotechnology would not fall into the category of excluded methods.

Regulation of Nanotechnology in other Organic Regulations

As an example of possible options in dealing with nanotechnology, the Materials Committee has found these references (via Organic Trade Assn research):

The Soil Association bans human-made nano-materials from organic cosmetics, foods and textiles.

In Australia, the proposal states that only nano-free products may carry organic certification.

In the US, at least one certifier has a statement in their policy manual to regulate the use of nanotechnology particles.

Request for Public Comment

In public presentations from the Organic Trade Association Nanotechnology Task Force, versions of the following questions are asked:

- 1. As currently understood, is Nanotechnology compatible with organic?
- 2. If not, are the current standards keeping nanoparticles out?
- 3. Are any sectors of the organic industry already using Nanotechnology?
- 4. What are the concerns about Nanotechnology in food, feed, petcare, textiles, personal care products, or any other product carrying the USDA Organic label?
- 5. Should organic standards (OFPA/ NOP rule) be updated to regulate the use or uses of Nanotechnology(ies).
- 6. How can the NOSB and the NOP protect the interests of the organic consumer, and the National Rule itself, vis a vis nanotechnology?

The Materials Committee recognizes the likely increasing use of nanotechnology in food production and handling. The Materials Committee requests public comment on these questions regarding the place of Nanotechnology in the production and handling of certified organic food. Public perspective on this increasingly important topic will guide the need and direction of potential recommendations made by the NOSB for rulemaking. Of particular interest is the definition of nanotechnology as it applies to organic production or handling and the compatibility of nanotechnology with the principles of organic production and handling.

Committee vote:

Moved: Katrina Heinze		Second: Dan Giacomini	
Yes- 5	No- 0	Absent- 0	Abstain- 0