

**National Organic Standards Board
Materials Committee
Nanotechnology in Organic Production, Processing, and Packaging
September 8, 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. Public comment responding to a previously published NOSB Materials Committee discussion document (May 2009) on Nanotechnology overwhelmingly called for the total prohibition of nanotechnology in certified organic products. This document proposes the prohibition of all Nanotechnology in organic production, processing, and packaging, except when it is required by law.

Background

Nanotechnology was a new developing science when The Organic Food Production Act of 1990 (OFPA) was passed by Congress and signed into law by the President. Nanotechnology is not mentioned in the OFPA.

Nanotechnology is the field of science dealing with the creation and control of very small particles of matter to create substances with new and unique properties and functions which are different than their chemically-identical larger counterparts naturally found in nature or made synthetically. Nanotechnology includes the manufacture and processing of these particles.

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”. However, not all nanoscale substances or nanoparticles are considered “nanotechnology”. Moreover, use of the term “nanotechnology” is not limited exclusively to particles of the nanoparticle size.

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 such as the 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.

This document defines “Nanotechnology” as the products intentionally manufactured, and processes involving the intentional manipulation of particles, at the size typically in the nanoscale area that create new properties and functions that are different from the properties and functions of the particles at the macro scale. Naturally occurring nanoscale particles are not intended to be included in this restriction. Nanoscale particles incidentally created through normal processing such as flour grinding or homogenation are not intended to be included.

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 create unique safety and regulatory questions because nanoparticles 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. Changes include but are not limited to: 1) changes in absorption via dermal, respiratory, or oral routes; 2) the ability of the particle to cross biological membranes of individual cells and potentially the blood-brain barrier; 3) increased occupational exposure regarding worker safety; 4) increased risk to the environment via multiple pathways of entry during manufacturing, transport, use or disposal; and 5) decreases in the rate of biodegradation. These changes offer great potential advantages in other areas such as medicine and food safety.

The National Organic Program (NOP) Rule was published in 2000. It does not mention Nanotechnology.

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))

While there was considerable public comment claiming that nanotechnology was or should be considered as ‘excluded methods’, the definition of excluded methods clearly limits itself to biological or cellular manipulation. Under the current definition, most nanotechnology would not fall into the category of excluded methods. Therefore, the Materials Committee believes that specific regulatory changes must occur to prohibit the use of nanotechnology materials in certified organic products.

Recommendation

The Materials Committee recommends that the NOP implement rule change to clarify that at present the use of all nanotechnology is excluded from all organic production, processing and packaging, except as required by law.

The Materials Committee recommends the following additions to the regulation:

§205.2 Terms Defined.

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.

§205.105 Allowed and prohibited substances, methods, and ingredients in organic production and handling.

(h) Nanotechnology in organic production, handling and the packaging of raw or processed products labeled as “100 percent organic,” “organic,” or “made with organic (specified ingredients or food groups),” except as required by law.

§205.270 Organic handling requirements.

(c) The handler of an organic handling operation must not use in or on agricultural products intended to be sold, labeled, or represented as “100 percent organic”, “organic”, or “made with organic (specified ingredients or food groups(s)),” or in or on any ingredients labeled as organic:

(1) Practices prohibited under paragraphs (e), ~~and~~(f), *and* (h) of §205.105.

§205.301 Product composition.

(c) Products sold, labeled, or represented as “made with organic (specific ingredients or food group(s)).” Multiingredient agricultural product sold, labeled, or represented as “made with organic (specified ingredients or food group(s))” must contain by weight or fluid volume, excluding water and salt) at least 70 percent organically produced ingredients which are produced and handled pursuant to requirements in subpart C of this part. No ingredients may be produced using prohibited practices specified in paragraphs (f)(1), (2), ~~and~~(3), *and* (8) of §205.301. Nonorganic ingredients may be produced without regard to paragraphs (f)(4), (5), (6), and (7) of §205.301. If labeled as containing organically produced ingredients or food groups, such product must be labeled pursuant to §205.304.

(f) All products labeled as “100 percent organic” or “organic” and all ingredients identified as “organic” in the ingredient statement of any product must not:

(6) Be produced using nonorganic ingredients when organic ingredients are available; ~~or~~

(7) Include organic and nonorganic forms of the same ingredient; *or*

(8) *Be processed (including packaging) using nanotechnology, pursuant to §205.105(g) of this chapter.*

Committee Vote:

Motion: Kevin Engelbert

Second: Katrina Heinze

Committee Vote: Yes - 4

No - 1

Abstain - 0

Absent – 0

Conclusion:

The NOSB Materials Committee recommends the NOP amend the regulations to exclude and prohibit the use of nanotechnology and the products of nanotechnology in certified organic production, processing, handling and packaging, except as required by law.

Minority Opinion

Nanotechnology in Organic Production, Processing, and Packaging

The Materials Committee recognized in the recommendation that nanotechnology is rapidly growing and evolving, that nanotechnology covers a wide range of materials and applications and that there are many unanswered questions about the potential effects of nanoparticles on human and animal health, as well as on the environment. Public comments received at the May 2009 NOSB meeting demonstrated that our stakeholders do not want nanotechnology to be used in organic until the unanswered questions about the effects of nanoparticles are answered.

This minority opinion is concerned that the recommendation for “Nanotechnology in Organic Production, Processing, and Packaging,” unilaterally prohibits nanotechnology, addressing the immediate desire of our constituents to prevent to use of nanotechnology in organic production, processing and handling, but creating a permanent negative perspective of nanotechnology. A prohibition of all nanotechnology defines that nanotechnology cannot be compatible with organic methods.

Yet today, naturally occurring nanoparticles exist in our industry resulting from, for example, homogenization of milk or grain milling. As these physical processes evolve, when do they become nanotechnology? Also, it is probable that, in the future, nanotechnology could offer benefits to the organic industry in areas like food safety or packaging. How will we explain that these types of nanotechnology are compatible while all nanotechnology is not compatible with organic practices? Most likely, if the current recommendation is adopted, allowing any nanotechnology in the future, regardless of the benefits and sound science supporting its compatibility with organic, would be seen as weakening the organic standards.

This minority opinion suggests an approach that would define nanotechnology to more clearly exclude nanoparticles created inadvertently as a result of allowed processes. Additionally, nanotechnology would be identified as a process that classified a material as synthetic. The synthetic classification would prohibit the use of nanotechnology unless a material that resulted from nanotechnology was petitioned for, and recommended by the NOSB for, listing on the National List of approved or prohibited substances. These petitions would allow the board to address on a case-by-case basis the breadth and evolution of nanotechnology.

Clearly, we should take strong action to address the concerns of our constituents. But the minority opinion would create a more flexible approach that would allow us to react on a case-by-case basis as this technology evolves.