



Policy Memorandum

To: Stakeholders and Other Interested Parties

From: Miles V. McEvoy, Deputy Administrator

Subject: Nanotechnology

Date: Approved on March, 24 2015

This memorandum clarifies the status of nanotechnology in organic production and handling under the U.S. Department of Agriculture (USDA) organic regulations at 7 C.F.R. Part 205.

Issue:

The National Organic Program (NOP) has received questions about the use of nanotechnology in organic production and handling.

Nanotechnology is science, engineering, and technology conducted at the nanoscale, which is about 1 to 100 nanometers. Nanomaterials are commonly associated with a size range (nanoscale) of 1 to 100 nanometers along at least one dimension. They may, however, exceed that size, and be defined by physical or chemical characteristics or behavior that distinguish them from bulk, or non-nanomaterial. Nanomaterials can occur naturally, for example in volcanic ash and ocean spray, and may also be incidental byproducts of human activity, such as homogenization or milling. They can also be produced intentionally with specific properties through certain chemical or physical processes. Nanomaterials have many commercial applications spanning different fields, such as medicine, electronics, and energy, as well as agricultural production and food processing. We use the term “engineered nanomaterials” to refer to substances specifically designed and manufactured to have unique properties or behavior attributable to particle size. We use the term “incidental nanomaterials” to refer to substances that are incidental byproducts of other manufacturing (e.g., homogenization, milling) or that occur naturally.

Policy:

In 2010, the National Organic Standards Board (NOSB) recommended that engineered nanomaterials¹ be considered synthetic and prohibited in organic production and processing. The NOSB proposed defining engineered nanomaterials as “substances deliberately designed, engineered, and produced by human activity to be in the nanoscale range of 1-300 nanometers, because of very specific properties or composition (e.g., shape, surface properties, chemistry)

¹ October 2010 NOSB recommendation, [Guidance Document— Engineered Nanomaterials in Organic Production, Processing and Packaging](#).



that result only in that nanoscale.” The NOSB-recommended definition would include all nanomaterials containing capping agents or other synthetic components, but not incidental particles created during traditional food processing, or naturally occurring nanomaterials.

The NOP does not consider nanotechnology to be intrinsically benign or harmful. This memorandum clarifies that the statutory framework for the review of substances intended for use in organic production and handling would also apply to engineered nanomaterials.

The Organic Foods Production Act of 1990 (OFPA) authorizes the Secretary of Agriculture to establish the National List of Allowed and Prohibited Substances. The National List specifies which synthetic substances may be used in organic production as well as any substances prohibited for use in organic production. Section 205.605 of the USDA organic regulations includes the list of synthetic and nonsynthetic substances that may be used in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s)).”

Under 7 U.S.C. 6517, the National List established by the Secretary at 7 C.F.R. 205.605 shall be based upon a proposed National List or proposed amendments to the National List developed by the NOSB. The statute further requires that any amendments to the National List must undergo a public notice and comment period before changes are made.

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.²

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 Nanotechnology³ and the U.S. Environmental Protection Agency’s policies on Regulating Pesticides that Use Nanotechnology⁴ and Control of Nanoscale Materials Under the Toxic Substances Control Act⁵ should be used as applicable.

² Refer to the NOP [Guidelines on Procedures for Submitting National List Petitions](#), 72 FR 2167.

³ U.S. Food and Drug Administration, Considering Whether an FDA-Regulated Product Involves the Application of Nanotechnology, <http://www.fda.gov/RegulatoryInformation/Guidances/ucm257698.htm>.

⁴ U.S. Environmental Protection Agency, Regulating Pesticides that Use Nanotechnology, <http://www.epa.gov/pesticides/regulating/nanotechnology.html>

⁵ U.S. Environmental Protection Agency, Control of Nanoscale Materials Under the Toxic Substances Control Act, <http://www.epa.gov/oppt/nano/>