

Overview of the Use of Definitions for Nanomaterials by U.S. Agencies

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Occupational Safety and Health Administration (OSHA)

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- *nanomaterial* is defined as the "material with any external dimension in the nanoscale or having internal structure or surface structure in the nanoscale", with *nanoscale* defined as the "length range approximately from 1 nm to 100 nm". This includes both *nano-objects*, which are discrete pieces of material, and *nanostuctured materials*, which have internal or surface structure on the nanoscale; a nanomaterial may be a member of both these categories.
- Other terms used include:
 - Nanoparticle, nanorod, nanowire, nanotube, etc.

Overview of U.S.

- National Nanotechnology Initiative (NNI):
 - Nanotechnology is the understanding and control of matter at the nanoscale, at dimensions between approximately 1 and 100 nanometers, where unique phenomena enable novel applications.
 - *Nanoscale* – the size range roughly 1 to 100 nanometers, where many of the fundamental structures of biology are formed, composite materials may take on their distinctive characteristics, and many important physical phenomena are found.
- Emerging Technologies Interagency Panel Coordination Committee (2011)

Government agencies with definitions of nanomaterials

- Regulatory purposes
 - EPA
 - TSCA – new and existing chemicals
 - FIFRA – includes pesticides
 - Research – internal and extramural research
 - CPSC
 - FDA
 - OSHA and GHS
- Research-related
 - USDA – NIFA and Forest Services
 - NIOSH
 - NIH
 - DOE

Regulatory Purposes

Environmental Protection Agency (EPA)

- Research - nanotechnology is defined as: research and technology development at the atomic, molecular, or macromolecular levels using a length scale of approximately one to one hundred nanometers in any dimension; the creation and use of structures, devices and systems that have novel properties and functions because of their small size; and the ability to control or manipulate matter on an atomic scale
- TSCA (2017) - Chemical substances that have structures with dimensions at the nanoscale -- approximately 1-100 nanometers (nm) -- are commonly referred to as nanoscale materials or nanoscale substances.
 - PMN, New and existing chemicals (reportable for substances containing over 1% nm)
 - Active participant in OECD WPMN
- FIFRA (pesticides) - An ingredient that contains particles that have been intentionally produced to have at least one dimension that measures between approximately 1 and 100 nanometer
 - Make determinations on case-by-case basis

Food and Drug Administration (FDA) (2014 guidance)

- Pharmaceuticals
- Cosmetics
- Medical devices
- Food ingredients and food contact substances (human), and food ingredients (animals)

Excerpt from FDA guidance (binding and non-binding):

At this time, when considering whether an FDA-regulated product involves the application of nanotechnology, FDA will ask:

1. Whether a material or end product is engineered to have at least one external dimension, or an internal or surface structure, in the nanoscale range (approximately 1 nm to 100 nm);

In addition, as we explain in more detail below, because materials or end products can also exhibit related properties or phenomena attributable to a dimension(s) outside the nanoscale range of approximately 1 nm to 100 nm that are relevant to evaluations of safety, effectiveness, performance, quality, public health impact, or regulatory status of products, we will also ask:

2. Whether a material or end product is engineered to exhibit properties or phenomena, including physical or chemical properties or biological effects, that are attributable to its dimension(s), even if these dimensions fall outside the nanoscale range, up to one micrometer (1,000 nm).

Consumer Product Safety Commission (CPSC)(2019)

- Nanomaterials are materials/particles that range in size from 1 to 100 nanometers (nm) in length.

Although certain nanomaterials may have the same name as other materials historically in use, because of their small size, these newer materials may demonstrate different physical and chemical properties. Some manufacturers use these new nanomaterials in their consumer products, with the stated purpose of improving the performance and durability of their products

Nanomaterials and the UN GHS and OSHA HCS

- UN GHS – no definition for nano within the GHS
 - Annex 4 (safety data sheets) recommends disclosure of particle size as well as other characteristics (e.g., surface area, structure, size range)
- OSHA uses the NNI working definition for guidance materials (no regulatory definition)
 - Requires particle size to be disclosed on SDS

Research related

U.S. Department of Agriculture (USDA)

- National Institute of Food and Agriculture
 - Science, engineering, and technology conducted at the nanoscale, which is about 1 to 100 nanometers
- Forest Services
 - Nanotechnology is a multi-disciplinary field of applied science and technology. The general theme is understanding and engineering matter at the atomic and molecular scales. The nanoscale ranges from 1 to 100 nanometers in at least one dimension.

National Institute for Occupational Safety and Health (NIOSH)

- Nanotechnology refers to engineered structures, devices, and systems. It is the manipulation of matter on a near-atomic scale to produce new structures, materials and devices.
- Nanomaterials have a length scale between 1 and 100 nanometers. At this size, materials begin to exhibit unique properties that affect physical, chemical, and biological behavior.
- Use other terms (nanoscale, nanoparticle, etc.) in some guidance materials

National Institutes of Health (NIH)

- Intra- and extra-mural research programs
- Nanoscale and nanotechnology - structures, devices, and systems with novel properties and functions due to the arrangement of their atoms on the 1–100 nm scale
 - Nanoscience - a convergence of physics, materials science and biology, which deal with manipulation of materials at atomic and molecular scales
 - Nanotechnology - the ability to observe measure, manipulate, assemble, control, and manufacture matter at the nanometer scale

Department of Energy (DOE) (2016)

- Research and safe handling in DOE facilities
 - Engineered nanoparticle means intentionally created (in contrast with natural or incidentally formed) material with one or more dimensions greater than 1 nanometer and less than 100 nanometers.
 - Unbound Engineered Nanoscale particles (UNP), those nanoscale particles that are not contained within a matrix under normal temperature and pressure conditions that would reasonably be expected to prevent the particles from being separately mobile and a potential source of exposure. An engineered primary nanoscale particle dispersed and fixed within a polymer matrix, incapable as a practical matter of becoming airborne, would be bound,” while such a particle suspended as an aerosol would be “unbound.” For example, relevant nanoscale particle types include intentionally produced fullerenes, nanotubes, nanowires, nanoropes, nanoribbons, quantum dots, nanoscale metal oxides, nanoplates, nanolayers, and other engineered nanoscale particles