EXPRESS STATEMENT*

Developing Safe Products Using Nanotechnology
Revised by the leadership of the SOT Nanotoxicology Specialty Section in May 2016

Nanotechnology is a means to develop and use materials, structures, devices, and systems that have novel properties and functions due to their small size. This technology represents the ability to control, manipulate, and engineer materials with at least one dimension in the nanometer range (i.e., 1–100 nanometers [nm]). Nanotechnology has the potential to create many new materials and devices with a vast range of applications, such as in medicine, material design, electronics, and energy production.

From a material science and chemistry perspective, what makes this emerging technology so exciting is the idea that as one decreases the particle size range, particle characteristics appear to change—often yielding completely new physical properties. For instance, titanium dioxide particle types, which have a white color, lose color and become colorless at decreasing size ranges less than 50 nm. Other particle types, which currently are utilized for electrical insulation applications, can suddenly become conductive or insoluble substances can become more soluble at sizes below 100 nm. These changes in physical properties enhance versatility and, thus, are likely to give rise to new industrial and medical applications, as well as more versatile products—and these possibilities have generated great interest in this potentially new technology.

The use of nanomaterials is expected to have great potential to improve consumer and industrial products, address critical energy needs, enhance bioremediation, and improve the medical field. This opportunity is based on the unique physical properties (e.g., magnetic, optical, thermal, mechanical, electrical) and quantum mechanics (e.g., electron configuration and confinement) that vary continuously or abruptly with changes in the size of some materials produced at the nanoscale. Many consumer products contain, or will contain, nanomaterials in order to enhance their performance.

The Project for Emerging Nanotechnologies at the Woodrow Wilson International Center for Scholars has an inventory of the products available to consumers containing nanomaterials (http://www.nanotechproject.org/inventories/consumer). As of 2015, the center listed more than 1,600 manufacturer-identified, nanotechnology-based consumer products introduced to the

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market. Examples of consumer products that contain nanomaterials include cosmetics, sunscreens, coatings, tennis balls, batteries, fuel additives, catalysts, paints, pigments, toner, tires, and cement. Nanomaterials also may be developed for specific medical purposes, including for the delivery of pharmaceuticals, to enhance the performance of medical devices, or for diagnostic imaging purposes.

The development and commercialization of products containing nanoparticles raises many of the same issues as with the introduction of any new technology, including concerns about the toxicity and environmental impact of nanomaterial exposures. As a consequence, identification of potential health risks is a prerequisite for assessing the safety of the new products that are being developed. The potential human and environmental health risks can be evaluated by considering the hazards posed throughout the product’s lifecycle—from manufacture to disposal or recycling. Both hazard and exposure potentials will vary widely among different nanoparticulate types and for a variety of applications. These concerns have led to a debate among advocacy groups and governmental agencies on whether implementation of special regulations for nanomaterial-containing products is warranted.

A variety of physio-chemical characteristics are known to influence the toxicity and transport of nanomaterials in the body and the environment. These include, but are not limited to, particle size, surface area, shape/structure, solubility, and surface coatings. Particle size and surface area are important material characteristics from a toxicological and health perspective because as the size of a particle decreases, its surface area increases, and this allows a greater proportion of its atoms or molecules to be displayed on its surface rather than within the interior of the material. These atoms or molecules on the surface of the nanomaterial may be chemically and biologically reactive, potentially contributing to the development of adverse health effects.

The exposure potential for nanoparticles also must be carefully considered when conducting safety or risk assessment analyses. The current focus for exposure assessment is on the occupational setting (i.e., workers engaged in the manufacture of products containing nanomaterials), as consumer exposure levels to “free” nanoparticles is expected to be very low. An additional complication is the development of appropriate dose metrics by industrial hygienists to assess personal exposures in the workplace. In this regard, the existing systems, such as mass concentration determinations, may not be suitable for measures of nanoparticle exposures, as several researchers have suggested that particle numbers or particle surface area may be a more accurate dose metric.

It seems clear that inhalation exposures are likely to be the most common means of exposure, but contribution of ingestion and dermal exposures also must be considered in the overall exposure
evaluation process. Toxicological research is being conducted to evaluate the likelihood nanomaterials crossing biological barriers to be absorbed through the lungs, gastrointestinal tract, or skin and being distributed to various tissues and organs.

The information gleaned from the exposure and hazard studies is critical to understanding how nanomaterials behave in occupational settings and in the environment; how they may affect those exposed; and, most importantly, how exposures to these agents can be controlled.

There also are potential environmental benefits of nanomaterials, such as their use in remediation, which is currently being implemented. The concerns expressed about the potential adverse impacts of nanoparticles and nanomaterials on the environment are currently focused on the following: fugitive emissions associated with the manufacturing process, waste disposal of manufacturing byproducts, the transport or transfer of materials for commercial purpose, the release of nanomaterials from consumer products, and the degradation of these products over their lifecycle. Current research is focused on the fate of nanoparticles or, more specifically, their mobility in air, soil, and water, as well as the chemistry of the materials, their degradation over time and the mechanisms responsible, and the ability of these materials to accumulate in the environment and serve as potential reservoirs of contamination and/or exposure.

In conclusion, nanotechnology is an exciting and emerging technology which has great potential to enable the development of products with novel properties for a wide range of commercial and medical applications. As with any new technology, there are questions pertaining to the potential health and environmental risks associated with manipulation of nanomaterials. Moreover, the success of this technology will require the perception that the benefits outweigh the risks. This goal only can be attained by comprehensive testing of a growing number of nanomaterials. It is anticipated that alternative testing of toxicity with cell culture models will eventually significantly reduce animal testing as the standard to evaluating risk of nanomaterials. A comprehensive risk evaluation process can be developed by assessing hazards and exposure, and this will ensure the safety and success of this new technology. Risk communication and risk management also will be an integral part of the process to ensure the safe development of nanotechnology-based products.

**Relevant Links:**
• US Environmental Protection Agency (US EPA) Research on Nanotechnology: https://www.epa.gov/chemical-research/research-nanomaterials

• US Food and Drug Administration (US FDA) Nanotechnology: http://www.fda.gov/ScienceResearch/SpecialTopics/Nanotechnology/default.htm