

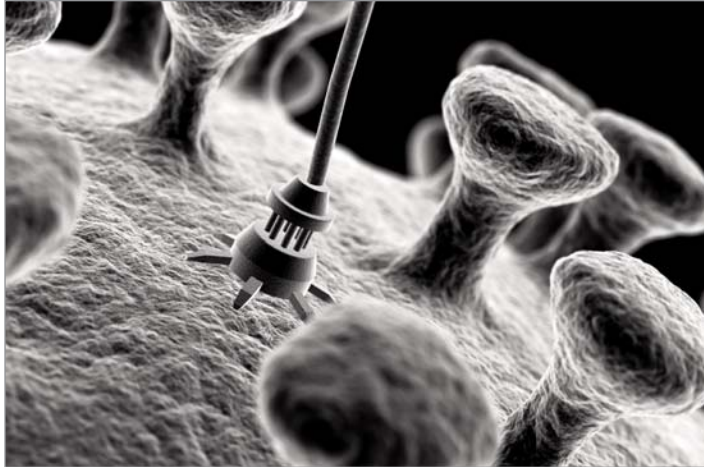


RISK BULLETIN

Nanomaterials and Nanotechnology: A Small, but Growing Risk

INTRODUCTION

The purpose of this bulletin is to provide an introduction to nanoscale materials, common applications and products, regulatory programs, and emerging liabilities associated with nanotechnology. Companies that utilize nanomaterials can utilize the resources presented in this bulletin to better understand potential issues and design proactive risk management programs that address exposures and prevent claims.



Nanomaterials have many unique properties that scientists are just beginning to understand. Use of nanomaterials may lead to impressive technological breakthroughs in the future, but mismanagement could also result in impacts to the environment and human health and safety. Regulatory agencies are still identifying information and research needs. There

are many data gaps that need to be filled before the risks associated with this new technology can be effectively managed.

The term nanotechnology was first coined in the 1970s, but nanomaterials did not begin to be studied in earnest until the late 1980s and early 1990s. In 2001, the National Nanotechnology Initiative (NNI) was established by the United States (US) government to coordinate nanotechnology research and development. Today the NNI consists of the individual and cooperative nanotechnology-related activities of 25 Federal agencies, which represent a range of research and regulatory roles and responsibilities. The NNI creates the framework for a comprehensive nanotechnology R&D program by establishing shared goals, priorities, and strategies. It also provides avenues for each individual agency to leverage shared resources.

Research and production of nanomaterials has become a big business. Market research indicates that worldwide annual sales of nano-enabled products already exceed \$200 billion. Further, it is estimated that over the next five years that 15% of all products (by value) will utilize nanotechnology and exceed \$1 trillion in sales. Additional research funding will be needed to support advances in nanotechnology. In the US alone, the 13 member agencies of the NNI that have nanotechnology R&D budgets already account for \$1.6 billion in the 2010 Federal budget.

DEFINITION

The NNI defines nanotechnology as the understanding and control of materials with dimensions between 1 and 100 nanometers, where unique phenomena enable novel applications. A nanometer (nm) is one-billionth of a meter (10^{-9}). For comparison, a single human hair is about 100,000 nanometers in diameter, while a single gold atom is about one-third of a nanometer in diameter. Unusual physical, chemical, and biological properties can emerge in materials at the nanoscale. These properties can differ in important ways from the properties of bulk materials and single atoms or molecules. Unique properties are most commonly observed with nanomaterials less than 30 nm in size.

The definition of nanotechnology does not include unintentionally produced nanomaterials, such as man-made diesel exhaust particulates or other airborne combustion by-products, nor does it include other nano-sized “ultra-fine” particles that occur naturally in the environment such as viruses or volcanic ash. Specifically, the NNI defines a technology as a nanotechnology only if it involves all of the following:

- Research and technology development involving structures with at least one dimension in the range of 1 – 100 nm, frequently with atomic/molecular precision
- Creating or using structures, devices and systems that have unique properties and functions because of their nanoscale dimensions
- The ability to control or manipulate on the atomic scale.

Nanotechnology is generally defined as the manipulation of nanoscale matter through certain chemical or physical processes that creates materials with specific properties for use in particular applications. These materials can be created in both “bottom up” processes (such as self assembly) that create nanoscale materials from atoms and molecules and “top down” processes

Nanomaterials are being used in a wide variety of applications including medicine, agriculture, energy, electronics, optics, water treatment, environmental remediation, and in various industrial materials and consumer products

(such as milling) that create nanoscale materials from their macro-scale counterparts. Thus the term “engineered nanoparticles” is often used to describe nanomaterials.

Currently, there are no consensus national or international standards on detection or measurement of nanomaterials. There are many analytical methods, but all currently have limitations. It is likely that numerous analytical techniques may need to be used to accurately obtain data on the various characteristics of a single nanomaterial.

APPLICATIONS AND PRODUCTS

Nanotechnology has, and will continue to, change the world we live in. The chemical and physical properties of nanomaterials give them unique electrical, catalytic, magnetic, mechanical, thermal, and imaging characteristics. Nanomaterials are being used in a wide variety of applications including medicine, agriculture, energy, electronics, optics, water treatment, environmental remediation, and in various industrial materials and consumer products (cosmetics, sunscreens, paints, coatings, appliances, computers, etc.)

According to worldwide estimates from the Project on Emerging Nanotechnologies (PEN), there are currently over 1,000 consumer products from over 24 countries using nanomaterials. Health and fitness items dominate these products, representing approximately 60%, followed by home and garden products, and food and beverage products. Currently, more products are based on nanoscale silver, used for its antimicrobial properties, than any other nanomaterial.

Most nanomaterials can be categorized into four types:

- **Carbon-based materials:** these materials are composed mostly of carbon and commonly take the shape of hollow spheres, ellipsoids, or tubes. Spherical or ellipsoidal carbon nanomaterials are called fullerenes, while cylindrical ones are called nanotubes. These particles have many potential applications such as improved films and coatings, lighter and stronger materials, and applications in electronics.
- **Metal-based materials:** these materials include quantum dots, nanogold, nanosilver, and metal oxides, such as zinc oxide. A quantum dot is a closely packed semiconductor crystal comprised of hundreds of thousands of atoms, which offer different optical qualities depending on the overall size.
- **Dendrimers:** nanosized polymers built from branched units which allow precise control of their size and shape. The surface has numerous chain ends that can be tailored to perform specific chemical functions. Three dimensional dendrimers contain interior cavities into which other molecules can be placed, which may be useful in applications such as drug delivery.
- **Composites:** nanoparticles combined with other nanoparticles or with larger, bulk-type materials. Nanomaterials are currently being added to products ranging from auto parts to packaging materials to enhance mechanical, thermal, barrier, and flame retardant properties.

REGULATIONS

Lack of specific regulations and policies addressing nanomaterial environmental, health and safety risks is a concern as new compounds and products are created. This creates uncertainty and unqualified liability for manufacturers and users of nanomaterials. Various regulatory agencies are in the early stages of evaluating the potential risks of

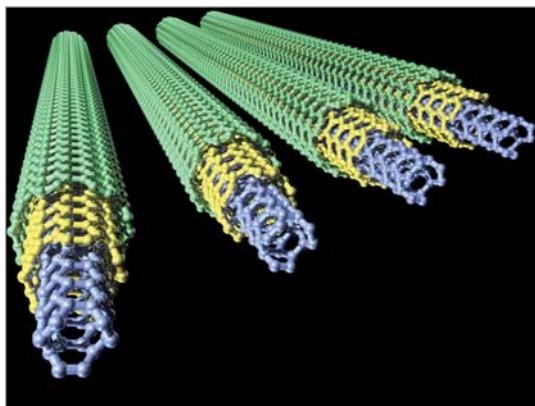
nanomaterials to human health and the environment. Worldwide most regulators are addressing nanomaterials using existing programs and mechanisms. This section focuses on current regulatory programs and activities in the US.

Product Regulation

The US Environmental Protection Agency (USEPA) has started evaluating newly created nanomaterials under the Toxic Substances Control Act (TSCA) and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). USEPA faces similar challenges under both of these programs in distinguishing between existing and new chemical substances. TSCA does not apply to pesticides, but many chemical substances with pesticide uses covered under FIFRA also have non-pesticide uses that are covered by TSCA. The USEPA Office of Pollution Prevention and Toxics and the USEPA Office of Pesticide Programs coordinate efforts on chemicals regulated under TSCA and FIFRA, respectively.

USEPA maintains a TSCA Chemical Substance Inventory of substances considered to be “existing” in U.S. commerce. Those substances not in the inventory are considered to be “new.” New chemicals are subject to the pre-manufacture notice program, which requires submission of detailed information for USEPA evaluation prior to manufacturing or importing the substance. USEPA currently intends to continue to apply existing approaches to nanomaterials based on molecular identity, rather than focus on particle size. USEPA does not expect that all nanoscale substances will qualify as new chemicals; however, if a nanoscale substance does not have a bulk/non-nanoscale equivalent with the same molecular identity, (e.g., carbon nanotubes and fullerenes) it will be handled as a new chemical.

USEPA's new and existing chemical programs under TSCA are supported by the Nanoscale Materials Stewardship Program (NMSP). The NMSP has identified various data gaps related to nanomaterial environmental, health and safety



issues and is currently reviewing how to address them. In 2009, USEPA proposed new rules under TSCA that will require additional reporting and testing of new and existing nano-scale materials to further USEPA's knowledge of these materials.

Similarly, FIFRA requires USEPA and States to register new pesticides (e.g., insecticides, herbicides, fungicides, rodenticides, etc.). The process of registration involves a review of active and inert ingredients; the particular site or crop on which it is to be used; the amount, frequency, and timing of its use; and storage and disposal practices. Any pesticide produced with a new nanomaterial ingredient would likely require review as a new formulation, and would almost certainly require review and registration if it involved a new application or purpose.

Other US regulatory agencies also provide oversight on products. The Food and Drug Administration (FDA) under the authority of the Federal Food, Drug and Cosmetic Act (FFDCA) evaluates the use and potential impacts of nanomaterials in new pharmaceuticals, cosmetics, food additives and other consumer products in accordance with existing protocols. Likewise, the Consumer Product Safety Commission (CPSC) is responsible for evaluating consumer products that may pose a fire, electrical, chemical, or mechanical hazard or can injure children. Assessment of the risks associated with new products will continue to be challenging for these agencies as they lack comprehensive mechanisms for identifying

nanotechnology or nano-enabled products before they enter the marketplace. The US is not alone as no other country has yet to establish mandatory requirements for industry reporting of nanomaterial use.

Human Health and Exposure

Regulation

Currently the Occupational Safety and Health Administration (OSHA) has not established worker exposure limits for nanomaterials. Similarly, there are no requirements for worker hazard communication. Companies currently rely on material safety data sheets and exposure profiles of bulk products.

Under the Occupational Safety and Health Act's General Duty Clause (29 USC 654) employers must provide a place of employment which is free from recognized hazards that are causing or are likely to cause death or serious physical harm to employees. This requirement obligates employers to evaluate potential workplace health and safety risks associated with emerging hazards such as nanomaterials. Therefore, until specific regulations are implemented, the interim measures discussed in this bulletin that have been suggested by the National Institute for Occupational Safety and Health (NIOSH) are recommended to help manage risk and establish an appropriate standard of care in the workplace.

Environmental Regulation

Nanomaterials also present the potential for environmental impacts associated with waste disposal and site cleanup under the Resource Conservation and Recovery Act (RCRA), and the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA) or "Superfund." One of the most comprehensive reviews of this issue to date was produced by PEN in cooperation with staff from the Environmental Law Institute. Although nanowastes are currently regulated under these programs, PEN identifies end-of-life strategies for nanomaterials that should be explored by USEPA to clarify regulatory applicability and adequacy. For example, some

nanomaterials may currently be classified as hazardous waste, while others such as consumer products, may be handled as non-hazardous solid waste. PEN calls for clear guidance from USEPA that will help avoid significant long term liabilities for industry, insurers, and investors. If the current framework of these regulatory programs is found to be inadequate, USEPA will need to determine what must be done to provide appropriate protection to human health and the environment.

HEALTH AND SAFETY RISKS

Nanomaterials are just a fraction of the size of most human and animal cells so they can easily be inhaled, ingested or absorbed into the body. Particles have the potential to migrate or accumulate in places that larger particles cannot. Human toxicity is still being studied and it is unknown if nanoparticles are more toxic than their macro-scale forms. Introduction of nanomaterials into cells may have short term negative effects such as plugging of membranes, inflammation, or poisoning. Long term effects remain to be seen. Exposure pathways and health effects are not well understood today, but much of the focus to date has been on the inhalation pathway and potential impacts to respiratory systems from exposure to airborne nanoparticles. Inhalation of carbon nanotubes has been the focus of study due to analogies with asbestos characteristics and potential health issues.

Although specific regulations regarding worker health and safety have yet to be developed, NIOSH is leading government research on workplace health and safety issues associated with nanomaterials. Although potential risks are still being studied, according to NIOSH evidence on the health effects of engineered nanoparticles is rapidly growing. NIOSH has published various guidance documents on the safe handling of nanomaterials, hazard surveillance, and medical screening. They identify workplace activities that

are considered higher risk, recommend various engineering controls and suggest implementation of a comprehensive risk management program.

Currently, NIOSH suggests that precautionary interim measures be taken for reducing work-related exposures and assessing potential risk. Their guidance includes in part:

- Taking "prudent measures" to control exposures
- Conducting hazard surveillance as the basis for implementing controls
- Using established medical surveillance approaches

NIOSH will continue to monitor and assess health effects and will update their recommendations as more definitive information becomes available. Currently, NIOSH concludes that there is insufficient scientific and medical evidence to recommend the specific medical screening of workers potentially exposed to engineered nanoparticles. Nonetheless, this lack of evidence does not preclude specific medical screening by employers interested in taking precautions beyond existing industrial hygiene measures.

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In addition to health concerns, nanomaterials may also present new workplace safety issues. Although insufficient information exists to predict the fire and explosion risk associated with powders of nanomaterials, nanoscale combustible materials could present a higher risk than coarser material with a similar mass due to increased particle surface area or other unique properties. Nanomaterials also have the potential to initiate catalytic reactions due to their unusual composition and structure that would not otherwise be anticipated. Such chemical reactions could result in worker and process safety concerns.

In addition to public organizations, there are also private non-governmental organizations such as PEN that are focused on nanotechnology risks. PEN is a partnership between the Woodrow Wilson International Center for Scholars and the Pew Charitable Trusts. It was established to help ensure that as nanotechnologies advance, possible risks are minimized, public and consumer engagement remains strong, and the potential benefits of these new technologies are realized.

ENVIRONMENTAL RISKS

There is very little literature on nanomaterial environmental toxicity, fate, and transport. Further research is needed. Ecotoxicity is not well understood; however, some nanoparticles such as copper and silver have been shown to be harmful to aquatic life. Nanoparticles have the potential to be absorbed by plants and animals resulting in acute or chronic toxicity. Bioaccumulation in plants and animals could also present a long term environmental concern.

Due to their small size, nanoparticles have the potential to be transported large distances in air or water when released into the environment. However, there is considerable uncertainty about the behavior of nanoparticles in the environment. Nanoparticles could stick together (aggregate) or fuse (agglomerate) thereby negating the unique properties associated with small particle size. However, research has shown that when nanomaterials are treated with compounds such as surfactants, this can create stability by inhibiting agglomeration and allow greater dispersal.

It is possible that airborne nanoparticles may be found to be readily washed out of the atmosphere resulting in more significant releases to soil, surface water and groundwater. Questions remain about whether nanoparticles will be readily adsorbed by soil, remain soluble in surface water and groundwater, or aggregate/agglomerate and precipitate out of solution. Conversely, nanoparticles in natural waters and wastewaters

may also be found to be more persistent in the environment due to difficulties in filtering or removing such small contaminants.

Nanomaterials have been studied for their potential uses in water filtration, spill cleanup and contaminated site remediation. Nanoparticles can be highly reactive due to their large surface area to volume ratio and can be readily mixed with other catalysts to enhance reactivity. For example, nanoscale titanium dioxide has been found by USEPA to hold promise for removal of arsenic from drinking water. Nanoscale iron has also been studied by USEPA and found to degrade chlorinated solvents such as trichloroethylene (TCE) in groundwater. This technology can be applied insitu via a trench filled with nanomaterials (i.e., permeable reactive barrier) or via groundwater injection wells.

However, use of nanomaterials for environmental remediation is not without risk. While the increased mobility and reactivity characteristics of nanomaterials may enhance remediation, they could also result in the possibility of nanomaterials migrating beyond a contaminated plume area, seeping into drinking water aquifers for wells, or discharging to surface water during the remediation process. The end result of placing large quantities of nanoparticles in the environment is unknown, and it is not clear if society is solving one problem while creating another.

RISK MANAGEMENT

It is clear that nanotechnology is in its infancy as a science and presents many unknown and emerging risks. So what does all this mean for companies that are involved in researching, manufacturing or using nanomaterials? While more research and regulation is being developed, firms would be prudent to incorporate evaluation of nanotechnology exposures into their enterprise risk management programs. In addition to environmental, health and safety risks, there may be other unidentified business risks resulting from

nanotechnology liabilities being addressed in company contracts or excluded from various insurance policies. Some of these liabilities may not emerge for years due to the evolving knowledge base on this subject.

Short- and long-term liabilities associated with nanotechnology may be uncertain, but risk assessments should be conducted to ascertain the potential exposures that may exist for a company's operations. The potential for releases and liabilities exists during most phases of a nanomaterial's life. A life-cycle review of products and operations should be completed to identify potential nanomaterial hazards associated with raw materials, products, packaging, transportation, and use, reuse, or disposal. Even basic identification of information gaps is useful in these early stages to create a path forward for more in-depth risk assessments in the future. Various screening tools have been developed to deal with emerging risks such as nanotechnology and help industry prioritize key issues, highlight uncertainties, and allow input of new information as it becomes available.

CONCLUSION

The focus going forward will be on "green nanotechnology," which will strive to reduce impacts to human health and the environment during manufacture, use, and disposal of these new materials. It is likely, however, that while nanotechnology may result in many great benefits to society in the future, there will always be human health and safety, environmental, and legal liability considerations for companies to address. The firms that embrace these technological challenges and actively manage their exposures will be the most successful.

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