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The Voice of the Defense Bar

Nanotechnology: U.S. Legal and Regulatory Developments

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Nanotechnology affects every sector of the U.S. economy and impacts our lives in a myriad of ways through the consumer goods and products we use on a daily basis. The Wilson Center has established a Consumer Products Inventory identifying over 1,600 manufacturer-identified, nanotechnology-based consumer products. (Project on Emerging Nanotechnologies – Woodrow Wilson International Center for Scholars, in cooperation with the Virginia Tech Center for Sustainable Nanotechnology, created the Nanotechnology Consumer Products Inventory, http://www.nanotechproject.org/cpi/.) According to Lux Research, the value of manufactured goods relying upon nanotechnology rose from $147 billion in 2007 to an estimated $3.1 trillion this year.

Nanotechnology is creating new technologies and novel materials with applications across many fields including medicine, information technology, aerospace, energy and transportation, among others. While nanotechnology is providing significant advancements in industrial, commercial and consumer settings, there is growing concern about the potential effects on human health and the environment of nanoscale materials.

This article will provide a brief overview of how nanotechnology is defined, insights on the regulatory framework and recent developments, possible concerns about nanomaterial use, and risk management considerations for U.S. businesses utilizing nanotechnology.

I. What Is nanotechnology?

The National Nanotechnology Initiative (NNI) describes nanotechnology as “the understanding and control of matter at dimensions between 1 and 100 nanometers, where unique phenomena enable novel applications.” The United States Environmental Protection Agency (U.S. EPA) defines nanotechnology as “the science of the very small and involves the manipulation of matter at the atomic or molecular level.” U.S. EPA concludes that nanotechnology has three important aspects: size, structure, and resulting novel properties. Scientists have not unanimously settled on a precise definition of nanomaterials but agree that they are partially characterized by their tiny size, measured in nanometers. A nanometer is one-millionth of a millimeter, or approximately 100,000 times smaller than the diameter of a human hair.
Nanosized particles exist in nature but also may be created in the case of engineered nanomaterials (ENMs). ENMs often exhibit unique optical, magnetic, electrical, and other properties, such as the following:

(1) Nanotechnology can be used to design pharmaceuticals that can target specific organs or cells in the body, such as cancer cells, and enhance the effectiveness of therapy.

(2) Nanomaterials can also be added to cement, cloth, and other materials to make them stronger but lighter.

(3) Nanomaterials can also be used in environmental remediation or clean-up to bind with and neutralize toxins.

The National Institute of Environmental Sciences (NIEHS) and the National Toxicology Program (NTP) conclude there are three key findings we should know about nanomaterials:

(1) There is no single type of nanomaterial. Nanoscale materials can in theory be engineered from minerals and nearly any chemical substance, and they can differ with respect to composition, primary particle size, shape, surface coatings, and strength of particle bonds. A few of the many examples include: nanocrystals, which are composed of a quantum dot surrounded by semiconductor materials; nanoscale silver; dendrimers, which are repetitively branched molecules; and fullerenes, which are carbon molecules in the form of a hollow sphere ellipsoid or tube.

(2) The small size makes the material both promising and challenging. To researchers, nanomaterial is often seen as a "two-edged sword." The properties that make nanomaterials potentially beneficial in product development and drug delivery, such as their size, shape, high reactivity, and other unique characteristics, are the same properties that cause concern about the nature of their interaction with biological systems and potential effects in the environment. For example, nanotechnology can enable sensors to detect very small amounts of chemical vapors, yet often there are no means to detect levels of nanoparticles in the air—a particular concern in workplaces where nanomaterials are being used.

(3) Research focused on the potential health effects of manufactured nanoscale materials is being developed, but much is not yet known. NIEHS is committed to developing novel applications within the environmental health sciences, while also investigating the potential risks of these materials to human health. (The National Institute of Environmental Health Sciences – Your Environment, Your Health – Nanomaterials, http://www.niehs.nih.gov.)

II. Potential Environmental, Health And Safety concerns Associated With ENMs.

With respect to potential impact to the environment, key questions that companies that manufacture and/or use ENMs must ask include:

1. What are the potential environmental concerns associated with this new technology?

2. Can industry and society expect toxic/hazardous material to be released into the environment during either the manufacture or end-use of nanoproducts?

3. Could nanoapplications lead to environmental degradation, particularly from bioaccumulation of nanoproducts in wildlife? (Environmental Implications of Nanotechnology – An Update, Leo Stander and Louis Theodore, International Journal of Environmental Research and Public Health 2011, 8,470-479, ISSN 1660-4601, http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3084472/.)

In addition to these key environmental questions, the National Institute for Occupational Safety and Health (NIOSH) has identified a number of potential health concerns associated with ENMs:

1. The potential for nanomaterials to enter the body is among several factors that scientists examine in determining whether such materials may pose an occupational health hazard. Nanomaterials have the greatest potential to enter the body through the respiratory system if they are airborne and in the form of respirable-sized particles. They may also come into contact with the skin or be ingested.

2. Airborne nanoparticles can be inhaled and deposit in the respiratory tract and may enter the bloodstream and translocate to other organs.

3. Nanoparticles may be more potent than large particles of similar composition in causing pulmonary inflammation and lung tumors.

4. Workers exposed to aerosols of some manufactured or incidental microscopic and nanoscale particles have reported adverse lung effects.

NIOSH has concluded that further study and research is needed to quantify these issues. NIOSH's publication, "Approaches to Safe Nanotechnology-Managing the Health and Safety Concerns Associated With Engineered Nanomaterials," provides a good summary of health and safety concerns and recommended precautionary measures needed in connection with the use of ENMs. (Approaches to Safe Nanotechnology – Managing the Health and Safety Concerns Associated With Engineered Nanomaterials, DHHS (NIOSH) Publication No. 2009-125 (March 2009), http://www.cdc.gov/niosh/docs/2009-125/pdfs/2009-125.pdf.)

III. What Is The Current Regulatory Regime For Enms In The United States?

In the United States, the federal agencies with primary regulatory authority over ENMs are:

(1) The U.S. Environmental Protection Agency (EPA), which regulates "chemical substances," including nanomaterials under the Toxic Substances Control Act (TSCA);

(2) The Occupational Safety and Health Administrator ("OSHA"), which regulates employee exposure to hazardous substances in the workplace;

(3) The U.S. Food and Drug Administration (FDA), which regulates a wide range of products, including foods, cosmetics, drugs, devices, and veterinary products that may utilize nanotechnology; and

(4) The U.S. Consumer Product Safety Commission (CPSC), which works to protect the public against unreasonable risks of injuries and deaths associated with consumer products.

TSCA provides the primary regulatory mechanism where information on the health and safety effects of ENMs are evaluated as part of the pre-manufacturing notice that must be submitted for any new chemical substance. However, many have questioned whether TSCA is up to the task of regulating ENMs. Possibly in response to such criticism, EPA proposed a new nanoscale chemical one-time reporting and recordkeeping rule on April 6, 2015. (80 Fed. Reg. 18330 (April 6, 2015), http://www.gpo.gov/fdsys/pkg/FR-2015-04-06/pdf/2015-07497.pdf.) Specifically, EPA's proposed rule would require companies that manufacture or process chemical substances in the nanoscale range to electronically report information, including the chemical identity, production volume, methods of manufacture, processing, use, exposure and release information, and available health and safety data. The public comment period closed on August 5, 2015 and U.S. EPA is in the process of reviewing comments prior to issuing a final rule.

Although OSHA recognizes that nanomaterials pose unique threats to worker's health and safety, there are very few occupational exposure limits applicable to nanomaterials. OSHA has issued recommended exposure limits for carbon nanotubes, carbon nanofibers, and titanium dioxide. For all other nanomaterials, OSHA recommends that employers minimize worker exposure using hazard control measures and best practices. However, OSHA provides little guidance with respect to specific hazard control measures and/or best practices.

The FDA has noted that it intends to regulate ENMs under its existing statutory and regulatory authorities. In an effort to assist the regulated community with respect to ENMs, the FDA has issued several guidance documents that can be found on the FDA's website. The most significant takeaway from these guidance materials is the FDA's strong encouragement that companies consult with the FDA before bringing FDA-regulated products containing ENMs to the market.

Similarly, the CPSA has also signaled that it intends to regulate ENMs under its existing regulatory framework, although it recognizes that since there is no pre-market registration or approval of products, the CPSA cannot evaluate a product's potential risk to the public until the product has been introduced into the marketplace. In an effort to take a more proactive approach, the CPSC has requested funding to establish a Center for Consumer Product Application and Safety Implication of Nanotechnology. The Center would be tasked with researching methods to quantify and characterize the mechanisms via which consumers could be exposed to ENMs in consumer products.

IV. Managing EHS NMs—What Every Business Should Know.

Notwithstanding the somewhat patchwork nature of the regulating regime and lack of clear guidance from the regulating agencies, the regulated community is still faced with the task of ensuring that their manufacture and use of ENMs does not result in an adverse impact on human health or the environment.

On March 20, 2015, the NNI released a report on "Stakeholder Perspectives On Perception, Assessment and Management of the Potential Risk of Nanotechnology." The report summarizes the results of a workshop held in 2013 that included representatives of academia, industry, not-for profit entities, and the federal government. Specific concerns identified by the workshop stakeholders were twofold: 1) the need to develop information on potential hazards and exposure potentials for nanotechnology; and 2) where data was available, the lack of clear direction on the weight and/or value to place on certain criteria or metrics framework when setting safety standards and regulatory policy. The same issues that were of concern to industry in 2013 continue to exist today and the regulating agencies described above have done little to clarify these issues.

As such, it is incumbent on any business that utilizes ENMs in their products and processes to ensure that the products that are put on the market are safe (as defined by legislative and common law standards) and do not pose an unreasonable risk to human health and the environment. To that end, companies that use these materials would be well served to ensure that they have effective risk management programs and policies in place to ensure that the products that they manufacture do not pose an unreasonable risk to human health or the environment, and to have a legally-defensible response to subsequent allegations that the ENMs at issue

Assessment method	Source	Website
Precautionary Matrix for Synthetic Nanomaterials	Federal Offices of Public Health and Environment (FOPH & FOEN) -Swit-	http://www.bag.admin.ch/nanotechnolo-gie/12171/12174/12175/index.html?lang=en
Nano Risk Framework	DuPont and Environmental Defense	http://www.nanoriskframework.com/
Risk Assessment of Manufac-tured Nanomaterials	New Energy and Industrial Technology Development Organization (NEDO)	http://en.aist-riss.jp/assessment/2721/
NanoCommission Assessment Tool	German Federal Military for the Environment, Nature Conservation &	http://www.bmub.bund.de/fileadmin/Daten_BMU/Download_PDF/Nanotechnologie/nano_
Precautionary Strategies for Managing Nanomaterials	German Advisory Council on the Environment	http://www.umweltrat.de/SharedDocs/Downloads/EN/02_Special_Reports/2011_09_Precautionary_Strategies_for_managing_Nanomaterials_KFE.
SafeNano Scientific Services	Institute of Occupational Medicine	http://www.safenano.org/
Cenarios -Certifiable Nano-specific Risk Management and Monitoring System	The Innovation Society (Switzerland)	http://innovationsgesellschaft.ch/wp-content/uploads/2015/01/CENARIOS_Factsheet_en-glisch_2015.pdf
REACH Implementation Proj-ect on Nanomaterials (RIPoN)	European Chemicals Agency (ECHA)	http://ec.europa.eu/environment/chemicals/nano-tech/reach-clp/ripon_en.htm
Work Health & Safety As-sessment Tool for Handling	Safe Work Australia	http://www.safeworkaustralia.gov.au/sites/swa/about/publications/pages/at201008workhealthand-
Stoffenmanager Nano 1.0	Netherlands Ministry of Social Affairs	http://nano.stoffenmanager.nl/
NanoSafer	The Industries Council of Occupation-al Health and Safety (Denmark)	http://nanosafer.i-bar.dk/
ANSES	French National Agency for Food Safe-	https://www.anses.fr/en/system/files/

do in fact pose an unreasonable risk to human health and the environment.

As noted above, the unique properties of ENMs make it difficult to pigeon-hole ENMs into a business's existing risk management program. Recognizing these issues, there are a number of risk-management frameworks that are specifically focused on ENMs. The following is a list that identifies various risk management frameworks that may be of use of companies that manufacture and/or use ENMs:

Among these risk management protocols, the Swiss Precautionary Matrix and the DuPont/EDF Nano Framework are two of the more popular frameworks being utilized by companies that manufacture and/or use ENMs.

The Swiss Precautionary Matrix, which is predicated on the precautionary principle which generally governs chemical management in the European Union, outlines a strategy for assessing and controlling the risks of ENMs. The precautionary matrix is designed to help industry and trade comply with their due diligence and their duty to exercise self-control opposite employees, consumers, and the environment. The goal of the matrix is to provide a mechanism pursuant to which potential adverse EHS impacts can be identified and precautionary measures developed to protect against adverse impacts to human health and the environment during each step of the ENM's life cycle.

Another popular risk management framework is a joint framework prepared by DuPont and the Environmental Defense Fund. The DuPont/EDF Nano Risk Framework has six steps:

Step 1: Requires the development of a general description of the ENM and its intended use. This step would include developing basic descriptions of chemical composition and form and size and intended uses (existing or new).
Step 2: Requires the development of three sets of profiles: the ENM's properties, inherent hazards, and associated exposures. These profiles would need to take into account the NM's full life cycle, from material sourcing to end-of-life disposal or recycling.
Step 3: Requires the entity to identify and characterize the nature, magnitude, and probability of risk presented by the ENM and its anticipated application.
Step 4: Requires the user to evaluate options for managing the risks identified in Step 3, along with a recommended course of action.
Step 5: Requires an evaluation of the information that has been developed in Steps 1-4 and making a decision as to whether to move forward with development and production.
Step 6: Requires implementation of a system of periodic and as-needed reviews to ensure that the information, evaluations, decisions, and actions of the previous steps are kept up-to-date.
There is no one-size-fits-all risk management framework for companies that utilize ENMs in the manufacturing processes or products. Rather, companies need to tailor a risk-management protocol that is appropriate for the operations and/or activities of the business.

V. Conclusion

Nanotechnology may hold the key to tremendous breakthroughs in medicine, health care, and drug therapies vital to battling the illnesses of our day. Moreover, nanotechnology will continue to aid in the advancement and progression of industrial, commercial, and consumer products. The threshold issue is how does nanotechnology interact with human health and the environment. Successful applications and long-term use of nanotechnology must be evaluated, taking into account the potential adverse impacts of ENMs human health and the environment and ensuring that the appropriate risk management protocols are in place to mitigate the potential adverse impact.

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