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EXPERT ANALYSIS

Nanotechnology: U.S. Regulatory Framework And Legal Risk Management

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Nanotechnology affects every sector of the U.S. economy and our lives in a myriad of ways through the consumer goods and products we use on a daily basis. The Woodrow Wilson International Center for Scholars has established a consumer products inventory identifying over 1,600 manufacturer-identified, nanotechnology-based consumer products.[1] 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 novel materials with applications across many fields including medicine, information technology, aerospace, energy and transportation. 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 commentary 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 using nanotechnology.

WHAT IS NANOTECHNOLOGY?

The National Nanotechnology Initiative, or NNI, describes nanotechnology as "the understanding and control of matter at dimensions between 1 and 100 nanometers, where unique phenomena enable novel applications."

The Environmental Protection Agency defines nanotechnology as "the science of the very small and involves the manipulation of matter at the atomic or molecular level." The 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 about 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 or ENMs. ENMs may exhibit unique optical, magnetic, electrical and other properties, such as the following:

- 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.
- Nanomaterials can be added to cement, cloth and other materials to make them stronger and yet lighter.

- Their size makes them extremely useful in electronics, and they can also be used in environmental cleanup to bind with and neutralize toxins.2

The National Institute of Environmental Health Sciences, or NIEHS, and the National Toxicology Program say there are three key findings about nanomaterials:

- 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.
- 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 and high reactivity, 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.
- 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.

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In terms of the legal framework for nanotechnology, NIEHS is not a regulatory agency and does not enforce statutes associated with nanomaterials or other hazardous substances. While a number of entities, such as NIEHS, National Toxicology Program and NNI are actively engaged in nanotechnology research and evaluation, they do not have legal authority to regulate the use of nanomaterials. The federal agencies with primary authority on nanomaterials have been:

- The Food and Drug Administration, which regulates a wide range of products, including foods, cosmetics, drugs, devices and veterinary products that may use nanotechnology.
- The Environmental Protection Agency, which regulates many nanomaterials regarded as "chemical substances" under the Toxic Substances Control Act.
- The Consumer Product Safety Commission, which works to protect the public against unreasonable risks of injuries and deaths associated with consumer products.

RECENT REGULATORY DEVELOPMENT

Concerns exist about the ability of existing regulatory framework to guard against adverse environmental health and safety impacts of ENMs. For example, in the European Union, where the precautionary principle guides chemical risk management practices, REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals) provides a mechanism pursuant to which information relating to the environmental and health effects of nanomaterials is generated and disseminated.

In the United States, the Toxic Substances Control Act provides the regulatory mechanism pursuant to which information on the health and safety effects of nanomaterials should be 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 nanomaterials.

Possibly in response to such criticism, the EPA proposed a new nanoscale chemical one-time reporting and recordkeeping rule April 6.[3]

Specifically, the agency proposed requiring 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.

There is a 90-day public comment period, and EPA anticipates a public meeting during this time frame to obtain additional input. The agency proposed the requirement under TSCA Section 8(a) to determine if further action, including additional information collection, is needed.

In an effort to try to identify and mitigate these risks, the NNI, which is an interagency program to facilitate the coordination of research and development of nanoscale science, engineering and technology at the federal level, has devoted resources toward evaluating the environmental health and safety risk posed by nanomaterials. A June 2014 progress report indicated that significant progress had been made on the following:

- Ensuring the development of comprehensive measurement tools that consider the full life cycles of engineered nanomaterials in various media.
- Collecting sufficient exposure data to inform workplace exposure control strategies.
- Enhancing the understanding of the modes of interaction between nanomaterials and the human body.
- Improving the assessment of transport and transformations of nanomaterials in various environmental media and biological systems and over full life cycles.
- Developing principles for establishing risk assessment and risk management practices for nanomaterials and ensuring that these risk are appropriately communicated to all stakeholders.
- Coordinating efforts to enhance data quality, modeling and simulation capabilities for nanotechnology.

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Earlier this year, the CPSC sought $7 million in new funding to establish a nanotechnology center and to create a five-year interagency agreement with the National Science Foundation. The proposed "Center for Consumer Product Applications and Safety Implications of Nanotechnology" would be a consortium of scientists tasked with researching methods to quantify and characterize the presence, release and mechanisms of consumer exposure to nanomaterials from consumer products.

The CPSC is a member of the NNI and clearly is working on a more proactive approach to assessing possible risks posed by nanomaterials in consumer goods, particularly those associated with children's products.

POTENTIAL CONCERNS

Nanotechnology has been described as the second coming of the Industrial Revolution, but environmental risks must be assessed and managed. At this time, there has been limited environmental research and study completed responding to key environmental questions, including:

- What are the potential environmental concerns associated with this new technology?
- Can industry and society expect toxic/hazardous material to be released into the environment during either the manufacture or use of nanoproducts?

- Could nanoapplications lead to environmental degradation, particularly from bioaccumulation of nanoproducts in living tissue?
- What impact will regulations have on this new technology?[4]

The focus of scientific study has been on human health and worker safety-related nanomaterials. Much more work is needed to fully understand the implication of nanomaterials in the environment.

The National Institute for Occupational Safety and Health has conducted research and performed human and animal studies in order to evaluate potential health concerns. NIOSH has identified a number of potential health concerns associated with nanomaterials:

- 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.
- Airborne nanoparticles can be inhaled and deposited in the respiratory tract and may enter the bloodstream and move to other organs.
- Nanoparticles may be more potent than large particles of similar composition in causing pulmonary inflammation and lung tumors.
- Workers exposed to aerosols of some manufactured or incidental microscopic and nanoscale particles have reported adverse lung effects.

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NIOSH is concerned that safety risks exist, too, but 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 precautionary measures needed in connection with nanomaterials use.[5]

WHAT EVERY BUSINESS SHOULD KNOW

On March 20, NNI released a report summarizing the results of a workshop held in 2013 that included representatives of academia, industry, not-for profit entities and the federal government.[6]

Specific concerns identified by the workshop stakeholders were twofold: the need to develop information on potential hazards and exposure potentials for nanotechnology, and 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.

As such, it is incumbent on any business that uses engineered nanomaterials in its 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.

Even where there are regulations governing the manufacture and use of nanomaterials (for example, REACH and TSCA), companies that use these materials would be should have effective risk management programs and policies in place to ensure that their products do not pose an unreasonable risk to human health or the environment, and should also have a legally defensible response to subsequent allegations that the nanomaterials at issue do in fact pose an unreasonable risk to human health and the environment.

Assessment method	Source	Website
Precautionary Matrix for Synthetic Nanomaterials	Federal Offices of Public Health and Environment (FOPH & FOEN) -Switzerland	http://www.bag.admin.ch/hnologie/12171/12174/12175/index.html?lang=en
Nano Risk Framework	DuPont and Environmental Defense – U.S.	http://www.nanoriskframework.com/
Risk Assessment of Manufactured Nanomaterials	New Energy and Industrial Technology Development Organization (NEDO) - Japan	http://en.aist-riss.jp/assessment/2721/
NanoCommission Assessment Tool	German Federal Military for the Environment, Nature Conservation & Nuclear Safety	http://www.bmub.bund.de/service/publications/downloads/details/artikel/responsible-use-of-nanotechnologies-1/
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.pdf?__blob=publicationFile
SafeNano Scientific Services	Institute of Occupational Medicine (IOM) – U.K.	http://www.safenano.org/
Cenarios -Certifiable Nanospecific Risk Management and Monitoring System	The Innovation Society (Switzerland)	http://innovationsgesellschaft.ch/wp-content/uploads/2015/01/CENARIOS_Factsheet_englisch_2015.pdf
REACH Implementation Project on Nanomaterials (RIPoN)	European Chemicals Agency (ECHA)	http://ec.europa.eu/environment/chemicals/nanotech/reach-clp/ripon_en.htm
Work Health & Safety Assessment Tool for Handling Engineered Nanomaterials	Safe Work Australia	http://www.safeworkaustralia.gov.au/sites/swa/about/publications/pages/201008workhealthandsafetyassessmenttool
Stoffenmanager Nano 1.0	Netherlands Ministry of Social Affairs and Employment	http://nano.stoffenmanager.nl/
NanoSafer	Industries Council of Occupational Health and Safety (Denmark)	http://nanosafer.i-bar.dk
ANSES	French National Agency for Food Safety, Environment and Labor	http://www.anses.fr/Documents/AP2008sa0407RaEN.pdf

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.

As noted above, the unique properties of engineered nanomaterials 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 chart identifies various risk management frameworks related to the use of ENMs:

Among these risk management protocols, the Swiss Precautionary Matrix and the DuPont/EDF Nano Framework are more widely used. The Swiss Precautionary Matrix, which is predicated on the precautionary principle that 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 environmental health and safety 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 nanomaterial'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 use ENMs in the manufacturing processes or products. Rather, companies need to tailor a risk management protocol that is appropriate for their operations and activities.

CONCLUSION

Nanotechnology may hold the key to tremendous breakthroughs in medicine, health care and drug therapies. Moreover, it will continue to aid in the advancement and progression of industrial, commercial and consumer products.

The threshold issue is how nanotechnology interacts 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 nanomaterials on the environmental, health and safety. These issues are not fully understood at this time, but the good news is that multiple federal and state agencies and other research organizations are dedicated to finding the answers.

NOTES

[1] Project on Emerging Nanotechnologies, Woodrow Wilson International Center for Scholars, Nanotechnology Consumer Products Inventory, http://www.nanotechproject.org/cpi/.

[2] Nat'l Inst. of Envtl. Health Scis., Nanomaterials, http://www.niehs.nih.gov/health/topics/agents/sya-nano/index.cfm.

[3] Chemical Substances When Manufactured or Processed as Nanoscale Materials; TSCA Reporting and Recordkeeping Requirements, 80 Fed.Reg. 18330 (Apr. 6, 2015), http://www.gpo.gov/fdsys/pkg/FR-2015-04-06/pdf/2015-07497.pdf.

[4] Leo Stander & Louis Theodore, *Environmental Implications of Nanotechnology – An Update*, Int'l J. Envtl. Research & Pub. Health (Feb. 10, 2011), http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3084472/.

[5] Nat'l Inst. for Occupational Safety & Health, Approaches to Safe Nanotechnology: Managing the Health and Safety Concerns Associated With Engineered Nanomaterials, Publication No. 2009-125 (March 2009), http://www.cdc.gov/niosh/docs/2009-125/pdfs/2009-125.pdf.

[6] Nat'l Nanotechnology Initiative, *Stakeholder Perspectives on Perception, Assessment and Management of the Potential Risk of Nanotechnology* (Mar. 20, 2015), http://www.nano.gov/node/1348.

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