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# Regulation of Nanotechnology

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## Introduction

Nanotechnology is rapidly increasing its influence on commercial and consumer products and processes. Nanotechnology continues to bring about material and performance improvements that are leading to improved processing efficiencies, product efficacies, and environmental health and safety. At Chubb Commercial Insurance, we have seen nanotechnology influence a wide range of products and processes among our existing and potential commercial clients. Following are some representative SIC codes where we already see nanotechnology having a commercial impact.

| | | | |
|---|---|---|---|
| 2851 | Paints and Allied Products | 3599 | Industrial Machinery |
| 3565 | Packaging Machinery | 3899 | Fabricated Textile Products |
| 3471 | Plating and Polishing | 5169 | Chemicals and Allied Products |

The applications in this space have ranged from silver nanotechnology providing anti-microbial properties to athletic wear, to nano titanium dioxide prolonging the ability of paints and coatings to with stand weathering.

In the life sciences space, the increased reactivity of many nano engineered substances, due to high surface area to mass ratios, has advantages in medical diagnostics, and the luminescent properties of bucky balls are enhancing imaging technologies. This is just a sample of some types of life science companies we have seen that are benefiting from nanotechnology in

| | | | |
|---|---|---|---|
| 8071 | Medical Laboratories | 3841 | Surgical and Medical Instruments |
| 3826 | Analytical Instruments | 2835 | Diagnostic Substances |
| 2834 | Pharmaceutical Preparations | 2833 | Medicinals and Botanicals |
| 3843 | Dental equipment | 3844 | X-Ray Apparatus and Tubes |

their products and processes.

As businesses increasingly look to nanotechnology for commercial advantages, it is important that safety professionals are aware of the potential for nanomaterials to be introduced into the environments for which they are responsible. A challenge confronted by today's safety professional is that very little direction has been provided thus far by regulators in addressing potential nanotechnology exposures in the occupational environment. Yet the new properties which are creating commercial advantages also have the potential to create new exposure dynamics.

In June 2011, the White House Emerging Technologies Interagency Policy Coordination Committee (ETIPC) developed a set of principles specific to the regulation and oversight of applications of nanotechnology, to guide the development and implementation of policies at the federal agency level. Two of the guiding principles of this initiative are:

- Avoid categorically judging all applications of nanotechnology as intrinsically benign or harmful; and
- A sound regulatory regime is important for building consumer confidence[1]

With this impetus, we are likely to see continued emphasis at the federal level on understanding the growing influence and potential risks of nanotechnology in general, and specific nanomaterials in particular.

The primary purpose of this paper is to provide an overview of the US federal regulatory approaches to nanotechnology, primarily from an environmental health and safety perspective. It will discuss current and proposed approaches to nanotechnology regulation from the various federal agencies, as well as those developed by non-governmental organizations that currently offer greater breadth of safety and health risk management guidance.

## Federal Government Nanotechnology Initiatives and Regulations

In the US, the Federal Executive Branch established the National Nanotechnology Initiative (NNI). The NNI is comprised of leaders of many federal agencies and departments. The NNI program, with eight key program areas, utilizes expertise from member agencies to encourage the discovery, development, and deployment of nanoscale science and technology. The NNI has four working groups including:

- Global Issues in Nanotechnology (GIN) Group
- Nanotechnology Environmental and Health Implications (NEHI) Group
- Nanomanufacturing, Industry Liaison and Innovation (NILI) Working Group
- Nanotechnology Public Engagement and Communications (NPEC) Working Group

[1] "White House ETIPC Releases Policy Principles Concerning Regulation and Oversight of Nanotechnology and Nanomaterials," Nano *and Other Emerging Technologies Blog*, Bergeson & Campbell, PC (accessed Feb 1, 2012) (http://nanotech.lawbc.com/2011/06/articles/united-states/federal/white-house-etipc-releases-policy-principles-concerning-regulation-and-oversight-of-nanotechnology-and-nanomaterials).

Since the formation of the NNI in 2000, the US federal government has budged $14 billion for 'the responsible development of nanotechnology', with $125.5 million budgeted in 2012.

The NNI released its Environmental Health and Safety (EHS) Research Strategy in September 2011. The intent of the EHS Research Strategy is to provide a framework that supports a science-based risk analysis and risk management strategy that federal agencies can use to maintain standards that protect human health and the environment as regards nanotechnology. As an additional goal, the EHS Research Strategy will provide guidance to manufacturers and importers to allow for responsible development and commercialization of nano products.

Many Federal agencies are involved in the EHS Research Strategy. The key components of the nano-EHS approach include improved methods of exposure assessment, research focused on hazard identification, and better understanding of dose-response relationships. These components are derived from the traditional conceptual site model used to establish existing environmental, health and safety standards for a wide range of substances. The National Institute of Occupational Safety and Health has taken the lead in researching potential occupational health issues and publishing draft guidance. NIOSH's leadership has provided the cornerstone for safety professionals to begin to appreciate the potential concerns presented by nanotechnology in the workplace. NIOSH's efforts have included field research to assess workplace processes, materials, and control technologies associated with nanotechnology.

The rule making approaches of the federal agencies are still developing, with FDA, EPA, OSHA and CPSC actively collecting and analyzing data to meet their respective agency's missions. EPA, for example, has a strong history in developing voluntary initiatives and collaborative partnerships with industry, academia, and other agencies within and outside the United States. EPA's Nanoscale Materials Stewardship Program (NMSP) is an example of a government-sponsored voluntary program intended to provide insights on industry-initiated safety and environmental protection protocols.

## Occupational Safety and Health Administration

OSHA's role in the potential development of Nano EHS standards is through its continued partnership in the NNI. OSHA's goal is to continue its policy of educating employers on their responsibility to protect workers.

At the current time, there are no established OSHA worker protection standards specifically for the manufacture or use of nanoscale materials. However, OSHA considers that most activities involving nanotechnologies fall under the "General Industry" OSHA Standards. Section 501(a)(1) of the OSH Act of 1970 requires employers to furnish a place of employment "free from recognized hazards" that are causing or can cause harm to employees.

Employers are also required under Section 5(a)(2) of the OSH Act to comply with occupational safety and health standards. Table 1 identifies situations where OSHA standards may apply as regards nanotechnology.

**Table 1: Potential applications of CFR 1900 to nanotechnology.**[2]

| ***Employer Responsibility*** | ***OSH Section*** |
|---|---|
| Recording and reporting injuries and illness | Section 1904 |
| General PPE Requirements | Section 1910.132 |
| Eye and Face Protection | Section 1910.133 |
| Respiratory Protection | Section 1910.134 |
| Hand Protection | Section 1910.138 |
| Sanitation | Section 1910.141 |
| Hazard Communication | Section 1910.1200 |
| Occupational Exposure to Hazardous Chemicals in Labs | Section 1910.1450 |

The Environmental Protection Agency

From a nanotechnology-specific rule making perspective, the lead federal agency has been the EPA. Basic frameworks the EPA has operated under, as regards nanotechnology, are the *Toxic Substances Control Act* and the *Federal Insecticide, Fungicide and Rodenticide Act*. While EPA has taken a leadership role on the Federal level from a rule making perspective, it is important to note that EPA has not come out with a position categorically labeling nanoscale materials as pollutants or treating these materials differently than it would other chemicals it regulates. Many of EPA's regulations are response oriented, and rely on a holistic evaluation to protect human health and environment. EPA commonly measures and enforces rules based on an aggregate risk to human health and the environmental, as opposed to OSHA's enforcement of regulations to protect individual workers and workplaces.

For many products that are manufactured, sold and/or applied, EPA's regulations require registration of these products as a condition of those products being introduced into the stream of commerce; often times EPA will then issue permitting requirements which enable the agency to manage aggregated exposure. Many of EPA's programs for nanoscale materials are currently in the information gathering stages, in which manufacturers, importers, or processors can voluntarily share information with EPA to enable tracking of production volumes and supply chains, for the sake of understanding potential impacts to human health and the environment. The NanoMaterials Stewardship Program (NMSP) is perhaps EPA's most visible voluntary program for nanotechnology. Between 2006 and 2009, EPA gathered information from 31 companies who voluntarily submitted information on over 130 nanoscale materials.

As nanotechnology continues to develop, EPA's regulations that may be impacted include:

- Toxic Substances Control Act (TSCA)
- Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)
- Others:
    - Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA)
    - Resource Conservation and Recovery Act (RCRA)
    - Clean Water Act

[2] US Code of Federal Regulations, CFR 1900

*Toxic Substances Control Act*

EPA is required by TSCA to compile, maintain, and publish a list of each chemical substance that is manufactured or processed in the United States. The inventory of over 84,000 chemical substances is available on-line (www.Data.gov). According to EPA, the agency has reviewed over 100 nanoscale materials since 2005 to determine if they should be subject to the TSCA oversight.

EPA believes that many nanoscale materials are "chemical substances," as defined under the Toxic Substances Control Act (TSCA) and can be subject to the law's rules and requirements. EPA's approach to regulating nanomaterials depends on whether the nanomaterial is already included on the TSCA Inventory (substantially similar to an inventoried substance) or if the nanomaterial is "new." In most cases, the nanomaterials are considered to be existing chemicals because the chemical identity has not changed. EPA considers the nanomaterials to be nano-sized versions of chemicals that already exist.

If there is any uncertainty as to whether a chemical is new or existing, EPA encourages manufacturers or importers to contact the EPA's New Chemicals program to arrange for a pre-notice consultation. As an alternative, the manufacturer or importer may submit a request to EPA for an Inventory search under the 'bona fide intent to manufacture' provision of 40 CFR, Section 720.25. EPA may require the manufacturer or importer to submit data on the nanoscale material to assist its determination if the nanomaterial is new or exists on the TSCA Inventory. Note that inclusion in the TSCA inventory does not imply any particular hazard. It simply means that it is a substance that the agency is authorized to track and possibly further regulate if there are concerns regarding potential risk.

*TSCA Requirements for New Substances on the TSCA Inventory*

For EPA to consider a nanomaterial to be a "new chemical substance', the molecular identity of the nanomaterial would not be identical to any chemical substance on the TSCA Inventory, and therefore would be considered to be new, and subject to premanufacture notifications (PMN) and Significant New Use Rules (SNURs). A discussion of these rules is provided below.

**Premanufacture Notifications**: Under TSCA, EPA requires manufacturers of new chemical substances to provide specific information for EPA's review prior to manufacturing chemicals or introducing them into commerce. EPA's review of the PMN may result in a TSCA Section 5(e) Consent Order. EPA can take action to ensure that those chemicals that pose an unreasonable risk to human health or the environment are effectively controlled. As a voluntary measure, the manufacturers can contact EPA if they cannot determine whether their nanoscale materials are subject to new chemical notification requirements under TSCA. However, using its authority under TSCA, EPA can require a manufacturer of nanoscale materials to submit information regarding the intended new use and provide information of the properties of the nanoscale material.

In some cases, a PMN exemption can be given to a manufacturer, provided that the manufacturer meets certain criteria outlined in TSCA. These exceptions include:

- A Low Volume exemption for a substance which is imported or manufactured in low volumes or under 10,000 kg per year

- A Low Release and Exposure (LoRX) exemption for substances with low environmental releases and human exposures
- A Polymer Exception for certain polymers
- Test Market Exceptions (TME) for chemical substances undergoing test marketing or proposed test marketing activities
- A Research and Development Exemption (R&D), if the new chemical substance is used for R&D purposes, in small quantities, and under the direction of a "Qualified Person," as defined by 40 CFR Section 723

**Significant New Use Rule (SNUR):** EPA developed a SNUR according to section 5(a)(2) of TSCA to ensure that EPA's reviews of new nanomaterials are appropriately conducted. Under the SNUR, manufacturers, importers, or processors of new nanoscale materials are required to submit a Significant New Use Notice (SNUN) to EPA at least 90 days before commencing their activity**.** A SNUN is a dataset of information on the nanoscale material, such as chemical identification, material characterization, and physical/chemical properties. In addition, the SNUN contains information on commercial uses, production volume, exposure and fate data, and toxicity data. Based on the SNUN, EPA can evaluate the intended uses of these nanoscale materials and, if needed, EPA may limit or even prohibit use if EPA determines the material may present an unreasonable risk to human health or the environment.

*TSCA Requirements for Existing Substances on the TSCA Inventory*

TSCA provides EPA with the tools to monitor chemical substances and mixtures, and to take specific measures to assess these substances and mixtures. EPA's intent is to provide protection against unreasonable risks to human health and the environment from existing chemicals. TSCA provides EPA with the authority to maintain its Inventory of
Chemical Substances, require testing of substances, regulate those substances that present an unreasonable risk, and coordinate certain actions on certain substances with actions taken under other federal laws. For manufacturers and importers of nanomaterials that are included on the TSCA Inventory, it may be foreseeable that the following rules be enforced:

**Information Gathering Rule**: The Section 8 (a) rule would require that persons who manufacture nanoscale materials notify EPA of certain information including production volume, methods of manufacture and processing, exposure and release information, and available health and safety data. TSCA Section 8(a) gives EPA authority to require manufacturers, importers and processors of chemical substances to maintain records of information of the materials being manufactured, imported, or processed. Examples of the information EPA can require to be reported include chemical or mixture identity, categories of use, quantity manufactured or processed, by-product description, health and environmental effects information, number of individuals exposed, and/or method(s) of disposal.

**Test Rule:** TSCA Section 4 test rules are a formal rulemaking process in which testing of materials is performed and EPA makes an "A" (Hazard) and "B" (exposure) determination. An "A" (Hazard) finding-based Section 4 Test Rule is a risk based finding. In it, the chemical exposure is a component of risk and EPA must demonstrate some possibility of exposure to the hazard. A "B" (exposure) finding, EPA has the following criteria that must be met:

- Substantial production/importation (1 million pounds); and

- Substantial release (1 million pounds or 10% of production/importation); or
- Substantial human exposure (1,000 workers or 10,000 consumers or 100,000 general population); or
- Significant human exposure (Determined on a case-by-case basis).

All TSCA Section 4 testing must be conducted using EPA-approved test methods or guidelines. In addition, the Test Rule requires EPA to make statutory findings of "data inadequacy" and "testing is necessary." Additional testing could be required, and the results would give EPA a stronger set of data to clarify potential health and environmental effects of the nanoscale materials.

To date, EPA has invoked TSCA to specify workplace controls for certain multi-wall carbon nanotubes. For these substances, TSCA requires:[3,4]

1. Use gloves impervious to nanoscale particles and chemical protective clothing;
2. Use a NIOSH–approved full-face respirator with an N -100 cartridge while exposed by inhalation in the work area; and
3. Distribute the …substance only to a person who agrees to follow the same restrictions

*US EPA's Federal Insecticide, Fungicide and Rodenticide Act and Nanomaterials*

In July 2011, EPA published a notice in the Federal Register proposing its plan for gathering information on nanoscale materials contained in pesticide products. In its proposal, EPA cites the need for additional information on the composition of pesticide products and describes several possible approaches to obtain the data.

There are three components to EPA's proposal. Two of these components utilize EPA's authority under FIFRA for gathering information on materials in pesticide products, including:

- Use section 6(a)(2) of FIFRA to obtain existing information regarding what nanoscale material is present in a registered pesticide product and its potential effects on humans or the environment. In this case, the registrant must inform EPA of relevant information relating to their products. This is an on-going requirement for the registrant to provide information to EPA, including if/when at any time the registrant has additional information regarding unreasonable adverse effects on the environment of the pesticide.
- Obtain information on nanoscale materials in pesticide products using data call-in notices under FIFRA section 3(c)(2)(B). In this case, EPA can send a request to a registrant requiring the registrant to provide additional data or other information on the nanoscale material. In some cases, the registrant may need to generate or compile this data.

The third component addresses issues related to new active ingredients in pesticides. Specifically, EPA outlines its approach for to how it determines whether a nanoscale active or inert ingredient is a "new" active or inert ingredient for purposes of FIFRA and the Pesticide Registration Improvement Act (PRIA). This approach is on a case-by-case basis and can occur

[3] http://www.gpo.gov/fdsys/pkg/FR-2011-05-06/pdf/2011-11127.pdf

[4] http://www.thefederalregister.com/d.p/2010-02-03-2010-2256

when an identical, non-nanoscale form of the nanoscale ingredient is already a registered pesticide.

*Other EPA Regulations Affecting Nanomaterials*

As nanotechnology increases its influence on commercial products and processes in the United States, other media-specific regulations (the Clean Air Act (CAA), Clean Water Act (CWA)) and waste management laws (Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) and the Resource Conservation and Recovery Act (RCRA)) may influence the management of these substances. As with the possible concerns regarding worker health and safety, the manufacture and use of certain nanomaterials could result in releases which, if not managed properly, have the potential to adversely impact human health and the environment. For example, under the current CAA and National Ambient Air Quality Standards, the size of the particles being monitored might result in new standards or limitations for manufacturing or release of nanomaterials. Rules on effluent limitations for National Pollutant Discharge Elimination System permits or toxic and pre-treatment effluent standards could be imposed through the provisions of the CWA. RCRA or CERCLA regulations for hazardous waste disposal could also be modified to capture specific nanomaterial waste streams if it is deemed they meet the definition of 'hazardous'.

Note there have been claims that the existing regulatory frameworks are inadequate for addressing the potential risks of nanomaterials. With TSCA, for example, one concern is that the current approach of only considering a substance 'new' if it is molecularly distinct from substances already listed does not account for the unique properties some substances exhibit at the nano scale. There are also concerns that the low volume exemption will limit the ability of the agency to address situations where there could be an unreasonable risk. [5] It is important for the safety professionals to realize that the regulation of nanotechnology is evolving and future responsibilities could be significantly expanded beyond what is described here.

Food and Drug Administration

In its statement on 'Regulation of Nanotechnology Products' the FDA points out that 'the cells and molecules with which FDAers work every day are 'nano' in size' and that 'FDA has not experienced an adverse reaction related to the 'nano' size of resorbable drug or medical device products.' FDA also states their intent to address technology issues as needed as they regulate all products on a 'product-by-product' basis, along with their intent to use their authority to require Premarket Approval, Premarket Acceptance and Post Market Surveillance as needed to regulate nanotechnology.[6]

At the same time, the agency is moving forward in developing a nanotechnology-specific strategy. In June 2011 the FDA published "Considering Whether an FDA-Regulated Product Involves the Application of Nanotechnology". Specifically, the agency named certain nano-

[5] International Council on Nanotechnology. 2000. Good Nano Guide – Short Courses, (retrieved March 1, 2012) (http://www.goodnanoguide.org/Short+Courses)

[6] US FDA, "FDA Regulation of Nanotechnology Products," (accessed March 1, 2012), (http://www.fda.gov/ScienceResearch/SpecialTopics/Nanotechnology/NanotechnologyTaskForce/ucm115441.htm)

characteristics that may be considered when attempting to identify applications of nanotechnology in regulated products.[7]

"With this guidance, we are not announcing a regulatory definition of nanotechnology," said Margaret A. Hamburg, MD, Commissioner of Food and Drugs. "However, as a first step, we want to narrow the discussion to these points and work with industry to determine if this focus is an appropriate starting place."[8]

## Consensus Standards and Industry Collaborations

As a complement to federal regulatory actions, the American Society of Testing Materials (ASTM) and the International Standards Organization (ISO) have proposed guidance specific to nanotechnology in the occupational setting. ASTM E2535 focuses on ways to minimize exposure to nanomaterials that have the potential to become aerosolized and inhaled during typical workplace tasks. The document outlines a program of safety practices for dealing with nanomaterials for which occupational exposure levels have not yet been established.

ISO created a Technical Committee to create standards for nanotechnologies. In 2008, the committee produced a Technical Report ISO/TR 12885 on health and safety practices in 2008. This document relies heavily on NIOSH's "Approaches to Safe Nanotechnology: An Information Exchange with NIOSH."

## Conclusion

As nanotechnology continues to be integrated into a wide variety of commercial and industrial products and processes, regulatory agencies and other standard setting organizations will continue to respond to these developments. In this dynamic state, it will be important for the safety professional to be aware of these developments and others so that they can most effectively influence safety and health practices in their organizations.

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[7] ibid

[8] US FDA, "FDA Takes 'First Step' Toward Greater Regulatory Certainty Around Nanotechnology," June 9, 2011

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