

Expert Analysis

Nanomaterials: A Regulatory Update

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The production of nanomaterials has skyrocketed in recent years as we have come to understand the infinite number of uses for these incredibly tiny particles, which measure between 1 and 100 nanometers (one-billionth to one-millionth of a meter). Because these tiny particles may be inhaled, ingested and absorbed into the skin, they have been the focus of concern by regulators. These potential risks are still uncertain, and traditional risk assessments are difficult to implement, so regulation to date has been limited. This article outlines the current compliance requirements that do exist and provides insight into future requirements.

FEDERAL REGULATIONS

The Environmental Protection Agency has imposed requirements specific to nanomaterials, whereas other federal agencies, such as the Food and Drug Administration, the Occupational Safety and Health Administration, and the Consumer Product Safety Commission, use existing regulations for nanomaterials. These and 21 other federal agencies coordinate their nanomaterial research and policy making through the National Nanotechnology Initiative, which was launched in 2000.

Despite these efforts, federal agencies have been blamed for not regulating nanomaterials in a way that protects human health and the environment. The EPA Office of Inspector General, for example, recently faulted the EPA for not obtaining sufficient information to manage the human health and environmental risks of nanomaterials.¹ The federal regulatory framework may be partly to blame for the lack of regulation; some believe its current structure does not provide federal agencies with adequate authority over nanomaterials.

EPA

The Toxic Substances Control Act regulates new and existing chemicals and would seem to be the most logical tool to federally regulate nanomaterials. Nanoscale versions of chemicals that are not already listed in the TSCA inventory are “new” chemicals under TSCA. Unless exempted, manufacturers and importers must file a pre-manufacture notification, or PMN, containing environmental and health data at least 90 days before manufacturing or importing a new chemical.² The EPA has received PMNs or exemption notices for more than 120 nanomaterials since 2005.³

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Upon completing the PMN review, the EPA can choose not to regulate the chemical, which it usually does, or it can impose restrictions on the use of the chemical under an order issued pursuant to TSCA Section 5(e) (applicable only to a specific manufacturer)⁴ or by issuing a “significant new use rule,” or SNUR (applicable to all manufacturers or processors).⁵ The EPA has issued SNURs for nanomaterials such as carbon nanotubes⁶ and infused carbon nanostructures.⁷ In contrast, nanoscale versions of chemicals that are already listed in the TSCA inventory⁸ are harder to regulate under TSCA because they are arguably not new and thus not subject to the PMN requirements described above.

In fact, the EPA has treated nanomaterials like their bulk versions when they have the same molecular identity.⁹ Because of this limitation, the EPA announced on its website in February 2010 that it would develop a categorical SNUR for nanomaterials.¹⁰ The categorical SNUR would make manufacturing or processing a nanoscale version of an already listed chemical a new use requiring the manufacturer or processor to submit a “significant new use notice,” or SNUN, for the nanoscale version.¹¹ A SNUN requires the manufacturer or processor to report certain information on the substance and allows the EPA to put conditions on the chemical’s use and handling as though it were a new chemical subject to the PMN process.

A SNUN differs from a PMN, however, because manufacturers may qualify for PMN exemptions that are not available to manufacturers and processors subject to a SNUN. The low-volume exemption, which exempts chemicals produced in volumes less than 10,000 kg per year,¹² may be most valuable to nanomaterial manufacturers, because many nanomaterials have yet to be produced at high volumes.

A nanomaterial may also be exempted from the PMN process if it meets certain low-release or low-exposure criteria, is used in research and development, is manufactured solely for export or, is used only in test marketing.¹³ The categorical SNUR, which the EPA indicated at a March 2010 conference would exempt chemicals for which 10 percent or less of its particle range is in the range of 1 to 100 nanometers, would presumably exempt fewer nanomaterials.

The EPA is planning other actions on nanomaterials under the TSCA. It also announced on its website in February 2010 that it intends to submit a proposed rule under TSCA Section 8(a) that would require manufacturers of nanoscale material to provide the EPA with environmental health and safety information, with an exemption for R&D and nanomaterials manufactured in small quantities.¹⁴

The EPA also announced that it will propose a rule under TSCA Section 4 to require testing by manufacturers and processors for certain nanoscale materials that are already in commerce.¹⁵ The EPA has still not proposed these rules, despite announced deadlines of year-end 2010 and, most recently, March 2012.

A much-discussed overhaul of TSCA, which has not been amended since 1971, would change how nanomaterials are regulated. Legislation was introduced in late 2011, but most believe it will not pass this session.

Nanomaterials, particularly nanosilver, are known for their antibacterial capabilities and, when included in pesticides, are subject to the Federal Insecticide, Fungicide and Rodenticide Act. Like under TSCA, new pesticides trigger requirements under FIFRA, including registration. In June 2011 the EPA issued a proposed policy that would obtain information on nanomaterials in pesticide products and would classify nanomaterials as a “new” ingredient under FIFRA.¹⁶

In December 2011 the EPA classified a nanosilver antimicrobial agent in textiles as “new” but conditionally approved the product, allowing the manufacturer to market

it while also requiring additional testing over four years to determine whether the product could ultimately be registered.¹⁷ In January the Natural Resources Defense Council petitioned the 9th U.S. Circuit Court of Appeals to set aside the conditional registration, alleging that the product will probably cause harmful effects and that the EPA had not adequately assessed the risks.¹⁸

The final EPA policy and the outcome of the NRDC lawsuit will greatly influence how nanomaterials are regulated under FIFRA.

A December 2011 report by the EPA Office of Inspector General emphasized that the agency has the authority to regulate nanomaterials released into the environment under the Clean Air Act; the Clean Water Act; the Comprehensive Environmental Response, Compensation and Liability Act; and the Resource Conservation and Recovery Act.¹⁹ Although the EPA has yet to act under these authorities, it could, for example, use information-gathering provisions of the Clean Water Act to collect information about the discharge of nanomaterials²⁰ or use RCRA to ensure proper management and disposal of nanomaterials as a hazardous waste.²¹

FDA

The FDA regulates drugs, biological products, devices, and certain food and color additives, and it has the authority to evaluate the effects of nanomaterials in these products.²² In June 2011, the FDA issued draft guidance proposing two ways in which it could require reporting on nanomaterials under its existing authority.²³ The guidance also outlined factors the FDA will consider when deciding whether products contain nanomaterials or use nanotechnology.²⁴ The FDA would use these factors for new products and products already on the market. Although not binding, the guidance could become the basis for binding FDA regulations on nanomaterials.

Finding the guidance inadequate, a group of consumer protection and environmental groups sued the FDA in December in the U.S. District Court for the Northern District of California for failing to respond to a 2006 petition asking the FDA to expressly regulate nanomaterials.²⁵ Since the lawsuit, the FDA has announced more draft guidance on nanomaterials. In April it announced guidance on significant changes in the manufacturing process, including the use of nanotechnology on food and color additives.²⁶ The FDA simultaneously announced guidance on safety assessments of nanomaterials in cosmetic products.²⁷

OSHA

Nanomaterials are subject to OSHA's "general duty clause," which requires employers to protect employees from "recognized hazards."²⁸ OSHA's other standards may also apply to nanomaterials. These standards include recording and reporting requirements; protections for the eyes, face and respiratory systems; and compliance with OSHA's Hazard Communication Standard.²⁹ In particular, the HCS requires employers to maintain material safety data sheets. Because MSDSs do not differentiate between the macro and nano versions of chemicals, employers can use existing MSDSs for the bulk versions of a nanomaterial and will need to create new MSDSs only for those nanomaterials with no macro version.

The National Institute for Occupational Safety and Health published a draft recommended exposure limit for nanotubes and nanofibers ($7 \mu\text{g}/\text{m}^3$) and an REL for ultrafine titanium dioxide ($3 \text{mg}/\text{m}^3$), although it is not legally enforceable.³⁰ NIOSH is a federal agency with mostly research capabilities, but its RELs are important because OSHA considers them when promulgating its legally enforceable permissible

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exposure limits. In addition, they potentially provide the standard of care in product liability claims.

CPSC

The Consumer Product Safety Commission regulates consumer products that are found to cause health risks once on the market. Like OSHA, the CPSC does not expressly regulate nanomaterials, but under existing CPSC statutes and guidelines, it may evaluate whether a product containing nanomaterials creates a defect that causes a substantial risk of injury to the public.³¹ Manufacturers, retailers and distributors also have immediate reporting requirements if they reasonably believe their product may cause certain health risks.³²

STATE REGULATIONS

States have begun taking their own actions on nanomaterials. Most states have been gathering information informally, but a few states, including Massachusetts, Wisconsin and California, have taken formal action.

Massachusetts

In 2007 Massachusetts created the Interagency Committee on Nanotechnology, which has been gathering information and holding workshops on the safe development of nanotechnologies.³³ In 2010 the Massachusetts Office of Technical Assistance and Technology published safety guidance on nanomaterials, which included recommendations on best management practices aimed at worker safety and prevention of release of nanomaterials into the environment.³⁴

Wisconsin

In February the Wisconsin Joint Legislative Council's Special Committee on Nanotechnology introduced a bill in the state Senate establishing a nanotechnology counsel and nanotechnology information hub to gather and disseminate information on nanomaterials.³⁵ The committee is also considering the establishment of a nanotechnology registry system and disclosure requirements.

California

California is the most active state in this arena. The Department of Toxic Substances Control has issued information requests known as data call-ins and begun implementing the California Green Chemistry Initiative,³⁶ which was passed in 2008. The DTSC issued the first nanomaterial data call-in to nanotube manufacturers in 2009³⁷ and the second in 2010 to manufacturers of certain nanometals.³⁸ The CGCI requires the DTSC to establish a toxics clearinghouse to identify chemicals of concern in consumer products and then issue regulations on those chemicals.

The regulations implementing the CGCI were to be issued by January 2011, but to date the DTSC has only finalized the regulations specifying the criteria to be used by the clearinghouse to identify the chemicals of concern. The criteria do not mention nanomaterials, but "[p]article size or fiber dimension" is listed as an "exposure potential" hazard trait.³⁹

The Safer Consumer Products Regulations under the CGCI have yet to be finalized, but the DTSC released its informal draft in October 2011.⁴⁰ The SCPR first requires the DTSC to create a list of chemicals of concern and a list of priority products containing those chemicals. Manufacturers must then notify the DTSC if they are using the chemicals and perform assessments on the chemicals and priority products

so that the DTSC can take steps to limit adverse effects on human health and the environment.⁴¹

The informal draft of the SCPR does not reference nanomaterials specifically, but the DTSC must apply the clearinghouse criteria, which, as noted above, uses size as a hazard trait to identify the chemicals of concern.⁴²

If more states follow California's lead, industry may push for federal action in an effort to have one universal rule rather than 50 state rules. States may hesitate to regulate nanomaterials, however, if such regulation is seen as unfriendly to business.

LOCAL REGULATIONS

The city of Berkeley, Calif., is the only local government to regulate nanomaterials. In 2006, the City Council amended its hazardous materials law to require researchers and manufacturers to report the types of nanomaterials they work with and how they handle the materials.⁴³

In response to Berkeley's actions, the city Cambridge, Mass., commissioned a committee to examine the Berkeley ordinance and develop recommendations about nanomaterials. The committee's 2008 report cited uncertainties about the effects on human health and the environment, and Cambridge did not enact a nanomaterials ordinance.⁴⁴ The committee instead advised Cambridge that it should better understand nanomaterials, encourage best practices by businesses and research institutions in the sector, and improve community access to information on nanomaterials.⁴⁵

INTERNATIONAL REGULATIONS

In the European Union, chemical substances are regulated under the Registration, Evaluation, Authorization and Restriction of Chemicals, or REACH, and the Classification, Labeling and Packaging of Substances and Mixtures, or CLP. Neither regulation explicitly refers to nanomaterials, but nanomaterials are covered by the definition of a "substance" under REACH.⁴⁶ REACH imposes registering and reporting requirements and is being implemented in stages between 2010 and 2018 on the basis of the tonnage of the substance being manufactured.⁴⁷ Nanomaterials classified as hazardous under CLP would be subject to labeling requirements, regardless of tonnage.

The EU Restriction of Hazardous Substances Directive restricts the use of six hazardous materials in the manufacture of certain types of electronic and electrical equipment but does not regulate nanomaterials. Amendments to this directive in July 2011 did, however, include the addition of a statement advising that restrictions on nanomaterials should be examined when scientific evidence becomes available.⁴⁸

The European Parliament recently passed the EU Cosmetics Products Regulation (no. 1223/2009), which requires, starting in January 2013, that cosmetics products containing nanomaterials must be the subject of notice to the European Commission six months before the product is placed on the market. Manufacturers must also disclose the type, size, quantity and certain safety data of the nanomaterials.⁴⁹ Cosmetics containing nanomaterials that are already on the market must make the same disclosures between January and July 2013.⁵⁰ The list of ingredients in such products must also clearly indicate the presence of nanomaterials.⁵¹

EU member states have taken their own steps to regulate nanomaterials. France, for example, has recently published a final decree that imposes reporting requirements starting in January 2013 for quantities of nanomaterials greater than or equal to 100 g.⁵²

The FDA regulates drugs, biological products, devices, and certain food and color additives, and it has the authority to evaluate the effects of nanomaterials in these products.

Countries outside the United States and EU are also taking action. For example, Australia updated its chemical reporting law to impose specific requirements on chemicals considered to be “industrial nanomaterials.”⁵³ Canada’s TSCA equivalent does not explicitly reference nanomaterials, but Canada’s health department released a “policy statement on its working definition of nanomaterials in October 2011.”⁵⁴

Regulation of nanomaterials in the United States and internationally is still in its infancy, but as the use of nanomaterials continues to grow, more governmental action is sure to follow.

NOTES

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- ³ EPA OIG Report, *supra* note 1.
- ⁴ 15 U.S.C. § 2604(e).
- ⁵ 15 U.S.C. § 2604(a)(2).
- ⁶ Multi-Walled Carbon Nanotubes and Single-Walled Carbon Nanotubes; Significant New Use Rules, 75 Fed. Reg. 56, 880 (Sept. 17, 2010) (to be codified at 40 CFR Parts 9 and 721), available at <http://www.gpo.gov/fdsys/pkg/FR-2010-09-17/pdf/2010-23321.pdf>.
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- ⁸ For example, titanium dioxide is the bulk version of nano titanium dioxide.
- ⁹ EPA, TSCA Inventory Status of Nanoscale Substances - General Approach (2008), available at www.epa.gov/oppt/nano/nmsp-inventorypaper.pdf.
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- ¹¹ *Id.*
- ¹² 40 CFR Part 723.50.
- ¹³ 40 CFR Parts 720 and 723.
- ¹⁴ See Control of Nanoscale Materials, *supra* note 10.
- ¹⁵ *Id.*
- ¹⁶ Pesticides: Policies Concerning Products Containing Nanoscale Materials, 76 Fed. Reg. 35,383 (June 17, 2011), available at <http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2010-0197-0001>.
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- ²⁰ *Id.* at 9.
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- ²⁴ *Id.*
- ²⁵ *Int’l Ctr. for Tech. Assessment v. Hamburg*, No. 11-6592, complaint filed (N.D. Cal. Dec. 21, 2011), available at <http://www.centerforfoodsafety.org/wp-content/uploads/2011/12/1-Pls-Complaint.pdf>.
- ²⁶ FDA, Guidance for Industry: Assessing the Effects of Significant Manufacturing Process Changes, Including Emerging Technologies, on the Safety and Regulatory Status of Food Ingredients and Food Contact Substances, Including Food Ingredients that are Color Additives (April 2012), available at <http://www.fda.gov/downloads/Cosmetics/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/UCM300927.pdf>.
- ²⁷ FDA, Draft Guidance for Industry: Safety of Nanomaterials in Cosmetic Products (April 2012), available at <http://www.fda.gov/Cosmetics/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/ucm300886.htm>.
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- ²⁹ The OSHA website highlights some of the applicable general industry OSHA standards for nanomaterials, http://www.osha.gov/dsg/nanotechnology/nanotech_standards.html.

- ³⁰ NIOSH, Occupational Exposure to Carbon Nanotubes and Nanofibers, NIOSH 161-A (November 2010), available at <http://www.cdc.gov/niosh/docket/review/docket161A/>
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- ³² *Id.*
- ³³ For more information see the committee's website at <http://www.mass.gov/dep/toxics/stypes/mic.htm>.
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- ⁴² *Id.*
- ⁴³ Berkeley Municipal Code, Chapter 15.12 (2006).
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- ⁴⁸ Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (July 1, 2011), available at <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32011L0065:EN:NOT>.
- ⁴⁹ Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products, available at <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32009R1223:EN:NOT>.
- ⁵⁰ *Id.*
- ⁵¹ *Id.*
- ⁵² Article L. 523-4 of the Environmental Code.
- ⁵³ National Industrial Notification and Assessment Scheme, Chemical Gazette (Oct. 5, 2010), available at http://www.nicnas.gov.au/Publications/Chemical_Gazette/pdf/2010oct_whole.pdf#page=14.
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