

Nanotechnology: Potential Risks and Regulation

Developments in nanotechnology have led to advances in medicine, agriculture, electronics, textiles, and numerous other fields. Nanoparticles are being used in everything from sunscreens and dental fillings to electronic device displays and memory chips. In 2010, there were over 1,300 manufacturer-identified nanotechnology-enabled products on the market, and some estimates suggest that nanotechnology manufacturing could grow to a \$3 trillion global industry by 2015. The rapid growth of the nanotechnology industry has been accompanied by research regarding the potential hazards of nanoscale particles, but, in many cases, this research has revealed more questions than answers. Thus the ultimate question—*Are nanomaterials safe?*—remains to be resolved.

What is Nanotechnology?

Nanotechnology is science, engineering, and technology conducted at nanoscale (about 1 to 100 nanometers) and involves the control and manipulation of individual atoms and molecules. See www.nano.gov/nanotech-101/what/definition. A nanometer is one billionth of a meter. (As a point of reference, a sheet of paper is about 100,000 nanometers thick.) See EPA Nanotechnology & Nanomaterials Research Fact Sheet, www.epa.gov/research/priorities/docs/nanotechnology-fact-sheet20121204.pdf. When nanoscale particles are created, quantum effects rule the behavior of the particles, and the properties of the materials such as melting point, electrical conductivity, fluorescence, mechanical strength, and chemical reactivity change as a factor of the particle's size. Nanomaterials have more surface area per unit of volume and are less affected by large-scale forces like gravity than the same chemical substances at larger sizes. These tiny particles are generally more reactive, are better catalysts, and show improved hardness and strength than larger particles.

Potential Risks

The same characteristic that makes nanomaterials popular for so many commercial and industrial uses—their size—renders them potentially hazardous to human health and the environment. Small particle size makes the materials extremely mobile and easily absorbed by the human body, even through the skin. Additionally, the durability and reactivity of these particles could make them more hazardous than larger particles of the same material. Moreover, once released, removal of the particles from the environment may be more difficult due to their small size.

As with other substances, the potential for health hazards depends on the particular nanomaterial at issue and the individual person's level of exposure. However, the unique characteristics of nanomaterials may render them more hazardous than a similar exposure to larger particles of the same substance because certain inhaled nanomaterials may be deposited in the respiratory tract resulting in inflammation and other serious damage. Additionally, some nanomaterials may penetrate cell membranes and impair cellular functions in ways that larger particles would not. As the use of nanomaterials in commercial products and industrial processes continues to grow, there exists the possibility of bioaccumulation in plant and animal organisms that could cause additional problems.

Regulation

A key issue facing regulators is a lack of data regarding potential health and environmental effects of nanomaterials. The field of nanotechnology is relatively new, and the research is simply not keeping pace with the evolving applications of nanotechnology, which can make effective regulation of these materials difficult. The lack of sufficient data may explain EPA's decision thus far to regulate nanomaterials on a case-by-case, chemical-by-chemical basis primarily under the Toxic Substances Control Act ("TSCA"), which authorizes EPA to regulate new chemicals and significant new uses of existing chemicals when they reach the market. This approach has allowed EPA to focus on the specific risks identified for particular nanomaterials in the context in which they are being used and to avoid making regulatory decisions based on sweeping generalizations about the nature of nanomaterials.

However, in July, EPA included as part of its 2013 Regulatory Agenda development of a proposal to establish reporting and recordkeeping requirements under TSCA for chemical substances when manufactured, imported, or processed as nanoscale materials. The proposal would require companies to notify EPA at least 90 days prior to beginning manufacture, import, or processing of nanoscale materials as part of a significant new use and require submission to EPA of information including the exposure and release information as well as available health and safety data. *See* www.reginfo.gov/public/do/eAgendaViewRule?publd=201304&RIN=2070-AJ54. According to the EPA website, the proposal, which would be the first step toward regulation of nanomaterials as a class, is expected to be published in the Federal Register by the end of the year. *See* yosemite.epa.gov/oepi/rulegate.nsf/byRIN/2070-AJ54.

Exposure to nanomaterials in the workplace is also governed by the Occupational Safety and Health Administration ("OSHA") General Industry standards. *See* OSHA Fact Sheet: Working Safely with Nanomaterials; www.osha.gov/dsg/nanotechnology/nanotech_standards.html. OSHA has recognized that, due to the differing characteristics of nanomaterials compared to larger particles of the same substance, current occupational exposure limits for a substance may not be protective for nanomaterials of the same substance. *See* OSHA Fact Sheet: Working Safely with Nanomaterials; www.osha.gov/dsg/nanotechnology/nanotech_standards.html. This is problematic because few exposure limits have been established specifically for nanomaterials. Nanomaterials may also be regulated by the U.S. Food and Drug Administration ("FDA") when the nanomaterials are incorporated into FDA-regulated products.

Tort Liability

As the nanotechnology industry continues to grow and nanomaterials are incorporated into more and more products, tort litigation is likely to follow. Nanomaterials are being used in a variety of household products, which may lead to products liability claims based on theories of defective design or failure to warn. Personal injury claims based exposure to nanomaterials released into the environment as part of the waste stream may also arise. Early studies have suggested that nanomaterials have the potential to cause pulmonary inflammation, tissue irritation, and lung tumors, and researchers have noted that one particular nanomaterial—carbon nanotubes—physically resembles asbestos fibers, which are known to cause mesothelioma.

Particularly in the absence of comprehensive regulation of nanomaterials, companies involved in the manufacture, sale, and distribution of products containing nanomaterials should remain vigilant in keeping up with new developments in health and safety research to ensure that workers are adequately protected, products are carefully designed to reduce risks to consumers, products are adequately labeled, and waste streams are controlled. To help avoid litigation, companies should also closely monitor new regulations and industry guidelines as they are promulgated.

ADDITIONAL ITEMS OF INTEREST:

Agency News:

Over 130 Chemicals Added to EPA's Safer Chemical Ingredients List

On July 24, EPA added to the Safer Chemical Ingredients List over 130 chemicals, including 119 chemicals that use fragrance for cleaning products. The list includes chemicals that meet the standards of the Design for the Environment (DfE) Safer Product Labeling Program and are safer alternatives based on a range of potential toxicological effects. For more information, go to www.epa.gov/dfe/saferingredients.htm.

EPA Proposes Electronic NPDES Reporting

On July 30, 2013, EPA published a proposed rule requiring NPDES regulated entities to electronically submit discharge monitoring reports (DMRs), notices of intent to discharge, and program reports in lieu of paper filings. According to EPA projections, the rule would save authorized NPDES programs approximately \$28.7 million annually by eliminating the requirement for state to input data from paper filings into electronic systems and streamline state requirements for annual reports. EPA is accepting comments on the proposed rule through October 28. The proposed rule is available at www.federalregister.gov/articles/2013/07/30/2013-17551/npdes-electronic-reporting-rule.

Facilities Must Submit TRI Data Electronically

On August 27, EPA published a final rule requiring electronic submission of Toxics Release Inventory (TRI) data via the TRI-MEweb online reporting software beginning January 21, 2014. The rule requires electronic submission of not only new filings, but also revisions and withdrawals of previously submitted TRI forms. However, trade secret TRI information may still be submitted in hard copy. A copy of the final rule is available at www.gpo.gov/fdsys/pkg/FR-2013-08-27/pdf/2013-20744.pdf.

EPA Proposes to Clarify CWA Water Quality Standards

On September 4, EPA proposed clarifications in six Clean Water Act (CWA) areas: (1) Administrator's determinations that new or revised water quality standards are necessary; (2) water body designated uses; (3) triennial reviews of state water quality standards; (4) antidegradation policies; (5) variances from water quality standards; and (6) compliance schedule authorizing provisions. EPA is accepting comments on the proposed rule until December 3. For more information about the proposed rule, go to water.epa.gov/lawsregs/lawsguidance/wqs_index.cfm.

New CO2 Standards for Power Plants Proposed by EPA

On September 20, EPA issued a new proposal for New Source Performance Standards (NSPS) for carbon dioxide (CO₂) emissions from new power plants. The proposed standards, which are the first uniform national limits for carbon pollution for new power plants, will require reliance on advanced technologies such as carbon capture and storage (CSS). The rule sets emission standards for fossil fuel-fired utility boilers and IGCC units at 1,100 lb CO₂/MWh gross over a 12-operating month period or 1,000-1,100 lb CO₂/MWh gross over an 84-operating month (7-year) period. For natural gas-fired stationary combustion units, the limits are set at 1,000 lb CO₂/MWh gross for larger units (greater than 850 mmBtu/hr) and 1,100 lb CO₂/MWh gross for smaller units (less than or equal to 850 mmBtu/hr). For more information go to www2.epa.gov/carbon-pollution-standards.

Civil Enforcement:

BASF to Pay \$5 Million for DDT Remediation

In July, BASF Corp. agreed to pay \$5 million to settle claims regarding contamination at a chemical plant in McIntosh, Alabama that the company acquired in 2009. The plant, which was previously owned by Ciba Corp., historically produced DDT, an insecticide banned by Congress in 1972. The property, which was placed on the Superfund list in 1984, has largely been remediated and the payment will be split among various agencies including the U.S. Department of the Interior, the U.S. Fish & Wildlife Service, the National Oceanic and Atmospheric Administration, and the Alabama Department of Conservation Natural Resources for use in restoration projects in the Mobile-Bay watershed.

Shell Oil to Spend \$115 Million for Air Pollution Controls at Texas Plant

On July 10, EPA announced a settlement with Shell Oil to resolve alleged Clean Air Act (CAA) violations at its Deer Park, Texas refinery and chemical plant. Shell has agreed to control air pollution at these facilities using innovative technology that will minimize flaring by recovering and recycling waste gases, complying with flare caps, and installing monitoring equipment to ensure that gases that are sent to flares are burned with 98% efficiency. Shell will also pay a \$2.6 million civil penalty and spend \$1 million to monitor benzene levels at the fence line of the facilities and release the monitoring data to the public via website.

Owner of Former Kentucky Coke Production Facility Resolves Alleged CAA Violations

The U.S. Department of Justice announced on August 22 that it had reached a settlement with AK Steel Corporation for alleged Clean Air Act (CAA) violations at its former coke production facility in Ashland, Kentucky. AK Steel will pay \$1.65 million in civil penalties and spend an additional \$2 million on supplemental environmental projects.

Family Dollar Settles FIFRA Claims for Misbranded Pesticides

In late August, North Carolina based company Family Dollar, Inc. agreed to pay \$602,438 in civil penalties to settle alleged violations of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) for selling misbranded antimicrobial bleach products whose labels did not conform to the labeling approved by EPA. Family Dollar also took steps to bring the products into compliance with FIFRA.

Columbia, South Carolina to Implement \$750 Million Sewer Improvements

The city of Columbia, South Carolina has entered into a settlement with EPA and the South Carolina Department of Health and Environmental Control to resolve Clean Water Act (CWA) violations resulting from sewage overflows. Under the settlement agreement, which was announced on September 10, Columbia will make improvements to its sanitary sewer system expected to cost approximately \$750 million and also implement a supplemental environmental project at an additional cost of \$1 million.

Criminal Enforcement:

Florida Company to Pay Florida's Largest Ever Wetlands Criminal Fine

On July 17, Lagoon Landing, LLC, a Panama City Beach, Florida company, and owner Brian Raphael D'Isernia were sentenced in federal court to pay a \$2.25 million criminal fine as well as a \$1 million community service payment for violations of the Rivers and Harbors Act and Clean Water Act for dredging an upland cut ship launching basin and filling wetlands without a permit. The fine represents the largest criminal fine for wetlands-related violations in Florida history. Other entities related to or controlled by D'Isernia were also involved in five separate but related civil settlements that will result in restoration of wetland areas.

Mississippi Man Sentenced for Fake Lab Results

On August 27, Tennie White, owner of Mississippi Environmental Analytical Laboratories, Inc., was sentenced in federal court in the Southern District of Mississippi to 40 months in prison for falsifying laboratory reports indicating results of waste water testing when, in fact, no testing had been performed. He was convicted at trial of two counts of false statements and one count of obstructing proceedings. White's sentence also included three years of supervised release following the prison time and a fine of \$1,000.

Haliburton Enters Guilty Plea for Destruction of Evidence

Haliburton Energy Services has admitted that it destroyed evidence following the Deepwater Horizon oil spill and pled guilty on September 19. Haliburton was ordered to pay the maximum fine of \$200,000 and was placed on three years probation. Haliburton destroyed computer simulations performed in May and June 2010 that analyzed whether certain pieces of equipment played a role in the disaster. Haliburton has also made a "voluntary contribution" of \$55 million to the National Fish and Wildlife Foundation and agreed to continue its cooperation with the investigation.

New York Man to Serve 14 Years for Mercury Attack

On September 19, Martin S. Kimber of Ruby, New York was sentenced to 14 years in prison, five years supervised release, and forfeiture of his home and car after pleading guilty to spreading mercury throughout Albany Medical Center including on food preparation services and food items in retaliation for having to pay hospital bills he considered "unfair." Mercury is a neurotoxin that can be inhaled or absorbed through the skin killing human nerve cells and leading to death, brain damage, speech impairment, and other serious injuries. Kimber was also ordered to pay \$200,451.48 in restitution to the Albany Medical Center as well as restitution to the federal government for expenses incurred in connection with the investigation.

ATTORNEY PROFILES

Richard E. Davis is a senior partner with Starnes Davis Florie LLP. He represents clients in federal and state courts in Alabama as well as in matters involving federal and state regulatory agencies. Richard's environmental practice includes Clean Water Act, Clean Air Act, and CERCLA litigation; natural resource and property damage claims; land use and water use issues; and the defense of corporations and individuals accused of environmental crimes as well as regulatory enforcement and compliance matters. Richard also defends personal injury actions based on alleged chemical exposure (so-called "toxic torts"). Richard is a Fellow in the Litigation Counsel of America Trial Lawyer Honorary; was listed in the 2008 - 2013 editions of Alabama Super Lawyers® magazine for Environmental Litigation, was selected for inclusion in the 2011 - 2014 editions of Best Lawyers in America®—in 2011 for both Environmental Law and Natural Resources Law and in 2012 and 2013 for both Litigation-Environmental and Natural Resources Law; and served as Chair of the Alabama State Bar Environmental Law Section in 2010-2011.

J. Scott Dickens is a partner with Starnes Davis Florie LLP. Scott's practice is primarily devoted to environmental and construction litigation. He has represented clients in all State and Federal Courts in Alabama, in arbitration proceedings before the American Arbitration Association and Alabama Building Commission, and in the United States Court of Federal Claims. Scott's practice includes CERCLA and RCRA litigation; architect and engineer liability claims, particularly relating to environmental issues; and construction related matters. He also frequently speaks at environmental and construction seminars. Scott is a 1996 graduate of Cumberland School of Law where he was a member of the *Cumberland Law Review*.

Amber M. Whillock is an associate with Starnes Davis Florie LLP. Amber's practice is primarily devoted to environmental litigation and regulatory compliance and includes defense of Clean Water Act and Clean Air Act claims; litigation of Comprehensive Environmental Response, Compensation, and Liability Act Contribution and cost recovery claims; defense of common law property damage claims; and defense of personal injury claims based on exposure to chemicals and other pollutants. While attending Cumberland School of Law, Amber was the Executive Editor of the *Cumberland Law Review*, a Thomley Scholarship Recipient, a George M. Stewart Banking Award Recipient and the recipient of numerous Scholar of Merit Awards.

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