



SHOOK, HARDY & BACON'S NANOTECHNOLOGY PRACTICE

April 2009

Shook, Hardy & Bacon has long recognized the significance of nanotechnology to our clients' interests. Our lawyers and analysts made a commitment a number of years ago to monitor the scientific, regulatory and litigation developments that arose as manufacturers continued to find new uses for nanomaterials in their products.

SHB has shared information about nanotechnology issues in two of our weekly newsletters—*Environmental & Chemical Update* and *Food & Beverage Litigation Update*—since at least 2002. Our timely communications about nanotechnology have focused on state, federal and international scientific and government reports and research; legislation and regulations; conferences; and legal literature.

The following is an overview of the material appearing in the newsletters we produced between January 2007 and April 2009. Specific items are linked to the reports in which they appeared, and links to original source materials can be found in the reports. The next compilation will occur in December 2009. If you would like to receive either of these reports by e-mail, please complete the request form on SHB's Web site.

REPORTS AND RESEARCH

Dozens of reports and scientific studies on nanotechnology were reported; many summarized emerging nanotechnologies, workplace-risk management and latest research and health concerns. Among them were:

1. **January 9, 2009: Food & Beverage Litigation Update;**

ISO Publishes Technical Report on Safe Handling of Nanotechnology in the Workplace

An International Organization for Standardization (ISO) technical committee focusing on nanotechnology issues has developed a technical report (ISO/TR 12885:2008) that provides "advice for companies, researchers, workers and other people to prevent adverse health and safety consequences during the production, handling, use and disposal of manufactured nanomaterials."

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Titled *Health and Safety Practices in Occupational Settings Relevant to Nanotechnologies*, the report "is expected to be widely adopted as a foundation for national nanotechnology occupational safety and health programs around the world," according to the project leader, who also serves as special assistant to the director of the National Institute for Occupational Safety and Health.

ISO is an international standard-setting organization that brings together experts from around the world to establish technical standards that are often adopted by the governments of member states; each national delegation develops its positions in consultation with all potentially affected stakeholders. The group that developed this report is ISO/TC 229.

2. March 21, 2008: Food & Beverage Litigation Update and Environmental & Chemical Update:

Friends of the Earth Issues Report on Nanotechnology in Food and Agriculture

Friends of the Earth has released a report calling for a moratorium on the use and sale of nanotech materials in foods and food packaging, citing potential risks to human health and the environment. The report, produced by the Australia, Europe and U.S.A. Friends of the Earth affiliates, provides a primer on nanotechnology and notes the ways it can be applied to agriculture, food processing, food packaging, and farm and food monitoring. It identifies 104 food products infused with nanomaterials or packaged in containers coated with nanoparticles and discusses specific kitchenware products incorporating the technology. It also names the food and beverage companies that are "engaged in nanotechnology research and development."

The groups, which are dedicated to environmental causes and a "healthy and just world," are urging a moratorium until

regulators establish specific safety laws that define nanomaterials as new substances. The report also asks for (i) extending the size-based definition of nanomaterials to include particles up to 300 nm; (ii) making safety assessment and product labeling transparent; (iv) involving the public in the decision-making process; and, (v) supporting sustainable food and farming.

Among the purported nanotechnology downsides explored in the report are its potential to make existing inequities in the global food system worse by concentrating agriculture, food distribution and retail sales in fewer hands; to "further erode our cultural knowledge of food and farming"; and to introduce new privacy concerns as packaging nanosensors will permit the collection of sensitive consumer information.

3. February 23, 2007: Environmental & Chemical Update:

EPA Issues Final "White Paper" on Nanotechnology

EPA has issued a white paper that details nanotechnology and nanomaterials research planned by the agency for the next few years. The document was prepared by a cross-agency workgroup created by EPA's Science Policy Council in December 2004. The workgroup was charged with identifying key scientific issues that EPA should consider to ensure that society acquires any environmental benefits offered by nanotechnology, as well as to better understand the potential risks. A draft was released for public comment in December 2005 (70 Fed. Reg. 75,812), then underwent independent peer review during an April 2006 meeting conducted by an EPA contractor. EPA finalized the document after considering comments received at the peer review meeting and from the public.

According to the final document, EPA's Office of Research and Development (ORD) would oversee much of the research, but other parts of the agency would also have roles. For example, the Office of Solid Waste

and Emergency Response is compiling a database of hazardous sites where project managers are considering nanoscale zero-valent iron to treat groundwater. The waste office is also preparing a fact sheet on the use of nanotechnology for site remediation, as well as evaluating the effects of engineered nanomaterials such as zero-valent that are used to treat contaminated sites. The Office of Air and Radiation will study the stability of various intentionally produced nanoparticles in the atmosphere and review an application to register a diesel additive that contains nanoscale cerium oxide.

In fiscal years 2007 and 2008, EPA will focus on identified high-priority areas, including (i) environmental fate, (ii) transport, (iii) transformation and exposure, (iv) monitoring, and (v) detection methods. During fiscal years 2009 and 2010, the agency will explore the effects, and specifically the toxicity, of the altered materials identified in the first two years. By 2011 and 2012, the agency hopes to have sufficient knowledge to assess, manage and communicate risks associated with engineered nanomaterials in the environment.

Other relevant items from SHB's *Environmental & Chemical Update* include:

May 4, 2007: Report Discusses "Green" Nanotechnology;

May 18, 2007: Study Claims Carbon Nanotubes Could Cause Respiratory Damage;

August 3, 2007: Report Addresses Possible Regulation of Nanowastes under RCRA and CERCLA;

August 24, 2007: Report Surveys Sunscreens Made with Nanoparticles;

September 14, 2007: Study Advocates Multiple Monitoring of Exposure to Airborne Nanoparticles;

November 2, 2007: Study Concludes Nanosized Copper Particles Damage Fish;

December 21, 2007: Survey of New England Companies Reveals Large Companies Are More Likely Concerned About Risks;

January 11, 2008: Lloyd's Releases Report on Nanotechnology Insurance Risks;

March 14, 2008: EC Committee Issues Report on Safety of Nanomaterials in Cosmetics;

April 18, 2008: Report Addresses Risk Management Approaches to Nanotechnology for State and Local Governments;

May 2, 2008: GAO Report Says Comprehensive Federal Strategy Needed for Overseeing Nanotechnology Research;

May 16, 2008: Study Assesses Exposure Risks to Nanoparticle Cerium Oxide;

June 6, 2008: Study Claims Multi-Walled Carbon Nanotubes Exhibit Asbestos-Like Effects in Mice;

July 25, 2008: Study Targets Environmental Uses of Carbon-Based Engineered Nanomaterials;

August 29, 2008: Report Critical of CPSC's Ability to Protect Consumers from Nanotechnology Risks;

September 12, 2008: Report Argues for Immediate Moratorium on Use of Carbon Nanotubes;

September 19, 2008: Report Urges Research on Nanoscale Silver in Consumer Products;

October 24, 2008: Study Claims Nanoparticles in Aluminum Oxide May Kill Blood Cells in Human Brain;

December 19, 2008: NRC Report Critical of U.S. Plan for Assessment of Nanotechnology Risks;

January 16, 2009: Study Claims Toxic Materials Enter Cells When Bound to Nanoparticles;

January 16, 2009: ISO Issues Technical Report on Use of Nanomaterials in the Workplace;

January 23, 2009: Report Claims FDA Incapable of Regulating Nanomaterials in Dietary Supplements;

February 20, 2009: Study Claims Iron-Containing Nanomaterials Can Cause Skin Damage;

March 13, 2009: Study Recommends Tiered Risk-Assessment Strategy for Nanomaterial Regulation; and

March 13, 2009: Study Claims Small Carbon Nanotubes Can Alter How Lung Cells React to Infections.

Additional material from SHB's *Food & Beverage Litigation Update* includes:

February 8, 2007: U.N. Releases Annual Environmental Report, Calls for Nanotech Regulation; and

December 12, 2008: NRC Report Faults Federal Strategy for Nanotechnology-Related Research.

LEGISLATION AND REGULATIONS

Our reports also summarized legislative and regulatory nanotechnology news, including these two items.

1. **February 22, 2008: Environmental & Chemical Update;**

EC Adopts Code of Conduct for Nanotechnology

The European Commission (EC) recently adopted a code of conduct for European Union member states to use as a basis for nanotechnology research and oversight. The EC anticipates that the code, while not mandatory, will help member states address legitimate concerns arising from nanotechnology development.

The code outlines seven principles stipulating that (i) research respect fundamental rights; (ii) activities be sustainable and not cause environmental harm or risks to health; (iii) research be conducted

according to the precautionary principle so that it anticipates environmental or health damage; (iv) activities be transparent; (v) research conform to the best scientific standards and good laboratory practices; (vi) governance of nanotechnology research be designed to promote innovation; and (vii) researchers be accountable for the environmental and human health impacts of their work. Under its Seventh Framework Program, the European Union is scheduled to spend \$5.1 billion between 2007 and 2013 on joint nanotechnology research projects carried out by EU institutions and organizations.

2. **February 27, 2009: Environmental & Chemical Update;**

EPA Announces TSCA Premanufacture Enforcement Initiative for Carbon Nanotubes

EPA reportedly announced that beginning March 1, 2009, it will begin enforcing a requirement that subjects many carbon nanotubes to review before they may be manufactured because they are considered "new chemicals" under TSCA. EPA issued a notice October 31, 2008, in which the agency said it considers most carbon nanotubes to be "chemical substances distinct from graphite or other allotropes of carbon listed on the Toxic Substances Control Act Inventory." 73 Fed. Reg. 64,946. The notice also said that many carbon nanotubes may be new chemicals as defined by section 5 of TSCA and that any chemical not listed on the TSCA inventory of chemicals that have been made in or imported into the United States are considered new chemicals under TSCA.

The notice advised manufacturers and importers of carbon nanotubes that are not on the TSCA Inventory to submit either a premanufacture notice (PMN) or an applicable exemption that would explain why a PMN was not needed under exemptions allowed by section 5 of TSCA. Section 5 exemptions apply in situations where the chemicals are to be made in very low

volumes or when EPA concludes that the likelihood of exposure is minimal. See *BNA Daily Environment Report*, February 20, 2009.

Other *Environmental & Chemical Update* nanotechnology items included:

February 16, 2007: EPA and EU Enter Cooperative Agreement on Nanotechnology Uses and Impacts;

May 4, 2007: City of Berkeley Issues Nanotechnology Material Disclosure Guide;

June 1, 2007: Report Recommends TSCA Be Amended to Regulate Nanomaterials;

June 1, 2007: U.K. Agency Publishes Bulletin Summarizing Scientific Knowledge on Nanoparticles;

August 10, 2007: ICTA Urges Regulation of Nanomaterials;

February 22, 2008: EC Adopts Code of Conduct for Nanotechnology;

February 22, 2008: NNI Publishes Strategy for Nanotechnology-Related Research;

January 30, 2009: Canada to Require Reporting on Toxicity of Nanomaterial; and

February 6, 2009: California DTSC Requests Toxicity Information from Carbon Nanotube Manufacturers.

SHB's *Food & Beverage Litigation Update* included these nanotechnology-related items:

August 3, 2007: FDA Task Force Issues Report Calling for Nanotechnology-Associated Guidance;

May 2, 2008: Petition Seeks Regulation of Nano-silver as Pesticide;

July 25, 2008: Kerry and Snowe Introduce Legislation to Bolster Nanotechnology Initiative; and

November 21, 2008: Comment Sought on Petition for Nanoscale Silver Rulemaking.

PUBLIC MEETINGS AND CONFERENCES

SHB newsletters regularly discussed nanotechnology public meetings and conferences, including the following two items.

1. **July 13, 2007: Environmental & Chemical Update;**

EPA to Sponsor Nanotechnology Pollution-Prevention Conference

EPA will host a conference September 25-26, 2007, to discuss the benefits that nanotechnology can offer by preventing pollution. 72 Fed. Reg. 35,991 (7/2/07). The conference will focus on three major areas of pollution prevention: (i) products that are less toxic, less polluting and wear-resistant; (ii) processes that are more efficient and wastereducing; and (iii) processes and products that use less energy and fewer raw materials because of greater efficiency. Attendees and presenters are encouraged to apply "life-cycle thinking" as they attend the conference, which is primarily directed at those who manufacture, import, process, or use nanoscale materials.

2. **April 17, 2009: Food & Beverage Litigation Update;**

Groups to Focus on Food Safety Implications of Nanotechnology

The United Nations' Food and Agriculture Organization (FAO) and World Health Organization (WHO) have announced a joint expert meeting titled Application of Nanotechnologies in the Food and Agriculture Sectors: Potential Food Safety Implications, to be held June 1-5, 2009, in Rome, Italy. The gathering will reportedly address the potential food safety risks that may arise from nanoparticles, particularly in the areas of (i) nanotechnology applications in plant and animal food production; and (ii) nanotechnology applications in food processing, packaging and distribution.

Other conference-related items that appeared in the two newsletters included:

May 18, 2007: CSL/JIFSAN Symposium to Focus on Nanotechnology;

August 17, 2007: EPA Issues Notice of Public Meeting on Nanoscale Stewardship Program;

December 21, 2007: NIOSH to Hold Public Meeting on Medical Screening for Workers Exposed to Engineered Nanoparticles;

August 15, 2008: FDA Announces Public Meeting on Nanomaterials; and

January 16, 2009: Public Forum to Target Safety of Exposure to Nanoscale Materials; EPA Gathers Data; Shareholders Urge Disclosure of Nanomaterials in Personal Care and Food Products.

LEGAL LITERATURE

SHB's *Food & Beverage Litigation Update* includes a section that focuses on legal literature which summarizes nanotechnology material appearing in law journals and other law-related publications. This item appeared in the Update on **April 3, 2009**.

James O'Reilly, "Nano's Dirty Little Secret: Industrial Users of Nanotechnology Should Start Developing a Daubert Strategy and Liability Defenses," *BNA Product Safety & Liability Reporter*, February 2009

University of Cincinnati College of Law Professor James O'Reilly recommends that defense lawyers begin preparing now for a reasonably predictable wave of litigation involving exposures to nano-sized materials that are being used in increasing number in a variety of foods and other products. According to O'Reilly, defense lawyers should be partnering with the health, safety and environmental professionals in key client organizations and

starting to revise material safety data sheets, referring to them as important vehicles for risk disclosure and excellent defense tools.

O'Reilly also suggests that counsel (i) "urge investment in engineering controls on the lines where the nanoparticles are dumped, sprayed or handled"; (ii) "encourage the medical department or industrial hygiene team to track the medical and compensation claims of lung and internal organ problems, and lost-time illnesses, that have both a base line among the worker population before nano-materials use, and a potential for a 'spike' increase after a period of use of the nanoparticles inside the workplace"; (iii) "be a 'best practices' advocate to the manager who makes the decision about worker safety investments"; and (iv) "watch the casualty insurers for signs of a selective aversion to nano-materials."

O'Reilly asks, "Why let your client become a much-publicized defendant in a landmark jury verdict and controversial set of appeals, when your client can invest less money and gain more worker appreciation by ventilation upgrades and issuing better personal protective equipment?" He also notes that the United States is lagging behind other countries in "gathering nanoparticle exposure and toxicity information," and speculates that "a deep pocketed plaintiff with sophisticated resources could utilize global scientists to make the case in a Delaware or Nevada courtroom."

Other legal-literature items summarized in SHB's *Food & Beverage Litigation Update* include:

June 15, 2007: Consumer Magazine Weighs Risks and Benefits of Nanotechnology; and

December 19, 2008: Michael Roberts, "International Legal Issues Concerning Animal Cloning and Nanotechnology – More of the Same or Are "The Times They Are A-Changin'?", *National AgLaw*, November, 2008. ■