



## SHOOK, HARDY & BACON'S NANOTECHNOLOGY PRACTICE

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December 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 May 2009 and December 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 June 2010. 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

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

1. **May 1, 2009: *Environmental & Chemical Update***

**OECD Report Addresses Lack of Standards in Assessing Workplace Exposure**

The Organization for Economic Cooperation and Development (OECD), an intergovernmental organization of 30 industrialized countries in North America, Europe and Asia, released a report April 21, 2009, that addresses how researchers should respond to a lack of standards for measuring workplace exposure to nanomaterials.

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The report recommends the adoption of consensus standards, biomarkers and other needed tools and resources. The report compiles guidance for exposure measurement and exposure mitigation in occupational settings, including the manufacturing and use of products in industrial, institutional and commercial settings. It also analyzes existing guidance for adequacy and identifies issues unique to manufactured nanomaterials. The report also summarizes background documents, including those from the U.S. Environmental Protection Agency (EPA), U.S. Department of Energy and the International Organization for Standardization, among others.

The report represents Phase 1 of a three-phase project. The other two phases will address exposure from contact with consumer products and environmental releases of manufactured nanomaterials, and exposure to environmental species resulting from environmental releases of manufactured nanomaterials, including those from consumer products.

**2. July 24, 2009: Environmental & Chemical Update:**

**Nanoengineered Materials Could Cut Cleanup Costs at Sites with Large-Scale Contamination**

A recent study by researchers from EPA and the Woodrow Wilson International Center for Scholars claims that using nanoengineered materials to remediate certain contaminated sites could potentially save billions of dollars. Barbara Karn, et al., "Nanotechnology and In Situ Remediation: A Review of the Benefits and Potential Risks," *Environmental Health Perspectives*, June 24, 2009. The study examines the case of a New Jersey manufacturing facility where it was estimated that using a tradi-

tional pump-and-treat method to remediate groundwater and soil contamination at the site would have cost \$4.16 billion, whereas the use of zero-valent iron nanoparticles would have cost approximately \$450,000. In another analysis involving a TCE cleanup, researchers found the use of iron nanoparticles reduced 99 percent of the TCE in groundwater in a matter of days. Nanoremediation methods use the application of reactive nanomaterials for transformation and detoxification of pollutants. According to the study, they work best on non-aqueous phase liquids such as TCE.

**3. August 14, 2009: Food & Beverage Litigation Update:**

**Researchers Consider Use of Nanoparticles to Color Water-Based Foods**

According to Louisiana and Arkansas university researchers, entrapping beta-carotene with nanoparticles could provide a way to use "natural" ingredients as food colorants. Carlos Astete, et al., "Ca<sup>2+</sup> Cross-Linked Alginate Nanoparticles for Solubilization of Lipophilic Natural Colorants," *Journal of Agricultural & Food Chemistry*, August 3, 2009. The research was undertaken in response to consumer concerns about the use of synthetic ingredients in food products. Using various production methods, solvents and nanoparticle sizes, the scientists found a method that produced substances which could readily be incorporated in an industrial scale process. Simply changing nanostructure concentration could, according to one of the authors, allow color changes "from dark orange to yellow."

**4. August 21, 2009: Food & Beverage Litigation Update:**

**Chinese Researchers Find Nanoparticles in Human Lung Tissue**

Chinese researchers studying seven women purportedly exposed to nanoparticles in the workplace for 5-13 months sought to deter-

mine if their shortness of breath and pleural effusions could be linked to their exposure. Y. Song, et al., "Exposure to nanoparticles is related to pleural effusion, pulmonary fibrosis and granuloma," *European Respiratory Journal*, August 20, 2009. According to the abstract of their article, "polyacrylate, consisting of nanoparticles, was confirmed in the workplace," and electron microscopy revealed nanoparticles in "the cytoplasm and caryoplasm of pulmonary epithelial and mesothelial cells," as well as in the chest fluid of the subjects. The researchers have concluded that the cases "arouse concern that long-term exposure to some nanoparticles without protective measures may be related to serious damage to human lungs."

The research has generated debate among nanotech researchers and scientists. Two of the women studied have reportedly died. Working in an unidentified Chinese printing factory, they were apparently exposed in a small, unventilated room without appropriate workplace health and safety protections while they inhaled fumes from heated polystyrene boards that had previously been sprayed with a polyacrylic ester paste. Some respiratory toxicologists reportedly doubt that nanoparticles were to blame for the serious illnesses and deaths experienced by the workers, believing that the symptoms were more typical of chemical exposure.

Occupational medicine experts agree that the study is not definitive and blame the "total failure in health and safety procedures" for the adverse health effects.

Nanotechnology expert Andrew Maynard, with the Woodrow Wilson International Center of Scholars, discussed the study's limitations in several science blogs. He was quoted as saying, "The study raises the bar for doing appropriate research as fast as possible to find out where the dangers might lie when working with nanomaterials."

Maynard reportedly suggested that the patients' symptoms were similar to those seen in animals intentionally exposed to nanoparticles. He concluded that despite the noted limitations, "this is a strong clinical study, and if viewed appropriately, will most likely help avoid similar incidents in the future." He agreed that long-accepted occupational practices would have prevented the illnesses and deaths.

Polyacrylates are plastics that come in a variety of forms, including those that make Plexiglas and "super glue," serve as binders for indoor and outdoor latex house paints, absorb fluids in disposable diapers, provide the "instant snow" used as set decoration for movie studios, and assist with seed germination, soil conditioning and hydroponics. See *Nature News*, *SafeNano Blog*, and *ICON Blog*, August 18, 2009.

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

**[May 1, 2009: International Research Review Claims Gaps Preclude Risk Assessments;](#)**

**[May 8, 2009: Report Urges New Federal Agency to Address Nanotechnology;](#)**

**[May 22, 2009: NIOSH Issues Report on Managing Health and Safety Concerns;](#)**

**[June 26, 2009: Study Claims Aluminum Nanoparticles Bind After Release into Soil;](#)**

**[August 21, 2009: Study Claims Iron Nanoparticles Can Damage Human Lung Cells;](#)**

**[November 6, 2009: Study Claims Inhalation of Certain Nanotubes Causes Lung Damage in Mice;](#)**

**[November 20, 2009: Nanomaterials Listed in Hazardous Data Bank;](#)**

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

**December 11, 2009: Researchers Develop Nanoparticle to Slow Oxidation, Extend Shelf Life**

**Legislation and Regulations**

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

**1. August 28, 2009: Environmental & Chemical Update:**

**EPA Withdraws Carbon Nanotube Rule After Receiving Notice of Adverse Comments**

EPA has withdrawn a rule that would have required manufacturers of some carbon nanotubes and 21 other chemicals to notify EPA at least 90 days before commencing manufacturing under TSCA's "new use" regulation. 74 Fed. Reg. 42,177 (8/21/09). EPA published the rule as a "direct final rule" in the June 24, 2009, *Federal Register* (74 Fed. Reg. 29,982). Under the procedure EPA uses to issue direct final rules, the agency must withdraw the rule and propose it again under standard rulemaking procedures if EPA is notified that someone plans to file, or has already filed, adverse comments. The standard procedure includes an opportunity for public comments.

According to press reports, a Washington, D.C., attorney notified EPA that he would file adverse comments on behalf of his clients who apparently claim the rule as published was ambiguous about the kind of nanotubes it covered. The rule as to the 21 other chemicals was not affected by this withdrawal. See *E&E News PM*, August 20, 2009.

**2. October 2, 2009: Food & Beverage Litigation Update:**

**EPA, EU Launch Research Strategies for Nanotechnology**

EPA and the European Union (EU) have announced separate plans to study nanotechnology, a field believed to have huge potential in food processing and packaging. EPA's strategy involves studying over the next several years how manufactured nanomaterials may harm human health and the environment. "EPA's role among federal agencies is to determine the potential hazards of nanotechnology and develop approaches to reduce or minimize any risks identified," according to an EPA news release. The research will use a "multidisciplinary approach that examines all aspects of nanomaterials in the environment, from their manufacture and use to their disposal or recycling."

The EU plans to develop a strategy on how best to reap the economic benefits of nanotechnology because of its "exceptional importance for being at the forefront of managing the shift to a low carbon, knowledge-based economy," according to an EU news release. "Mastering such technologies lays [a] stable foundation for well-paid jobs in the EU and allows for sustainable, broadly shared growth. The EU still faces significant obstacles in achieving the wide and timely industrial deployment of these technologies." See *EPA News Release*; *EU News Release*, September 30, 2009.

**3. October 9, 2009: Environmental & Chemical Update:**

**Nanomaterials Research Strategy Announced**

EPA has released a new strategy to guide its research into how nanomaterials used in a number of consumer products might be harming human health and the environment. Nanomaterials, particles between about 1 nanometer and 100 nanometers

in size, are used in hundreds of consumer products, including sunscreen, cosmetics and sports equipment.

According to EPA, the strategy focuses on identifying sources, fate, transport, and exposure to nanomaterials; understanding the human health and ecological effects of nanomaterials to inform risk assessments and test methods; developing risk assessment approaches; and preventing and mitigating risks.

The strategy is intended to help decision-makers answer these questions: (i) What nanomaterials, and in what form, are most likely to result in environmental exposure?; (ii) What particular nanomaterial properties may raise toxicity concerns?; (iii) Are nanomaterials with these properties likely to be present in environmental media or biological systems at concentrations of concern, and what does this mean for risk?; and (iv) If the answer to previous question is yes, can the material's properties be changed or can exposure be mitigated?

Other *Environmental & Chemical Update* nanotechnology items included:

**[July 10, 2009: EPA Imposes Notification Requirement on Carbon Nanotube Manufacture](#)**

**[August 21, 2009: EPA's ITC Issues 64<sup>th</sup> Report and Requests Information on Nanoscale Materials Risks](#)**

**[December 11, 2009: EU Adopts Revised Cosmetics Regulation Requiring Labeling of Nanoscale Ingredients](#)**

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

**[November 20, 2009: Australian Agency Seeks Comment on Proposal to Regulate Industrial Nanomaterials; Scientific Studies Continue to Generate Debate over Potential Health Effects](#)**

**[December 11, 2009: Public Health Activists Urge SEC to Increase Corporate Disclosures of Emerging Risks](#)**

## MEDIA COVERAGE

SHB's *Food & Beverage Litigation Update* includes a section that focuses on media coverage, and includes summaries of stories about nanotechnology appearing in major news publications and media outlets. The following story appeared in the *Update* on **[December 4, 2009](#)**.

**["Nanocosmetics: Tiny Size, Big Potential," nanovip.com, December 1, 2009](#)**

Noting the absence of significant regulatory oversight, this article discusses the use of nanotechnology in foods, food packaging and food supplements. While the Food and Drug Administration has decided not to regulate products according to the technology used, it will apparently issue a guidance document on nanotechnology in 2010. The article cautions that "companies need to realize the EU, Canada and the State of California have all requested information from manufacturers of nanoscale products."

According to the market data on nanotechnology, while little food with nanotech ingredients are on grocery store shelves today, food packaging is an active application that accounts for billions in sales. Manufacturers are apparently using the technology to develop "improved tastes, color, flavor, texture and consistency of foodstuffs, increased absorption and

bioavailability of nutrients and health supplements, new food packaging materials with improved mechanical, barrier and antimicrobial properties, and nano-sensors for traceability and monitoring the condition of food during transport and storage.”

The article also discusses how nanotechnology is being incorporated into nutrition via micelles, “the tiniest of capsules that form naturally when nature requires a fat-soluble substance to be soluble in water,” and liposomes. An Israeli-based company is reportedly using micelles as a delivery system for vitamins, omega-3s, beta-carotene, isoflavones, and lutein, while Australian researchers are developing “chitosan-based biopolymers to encapsulate and protect antioxidants from the low pH in the gut, so they can make it to the small intestines and be released in a controlled manner.”

The article concludes by observing how little is known about where “nano-enabled substances will go in the body and how they will affect health. . . . This lends to a fear by regulators and consumers, both of which have been slow to learn about nanotech. It is truly an infant frontier that hopefully does not become another cowboy-filled Wild West the natural products industry does not need.”