



SHOOK, HARDY & BACON'S NANOTECHNOLOGY PRACTICE

June 2010

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 and June 2010. 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 2010. If you would like to receive either of these reports by e-mail, please complete the request form on SHB's Website.

SCIENTIFIC / TECHNICAL ITEMS

Two reports in our *Environmental & Chemical Update* summarized workplace-risk management issues regarding nanotechnology.

They were:

1. **February 19, 2010: Nanotechnology:**

EC Funded Consortium Launches Web Site to Track Nanomaterial Exposure

A consortium funded by the European Commission (EC) has launched a Website to track information on occupational and consumer exposures and environmental releases of nanomaterials. The online resource will focus on carbon nanotubes, mass-produced nanomaterials, such as titanium dioxide, and specialized nanomaterials, such as nanosilver. Consortium members include 11 research and industry organizations that will examine information from peer-reviewed studies as well as government academic information that has not been published in scientific journals.

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2. April 16, 2010: Insurance Coverage:

Insurance Company Announces Coverage for Nanomaterials

Lexington Insurance has announced that it will provide integrated liability coverage for medium to small companies in the United States manufacturing or distributing nanoparticles and/or nanomaterials. Coverage highlights include general liability, products liability, products pollution liability, and product recall liability. The company also provides an array of risk management services related to nanoparticles and nanomaterials.

LEGISLATION AND REGULATIONS

Our *Environmental & Chemical Update* also summarized many legislative and regulatory nanotechnology news items, including:

1. February 12, 2010: TSCA/ Nanotechnology:

EPA Proposes SNURS for Certain Multi-Walled Carbon Nanotubes

EPA has proposed a significant new use rule (SNUR) for certain multi-walled carbon nanotubes for which the agency has received a premanufacture notice under TSCA. *75 Fed. Reg.* 5,546 (02/03/10). The proposed rule identifies the multi-walled carbon nanotubes by the number of their premanufacture notice, P-08-199. According to the agency, the proposed rule applies to those nanotubes only.

The nanotubes will be used as an additive/filler for polymer composites and support media for industrial catalysts. For other uses, a manufacturer or importer would need to file a SNUR notice at least 90 days before the new use. EPA is accepting comments on the proposed rule through March 5, 2010.

2. February 19, 2010: Nanotechnology:

EC Announces Projects to Determine Whether REACH Adequately Covers Nanomaterials

The European Commission (EC) reportedly announced February 2, 2010, three projects designed to determine whether new guidance is needed to ensure that the European Union's registration, evaluation and authorization of chemicals (REACH) regulation provides adequate coverage of nanomaterials. The three projects deal with chemical identification, information requirements and assessing the safety of nanoscale chemicals.

The chemical identification project will be led by the Institute for Health and Consumer Protection, which will assemble a group of experts from member states, industry and nongovernmental organizations. A consortium of research and industry groups led by the United Kingdom's Institute for Occupational Medicine will coordinate the projects on information requirements and chemical safety assessment. The projects were started in January 2010 and are scheduled to continue for 12-15 months. See *European Commission Joint Research Centre Press Release*, February 2, 2010.

3. April 23, 2010: Nanotechnology:

OECD Issues Current Developments/ Activities Report on Safety of Manufactured Nanomaterials

The Organization for Economic Cooperation and Development (OECD) has released a report summarizing current and planned activities related to the safety of manufactured nanomaterials based on the sixth meeting of the Working Party on Manufactured Nanomaterials, held in October 2009. The meeting was attended by 110 participants representing OECD member countries; the European Commission (EC); the International Organization for Standardization; United Nations agencies; non-OECD countries; and business, industry and nongovernmental organizations.

OECD is an intergovernmental organization with representatives from 30 industrialized countries in North America, Europe and the Asia and Pacific region, as well as the EC. The organization hosts periodic meetings to discuss solutions to international issues and conducts its work through more than 200 specialized committees and working groups composed of member country delegates.

4. May 7, 2010: Nanotechnology:

UCSF Report Recommends State Regulation of Nanomaterials

A recent University of California, San Francisco (UCSF) report recommends that the state Office of Environmental Health Hazard Assessment (OEHHA) explore health risks posed by nanomaterials and how to address those risks within the state's regulatory structure. Authored by scientists at UCSF's Program of Reproductive Health and the Environment, the report includes policy recommendations designed specifically for OEHHA to address the potential health risks identified.

The report stresses the importance of requiring manufacturers to provide sufficient data to determine whether their products pose a significant health risk, and it suggests that existing state laws could be employed to identify and define particles and "priority" properties, develop a list of characteristics for nanomaterials and create a framework for making regulatory decisions based on use of nanomaterials and their exposure potential. The report also suggests that existing laws could be employed to assess potential exposure risks using existing hazard traits from other chemicals and toxicological and environmental-health-related endpoints, evaluate risk assessment guidelines to determine if they can sufficiently cover nanomaterials and require labels to specify that a product contains nanomaterials.

Other recommendations include (i) developing definitions that describe the difference between nanomaterials or nanoparticles and other small-molecule chemicals; (ii) identifying the existing sources of nanomaterials; (iii) collecting information on the fate and transport of the materials; and (iv) requiring that a consumer product, already on the market and made with nanomaterials, be tested for exposure potential.

5. June 18, 2010: Nanotechnology:

OECD Revises Guidance on Testing of Manufactured Nanomaterials

The Organization for Economic Co-operation and Development (OECD) has revised a guidance document on safety testing of manufactured nanomaterials. The revised document was prepared by the organization's Working Party on Manufactured Nanomaterials and revises an initial version of a document released in 2009.

OECD's manufactured nanomaterials safety program "aims to generate safety information through testing for human health and environmental effects based on OECD test guidelines and other internationally agreed methods." Program testing focuses on nanomaterial information/ identification, physical-chemical properties and material characterization, environmental fate, environmental toxicology, mammalian toxicology, and material safety, according to OECD. The guidance will be regularly updated and amended based on comments received from delegations. OECD is an intergovernmental organization in which representatives of 31 industrialized countries in North America, Europe, Asia, and the Pacific region meet to coordinate and harmonize policies and respond to international problems.

SHB's *Food & Beverage Litigation Update* included these 10 nanotechnology-related regulatory items:

January 8, 2010: UK Nanotechnology Report Critical of Food Industry

In a development that could have a significant impact on the global food industry, the UK's House of Lords has completed an inquiry into the use of nanotechnology in foods, food packaging and food contact materials. In a January 8, 2010, press release and comprehensive report accompanied by a separate volume of evidence, the Lords' Science and Technology Committee criticizes the food industry for "not publishing or discussing details of its research in this area."

The committee calls for the government "to adequately fund research into potential health and safety risks arising from the use of nanomaterials in the food sector" and recommends that the Food Standards Agency "contribute to consumer confidence in the use of nanomaterials in food by maintaining a publicly available register of food and food packaging containing nanomaterials."

Noting the unavailability to border and port authorities of "tests to check whether imported food contains nanomaterials," the committee "raises concerns about the potential for the illegal importation of food products containing nanomaterials not approved for use in food in the EU." Accordingly, the committee's report suggests that these concerns be addressed "by providing consumers with information about products containing nanomaterials, and by the Government ensuring that practical tests are developed for enforcement authorities to use on imported food."

The committee contends that public distrust over genetically modified (GM) foods was fueled by a lack of transparency. Lord Krebs,

who chairs the committee, was quoted as saying, "The food industry must also be more open with the public about research it has undertaken in this area and where it sees nanomaterials being used in food production in the future. The lesson from the public reaction to GM foods is that secrecy breeds mistrust, and that openness and transparency are crucial to maintain public confidence." A YouTube® video of Lord Krebs discussing the committee's recommendations will apparently be made available.

The committee's focus is on food products, additives and supplements; food contact packaging; food manufacturing processes; animal feed; pesticides and fertilizers; and products that may come into contact with food, such as food containers and cooking utensils. Not considered at this time were nanomaterial waste products or potential effects on the environment. The report follows a public inquiry into nanotechnology undertaken in 2009 to consider (i) "State of the science and its current use in the food sector"; (ii) "Health and safety"; (iii) "Regulatory framework;" and (iv) "Public engagement and consumer information."

January 29, 2010: U.S. Congress Turns Attention to Nanotechnology Issues

Legislation recently introduced in the House and Senate would take different approaches to the continuing development and use of nanotechnology. Senators Mark Pryor (D-Ariz.) and Benjamin Cardin (D-Md.) have co-sponsored a bill (S. 2942), the "Nanotechnology Safety Act of 2010," that would establish a program within the Food and Drug Administration (FDA) to investigate nanoscale materials used in FDA-regulated products to assess their "potential toxicity" and interactions with biological systems. The measure would appropriate \$25 million for each year from 2011 through 2015 to carry out the program.

Among other matters, the proposal calls on FDA to assess scientific literature and data, develop models to formulate general principles for “the behavior of classes of nanoscale materials with biological systems;” undertake collaborative efforts to understand the “science of novel properties at the nanoscale that might contribute to toxicity;” build agency expertise on these issues, ensure ongoing training, and “participate in international and national consensus standards activities.” The bill has been referred to the Senate Committee on Health, Education, Labor, and Pensions.

Representative David Wu (D-Ore.) has introduced the “Nanotechnology Education Act” (H.R. 4502), which calls for the National Science Foundation director to establish “a nanotechnology in the schools program to strengthen the capacity of eligible institutions to provide instruction in nanotechnology.” The director would be authorized to award \$400,000 grants to eligible secondary and post-secondary schools to acquire nanotechnology equipment and software, develop appropriate instructional programs and provide related teacher education and certification. Designed to strengthen the capacity of the nation’s schools to “prepare students for careers in nanotechnology;” the proposal has one co-sponsor and has been referred to the House Committee on Science and Technology.

January 29, 2010: California DTSC May Take Action Under Carbon Nanotube Information Call-In Program

California’s Department of Toxic Substances Control (DTSC) has been gathering information from companies that produce or import carbon nanotubes in the state and has posted the information received by its January 22, 2010, deadline on the agency’s Web site. The agency has also indicated which companies did not submit the information requested;

a news source reports that DTSC may take action through the attorney general’s office against them.

DTSC launched the information call-in program in 2009, hoping to identify information gaps and build data about carbon nanotubes. Manufacturers and importers were requested to supply information about “analytical test methods, fate and transport in the environment, and other relevant information.” The agency’s initial request involved reactive nanometal oxides, including aluminum oxide, silicon dioxide, titanium dioxide, and zinc dioxide. It has since identified as nanomaterials of interest nano silver, nano zerovalent iron and cerium oxide.

According to a press report, agency sources have found some trends emerging from the company responses, including (i) research facilities and manufacturers use existing environmental health and safety policies to contend with human health exposures; (ii) universities treat nanomaterial waste like other lab waste; (iii) no one appears to know what customers are doing with carbon nanotubes or how they are disposing of them; and (iv) this lack of knowledge can be attributed to a lack of regulatory parameters or business practices requiring or promoting the collection of this data, which also could involve confidential business information and trade secrets. See *Inside CalEPA*, January 29, 2010.

February 5, 2010: EPA Proposes Significant New Use Rule Under TSCA for Carbon Nanotubes

The Environmental Protection Agency (EPA) has issued a proposed rule that “would require persons who intend to manufacture, import, or process [multi-walled carbon nanotubes] for an activity that is designated as a significant new use by this proposed rule to notify EPA at least 90 days before commencing that activity.” The activities identified in the proposed rule as “a significant new use” are (i) “protection in the workplace” (“full-face respirators with N100

cartridges”), and (ii) “industrial, commercial, and consumer activities” (“additive/filler for polymer composites and support media for industrial catalysts”). According to the notice, EPA has issued the proposal under the authority of the Toxic Substances Control Act (TSCA) and would adopt the 90-day notice requirement to give the agency the opportunity to evaluate the intended use and “prohibit or limit that activity before it occurs,” if necessary. Comments must be submitted by March 5, 2010. See *Federal Register*, February 3, 2010.

February 12, 2010: EC Report Provides Overview of Projects Tracking Public Debate on Nanotechnology

The European Commission has released a report, “Understanding Public Debate on Nanotechnologies: Options for Framing Public Policy,” that discusses several commission projects designed to assess “the nature of public debate on nanosciences and nanotechnologies, and the ways in which deliberative approaches could lead to better governance of these technologies.” The overview includes summaries of the FramingNano, Nanocap, Deepen, and Nanoplat projects. The authors, who were involved as coordinators or participants in these projects, acknowledge that nanotechnology policy is still in its initial phases of development and could be overwhelmed by the sheer volume of products expected to enter the market in the near future. They note that international authorities have not yet agreed to definitions relating to the technology and that the European Union is regulating nanoparticles as “chemical substances” under REACH. Among other matters, they observe that nanotechnology in food is expected to be defined as a “novel food,” much like genetically modified foods have been defined since the 1990s, and

that a food-additive proposal before the European Parliament is the “first piece of legislation to include explicit reference to nanotechnology.”

March 19, 2010: FSA to Create Nanotechnology Research Registry

The U.K. Food Standards Agency (FSA) Board has reportedly agreed to maintain a confidential database of food industry research into nanotechnology, as well as a public registry of food and food packaging products that contain both approved nanomaterials and materials appearing to have nanoscale elements. “The way that we respond in terms of nanotechnology is a test case for the way we, as a regulator respond, to emerging and new technologies,” FSA Chief Scientist Andrew Wadge was quoted as saying.

According to media sources, FSA accepted the recommendations put forth in a House of Lords Science and Technology Committee report, which called on regulators to develop risk assessment procedures and prioritize research into the safety of nanotechnology. In making its assessment, the committee had apparently favored mandatory industry participation, claiming that a lack of transparency had previously led to public distrust of genetically modified crops. Additional details about this report appear in issue 332 of this Update. See *FoodNavigator.com*, March 15, 2010; *Meridian Nanotechnology and Development News*, March 17, 2010.

April 9, 2010: Science and Technology Advisors Assess Federal Nanotechnology Initiative

The President’s Council of Advisors on Science and Technology has released a report to the president and Congress assessing the National Nanotechnology Initiative (NNI), “which coordinates Federal research and development activities involving the manipulation of matter at scales smaller

than 100 billionths of [a] meter.” The third in a decade-long series of assessments, the report lauds the NNI for making the United States a nanotechnology leader but notes that aggressive competitors “such as China, South Korea, and the European Union,” pose a threat to that leadership position.

The report makes a number of recommendations, including increased investment in product commercialization and technology transfer and a strengthened commitment to “explore in more orderly fashion environmental, health, and safety issues.” Noting the role that nanotechnology plays in consumer products, including foods, the report also envisions how it can be used in information technology, health care, the development of high-strength materials, energy and the environment, and national security.

In a related development, the U.K. government has reportedly responded to a House of Lords report calling on industry to disclose details about its nanotechnology research by warning that mandatory reporting requirements could deter companies from doing that research in Britain and trigger a research and development exodus. The government also reportedly observed, “It seems doubtful whether existing legal powers could be used to compel U.K. food companies to provide information about their research activities or their plans for future product launches. Introducing a mandatory reporting system would therefore require new legislation.” See *FoodProductionDaily.com*, March 31, 2010.

April 23, 2010: Draft Nanotech Policy Framework for California Scheduled for Discussion and Comment

The University of California-San Francisco Program on Reproductive Health and the Environment has developed draft policy recommendations to address potential health risks from nanomaterials and

nanotechnology. When finalized, the document will be presented to California EPA’s Office of Environmental Health Hazard Assessment (OEHHA) to better inform the agency’s risk assessment recommendations. The draft will be considered during a Science Advisory Panel meeting on May 5, 2010, and all public comments are due on that date.

Among the recommendations for OEHHA in the draft report are to (i) assess whether nanomaterials are already covered under the agency’s existing policy structure, (ii) determine if nanosized materials are more toxic than “their bulk material,” (iii) identify the extent of nanomaterial use in products, including food contact materials and foods, and (iv) “require labeling for nanomaterials that contain known carcinogens or reproductive effects.”

May 7, 2010: EPA’s New “Nanomaterials” Definition to Affect Pesticide Registrations

With a new working definition of “nanomaterials,” the Environmental Protection Agency (EPA) is apparently poised to launch new regulatory policies including those addressing the registration of pesticides under the Federal Insecticide, Fungicide & Rodenticide Act (FIFRA). The definition, revealed during a PowerPoint® presentation at an April 29, 2010, Pesticide Program Dialogue Committee meeting, is as follows: “An ingredient that contains particles that have been intentionally produced to have at least one dimension that measures between approximately 1 and 100 nanometers.”

The pesticide registration policy, expected to be published in the *Federal Register* in June, would allow EPA to use section 6(a)(2) of FIFRA, which “requires pesticide product registrants to submit adverse effects information about their products,” to gather information about the use of nanoscale materials in pesticides. Registrants would be required to report the inclusion of nanoscale materials in a pesticide product already registered or pending registration. Under another new policy, EPA would deem

nanoscale versions of conventional pesticide ingredients as “new active ingredients,” thus requiring disclosure and possible regulation even if the conventional ingredient is already registered. According to a news source, industry representatives have expressed concerns about EPA’s nanomaterial policies, suggesting that they represent a “controversial interpretation” of the law. See *Inside EPA*, April 30, 2010.

June 18, 2010: ISO Nano-Product Labeling Standard with Implications for Food Industry on ANSI Webinar Agenda

The American National Standards Institute (ANSI) has announced a July 9, 2010, Webinar to provide an overview of the current draft of an Organization for Standardization (ISO) document titled “Guidance on the labeling of manufactured nano-objects and products containing manufactured nano-objects.”

According to ANSI, “this nano-labeling document will likely have broad implications for a number of U.S. industry sectors, including

food safety/industry, cosmetics and chemicals.” The draft ISO guidance document is expected to be distributed for a vote by June 18 to national advisory groups participating in the development of international nanotechnology standards. The ANSI-accredited technical advisory group (TAG) that represents U.S. positions before ISO is interested in comments on the draft to develop the U.S. position and vote. Internet reservations are required to participate in the Webinar.

ISO standards and technical materials, developed on an international level, often form the basis for national regulations. They are developed by stakeholders who participate through individual country advisory groups, such as the ANSI-accredited U.S. TAG to ISO/TC 229 Nanotechnologies. The document under consideration is a “technical specification” (TS); the European Committee for Standardization (CEN) Technical Committee 352 Nanotechnologies leads this TS development activity. ■