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Dr. Beck directs Gradient's nanotechnology, toxicology, and risk assessment practices.

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Recent Government Briefs

Wisconsin State Representative Proposes Creation of Statewide Nanotechnology Registry

<http://www.thedailypage.com/media/2008/01/09/Berceau%20nanotech%20letter%20120307.pdf>

Wisconsin state representative Terese Berceau has called on several state agencies to create a registry that tracks the use of nanomaterials. The proposed registry would require nanotechnology companies to report the types (e.g., carbon nanotubes), forms, and amount of nanoparticles that they are producing or using. It would also require companies to furnish other important EHS-related information such as toxicological properties of nanomaterials, how nanoparticle use/manufacture will be monitored, and how nanomaterials will be transported, tracked, and disposed. Last, it would require that nanotechnology companies report how they will prevent unintentional releases and how the effects of potential releases would be mitigated. Recognizing that many materials and processes are considered proprietary, Rep. Berceau's proposal states that information beyond public health and regulatory concerns will not be released to the public.

Characterizing the Potential Risks Posed by Engineered Nanoparticles: A Second U.K. Government Research Report

<http://www.defra.gov.uk/environment/nanotech/research/pdf/nanoparticles-riskreport07.pdf>

This report, published by the UK Government Department of Environment, Food and Rural Affairs, reviews the

status of research pertaining to nanomaterials since the first research report was issued in 2005. The first report outlined 19 EHS-related objectives and proposed research activities to be taken forward by the Nanotechnology Research Co-ordination Group (NRCG). This report provides an update on NRCG's objectives and discusses funding additional research. It places UK activities in an international context, noting that the UK's nanotechnology programs are similar in size compared to other industrialized countries. It recommends that nations pool the results of their nanomaterials research. Last, the report examines the progress and findings of five nanotechnology task forces which were convened in 2006, to follow research activities in nanoparticle standardization, exposure, human and environmental hazards, social dimensions, and economic implications.

Reports, Reviews, White Papers, and Books

Nanotechnology Recent Developments, Risks, and Opportunities

Published by Lloyd's of London

http://www.lloyds.com/NR/rdonlyres/B9C7371E-83D4-49DD-8268-5D6C800FBDDF/0/ER_Nanotechnology_Report.pdf

Since nanotechnology-related industries are growing internationally, insurance group Lloyd's of London examined the positive effects and loss potential that nanotechnology poses to their industry. In this report, Lloyd's recognized the potential of how nanotechnology may affect their decisions in paying claims, deciding terms, conditions, and pricing. It lists potential benefits such as advances in medicine, safer building/manufacturing materials, and pollutant reduction. They also list worst-case nanomaterial risks such as material spills, product recalls, unexpected health effects, and workers' compensation issues, pointing out that a "wait and see" approach is a dangerous way to determine the probability of these risks. Recognizing the state of research regarding impacts on health and the environment, as well as the vacuum of nanotechnology regulation, Lloyd's recommends that exposure to nanotechnology be carefully examined. They conclude that insurers should contemplate future adverse scenarios and potential costs.

A Survey of Environmental, Health and Safety Risk Management Information Needs and Practices among Nanotechnology Firms in the Massachusetts Region

By John E. Lindberg, MS, and Margaret M. Quinn, ScD, of

University of Massachusetts Lowell

http://www.nanotechproject.org/publications/archive/a_survey_environmental_health_safety/

This study assessed the current state of nanotechnology risk management practices among firms in Massachusetts. A web-based questionnaire was sent to 180 nanotechnology firms to evaluate environmental health and safety (EHS) needs and practices in nanomaterials production and use. The results of the survey indicated that while the majority of respondents actively take steps to manage EHS risks, a large percentage of firms lack sufficient information to quantify risk or do not believe there is EHS risk associated with their nanomaterials. Firms that were taking steps to manage risk were relying on material safety data sheets, expert judgment, best practices, and current regulatory requirements. Larger firms were more likely to take steps to manage EHS issues, while smaller firms often did not recognize risk in their materials. Overall, the study found that the ability to manage risk is limited by a lack of information on the health and environmental impacts of nanotechnology.

Upcoming Meetings and Conferences

Nanogovernance 2008: Innovative Approaches to Nanotechnology Environmental Governance

February 12, 2008 Washington, D.C.

<http://www.nanogovernance.com>

Sponsored by The George Washington University Law School, Porter Wright Morris & Arthur LLP, and the Environmental Law Institute, this two-session conference features speakers on issues surrounding the environmental regulation and governance of nanotechnology and will include group discussions on future environmental governance for nanotechnology. Speakers will include representatives of the US Environmental Protection Agency, U.S. Chamber of Commerce, private corporations, and several non-profit and special interest groups whose interests include promoting nanotechnology research. This conference allows participants to presubmit questions and comments to the conference speakers.

1st Annual Conference on Nanotechnology Law, Regulation and Policy

February 28-29, 2008 Washington, D.C.

<http://www.fdli.org/conf/431/>

Presented by the Woodrow Wilson International Center for Scholars Project on Emerging Nanotechnologies, Arizona State University and the Burdock Group, this conference will bring together stakeholders in nanotechnology, science, business, law, regulation, and policy in the food and drug industry. Representatives from the FDA, EPA, USDA, and OSHA will provide updates on the most recent nanotechnology regulatory activities. The conference will also address questions on future Congressional action, as well as business

and international aspects of nanotechnology.

Nanotechnology: The Future of EHS Regulatory Policy

March 20, 2008 Baltimore, Maryland.

<http://guest.cvent.com/EVENTS/Info/Summary.aspx?e=3ee8ee31-7c95-4638-be24-985a78801145>

Hosted by Keller & Heckman LLP and NanoReg News, this one-day session will feature leaders in public policy who will discuss corporate and regulatory governance related to developing an environmental health and safety (EHS) framework for nanotechnology-related products of the future. The agenda includes discussions of the regulatory outlook for nanomaterials under the Toxic Substances Control Act (TSCA) and the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), approaches contemplated by regulatory agencies such as the FDA, and future actions to be taken to regulate and standardize nanomaterials.

2nd International Conference on Nanotoxicology

September 7-10, 2008 Zurich, Switzerland

<http://www.nanotox2008.ch>

Hosted by the University of Zurich and the Swiss Federal Institute of Technology, this conference aims to address the hazards of and exposure to nanomaterials. Participants, who will include the public and stakeholders, will have the chance to attend panels on the biological effects of nanomaterials and learn about the development of new methods and standardization processes. The conference program will cover topics such as exposure to and uptake of nanomaterials, the biological effects and mechanisms of nanomaterials, and the properties of special materials associated with nanotechnology.

Hot-off-the-Presses Peer-Reviewed Research Articles of Note

Baker, G.L., et al. 2008. "Inhalation toxicity and lung toxicokinetics of C₆₀ fullerene nanoparticles and microparticles." *Toxicological Sciences* 101(1): 122-131. Abstract: <http://toxsci.oxfordjournals.org/cgi/content/short/101/1/122>

Synopsis:

- Despite the fact that C₆₀ fullerenes have been detected in air samples from both urban and occupational environments, no inhalation studies have been reported, with experimental studies primarily assessing the toxicity to biological systems of C₆₀ fullerenes in aqueous solutions. The present study was conducted to address this knowledge gap and to investigate the toxicity of C₆₀ fullerenes after inhalation exposure.
- Stable aerosols of dry C₆₀ fullerenes were generated for both a nanoparticle size distribution (count median diameter 55 nm; average mass concentration 2.22

mg/m³; particle concentration 1.02 x 10⁶ particles/cm³), and a microparticle size distribution (mass median aerodynamic diameter 0.93 μm; average mass concentration 2.35 mg/m³). Rats were exposed to aerosols *via* a nose-only exposure unit for 3 hours/day, for 10 consecutive days. A subset of rats from each group was euthanized on day 10, and gross anatomic examinations, complete necropsies, and tissue histopathologies were performed. Another subset was allowed to recover for 17 days, with blood and bronchoalveolar lavage samples taken throughout the recovery period for tissue burden analyses.

- Minimal toxicity was observed in both nanoparticle- and microparticle-exposed groups. There was no evidence of body or organ weight changes, gross anatomic lesions, or microscopic lesions in brain, eyes, liver, kidneys, spleen, heart, lungs, large and small intestine, testes, epididymides, urinary bladder, lymph nodes, larynx, or nose.
- Statistically significant, albeit small in magnitude, differences in hematology and serum chemistry were observed in both exposure groups compared to controls. In the nanoparticle-exposed group, small but significant decreases were observed in red blood cells, hemoglobin, and packed cell volume. Blood glucose was also increased. In the microparticle-exposed group, decreases were observed in white blood cells, monocytes, eosinophils, and platelets. Bile acids and creatine kinase were increased, while albumin was decreased.
- In bronchoalveolar fluid (BALF), no differences in cell counts or cell type were observed. In the nanoparticle-exposed group, protein concentrations in BALF were decreased. In the microparticle-exposed group, there were changes in cytokine concentrations suggesting pulmonary inflammation, although no lung lesions were evident. Macrophages from both groups contained, brown, globular, intracytoplasmic pigment, indicating some of the C₆₀ was inside the cells.
- The lung burden of C₆₀ fullerenes was 47% greater for nanoparticle-exposed than for microparticle-exposed rats. The half life in the lung was 26 days for nanoparticles, and 29 days for microparticles. C₆₀ fullerenes were not detected in whole blood.

Implications:

- This study presents the first toxicity assessment of inhalation exposure to C₆₀ fullerenes. A significant achievement of this study was the development of a method for creating a stable atmosphere of dry aerosolized C₆₀ fullerenes. This exposure method, which uses dry aerosolized particles and thus eliminates the problem of possible toxic effects from solvents, will facilitate the performance of future inhalation toxicity studies, including those in which steady state lung burdens are reached in order to assess the toxicity of

chronic C₆₀ fullerene exposures.

- The similarity in the half lives of C₆₀ fullerene nanoparticles and microparticles suggests they may be eliminated from the lung by a common mechanism. Additional study is needed to further explore this hypothesis and determine a possible mechanism.
- Minimal toxicity of C₆₀ fullerene nanoparticles was evident at exposure concentrations higher than those found in urban environments (approximately 1,400-fold higher by mass concentration and 35-fold higher by particle concentration), or in occupational environments (14-fold higher by mass concentration), indicating little potential for acute toxicity at likely human exposure levels.

Helland, A, et al. 2008. "Risk assessment of engineered nanomaterials: a survey of industrial approaches." *Environ. Sci. Technol.* 42(2):

640-646. Abstract: <http://pubs.acs.org/cgi-bin/abstract.cgi/esthag/2008/42/i02/abs/es062807i.html>

Synopsis:

- Given the general absence of regulations that specifically address nanomaterials and take into account their specific properties, this study was conducted to investigate the risk assessment procedures and precautionary measures voluntarily undertaken by industry to manage the environmental health and safety of nanoparticulate materials (NPM).
- The study authors designed a questionnaire to gather information from representative industries involved in nanomaterial production and application in Germany and Switzerland. The questionnaire addressed the general properties of nanomaterial products in the market and voluntary industrial initiatives related to nanomaterial risk and safety. This survey began by asking for a product description and the type of involvement with nanomaterials (*i.e.*, whether the company produced, bought, or refined nanoparticulate material), and collected data in three main areas: (1) material properties, (2) exposure and hazard assessment, and (3) risk assessment.
- Following its distribution to 135 German and Swiss companies with nanomaterial-based products currently available on the market, 40 companies returned the questionnaires, for a response rate of 29.6%. Questionnaire responses indicated that a majority of companies (50.0-67.5%, n=20-27) have the opinion that their nanomaterial-based products have a negligible potential for release throughout the product lifecycle. Questionnaire responses indicated a general lack of product-specific data to support these opinions, with few companies (17.5-25%, n=30-33) evaluating the potential for uptake by humans or aquatic and soil organisms along any stage of the product lifecycle.

- Of the 40 respondents, 26 companies (65%) indicated that they did not conduct risk assessments for their nanomaterial applications, while 13 companies (32.5%) responded that they sometimes or always performed risk assessments. Ten companies (25%) reported conducting toxicity tests, with nine companies answering that they conducted acute toxicity tests and fewer companies reporting the performance of long-term tests: (in descending order) mutagenicity (n=5) > carcinogenicity (n=4) > immune toxicity (n=3) > hormone activity (n=1).
- Based on the questionnaire results, which indicated an overall lack of a proactive risk assessment and risk management strategy among the surveyed companies, the study authors concluded that “the development of risk and safety decision frameworks in industry seems therefore necessary to ensure that the potential risks of engineered nanomaterials are taken into consideration.”

Implications:

- As discussed by the study authors, the questionnaire results indicate that few companies are proactively performing risk assessments for NPM products, nor was there any relationship between NPM characteristics, risk assessment procedures, and precautionary measures. These findings have possible negative implications for public perception of nanotechnology, as the public could interpret them to mean that industry is insufficiently prepared to address potential nanotechnology EHS risks.
- Since the survey indicated that few companies are actively investigating the fate of nanomaterials in either the use or disposal stages, additional research is needed to better understand the basis and support for the prevalent industry opinion that their NPM products or applications present little opportunity for potential uptake by humans or aquatic and soil organisms along any stage of the product lifecycle.
- Of the small number of large (>1,000 employees) companies returning the survey (n=6), 4 reported that they performed risk assessments for their NPM products or applications. Given the small sample size of this study, further study is needed to explore whether and why there may be differences in risk assessment practices between large and small companies, and what the key impediments to industrial risk assessment activities are.
- The study authors reported gathering a highly diverse dataset on nanomaterial properties (*i.e.*, size, shape, chemical composition, adsorption capacity, surface modifications, surface charge, size distribution changes, degradability) that challenged their ability to group NPM into categories related to their potential for risk. Findings such as these highlight the need for additional research to identify the properties most predictive of potential risk and to design predictive risk models.

Guest Contributor

By John Balbus, MD, MPH

Chief Health Scientist for Environmental Defense
Seeking Assurance on Nanomaterial Risks

This is an odd time of advance and retreat in the effort to ensure that the potential risks of nanotechnology are effectively addressed. While early risk-related studies show a mix of positive and negative results for different materials in different settings, most of the critical questions remain unanswered. Yet some federal officials in charge of both promoting and overseeing nanotechnology development seem intent on tamping down the urgency expressed by other stakeholders – industry, NGOs and academic researchers alike – to pursue a much more aggressive and comprehensive assessment of potential nanomaterial risks.¹ This is bad news, not only for the responsible development and public acceptance of nanotechnology, but also for companies that are on the receiving end of potential nanomaterial risks.

Insurers have been especially sensitive to the business consequences of nanotechnology’s potential environmental and health risks. Several years ago, Swiss Re² was among the first to raise awareness of nanotechnology’s potential to harm humans and the environment and the potential financial repercussions. More recently, Lloyd’s of London issued a report³ cautioning that “the ‘wait and see’ approach is increasingly becoming a dangerous way to determine the risks.” Lloyd’s recommends that “it is in the interest of insurers that any debates on the health effects or possible risks of nanotechnology are discussed in an open, transparent and public format.”

Lloyd’s highlights the Nano Risk Framework⁴ issued last year by Environmental Defense and DuPont as its case study for how companies and insurers can properly assess, manage, and communicate nanomaterial risks in the absence of government regulation. A prime motivation for the Framework was concern over the slow pace of government action to address potential risks.

The Framework is designed to comprehensively identify potential risks of a nanotechnology product before commercialization as well as to facilitate communication of those risks and the steps taken to address them. Based on an iterative process, the Framework guides users in developing information and assessing risks at different stages of product development, using a lifecycle approach. Data and decisions are documented using an output template that can also be used to communicate with a company’s stakeholders, including the public.

Historical examples of leaded gasoline, PCBs and asbestos have all demonstrated how dangerous a “wait and see” approach to emerging technologies can be. And the loss of European markets for genetically modified organisms because of negative consumer perception demonstrates how short-sighted and costly inadequate risk assessment and risk communication can be. Lloyd’s advises that “insurers operating in the field of nanotechnology would do

well to seek evidence of whether projects they are covering have followed this [Nano Risk] framework.” Developers and users of nanotechnology would indeed do well to heed this advice by proactively and thoroughly assessing, mitigating and communicating about the potential risks of their products.

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Coming In the Next Issue

Recent research findings on the bioaccumulation potential of carbon nanotubes in worms.

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