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Nanotechnology Law Report

Legal Issues Surrounding Nanotechnology & General Nanotechnology News & Events

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INSIDE THIS ISSUE

Recommendations for New Nano-Specific Regulation

The Woodrow Wilson International Center for Scholars' Project on Emerging Nanotechnologies recently issued a report outlining where it believes the next White House should start with the issue of nanotechnology regulation.

J. Clarence Davies, "Nanotechnology Oversight: An Agenda for the New Administration," Woodrow Wilson International Center for Scholars, Project on Emerging Nanotechnologies, PEN 13, July 2008.

Among other suggestions, Mr. Davies advocates enacting new nano-specific legislation in the following areas:

Toxic Substances Control Act: Mr. Davies offers specific legislative language for amending TSCA "to make clear that nanomaterials are covered as new substances." Other changes he suggests: "remove the catch-22 that requires EPA to show that a new chemical poses a risk before the agency can obtain enough information to determine whether it actually poses a risk;" "remove the conditions and requirements that guarantee that EPA can never regulate an existing substance;" and narrow TSCA's confidential business information and data sharing provisions.

Federal Food, Drug, and Cosmetic Act: Mr. Davies argues that the FFDCA should be amended to require submission and review by FDA of cosmetic active ingredient registration information. He further maintains that "FDA should also be authorized to forbid marketing of any cosmetic containing an ingredient that is not safe or for which adequate test data are not available," and that applicable FDA laws should be altered "to make clear where and how to draw the line between a drug and a cosmetic." Mr. Davies additionally recommends requiring premarket safety testing on food and cosmetic ingredients incorporating nanoscale materials and increased post-marketing surveillance and reporting.

Dietary Supplement Health and Education Act: Mr. Davies calls for amending DSHEA so that it does not prohibit "FDA from imposing testing or approval on dietary supplements (vitamins, herbs, etc.) and placing the burden of proof on FDA to provide that a supplement is safe."

Other recommendations by Mr. Davies include:

Research: dramatically increase federal nano-related EHS research funding (FY 2009 - $100 million; FY 2010 - $150 million); require a federal peer-reviewed EHS research plan; strengthen NNI; encourage separation of NNI promotional and oversight functions; and establish a Nanotechnology Effects Institute.

Regulatory Coordination: establish an

interagency group devoted solely to nanotechnology regulation; develop a nanotechnology plan within each agency; and improve intergovernmental coordination.

Environmental Protection Agency: define nanomaterials as "new" chemical substances and/or "significant new uses" of existing chemical substances under TSCA; promulgate a compulsory information collection rule under TSCA Section 8; expand regulation of anti-microbials under federal pesticide law; promote "green" technology; and evaluate the application of other EPA statutes to nanotechnology.

Food and Drug Administration: establish criteria for determining which nanomaterials are "new" for regulatory purposes; collect information on safety testing, forthcoming products, and adverse effects; regulate cosmetics and dietary supplements.

Occupational Safety and Health Administration: communicate with workers and firms about nanotechnology; use existing OSHA regulations to deal with nanoparticles; issue OSHA standards for nanomaterials.

Consumer Protection Safety Commission: hire new staff to study nanotechnology exposure; create a chronic hazard advisory panel for nanotechnology products posing significant exposure risks.

Voluntary Efforts: use the DuPont-Environmental Defense Nano Risk Framework as a basis for analyzing nanotechnology risks; issue a nanotechnology handbook for small businesses.

Public Involvement: give the public more information about nanotechnology; obtain the public's views about nanotechnology; convene a stakeholder dialogue.

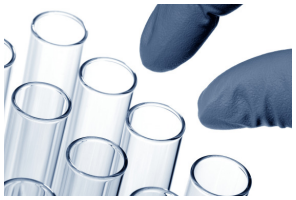
Mr. Davies concludes his article with an interesting analogy: "[N]anotechnology comes in a treasure chest of riches and a Pandora's box of evils. The challenge of the new century and to the new administration is to use the treasure while keeping shut the lid on the Pandora's box."

OECD To Begin Testing Nanoparticles

On June 2, 2008, the Organization for Economic Co-operation and Development (OECD) released the results of the first stage in its effort to study the impacts of certain nanoparticles. In 2006, the OECD formed its Working Party on Manufactured Nanomaterials to implement the "Project on Safety Testing of a Representative Set of Manufactured Nanomaterials." The Project was divided into two parts: (1) develop a priority list of nanomaterials currently, or soon to be, in commerce for health impact study and (2) develop a program for the testing and understanding those nanomaterials. The June 2 report is the culmination of the first step–the creation of a list of nanomaterials to be studied.

The full report can be found at http://www.olis.oecd.org/olis/2008doc.nsf/LinkTo/NT00003282/$FILE/JT03246895.PDF, and includes both the list of materials to be studied as well as the focus areas for the study. OECD determined that fourteen materials will receive initial study. Each was identified due to its presence in the commercial market or its near-term commercial applications. As such, OECD considers the list a "snapshot in time" of the nanomaterials that are important now. Specifically, OECD will study (in no particular order):

- Fullerenes
- Single-walled carbon nanotubes
- Multi-walled carbon nanotubes
- Silver nanoparticles
- Iron nanoparticles
- Carbon black
- Titanium dioxide
- Aluminum oxide
- Cerium oxide
- Zinc oxide
- Silicon dioxide
- Polystyrene
- Dendrimers
- Nanoclays



The working group will study each of the above for the following metrics: information and identification, physical and chemical properties, environmental fate, environmental toxicology, mammalian toxicology, and material safety.

Although no date has been set for release of the completion of step two - the results of the study - step one is important in determining the risks and benefits of commercially available nanomaterials. Clearly, this is an aggressive undertaking, and time will be needed to complete the full report in a way that is thorough and useful. Keep an eye out for the results of this important study.

Nanotechnology Standards for Health, Safety, and Environmental Factors

This second article in a series on nanotechnology standardization introduces the international working group that, under US leadership, is creating the standards needed to support the health, safety, and environmental aspects of nanotechnology.

In the post-war era of the late 1940s, global leaders of government and industry formed a central body to "facilitate the international coordination and unification of industrial standards." Twenty-six member nations came together in 1947 to form the International Organization for Standardization (ISO).

ISO and its national member bodies – including the American National Standards Institute (ANSI) – are constantly evolving to meet changing demands. Today, ISO is addressing issues such as industrialization, the advancement of information technologies, quality, the environment, and the health and safety of workers and consumers. Today, roughly one of every twenty ISO standards addresses issues pertaining to health, safety or the environment.

In July 2005, ISO formed a new Technical Committee to help focus the world's attention on standards that would support the growth of nano-related industries. The scope of that committee, ISO/TC 229 – *Nanotechnologies*, includes standardization in the areas of terminology and nomenclature; measurement and instrumentation; material specifications; and health, safety and the environment. The standards that are being created by this Committee can be utilized by national bodies to support regulatory activity within nanotechnology development, which in turn supports workers that encounter nanotechnologies on the job.

As new materials, structures, devices and systems are developed that derive their properties and function due to their nanoscale dimensions, standards act to enhance the development of these technologies by encouraging cooperation and collaboration in the industry. Bringing experts together for the purpose of standardization promotes the best uses and highest functioning of nanotechnology across the wide range of industries that it affects.

"Standards are important for supporting research aimed to safely develop and apply nanotechnology for societal benefit and economic growth," said Clayton Teague, director of the National Nanotechnology Coordination Office, Executive Office to the President of the United States. "Standards are equally important for research aimed to better protect public health and the environment, and for facilitating the review and regulation of nanotechnology-based materials and products. They are therefore one of the foundational components that enable effective assessment of products created with nanomaterials, as well as development of associated policies and best practices to protect the people who manufacture, work with, and use those materials."

Work in Progress for Health and Safety Standards

ISO TC 229's standard-setting activities are assigned to four Working Groups (WGs). Responsibility for the development of science-based standards for the safe development and use of nanotechnologies falls to WG 3, *Health, Safety and Environment*. Operating under the leadership of Steven Brown of Intel Corporation (USA), the group has become a focal point for nanotechnology safety experts.

Representatives from seventeen of TC 229's thirty participating national bodies are active in the work of the WG. Several other internationally-recognized bodies participate as liaisons to the committee, including: the European Committee for Standardization (CEN) TC 352, *Nanotechnologies*; the European Commission Joint Research Centre (EC-JRC); and the Organisation for Economic Co-Operation and Development Working Party on Manufactured Nanomaterials (OECD WPMN).

Its workload is heavy, with five active projects and a proposed sixth work item now under consideration.

As announced in last month's article, the WG's most mature document, a guidance document that provides critical information on occupational safety for those involved in the manufacture and use of nanomaterials in the workplace, was recently finalized.

Publication of the report, entitled *Health and safety practices in occupational settings relevant to nanotechnologies*, is anticipated by year-end 2008.

"This technical report will serve as a foundation for responsible national nanotechnology occupational safety and health programs worldwide," said Vladimir Murashov, special assistant on nanotechnology to the director of the National Institute for Occupational Safety and Health (NIOSH), and the project leader for this initiative.

The report builds on guidance originally provided by NIOSH, the federal agency responsible for conducting research and making recommendations for the prevention of work-related injury and illness.

Japan and South Korea have also stepped forward in leadership roles, serving as project leaders for three of the WG's other active projects:

- *Endotoxin test on nanomaterial samples for in vitro systems;*
- *Generation of nanoparticles for inhalation toxicity texting; and*
- *Monitoring nanoparticles in inhalation exposure chambers for inhalation toxicity testing.*

The fifth – and newest – WG 3 work item, Guidance *on physico-chemical characterization of engineered nano-objects for toxicologic assessment*, will serve as a reference for characterizing nano-objects for toxicology testing. The United States, under the leadership of Dr. Richard C. Pleus (Intertox) is spearheading this effort.

How to Participate

For each ISO Technical Committee or Subcommittee where the U.S. is a participating member, ANSI accredits a Technical Advisory Group (TAG) to develop and transmit our national positions on standards proposals and related activities. In the case of nanotechnology activities within ISO, one U.S. TAG, supported by multiple working groups, determines U.S. positions and advocates those positions at ISO

Dr. Laurie Locascio of the National Institute of Standards and Technology (NIST) chairs the U.S. ISO/TC 229 TAG Working Group on Health, Safety and Environment. Members of the TAG WG include representatives of academia, government, standards developing organizations, and industry. With this expert input, the TAG WG prepares the U.S. position for WG 3 issues, recommends future work items, and considers proposals from other national bodies.

"With Steve Brown's leadership of the WG, and the active participation of our TAG members, the U.S. has the ability to help set the pace of nanotechnology standardization for health, safety, and the environment," said Dr. Locascio. "Developing standards in this area will have a powerful impact on our ability to move this technology platform forward in a responsible manner."

Participation in the U.S. ISO/TC 229 TAG Working Group is open to all nationally interested stakeholders, and the TAG actively seeks participants who have expert knowledge in all aspects of nanotechnology as it relates to health, safety, and the environment. To join the U.S. TAG for ISO/TC 229 or any of its WGs, contact Heather Benko (hbenko@ansi.org; 212.642.4912).

For more information on the U.S. TAG for ISO/TC 229, visit www.ansi.org/iscotc229tag.

Stay Tuned: The next article in this series will introduce ISO/TC 229/WG 1, *Terminology and nomenclature.*

Canada Issues Report on Regulatory Challenges Facing Nanoscale Materials

An expert panel on nanotechnology was convened by Health Canada to conduct an eight-month research project assessing "the state of knowledge with respect to existing nanomaterials properties and their health and environmental risks, which could underpin regulatory perspectives on needs for research, risk assessment and surveillance."

> *Council of Canadian Academies, "Small is Different: A Science Perspective on the Regulatory Challenges of the Nanoscale," July 2008.*

Notable findings by the panel were: uncertainty in regulation and science can hamper commercial development of new products; the private sector prefers regulatory certainty; "[a]t present, it is not possible to implement a robust and reliable 'science based' regulatory approach to nanoproducts;" the cornerstone of Canada's use of the precautionary principle means that there should be approval of a product before entry into commerce if any health uncertainty is displayed; and regulation should follow only after meaningful public input.

As a result of its broad survey, the panel found that, although "it is not necessary to create new regulatory mechanisms to address the unique challenges presented by nanomaterials, existing regulatory mechanisms could and should be strengthened." Specific recommendations include:

- Development of interim terminology and classification for nanomaterials to facilitate EHS research;
- Possible modification of regulatory triggers for when a new nanoscale material/substance should be re-

viewed for possible EHS risks;

- Development of standard safe-handling procedures/ techniques for nanoscale materials;
- Development of new worker, consumer, and environmental surveillance metrologies;
- Use of an adaptive life-cycle approach when analyzing potential nano-related EHS risks; and
- Facilitation of adequately funded intra and inter government EHS research.

The panel's report concludes with what has become the "gold-standard" summation for nanotechnology reports: "Research is needed to identify these properties of a nanomaterial that enables it to elicit an adverse biological response. Further research is needed to identify appropriate regulatory responses regarding nano-material exposure."

Environmental Pollution from Nanosilver Socks?

A recent study by two Arizona State University researchers found that socks made of fabric incorporating nanoscale silver may potentially release that silver into wash-water.

T. Benn, et al., "Nanoparticle Silver Release into Water from Commercially Available Sock Fabrics," ENVIRONMENTAL SCIENCE & TECHNOLOGY, Vol. 42, at 4133-4139 (2008).

Why put silver in your socks? Because it is a well-known antimicrobial agent and microbes cause sock odor. Kill the microbes, and your feet smell fresh. At least that is the marketing angle.

Several environmental NGOs, however, are concerned with whether silver might be released from the socks, enter the washwater and wastewater streams, and continue to keep on killing microbes. While you may not want microbes in your socks, they are a vital part of the ecosystem. The authors theorize that "[t]he ubiquitous use of commercial products containing n-Ag could potentially compromise the health of many ecosystems." (This is yet another twist to the Samsung Silver Care washing machine controversy from a couple of years ago).

As for the socks themselves, the researchers selected pairs from Sharper Image, Fox River, Arctic Shield, Zeusah, and AgActive "based on the manufacturers' claims that the socks contained nanoparticles of silver. " We checked the advertising for ourselves, and only Arctic Shield and AgActive London actually make nanosilver claims, while Fox River and Zeusah make general silver and/or silver ion claims. As for the Sharper Image socks, the company is in the final stages of bankruptcy and is closing its stores. Its new owner may or may not continue direct sales through its catalog and the internet. No word on whether they will continue to sell socks at all.

Perhaps the most interesting thing about the advertising were the efficacy claims:

- "Your feet feel and smell fresher for longer."
- "Stay fresh no matter how long you wear them."
- "You can wear our socks for days on end and they won't smell."
- "Just by wearing [our] socks we guarantee no more foot odor."
- Testimonial: "I bought some of [your] socks for my nephew when he came to stay with me for the holiday. His feet always smelled but with the new socks, the smell is all gone. I am very happy."
- Testimonial: "I wore them three days and there was no smell at all."

Regarding the test itself, the socks were first analyzed for their nanosilver content. Three of the six socks contained silver particles in the 100-500 nm range; only one contained silver particles in the traditional nanoscale range (under 100 nm). The socks were then washed three times in ultra-pure distilled laboratory water for 24-hour or 1-hour periods using an orbital shaker/agitator. No soaps or detergents were used. The researchers analyzed the resulting washwater.

To cut a long story short, the researchers found that "at least some of the n-Ag is released into the washwater as nanoparticles; not just as dissolved ionic silver."

As for total silver release, three of the six socks were found to have leached silver into the wash-water. (Sharper Image, Fox River, AgActive London). During the three 24-hour tests, the AgActive socks released a total of 19 of their 20 micrograms of silver, the Fox River socks released 165 of their 31,241 micrograms of silver, and the Sharper Image socks released 1578 of their 1845 micrograms of silver. In the three, 1-hour tests, the Sharper Image socks released 1020 micrograms of silver, and the Fox River socks released 390 micrograms of silver.

Interestingly, socks washed in plain tap water did not release nearly as much silver as those washed in the ultra-pure, distilled, laboratory water.

Nano-Silver EHS Backgrounder

With all of the interest in nanosilver generated by the recent EPA petition filed by the International Center for Technology Assessment, we wanted to provide some background material on EHS issues surrounding silver. A couple of disclaimers: the material is not comprehensive, and you might see parts of it again in "NANOTECHNOLOGY LAW AND POLICY" which should be published by Thomson-West legal publishers sometime in 2009.

Silver (CASRN 7440-22-4) is a naturally occurring metal. It is usually found in extremely low concentrations in natural waters. "Humans are exposed to small amounts of silver from dietary sources." "Silver levels of less than 0.000001 mg silver per cubic meter of air (mg/m3), 0.2-2.0 parts silver per billion parts water (ppb) in surface waters, such as lakes and rivers, and 0.20-0.30 parts silver per million (ppm) in soils are found from naturally occurring sources." A 50 year old person has "an average retention of 0.23-0.48 g silver."

Silver production in 1999 was estimated at 15.5 million kilograms worldwide, with Mexico and the US leading the list of producers. Approximately 2.5 million kilograms of silver in various forms is lost to the environment in the US every year; 29% of that amount is released to water and 68% to land. The most prevalent release routes are purportedly from smelting operations, photographic processing supplies, electrical component and wire manufacturing, coal combustion, electroplating operations, and cloud seeding. NIOSH estimates that 70,000 people are exposed to silver in the workplace each year and inhalation is the most important route of exposure.

People and Animals. Silver has exhibited no known toxic effects to humans. According to the EPA, human health effects from breathing, eating, and/or drinking silver are "unknown." However, if you eat, drink, or breathe enough of it, your skin may turn a blue-gray color. This permanent cosmetic condition, called "argyria," is not harmful to health. It results from silver depositing in the dermis layer of skin. Breathing high levels of silver dust may cause breathing and respiratory problems, throat irritation, or stomach pain – as with other types of particulate matter. Silver is not a known human carcinogen but has been shown to cause cancer when inserted in lab animals under certain conditions. There are few, if any, toxicity animal studies based on oral or respiratory silver intake. "Tests in animals show that silver compounds are likely to be life-threatening for humans only when large amounts (that is, grams) are swallowed and that skin contact with silver compounds is very unlikely to be lifethreatening." Some occupational studies intimate that exposure to silver may cause kidney problems, although more research is needed on this issue.

Silver Ions. Monovalent silver ions are very rare in the natural environment. "The acute toxicity of silver to aquatic species varies drastically by the chemical form and correlates with the availability of free ionic silver." "For freshwater fish, the acute toxicity of silver is caused solely by silver ion interacting with the gills . . ." "On the basis of available toxicity test results, it is unlikely that bioavailable free silver ions would ever be at sufficiently high concentrations to cause toxicity in marine environments." "About 95% of the total silver [lost to water in the environment] is removed in publicly owned treatment works from inputs containing municipal sewage and commercial photprocessing effluents, and effluents contain less than 0.07 µg ionic silver/litre."

Drinking Water. The federal government has issued guidelines concerning the maximum level of silver allowed in drinking water (Maximum Contaminant Level – MCL): long term exposure is limited to 0.1 mg/L (previously 0.05mg/L), and short term exposure (1-10 days) is limited to 1.142 mg/L. The silver MCL was first promulgated by the United States Public Health Service in 1962 before the Environmental Protection Agency was ever formed. Silver was included on the original list on the basis of epidemiological data and the fact that it was used as an antimicrobial. The epidemiological data was based on exposures to medicinal silver and exposures through mining and metalworking. In 1989, EPA proposed changing the MCL for silver from 0.05 mg/L to 0.09 mg/L because the only potential human health concern was from argyria. "The proposal was finalized, using an MCL of 0.1 mg/L, on January 30, 1991."

Surface Water. Silver in surface water tends to settle into the sediment. "Silver can remain attached to oceanic sediments for about 100 years under conditions of high pH, high salinity, and high sediment concentrations of iron, manganese oxide, and organics." Silver levels in pristine surface water in unpolluted areas are approximately 0.01 µg /L and approximately 0.01 - 0.1 µg/L in urban and industrialized areas. The federal government regulates silver in surface water through the Federal Water Pollution Con-

trol Act (aka/ Clean Water Act) -- 33 U.S.C. § 1251. "The silver criteria contains values to protect human health from ingestion of contaminated aquatic organisms and maximum acceptable concentrations to protect organisms that live in freshwater and salt water from toxic effects. The human health part of the silver criteria was drawn directly from the drinking water MCL. Criteria for the protection of aquatic life, on the other hand, were derived using a newly developed set of guidelines that called for extensive laboratory test data. The values are given as total recoverable silver." The freshwater criteria maximum concentration for silver is (3.2) 100mg/L, and saltwater is (1.9).

Air. Silver is not considered an air pollutant harmful to public health or the environment under the National Ambient Air Quality Standards mandated by the Clean Air Act. Purportedly "[t]reatment of air emissions containing silver is not a concern as atmospheric emissions rarely approach the federal threshold limit value for occupational exposure of 0.01 mg/m3."

Workplace. Workplace exposures to silver present unknown/unquantified health risks to humans. Most occupational exposures to silver are purportedly through photographic processing chemicals (dermal) or inhalation of silver dust particles from the ambient air. OSHA has set the maximum air quality standard for silver at 0.01 mg/m^3 based on an 8-hour workday and 40-hour workweek.

Regulation of Silver Hazardous Waste. The Resource Conservation and Recovery Act (RCRA) is designed in part to prevent leaching of hazardous concentrations of particular toxic constituents into groundwater and looks back to Primary Drinking Water Standards. Any waste that contains 100 times the amount of the relevant constituent is considered a hazardous waste. The "100 times" level was designed to compensate for the dilution of materials as they pass through soil when headed for ground water. Note, however, that the RCRA standard does not track the 1997 amendment to the drinking water standard. Since the original drinking water standard for silver was 0.05mg/L, the maximum allowable limit is 5.0 mg/L for RCRA purposes. Wastes containing silver at this level or above are labeled as "hazardous wastes" under RCRA and are subject to further regulation under that Act. "Under CERCLA, silver-bearing hazardous wastes are designated as hazardous substances with a reportable quantity (RQ) equal to 1 pound (.454 kg)." Any release that exceeds the RQ in a 24-hour period must be reported to the National Response Center.

Select Bibliography:

"Toxicological Profile for Silver," Agency for Toxic Substances and Disease Registry, U.S. Public Health Service (December 1990).

P.D. Howe, et al., "Concise International Chemical Assessment Document 44: Silver and Silver Compounds: Environmental Aspects," World Health Organization (2002).

US EPA Integrated Risk Management System (IRIS), Silver (CASRN 7440-22-4), http://www.epa.gov?IRIS/subst/0099.htm.

"25 Years of the Safe Drinking Water Act: History and Trends."

Many states also regulate silver. Some state standards are more restrictive than EPA standards. See, e.g., "The Regulation of Silver in Photographic Processing Facilities," Kodak Environmental Services, J-124 (1996).

T. Purcell, et al., "Historical Impacts of Environmental Regulation of Silver," Environmental Toxicology and Chemistry, Vol. 18, No.1, pp. 3-8, 1999.

Aquatic life testing guidelines can be found at Fed. Reg. 45:79341 – U.S. EPA. 1980. "Guidelines for determination of ambient water quality for the protection of aquatic organisms and their uses."

65 C.F.R. 31682

"The Regulation of Silver in Photographic Processing Facilities," Kodak Environmental Services, J-124 (1996).

US EPA, Solid Waste and Emergency Response (5305W), RCRA Photo Processing, EPA530-K-99-002, January 1999.

"*nano*" The Magazine for Small Science

Last month's edition of *nano* magazine featured a short article entitled "Asbestos Repeated? Assessing Risk in Nanotube Technologies." The article discusses the recent Poland/Donaldson paper published in *Nature Nanotechnology* that has been getting so much attention. Beyond the article, this much-recommended magazine is published in the UK and features articles on international nanotechnology research, development, and commercialization. You can download a copy of the magazine at: www.nanomagazine.co.uk/onlinecopies.php?email=.

NNI Reauthorization Stalling in Senate

The National Nanotechnology Initiative re-authorization bill on the Senate side, S.3274, is getting bogged down and is in danger of not passing before the end of the term later this year. Some NGO's see this as an opportunity to try to get the 10 percent funding increase for EHS research back into the bill, but attempting such an effort may endanger passage by the full Senate, which is needed to keep the NNI going. If the full Senate does not pass the bill before the end of the session, the whole process will have to be restarted and approved by both chambers. Since a markup has not yet been done, passage by the end of this Congress would already be tight on the calendar. We will keep an eye on the progress to see what happens between now and the end of the year.

Senators Propose New Nanotechnology Prize

Senators Snowe and Widen introduced a bill that would create a Nanotechnology Innovation Prize in up to four areas: green nanotechnology, alternative energy applications, improvements in human health, and the commercialization of consumer products. Senator Wyden stated that the prize is "a vital tool to help ensure that public and private resources will be utilized in a coordinated way and will be devoted to solving the complex and pressing problems that America faces today. This bill will also spur technological investment and create jobs here at home." You can see Senator Wyden's full statement regarding the bill at:

wyden.senate.gov/newsroom/record.cfm?id=300765&

and Senator Snowe's press release at:

snowe.senate.gov/public/index.cfm?FuseAction=PressRoom.PressReleases&ContentRecord_id=2c7a29d2-802a-23ad-4733-e69c65145bee.

New Lux Nano-EHS Summary

A new Lux Research quarterly report -- "Nanomaterials State of the Market Q3 2008: Stealth Success, Broad Impact" -- contains a section summarizing the state of nano-related environmental, health, and safety issues in the U.S. The report contains a very helpful time-line of key nano-related EHS events occurring between the fourth quarter of 2007 and the third quarter of 2008.

Other highlights are Lux's findings that the rate of nano-related publication has doubled in recent years; studies regarding the potential EHS concerns of nanoscale metals are approaching parity with publications concerning carbon and ceramic nanoscale materials; research papers on possible nano-related hazards far exceed those on possible nano-related exposures; there has been a demonstrable increase in research studies on possible nano-related ecological risks; public opinion regarding nanotechnology is mixed, but not negative; and NGO's are still pushing for more regulatory action. Lux, of course, offers detailed analysis on all of these issues, and you can find out how to purchase a copy of Lux's highly regarded report at http://www.luxresearchinc.com/contact.php.

Lux, however, reached one conclusion with which we respectfully disagree. Lux thought the media coverage of the recent Poland *Nature Nanotechnology* article was "reassuringly judicious." You can see our prior post at http://www.nanolawreport.com/2008/06/articles/media-rips-carbon-nanotubes/

which reflects our view that the media coverage of the asbestos-carbon nanotube analogy posited in the Poland article was overblown.

C. Poland, et al., "Carbon nanotubes introduced into the abdominal cavity of mice show asbestos-like pathology in a pilot study," NATURE NANOTECHNOLOGY, May 20, 2008.

New Australian Nano-Regulation Report

The Australian Office of Nanotechnology recently released a report prepared for the Australian government by the Centre for Regulatory Studies at Monash University -- "A review of possible impacts of nanotechnology on Australia's regulatory framework."

Among other things, the report identifies six possible gaps in existing Australian law and regulations that might be of concern in the context of nanotechnology:

1. Some nanoscale materials may not be considered the same chemical substances as their bulk counterparts;

2. Weight or volume-based regulatory triggers may not be appropriate for nanoscale materials;

3. There is insufficient knowledge concerning the potential adverse environmental, health, and safety effects of nanotechnology;

4. Current risk assessment protocols may be insufficient for nanoscale materials;

5. Current research and development exemptions in Australian law may need to be closed; and

6. To the extent the existing Australian regulatory framework incorporates external guidelines and standards, those may need to be adjusted to adequately cover nanotechnology.

Additionally, pages 25 through 27 of the report provide a handy chart of the existing Australian regulations that the authors believe may be applicable to nanotechnology.

Clearly, a lot of thought and work went into the report. It is well worth reading.

Nano Contact Lens

The Guardian reports that a University of Washington scientist is developing a contact lens LED display that uses nanoscale circuits. If it works, the lenses may be powered by either solar or radio-frequency power transmission and could be theoretically used to superimpose text messages, direction indicators, or even close captioning on the eye itself. Bio-compatibility is an issue.

Regarding this last issue, of the articles we found, the most on point was:

> *J. Roberts, "Phototoxicity and cytotoxicity of fullerol in human lens epithelial cells*," TOXICOLOGY AND APPLIED PHARMACOLOGY, Vol. 228, at 49-58 (2008).

The article reports on a study of the ocular toxicity of hydroxylated fullerenes, which "determined that fullerols are both cytotoxic and phototoxic to human lens epithelial cell model system in the presence of either UVA or visible light." The researcher exposed human lens cells and whole rat eye lenses to a fullerol suspension for 24- and 1-hour periods, both in the dark and in visible light. Both the human lens cell and the rat lenses absorbed some of the fullerene solution. The author reports that "fullerol exhibits both dark cytoxicity and phototoxic effects on human lens epithelial cells." This could theoretically cause a loss of lens transparency, leading to cataracts. The study concludes that "before fullerols are used in the future to deliver drugs to the eye, their potential side effects on the human eye should be further examined."

Other articles we found were:

- A. de Compos, et al., "Chitosan nanoparticles as new ocular drug delivery systems: in vitro stability, in vivo fate, and cellular toxicity," PHARMACEUTICAL RESEARCH, Vol. 21, No. 5 (May 2004). ("No inherent toxicity can be attributed to the [Chitosan] nanoparticles at concentrations as high as 2mg/ml. In addition, the viability of the recovered cells was totally preserved irrespective of the nanoparticles concentration.");
- M. Alonso, et al., "The Potential of Chitosan in Ocular Drug Delivery," JOURNAL OF PHARMACY AND PHARMACOLOGY, Vol. 55, at 1451-1563 (2003). ("Preliminary studies performed in conjunctival cell cultures have shown the low toxicity of Chitosan nanoparticles.");
- B. Short, "Safety Evaluation of Ocular Drug Delivery Formulations," TECHNIQUES AND PRACTICAL CONSIDERATIONS, TOXICOLOGY PATHOLOGY, Vol. 36, at 49-62 (2008);
- Y. Diebold, et al., "Ocular drug delivery by liposome-chitosan nanoparticles complexes (LCS-NP)," BIOMATERIALS, Vol. 28, at 1553-1564 (2007);
- J. Bourges, et al., "Ocular Drug Delivery Targeting the Retina and Retinal Pigment Epithelium Using Polyactide Nanoparticles," INVESTIGATIVE OPHTHALMOLOGY & VISUAL SCIENCE, Vol. 44, No. 8 (2003); and
- R. Bejjani, et al., "Nanoparticles for gene delivery to retinal pigment epithelial cells," MOLECULAR VISION, Vol. 11 at 124-132 (2005).

NanoMedicine Summit 08

Our friends at NorTech, Case Western Reserve University, and the Cleveland Clinic have just announced their NanoMedicine Summit 08 which will be held in Cleveland, Ohio on September 25 and 26, 2008. The Summit will cover the use of nanotechnology in imaging, drug delivery, biological investigation, basic nanomedicine research, and gene therapy. September is a great time to visit Cleveland, so make plans now to attend.

http://www.nanomedicinesummit.org/.

EPA's Nanoscale Materials Stewardship Program Receives New Submissions

The first phase of EPA's voluntary Nanoscale Materials Stewardship Program (NMSP) closed on July 28, 2008. For those keeping track, the most up-to-date NMSP participation statistics as of July 24, 2008 follow. It is shaping up to be a very respectable list of participants.

Submissions Under Basic Program: (9 submissions - covering 68 nanoscale materials) DuPont; Nanophase Technologies Corporation; Nantero; Office ZPI; Quantum Sphere; Strem Chemicals; Swan Chemicals Inc.; Unidym; and one Confidential Business Information Submission.

Commitments to Submit Information Under Basic Program: (11) Arkema; BASF Corporation; Bayer Material Science; Dow Chemical; Evonik/Degussa; General Electric; International Carbon Black Association; Nanocyl North America; PPG Industries; Sasol North America; and Synthetic Amorphous Silica and Silicate Industry Association.

Commitments to Participate in the In-Depth Program: (2) Swan Chemicals Inc.; and Unidym.

Cambridge Nanotechnology Advisory Committee Recommends Nanoscale Material Registration

Porter Wright attorney John C. Monica, Jr., served as part of the Nanotechnology Advisory Committee of Cambridge, Massachusetts (NAC), which, after a year of deliberation and information gathering, recommended that the City require the registration of engineered nanoscale materials within city limits. The Cambridge City Counsel adopted those recommendations. (See next article.) Cambridge – host to approximately one dozen nanotechnology-related businesses – is just the second U.S. city (behind Berkeley, California) to require registration of nanomaterials.

"Interest in regulating nanotechnology has increased in recent years due to the recognition that certain materials may take on new and unexpected properties when they are engineered at the nanoscale," said Monica, a partner in the Washington, D.C. office of Porter Wright Morris & Arthur, LLP and a recognized national authority on nanotechnology product liability and environmental health and safety issues. "The City of Cambridge has approached nanotechnology in a very deliberate, considered manner and appears poised to take steps that promote public safety without stifling nanoscale innovation," he continued.

The NAC – comprised of citizens, scientists, industrial hygienists, university faculty, nano-businesses, and private environmental consulting firms – also recommended that Cambridge's City Counsel act to assist businesses with updates to health and safety plans for workers; educate the public; track health and safety developments; and monitor regulatory initiatives in other jurisdictions.

The City's steps follow closely on the heels of the July 28, 2008 deadline for the first phase of the United States Environmental Protection Agency's (EPA's) voluntary registration program – the Nanoscale Materials Stewardship Program (NMSP). NMSP asked companies to report voluntarily to EPA existing data concerning nanoscale materials' uses, hazards, exposure levels, and risk-management practices. To date, about 20 companies have provided or promised to provide information.

Cambridge City Council Adopts Advisory Committee's Recommendations

This article was authored and contributed by Terrence F. Smith, Director of Government Affairs, Cambridge Chamber of Commerce.

The report of the Nanomaterials Advisory Committee was on the agenda at the July 28 meeting of the Cambridge City Council. The Council's actions bode well for continued manufacturing, processing, research and development using nanotechnology in Cambridge. The Council accepted the report of the Nanomaterials Advisory Committee with little comment and placed the report on file.

The discussion was brief. Councillor Davis, who filed the original order, said she was satisfied with the report. City Manager Healy stated that the report is balanced and the next steps will provide the City with a better idea of who does what in Cambridge. He also said that the LEPC has prepared the survey recommended in the report. Councillor Murphy said that the report reflects on the strengths of the Cambridge Public Health Department and the ability of the City to bring together "world class" experts on the Nanomaterials Advisory Committee.

There was a question about nanomaterials getting into the City water supply. The Manager stated that he did not know whether it is possible to test for nano, as the City had done for pharmaceutical products several months ago, but would look into it. It should be noted that Massachusetts strictly regulates industrial wastewater. The Council took no formal action regarding this request but this issue may come up again.

If readers wish to view the discussion, the video of the meeting should be posted later this week on the City of Cambridge website at http://www.cambridgema.gov/council-archive.cfm. The discussion took place beginning around 8:15 p.m., which would be about 2 hours and 45 minutes into the meeting.

California Considering Statewide Nano Regs

At least one California legislator is said to be considering statewide legislation to "monitor and regulate" nanotechnology . Assemblyman Mike Feuer chaired a meeting on April 23 at UCLA to discuss options for developing nanotech regulation without impairing its growth. Assemblyman Feuer is one of the leading voices in California concerning nanotechnology regulation.

While the legislation is not expected to be introduced until sometime next year, different options are said to be under consideration. One option creates a multi-agency task force led by the University of California and the California EPA, while another option calls for quick action by EPA itself.

This is another example of state and local regulatory bodies stepping in to create nanotechnology oversight regulation in the absence of perceived federal activity. California's consideration joins Berkeley, Cambridge, and Wisconsin as the potential "first-movers."

The Geckos Are Back!

Remember way back, when we first started related interesting nanotechnologies of note, and there was a short story on the gecko's ability to walk on walls? Here's a hint: go read this story www.nanolawreport.com/2006/12/articles/geckos-use-nanotechnology.

Well, they're back!

Earlier this week, the NPR show Marketplace did a story on the research currently being done to study the gecko's ability to climb walls and ceilings by using nano-hairs on its feet to create new adhesives that are strong and reusable. It is a fun story to listen to and is a good reminder of the things that are already out there in nature making use of nanomaterials that may have other uses in our lives. Sometimes the best idea is right in front of us in nature.

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Nano science images provided UT-Battelle, which manages Oak Ridge National Laboratory for the Department of Energy

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