

Nanotechnology Law Report

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Nanotechnology: A New Weapon in the Battle Against Counterfeit Goods. As recently noted in Nanowerk, counterfeiting is lucrative and often difficult to detect. Drug counterfeiting is particularly problematic because it compromises patient safety and causes monetary losses and erosion of brand value. The Center for Medicine in the Public Interest estimates that counterfeit drug sales are growing at an annual rate of about 13% – nearly the twice the growth rate of genuine pharmaceutical products – and could reach \$75 billion by 2010.

Current anti-counterfeiting strategies rely heavily on supply chain monitoring and control, which may include the use of specially printed labels and radio frequency identification (RFID) tags to identify products at the package level. These labels and tags are readily visible to counterfeiters who often attempt to circumvent or replicate them. More importantly, their use is limited to tracking of packages, not package contents.

Nanoencryption provides a new tool for distinguishing between genuine and counterfeit goods, particularly pharmaceuticals. Individual tablets or other unit doses may be tagged, not just the package that holds them, and the tags are invisible to the naked eye. Further, authentication is quick and does not destroy the tablet which can be used later as evidence in a civil or criminal action. Nanoencryption also may be useful in authenticating other frequently counterfeited items such as currency, auto and aircraft parts, software, and luxury goods.

Nanotechnology and Nature: Can We Reduce Any Risks and Still Reap the Benefits?

Resources For the Future and the Woodrow Wilson International Center for Scholars co-sponsored the June 5, 2007 panel discussion "Nanotechnology and Nature: Can We Reduce Any Risks and Still Reap the Benefits?" at RFF's offices here in Washington, D.C. Panel speakers were Terry Davies (RFF), Andrew Maynard (WWICS), Celia Merzbacher

(White House), Marti Otto (EPA), and Jennifer Sass (NRDC).

Terry Davies initiated the panel discussion by providing some background information on nanotechnology, discussing the broadness and depth of the technology, and highlighting the dilemma of balancing nanotechnology's potential benefits against any potential EHS risks. He defined the basic issue at the core of this dilemma as not whether one is "for" or "against" nanotechnology, but rather the degree of caution that should be exercised as the technology is put to commercial uses. To explain his point, Mr. Davies presented a nanotechnology policy regulatory continuum familiar to those monitoring WWICS's recent work -- a total moratorium at one end of the spectrum all the way to absolutely no-new regulation at the other. In between are the additional choices of a partial moratorium, totally new legislation, and "tinkering" with existing regulations. Mr. Davies should be credited with not forcing his own views on the continuum on a captive audience. Instead, he referred interested parties to his paper recently published by WWICS -- "EPA and Nanotechnology Oversight for the 21st Century."

Andrew Maynard then provided general background information on what nanotechnology is, its potential benefits, and its potential risks. Regarding potential benefits, Mr. Maynard mentioned four applications: stronger and lighter materials; improved energy storage and generation; provision of clean water; and dramatic improvements in medicine. After discussing benefits, Mr. Maynard then turned to an EHS risk theme. He noted that the industry faces two types of risks -- potentially real EHS risks which are being investigated by scientists and government, and public perception of these alleged risks which needs to be equally considered. Mr. Maynard further referenced the July Consumer Report article regarding nanotechnology. He noted that the magazine compared 8 nano-based sunscreens to several "traditional" sunscreens which supposedly did not contain nanoparticles. The magazine found

"traditional" sunscreens worked just as well as the nano-variety and concluded that nano-based sunscreens were not needed.

Celia Merzbacher from the White House spoke next and did a nice job of outlining federal spending and research priorities both on R&D and into the potential EHS ramifications of nanotechnology. Ms. Merzbacher highlighted the federal government's requested budget for nano-research in 2008 -- \$1.5 billion total, with \$60 million of this amount requested for EHS research. She also covered some of the beneficial uses of nanotechnology including solar cells, clean water technologies, thermoelectric materials, energy storage, fuel cell technology, catalysts, and nano-manufacturing. She explained the US government currently spends about 1/4 of the total world wide government funds allocated to nano-RD and is the world-leader in this regard. Ms. Merzbacher closed her presentation with some examples of EHS research being conducted by NIOSH and the National Cancer Institute, and explained how there is a parallel need for industry sponsored research regarding EHS implications of its own products and also for research collaboration by governments worldwide.

Marti Otto spoke next regarding EPA's research into various applications and implications of nanotechnology. She provided some interesting slides showing how EPA has funded various nano-related research over time, and also highlighting EPA's major position papers including its February 2007 nanotechnology white paper. Ms. Otto then described several beneficial environmental applications of nanotechnology under consideration by EPA including: use in remediation of hazardous wastes; green manufacturing; energy conservation and storage; real time monitoring and detection of pollutants in the environment; homeland security research; nano water filtration; and nano smoke stack emission mitigation. Of particular note, she mentioned EPA's efforts to use nanoscale zero valent iron particles to remediate contaminated underground water plumes.

Jennifer Sass closed the panel by advocating a limited moratorium on the use of nanomaterials in certain contexts. In keeping with NRDC's recent position paper, she recommended prohibiting the use of "unsafe" or untested nanoparticles in consumer applications; a complete nano-life-cycle assessment before consumer products are introduced to the public; the full and meaningful participation of the public and workers in any

regulatory scheme; and addressing social and ethical considerations at the same time and at the same pace at which the business side of the industry is developing.

New Report: Nanotechnologies for Energy and the Environment. Research and Market recently announced the publication of a new report addressing environmental uses and applications of nanomaterials. The report covers many applications, environmental media, and toxicology, and, "describes nanotechnologies, nanomaterials, nanotechnology companies, universities and research centers related to nanotechnologies for new environmental technologies. Areas covered by are leading edge research in emission reduction, environmental remediation and monitoring, green manufacturing, water filtration and treatment, energy conversion and storage, alternative energy and toxicology. "

The report's table of contents is available at http://www.researchandmarkets.com/reportinfo.asp?report_id=471706&t=t&cat_id= and the full report can be purchased for EUR 1,584 (approximately \$2,100.00).

Inside OSHA Report on AFL-CIO Nanotechnology Efforts. Inside OSHA published a June article entitled "Labor Groups Begin Collecting Nanotechnology Exposure Data." The article quotes an AFL-CIO industrial hygienist as indicating the union is gathering data on workers exposed to nanomaterials in the workplace, and that it is "surveying workers to identify potential adverse effects from the controversial new technology and to track any occupational hazard trends within the industry."

The article is a little unclear in some respects. After personally speaking with the AFL-CIO industrial hygienist in question, we learned that the AFL-CIO (like many other groups) is watching nanotechnology very closely and is reviewing all new EHS information as it is published in the public domain. The scientist did not mean to imply that the AFL-CIO is currently out measuring and sampling nanoscale materials in the ambient workplace environment.

NanoReg News Report on Nanotech 2007. NanoReg News recently published an article regarding NSTI's Nanotech 2007 conference which took place in Santa Clara, California during the last week of May. The article contained a nice quote from an exclusive interview with Australian

nanotechnology officials regarding that country's investment in nanotechnology, and also commented on the EHS panels occurring on the first day of the conference.

Analysis: Consumer Reports Sunscreen Article.

As is hopefully apparent to our readers, nanolawreport attempts to provide balanced coverage of nano-related EHS and legal issues. The recent Consumer Reports article "Our first tests: Nanoparticles found in many sunscreens" was not particularly well-balanced.

The article implies that laboratory studies of sunscreens containing zinc oxide or titanium dioxide nanoparticles have shown that it "damage[s] DNA of cells and possibly cause[s] other harm as well." A clearer distinction should have been drawn between lab tests of unbound zinc oxide and titanium dioxide nanoparticles versus sunscreens containing those substances. There are no scientific studies showing sunscreens containing zinc oxide or titanium dioxide nanoparticles can cause cell DNA damage.

Further, the article refers to inhalation studies without reminding readers that it is virtually impossible to inhale nanoparticles bound in a sunscreen lotion (please let us know if you are aware of any brands of powdered sunscreen that contain nanoparticles), and also there is no evidence to suggest such nanoparticles are ever released in respirable form from sunscreen lotions actually applied to human skin.

Finally, no sunscreen can do its job properly if it is rarely used. The article essentially concluded that sunscreens containing nanoparticles are not truly needed without at least mentioning the potential benefit of more people using sunscreen containing nanoparticles more often because of cosmetic/appearance issues. It would have been interesting if Consumer Reports had actually surveyed consumers about which product they liked better and were more likely to use more frequently.

New Carbon Nanoparticle Toxicity Study.

Zhu, X., et al., "Developmental Toxicity in Zebrafish Embryos After Exposure to Manufactured Nanomaterials: Buckminsterfullerene Aggregates and Fullerol," ENVIRONMENTAL TOXICOLOGY & CHEMISTRY, Vol. 26, No. 5, pp. 976-979 (2007).

In this paper, several scientists test two nanomaterials -- buckyballs nC60 and fullerenes C60(OH)16–18 -- on zebrafish embryos to determine whether these two particular nanomaterials are developmentally toxic under certain circumstances. The scientists purportedly eliminated material purity and solvent toxicity concerns that have plagued some prior tests, allowing them to fully focus on the nanomaterials themselves.

Measurement intervals after exposure to buckyball and fullerol nanoparticle concentrated solutions varied from 12 to 96 hours. Here are some of the findings:

1. Fish embryos exposed to a fullerol solution (50 mg/L) experienced no changes in mortality rate, slightly decreased hatching rates, and no alteration in heart beats or pericardial edema.
2. Fish embryos exposed to a buckyball solution (1.5 mg/L) experienced high mortality rates, significantly reduced hatching rates, a slowed heart beat, and increased pericardial edema.
 - After 96 hours, embryos exposed to control solutions experienced less than 3% mortality, compared to 55% mortality for those exposed to the buckyball solution.
 - Regarding hatching rates, after 60 hours, embryos exposed to control solutions had a 44% hatching rate, compared to 0% for those exposed to the buckyball solution.
 - Surviving embryos exposed to the buckyball solution experienced heart beats slowed by 50% at 48 hours after exposure, and 77.8% experienced pericardial edema.

The scientists concluded: "Structurally, [fullerenes are] a derivative of [buckyballs] with 16 to 18 hydroxide radical groups connected by covalent bonds. This fullerol had no detectable developmental toxicity . . . similar to the results of other cytotoxicity experiments. Apparently, toxicity decreases as the number of chemical groups attached to [the buckyballs] (and their attachment symmetry) increases."

Also notable was a separate test in which the researchers exposed zebrafish embryos to a solution of buckyballs and GSH (glutathione) which is a known antioxidant. With GSH added to the mix, survival rates were markedly increased (80% with GSH after 96 hours compared to 55% without GSH),

hatching rates were increased (100% survival with GSH after 96 hours compared to 15% without GSH), slowing heartbeat rates were lessened (no slowed heart beat with GSH after 48 hours compared to 50% without GSH), and less pericardial edema occurred (30% with GSH after 96 hours compared to 80% without GSH). Thus, the scientists concluded that even though it "did not completely prevent embryo damage," the "developmental toxicity of [buckyballs] was effectively attenuated by GSH."

Russian Nanotechnology. Several sources report the Russian Government has created a state agency to oversee nanotechnology issues. Nanowerk reports the new government body "will ensure interaction between government, business and scientists in the implementation of the state policy in the spheres of nanotechnology and nano-industry." And, the lower house of the Russian Parliament is considering legislation that would form Russia's first nanotechnology based company.

Additionally, Small Times reports Russian and American interests are collaborating for nanotechnology research and development as well as helping Russian counterparts present new technologies and discoveries while assisting with patent and other intellectual property protections.

Cambridge Nano-ordinance Process Underway. A recent article in Mass High Tech magazine discusses the City of Cambridge's efforts to implement its own nanotechnology hazardous materials ordinance in response to Berkeley, California's efforts last December. Although there are some inaccuracies in the article (for example we are unaware of any protests related to nanotechnology in Cambridge) the gist of the article is accurate. The City has formed an advisory panel which is going to meet for the next six months before making a recommendation to the City on whether or not to enact a nanordinance and, if so, what it should look like. Because of the unique scientific and legal resources being applied to this process in Cambridge, the results of the advisory board process may end up being replicated on local and state, possibly even federal, levels across the country. We have worked very hard to secure a spot on the City's advisory panel and to open a candid and direct dialogue with the City and its Director of Environmental Health to ensure adequate industry representation in this process. Please feel free to call or email us if you are interested in joining our industry coalition or if you would like additional information.

A Look at Woodrow Wilson's "EPA and Nanotechnology Oversight" Paper. In late May, the Project on Emerging Nanotechnologies at the Woodrow Wilson International Center for Scholars published Terry Davies' thoughtful paper "EPA and Nanotechnology: Oversight for the 21st Century."

Among other notable credentials, Mr. Davies is a former EPA official from the Bush I administration and before that had a hand in drafting the plan that created EPA as well as in drafting the Toxic Substances Control Act (TSCA) back in the 1970s. His paper contains five sections: (I) Setting an Agenda; (II) The Current Situation; (III) Tools for Dealing with Nano; (IV) EPA in the 21st Century; and (V) Next Steps.

Of primary interest to our readers are most likely the five pages on "Reforming Regulation" which appear in the "Tools for Dealing with Nano" section. In these pages Davies sets forth eight new possible federal regulatory approaches to nanotechnology. The eight approaches which are not mutually exclusive follow:

1. Collaborative Regulation: Under this approach nanomanufacturers would be required to develop a sustainability plan under criteria and rules jointly created by EPA, FDA, USDA, CSPPS and possibly other federal agencies. These rules would contain three primary elements: (i) a life-cycle assessment of all potential environmental impacts presented by each nanomaterial or product; (ii) comprehensive toxicity and exposure data related to the particular material and its use; (iii) specific risk management steps taken by the manufacturer-- including product labeling -- along with an explanation of why the steps are adequate to protect against unacceptable risks.

Under this approach, the sustainability plan would not be subject to government review or approval unless a concerned citizen petitioned for review or the government suspected the plan was fundamentally flawed in some respect. Manufacturers would be required to update the plan on a period basis. There would be severe penalties for noncompliance.

2. Voluntary Plan With Strict Liability: Under this approach nanoproducts would not be subject to premarket approval, but manufacturers would be strictly liable for any adverse health or environmental caused by their

products. The government would be authorized to sue for damages and would be given sufficient resources to monitor and detect any adverse health or environmental effects.

3. Disclosure-Based Approaches: Davies points to Berkeley, California's recent nanotechnology ordinance as an example of this approach. We have previously posted some of our thoughts about the Berkeley approach in this publication. Davies also argues that this approach could contain a nano labeling requirement, which the Berkeley ordinance does not.

4. Labeling and Liability: Under this approach nanomanufacturers would be required to notify EPA before they market nanoproducts to the public and the products would wear a label saying they employ nanotechnology. If the products contain nanoparticles in "free form," there would be an additional safety screening process before marketing would be allowed, post-marketing monitoring, and a bonding requirement to cover potential liability.

5. Trust But Verify: The federal government would collaborate with industry trade associations to create general codes of conduct governing the use of nanomaterials in that industry. Trade associations would adopt these codes and compliance would be verified by the EPA or its agent. The EPA would also be responsible for promulgating nano-specific safety tests and safeguards which would be incorporated into the codes. The codes would also be applicable to businesses who are not part of any trade association.

6. Coalition: Davies suggests this approach would be structured much like the DuPont/Environmental Defense Nano Risk framework. We have previously posted some of our thoughts about the Nano Risk framework in this publication. Companies complying with the framework would be entitled to label their products accordingly.

7. Regulation with Reward: Under this approach the EPA would establish nano-specific safety testing requirements. If a company's product passed these tests it could carry an EPA approved label. If it failed the tests, the manufacturer would have to submit a risk management plan for approval by EPA. This

approach also provides other minor perks to compliant companies.

8. Exposure-based Regulation: Here, manufacturers would submit life-cycle exposure assessments for each product they make which would be reviewed by a variety of government agencies who would then determine what steps are needed to limit or manage potential adverse exposure. The government could require companies to conduct any toxicity and/or ecological testing necessary for the government to make its determination.

Risk Assessment for Nanomaterials: Current Developments and Trends. Contributed by Igor Linkov (Society for Risk Analysis/Intertox), Mike Ellenbecker (Mass. Toxic Use Reduction Institute), and Sam Lipson (Cambridge Public Health Department).

With over 400 products in use today, what information is available to demonstrate that nanomaterials do not pose unnecessary risks to human and environmental health? What areas are in need of Environmental Health and Safety (EHS) science? How could risks and environmental impacts of nanomaterials throughout the product life-cycle be minimized with engineering practices to improve product safety and to avoid potential future litigation? To help answer some of these questions, a one-day training course at MIT was designed to help navigate the ever-changing world of nanotechnology. One hundred and forty participants representing academia, industry, government and consulting attended the one-day course. Fourteen lecturers covered a diverse range of topics essential for professionals in nanotechnology and biotechnology.

In the introductory session, Mr. Robert Healy, City of Cambridge Manager, opened workshop and highlighted its importance for the proposed city ordinance regulating nanomaterial followed by Dr. Kim Thompson, SRA President, who introduced risk assessment fundamentals and related risk assessment methods and tools for nanotechnology. Dr. Travis Earles of the White House Office of Science and Technology reviewed government activities designed to improve nanomaterials EHS and increase understanding of risks.

Exposure assessment and risk characterization session started with presentation by Dr. Mike Ellenbecker of Mass Toxics Use Reduction Institute,

one of the workshop sponsors. Dr. Ellenbecker's presentation reviewed methods and tools available for exposure assessment. One important conclusion from his research is that even though sound industrial hygiene practices may reduce worker exposure to nanomaterials, additional research is necessary to confirm that the protection is sufficient to minimize exposure to nanoparticles specific to the process. Dr. Kristen Kulinowski of ICON followed with summary of exposure assessment and risk characterization research. Dr. Jeff Steevens of the US Army Corps presented nanomaterial impacts on ecological receptors, an often overlooked area that is currently attracting attention. Dr. Jackie Isaacs of Northeastern University Center for High-rate Nanomanufacturing (workshop sponsor) introduced Life-Cycle Assessment (LCA) as a tool for nanomanufacturing process improvement. She highlighted that information on EHS impacts of nanomaterials / products is largely missing.

Occupational exposure is probably the risk frontier for nanomaterials health and safety. Dr. Murashov of NIOSH reviewed current activities and programs supported by NIOSH and other agencies in the US. Dr. Sheremeta presented efforts in Canada, including developing strategic programs that enable relevant risk-focused research. Dr. Linkov and Hull introduced NanoSAFE, a practical EHS management approach developed from within the nanotech industry that has been praised by government and industry experts in providing a comprehensive yet practical strategy for managing emerging nanotechnology risks in industrial settings.

The session on policy implications of nanotechnology started with Dr. Michelson summary of activities at the Woodrow Wilson Center designed to monitor regulatory development in the field of nanotechnology. Dr. Michelson moderated session where Sam Lipson of City of Cambridge informed about background behind the proposed city ordinance and John Monica and James Votaw, two attorneys renowned for their nanotechnology work reviewed current regulatory environment on City, State and Federal levels.

The final session included several talks on risk management. The focus of Drs. Shatkin and Davis presentation was on the current activities in EPA/ORD designed to develop risk management framework and case studies. Dr. Karkan of Health Canada focused on medical devices and management of health risks. Dr. Linkov concluded workshop by linking evolving tool of multi-criteria

decision analysis with emerging issues and data gaps in nanomaterials risk assessment and characterization.

Nanotechnology is a broad and complex field of research and manufacturing with many discrete decision-points. For example, some decisions might be based upon an ability to predict which nanomaterials will have favorable chemical characteristics and lower toxicities, to identify important knowledge and technology gaps, and to develop effective communication with stakeholders and the general public. The lectures coupled with panel discussions and Q&A allowed participants to gain an awareness of the critical issues in this evolving field and a set of conceptual tools needed to make decisions and prioritize challenges in their own organizations.

The workshop was sponsored by SRA Decision Analysis and Risk Specialty Group and New England Chapter, Massachusetts Toxics Use Reduction Institute, MI, Northeastern University and the City of Cambridge. Workshop slides are available from Dr. Igor Linkov, ilinkov@intertox.com (a modest fee will be charged to benefit SRA).

Nanotech and Health Care. A recently released study entitled Nanotechnology in Health Care to 2011 from Freedonia Group, Inc., a Cleveland-based industry research firm, reports that demand for nanotechnology medical products will increase over 17 percent per year to \$53 billion in 2011 and then to more than \$110 billion in 2016. The study predicts that the greatest short-term impact will be the development of nanotechnology medical products related to cancer and central nervous system disorders as well as orthopedic nanoimplants.

The report also states: "the critical need for new or improved therapies for many medical conditions will promote the adaptation of nanotechnology to an expanding number of pharmaceuticals. The total market for nanomedicines will command strong growth over the long term. Treatments based on humanized monoclonal antibodies, nanopolymers and nanoproteins will drive gains, with compounds for cancer, heart diseases, neurological disorders and viral infections leading new product introductions and growth opportunities."

Nanosilver Antibacterial Properties. Does Shape Matter? Two South Korean scientists recently published a research paper on the issue of whether

different shapes of nanosilver particles have different antibacterial properties. The short answer is apparently "yes."

See Pal, S., et al., "Does Antibacterial Activity of Silver Nanoparticles Depend on the Shape of Nanoparticle? A Study of the Gram-Negative Bacterium Escherichia coli," APPLIED ENVIRONMENTAL MICROBIOLOGY, Vol. 73, No. 6, 1712-20 (March 2007).

The authors began by noting that "silver has been employed most extensively since ancient times to fight infections and control spoilage," and ". . . in minute concentrations, silver is nontoxic to human cells. The epidemiological history of silver has established its non toxicity in normal use." Their specific experiment exposed E. coli bacteria to three different shapes of nanoparticles: (1) truncated triangular nanoplates; (2) nano spheres; and (3) nano rods. Of the three shapes, the truncated triangular nanoplates had the greatest antibacterial properties.

The authors concluded that "[t]he difference in the observed trends in E. coli inhibition can be explained in terms of the percent of active facets present in nanoparticles of different shapes." Truncated triangular silver nanoplates, with {111} active facets, exhibited higher inhibition than nano spheres and pentagonal nano rods, both of which have primarily {100} active facets (with lesser amounts of {111} active facets). The authors speculate that "silver nanoparticles with the same surface areas but with different shapes may also have different effective surface areas in terms of active facets."

Will standard air filtration techniques work with nanoparticles? This question has come up on several nanotechnology panels we have attended over the past 6 months. Here is a short lay person's analysis of the most helpful article we have found on the subject.

Kim S., et al., "Experimental study of nanoparticles penetration through commercial filter media." JOURNAL OF NANOPARTICLE RESEARCH (2007) 9:117-125.

This study measured silver nanoparticle (3nm - 20nm) penetration through several filter media. The nine filter media selected for the tests fell into three categories: four were made of fiberglass, four were made of electret, and one was made of nanofiber. The four fiberglass media had effective pore

diameters of 8.8nm, 13.4nm, 16.1nm, and 26.2nm. Two of the four fiberglass media approached HEPA standards, while the other two were more in line with HVAC standards. The three different face velocities used for the tests were: 5.3 cm/s (which is a standard face velocity for testing respirator filter media), 10 cm/s, and 15 cm/s. Particle sampling times varied.

Results for all of the filter media were promising. The scientists found ". . . particle penetration decreases continuously down to 3nm as expected from the classical filtration theory, and there is no significant evidence of nanoparticle thermal rebound down to 3nm . . ." Obviously, the study only looked at nanosilver particles, and then only looked at them down to 3nm. What happens below that size-range still needs to be determined. Additionally, will tests on nanomaterials other than pure silver (here 99.999% pure) produce similar results? Or do different nanomaterials behave differently in filter media? Is the shape of the nanoparticle relevant to the test; will nanofibers provide different results than nanospheres, etc.?

DuPont and Environmental Defense Launch Nano Risk Framework at Woodrow Wilson Center. DuPont and Environmental Defense jointly launched their Nano Risk Framework on June 21, 2007 at the Woodrow Wilson International Center for Scholars. Two speakers from each principal introduced the framework, and were then followed by a panel discussion including three speakers representing other nanotechnology stakeholders.

Gwen Ruta, Director, Corporate Partnership Programs, ED spoke first regarding how the framework's underlying partnership came into existence. She indicated that ED first became interested in nanotechnology because of its potentially promising environmental and energy saving applications. As it explored those areas, ED also became aware of potential EHS concerns surrounding the manufacturing and use of engineered nanomaterials. ED then looked for a possible corporate partner to address nano-related EHS issues in an attempt to make sure the industry, "gets it right the first time," unlike what Ms. Ruta believes transpired with CFCs, DDT, and asbestos.

Ms. Ruta indicated ED then approached DuPont and learned the corporation felt the same way ED did about addressing nano-related EHS issues earlier rather than later. Ms. Ruta further indicated that even though DuPont and ED may have different

approaches, they were able to use those differences to create a strong partnership that takes advantage of divergent perspectives. She noted the framework is being implemented at an early stage in nanotechnology development and is not simply an afterthought. Ms. Ruta concluded by characterizing the framework as a "stepping stone" for future nano-related EHS efforts, a challenge to other companies to make similar efforts, and a challenge to EPA/FDA/OSHA to make progress on nano-related regulatory issues and fund more nano-related EHS research.

Linda Fisher, Vice President and Chief Sustainability Officer, DuPont next provided her perspective on the framework. She hoped implementing the framework may avoid some of the pitfalls familiar to the biotechnology industry and believed it should also provide helpful guidance to EPA as it considers how to regulate engineered nanomaterials. Additionally, Ms. Fisher indicated DuPont has made the framework mandatory for all of its own internal products and processes using nanomaterials, and gave examples of three specific instances in which DuPont has already used the framework to evaluate: (1) a titanium dioxide material used in plastics to protect against sun penetration; (2) the use of carbon nanotubes in certain polymer composites; and (3) the use of zero-valent iron for environmental water remediation purposes. Regarding this last instance, Ms. Fisher indicated applying the framework showed DuPont it lacked sufficient information about some aspects of the project. DuPont then made the decision to put off pursuing a pilot test of the project until further information could be gathered. Finally, Ms. Fisher indicated the framework is not intended to be a substitute for government regulation, although she encouraged EPA to take the framework into consideration when determining how to regulate engineered nanomaterials.

Scott Walsh, Project Manager, Corporate Partnerships Program, Environmental Defense and Terry Medley, Global Director of Corporate Regulatory Affairs, DuPont, then jointly presented an overview of the Nano Risk Framework itself. These two individuals were the team leaders for the partnership process and were repeatedly commended for all of their hard work. Messrs. Walsh and Medley characterized the framework as "comprehensive, practical, and flexible." They noted the six step framework is designed to be applied to a variety of nanomaterials in a variety of processes/products, and is not intended to be a "one

size fits all" document. To this end, Messrs. Walsh and Medley noted the framework allows a company to use "reasonable worst case scenario" assumptions when existing EHS data does not exist. They also stated that at the end of the day, the framework requires the implementation of "expert judgment" and is very flexible in this regard. They also addressed criticism regarding the possible costs posed by the framework to small and mid-sized businesses. Messrs. Walsh and Medley indicated the framework was designed to be flexible enough to keep costs down. To this end, they pointed to three case studies DuPont has undertaken, initial summaries of which are posted on the Nano Risk Framework website. Final versions of these case studies (when posted) are promised to include cost and labor estimates for the three above-mentioned scenarios.

The Nano Risk Framework itself is 85 pages long. We cannot cover it in full here. Nevertheless, the six basic analytical steps in the framework are:

1. Describe the nanomaterial and its intended application.
2. Create a thorough life-cycle profile of the specific nanomaterial and its intended applications. This step looks at three specific issues within the life-cycle analysis process: (a) material properties; (b) hazards; and (c) exposure possibilities.
3. Evaluate the risk posed by the particular nanomaterial in all reasonably foreseeable uses. This step requires using existing EHS data if it available. If unavailable, companies can either analogize to similar materials for which such data is available or assume a "reasonable worst case scenario."
4. Assess the risk presented by the above evaluation.
5. Decide whether to proceed with the process/product, limit its scope, or stop based on the above risk assessment.
6. Review, adapt, and modify the above process as needed. This step also includes identifying specific triggers for new reviews based in part on changes in use, amount used, and/or available EHS data.

The three subsequent panel discussion speakers were:

Sean Murdock, Executive Director, NanoBusiness Alliance: Mr. Murdock applauded the robust nature of the framework and commented on how theoretically it should be equally applicable to a variety of existing chemicals that are far more hazardous than engineered nanomaterials. He also attempted to dispel the myth that most nanotechnology companies are small, unsophisticated "start-ups." He explained that many companies take EHS issues very seriously and have hired industrial hygienists and other consultants to assist them on these issues. While Mr. Murdock had questions concerning how expensive the framework might be to implement, he also believes that it provides a good first step in the right direction .

Jim Willis, Chair, Organization for Economic Co-operation and Development (OECD), Working Party on the Manufacture of Nanomaterials: Mr. Willis briefly explained the six nanotechnology projects OECD currently has underway. More information on these projects can be found on OECD's website.

Andrew Maynard, Science Advisor, Project on Emerging Nanotechnologies, Woodrow Wilson International Center for Scholars: Mr. Maynard believes the framework is important because it is the first comprehensive guidance document to recommend specific steps in EHS analysis related to nanomaterials. He also stated some of the largest challenges confronting the nano-industry are to move beyond a "chemical mindset" when it comes to regulation, the need to "ask the right questions in the first place" when evaluating EHS-regulatory and governance issues, and the need to mine existing nano-related EHS data for application to the situations currently confronted.

The Woodrow Wilson Center intends to post a webcast of the entire event at:
http://www.wilsoncenter.org/index.cfm?topic_id=166192&fuseaction=events.preview&event_id=244896.

An Instance of Nanosilver Uptake From Wound Dressing? The healing speed of burn victims is sometimes delayed by wound inflammation caused by bacteria. Silver is sometimes used as an antimicrobial agent to kill bacteria in these instances. We recently ran across an interesting March 2006 medical case report regarding an incident of possible nanosilver uptake by a young burn victim through his wound dressings.

No broad conclusions should be drawn from the anomalous article which is summarized below.

A healthy 17 year old male sustained severe burns over 30% of his body. His wounds were dressed with nanosilver wound dressings which were then changed and reapplied on the fourth and sixth days after the injury. On the sixth day after the injury "the patient gradually developed a grayish discoloration of his face with remarkable pale-bluish lips . . ." and "[s]imultaneously he was found to have elevated . . . liver enzymes." Ultrasound images also showed that he had a slightly enlarged liver and spleen. In tests conducted the following day, silver levels in the patient's blood and urine were elevated.

The patient's wound dressings were then changed to a non-silver type. The grayish color left his face after a few days and his liver functions again tested normal. The patient was discharged from the hospital seven weeks after his injury, and still had an elevated blood silver level. The patient was finally retested ten months after his discharge and no meaningful amounts of silver were found in his blood or urine.

Interestingly, the nanosilver dressings in question were previously tested by FDA for toxicity to mammalian tissue and showed no adverse effects. FDA tests also showed no evidence of systemic silver absorption and clinical studies showed no adverse effects.

The doctors examining this unusual case concluded that although "[t]he phenomenon described does not match argyria, which is a permanent disorder caused by silver deposition in the skin's microvessels in patients who are exposed to chronic silver toxicity," . . . "it is appropriate to keep the possibility of the toxic silver effect in burn patients treated with [this]silver-coated wound dressing in mind. The silver levels in plasma and/or urine should be monitored."

See Trop, M., et al., "Silver coated dressing caused raised liver enzymes and argyria-like symptoms in burn patient," JOURNAL OF TRAUMA-INJURY INFECTION AND CRITICAL CARE, March 2006.

Discussion Paper for Canadian Nanotechnology Policy. On March 16, 2007, the Canadian Institute of Environmental Law and Policy conducted a one-day symposium on policy considerations related to nanotechnology. The Institute recently released a

discussion paper summarizing the thoughts concerning nanotechnology regulation in Canada. The paper identifies those areas that the Institute believes will help drive a nanotechnology policy framework.

The report, available on the Institute's website, lists twelve policy considerations that it believes should be considered as a policy framework is developed. Those policy considerations are: (1) societal goals, (2) public education and engagement, (3) activity and information inventories, (4) identification of lead agencies, (5) technical issue identification such as terminology and metrology, (6) regulatory framework priority identification including risk assessment, science, and stakeholder involvement, (7) labeling and consumer protection, (8) liability and intellectual property issues, (9) support for science and research, (10) commercialization and economic benefits, (11) training, and (12) security.

The report delves into each consideration in more detail, but the Institute believes that each should be developed in order to establish a solid nanotechnology framework in Canada.

Interestingly, the report also touches on barriers to a national nanotechnology policy in Canada, many of

which are the same as those facing the United States. The report cites such policy development challenges as the lack of information and lack of tools to "deal responsibly" with nanomaterials already in commerce. The needed tools the Institute points to include: standard definitions, labels, and data sheets, as well as "structures and resources for public education and engagement."

Through consideration of the twelve points above, the Institute believes that Canada can begin to create a policy framework. The Institute states that at this early stage, "our proposed policy framework focuses on goals; on what needs to be attended to; and to a lesser extent how it should be done: the elements of a policy framework."

Ohio 7th in Nanotech and Microtech Innovation.

The Cleveland Plain Dealer recently reported on Ohio's standing in nanotechnology and microtechnology innovation. According to Small Times Magazine, Ohio is now 7th in the nation, returning to the top 10 after dropping off last year. This puts Ohio in good company with nanotech heavyweights Massachusetts (#3), New Mexico (#2), and California (#1).

Events and Publications

Nanotechnology Symposium. John Monica is speaking on "EPA regulation of nanotechnology" at the World Future Society's upcoming "Nanotechnology: Innovations and Opportunities" symposium taking place in Minneapolis, Minnesota on July 29, 2007.

Nanocomposites 2007. John Monica is speaking on "Government Regulation of Nanotechnology" at ECM's upcoming 3 day polymeric nanocomposite symposium taking place in Las Vegas, Nevada from September 5 - 7, 2007.

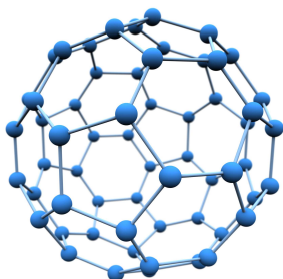
Nanotechnology Application Summit. Porter Wright's nanotechnology practice group will be teaching an Environmental Health and Safety workshop at NanoAppSummit 2007 taking place in Cleveland, Ohio on October 22 - 25, 2007. The group is also taking an active role in assisting with the summit and in arranging speakers. The summit will offer four days of interesting activities including: a basic nanotechnology tutorial; EHS workshop; automotive session; cleantech session; and defense application session.

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