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*Environmental, Health, and Safety  
Legal Implications*

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Nanotechnology Law Report

# FIRM BACKGROUND

Multi-disciplinary team of 8 attorneys with nanotechnology related expertise in environmental law, food and drug regulation, government affairs, health care, intellectual property, international business, occupational health and safety regulation, product liability, and voluntary standard setting. Representative clients include nanomaterial manufacturers, pharmaceutical companies, start-up nanotechnology companies, nano-related business groups, consumer product manufacturers, and smaller chemical manufacturers.

Associate editor for legislative and regulatory issues for Nanotechnology Law & Business, peer-reviewed journal.

American National Standards Institute (ANSI), Technical Advisory Group (TAG) to the International Standards Organization (ISO), Technical Committee (TC) 229 – Nanotechnologies.

ASTM International, Committee E56 on Nanotechnology.

Nanotechnology Advisory Panel, City of Cambridge, Massachusetts.

**“Nanotechnology and the Law,”** full length legal text accepted for publication in February 2009 by West Thomson Legal Publishers.

**“FDA Labeling of Cosmetics Containing Nanoscale Materials,”**  
Nanotechnology Law & Business, Vol. 5, No. 1, Spring 2008.

**“FDA Should Systematically Gather Basic Nanomaterial Information,”**  
Food and Drug Law Institute, Insider, February 19, 2008.

**“Ramping up the EPA's Nanoscale Materials Stewardship Program,”**  
Small Times Magazine, Vol. 7, No. 5, September/October 2007.

**“EPA's latest public meeting discusses nanocharacterization specifics,”**  
Small Times Online, September 18, 2007.

**“EPA's nano stewardship program concept paper draws response,”**  
Small Times Online, August 10, 2007.

**“EPA reviews EHS implications of nanotechnology,”**  
Small Times Magazine, Vol. 7, No. 3, May/June 2007.

**“The perils of pre-emptive regulation,”**  
Nature Nanotechnology, Vol. 2, February 2007.

**“Preparing for Future Health Litigation:  
The Application of Products Liability Law to Nanotechnology,”**  
Nanotechnology Law & Business, February 2006.

# NANO GOVERNANCE 2008

February 12, 2008

[www.nanogovernance.com](http://www.nanogovernance.com)

The George Washington University Law School, Porter Wright Morris & Arthur LLP, The Environmental Law Institute.

U.S. Environmental Protection Agency, DuPont, Meridian Institute, U.S. Chamber of Commerce, British Standards Institution, International Organization for Standardization, The White House, American Bar Association Section of Environment, Energy and Resources, Organization for Economic Co-operation and Development, Institute of Nanotechnology, Woodrow Wilson International Center for Scholars, International Center for Technology Assessment, Environmental Defense, The George Washington University, NanoBusiness Alliance, and the Environmental Law Institute.

# NANO GOVERNANCE 2008

*Question Presented for Discussion:* Is it possible or desirable to merge existing approaches to create a comprehensive environmental governance regime for nanotechnology? If so, how?

# Nanotechnology Law Report

March 2008

Porter Wright Morris & Arthur LLP

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## Congressional Research Service Issues Report on Nano-Regulatory Challenges



The Congressional Research Service (CRS) issued "Engineered Nanoscale Particles and Derivative Products: Regulatory Challenges" late last January. The document suggests several approaches to nano-related Environmental, Health, and Safety (EHS) regulatory issues.

At the outset, CRS notes that "enthusiasm and investment in nanotechnology are somewhat restrained . . . by questions about the possible EHS risks associated with this new technology." CRS then identifies numerous challenges facing any federal regulatory attempt: (i) lack of data characterizing nanomaterials; (ii) lack of standardization in nomenclature, metrics, and materials; (iii) proprietary nature of certain information; (iv) difficulty in communicating between academic disciplines; (v) limited financial resources; and (vi) possibly inadequate statutory authority.

Acknowledging these potential difficulties, CRS identifies four possible regulatory approaches:

- **Increase research and standardization funding.** CRS reports that "[a]ccording to the Chairman of the House Subcommittee on Research and Science Education of the Committee on Science, 'the basic position of most outside observers from industry and non-governmental organizations is that the funding level should be on the order of 10% of the [National Nanotechnology Initiative's (NNI) total funding, rather than the current

4%.'" This would increase federal nano-related EHS funding to approximately \$152 million based on NNI's proposed FY2009 budget.

- **Reallocate existing federal research funding.** CRS suggests reevaluating how existing nano-EHS research funds are divided among federal agencies given research priorities. CRS leaves it to the National Science Foundation and NNI to determine whether reallocation is appropriate.
- **Adopt a national or international research strategy.** CRS notes that this approach is difficult to implement without first conducting comprehensive EHS research. Additionally, when NNI first created its general nano-EHS-research framework in 2007, it identified five research categories and some specific needs, but it did not prioritize its suggestions.
- **Enact legislation and/or restrictions.** Finally, CRS notes that existing laws are probably adequate to govern any potential EHS risk posed by nanotechnology but that they were not written with nanomaterials specifically in mind. As a result, CRS suggests that agencies may need to develop new policies, produce guidance documents, and possibly issue regulations to make existing statutes specifically applicable to nanomaterials.

This newsletter is provided for informational purposes. It provides no legal advice nor does it create an attorney-client or any other type of relationship.

# TOPICS OF INTEREST

- Federal EHS Research Strategy Tangle
- Federal EHS Research Funding
- State and Local Regulation
- EPA's Nanoscale Material Stewardship Program
- ED DuPont Nano Risk Framework
- FDA Product Labeling
- FDA Data Collection

# **1. Federal EHS Research Strategy Tangle**

# Federal EHS Research Strategy Tangle

An unlikely group of 17 industry and environmental associations has recently come together and asked EPA to begin working with the NAS to develop a federal nano-specific EHS research roadmap -- as requested by Congress back in January 2008. Not only have EPA and NNI already recently published their own nano-EHS research roadmaps, NAS recently began reviewing NNI's efforts in early April, and EPA's roadmap is scheduled for peer-review starting this month. President's Council of Advisors on Science and Technology just assessed NNI and its strategic plan.

## **2. Federal EHS Research Funding**

# Federal EHS Research Funding

Congress introduce a bill this month mandating that ten percent of the National Nanotechnology Initiative's budget be directed to researching potential environmental, health, and safety issues related to nanotechnology. Current EHS funding is set at about four percent of NNI's annual budget, and the new level would be about \$150 million for FY2009 if the bill makes it into law. The Senate is also likely to introduce a companion bill later this month.

# Federal EHS Research Funding

## Government Accountability Office (GAO) Report

NNI reported that federal agencies spent a total of \$37 million in FY 2006 researching the potential EHS risks of nanotechnology.

GAO found that this figure was off by about 18%, and that 22 of the 119 projects identified by NNI had little to do with how nanotechnology may pose EHS risks.

Twenty of the mislabeled projects were sponsored by NSF, two were sponsored by NIOSH, and funding totaled approximately \$6.5 million.

GAO also found that NNI failed to capture some ongoing federal nano-related EHS research in its estimate "because the agencies that conduct this research do not systematically track it as EHS-related."

# **3. State and Local Regulation**

# State and Local Regulation

Woodrow Wilson International Center for Scholars' Project on Emerging Nanotechnologies (PEN) recently published S. Keiner's, "Room at the Bottom? Potential State and Local Strategies for Managing the Risks and Benefits of Nanotechnology," March 2008.

". . . the time is ripe for states and localities to explore action for managing nanotechnology risks and benefits because there seems to be very little interest or urgency among U.S. federal agencies in initiating a nationwide approach to overseeing the potential environmental and public health impacts of nanotechnology."

Berkeley, California. Cambridge, Massachusetts.

California, Michigan, Minnesota, Massachusetts, New York, and New Jersey

# State and Local Regulation

**"The perils of pre-emptive regulation,"**  
Nature Nanotechnology, Vol. 2, February  
2007.

# **4. EPA's Nanoscale Material Stewardship Program**

# EPA's Nanoscale Material Stewardship Program

- The first "basic" level seeks information EPA believes is already in most companies' possession or should be easy for them to ascertain: materials characterization, hazard, use, potential exposure, and risk management practices. These broad topics, of course, have numerous subtopics. The draft questionnaire for this "basic" level is 25 pages long. Six months.
- The second, "in depth" level asks select participants to essentially partner with EPA to collect additional data on a specific limited number of nanomaterials of greatest potential concern (tbd). Participants will jointly review existing data, conduct preliminary assessments, identify any additional data needs, and then work on a joint action plan. Two years.

# EPA's Nanoscale Material Stewardship Program

Two companies have already made NMSP submissions: (i) DuPont and (ii) 2PI, and ten others have provided letters of intent to participate: (i) BASF; (ii) Bayer; (iii) Dow; (iv) Evonik; (v) GE; (vi) Nanocyl; (vii) Nanophase; (viii) PPG; (ix) Sasol North America; and (x) Strem Chemical. Arizona State University has also submitted a letter of intent.

# **5. ED DuPont Nano Risk Framework**

# ED DuPont Nano Risk Framework

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 looking at (a) material properties; (b) hazards; and (c) exposure possibilities.
3. Evaluate the risk posed by the particular nanomaterial in all reasonably foreseeable uses, using existing EHS data if it available, or 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. Make a decision about 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.

# **6. FDA Product Labeling**

# FDA Product Labeling

"FDA Labeling of Cosmetics Containing Nanoscale Materials,"  
Nanotechnology Law & Business, Volume 5, Issue 1 (Spring 2008)

Numerous products are regulated by the U.S. Food & Drug Administration (the "FDA") that contain nanoscale materials. As more products come to incorporate nanomaterials, the number of products correspondingly regulated will only increase. The FDA does not currently require labels stating that products incorporate nanomaterials. The position of the FDA not to require labels indicating that products contain nanomaterials has been controversial for some advocacy groups. In this article, we examine existing cosmetic labeling requirements in the context of recent calls by advocacy groups for special labels for cosmetics containing nanoscale materials. While the FDA has made a serious attempt to address cosmetic nano-labeling issues, a more rigorous analysis of some nano-labeling arguments is necessary.

# 7. FDA Data Collection

# FDA Data Collection

"FDA Should Systematically Gather Basic Nanomaterial Information," Food and Drug Law Institute, *Insighter*, February 2008.

"FDA only regulates certain categories of products. Existing requirements may be adequate for most nanotechnology products that we will regulate. These products are in the same size-range as the cells and molecules with which FDA reviewers and scientists associate every day. In particular, every degradable medical device or injectable pharmaceutical generates particulates that pass through this size range during the processes of their absorption and elimination by the body. To date, FDA has no knowledge of reports of adverse reactions related to the `nano` size of resorbable drug or medical device products. If new risks are identified, arising from new materials or manufacturing techniques for example, new tests or other requirements may be needed."

# FDA Data Collection

"But such issues of agency authority are overshadowed by an even more basic question of agency oversight. To illustrate, try this: Place a general telephone call or email inquiry to FDA and ask whether the agency keeps a list of FDA-approved products employing nanoscale materials. Then dig deeper and call each of the six FDA centers (CDER, CFSAN, CBER, CVM, CDRH, and NCTR) and ask the same question. Unfortunately, no such list exists. In fact, FDA freely admits that it does not currently track this information."

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