

# Nanotechnology Law Report

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**ABA Teleconference: The Clean Air Act and Nanotechnology.** The ABA Section of Environment, Energy, and Resources held a teleconference on January 16, 2007 on The Clean Air Act (CAA) and Nanotechnology.

The first presenter discussed the National Nanotechnology Initiative (NNI), a federal research and development program with members from 25 federal agencies that coordinates multi-agency efforts in nanotechnology. The NNI's primary report, "Environmental, Health, and Safety Research Needs for Engineered Nanoscale Material," can be found at <http://www.nano.gov/>.

The second presenter spoke about the Oklahoma Nanotechnology Initiative, which can be found at [www.oknano.com](http://www.oknano.com). The Initiative serves as a clearinghouse for Oklahoma nanotechnology information, and advocates the (1) development and handling of nanoproducts in safe and environmentally responsible ways, (2) continued development of nanotechnology without the uncertainty created by misguided and overly zealous regulation resulting from fear and ignorance, (3) collaboration between government and private industry regarding research projects exploring the physical and chemical characteristics of engineered nanoparticles and developing new test methods, protocols and standards to help move nanoscale manufacturing to commercialization, and (4) development an adequate data set allowing appropriate evaluation of the risks to human health and the environment from exposure to engineered nanostructures, byproducts, or materials incorporating them, and/or the release of these materials into the environment.

Current Initiative issues and concerns include: (1) Where will the funds for toxicology studies come from? (2) If industry does the studies, how will the studies (and considerable expenditures) be perceived? (3) Over-regulation is inherently wasteful and will greatly reduce the US's competitive advantage. (4) The US is currently the world leader in nanotechnology research and applications,

however, competition from China, Japan and the EU is rapidly overtaking the US. (5) Even before comprehensive toxicological data is developed, the industry should focus on determining the point in the manufacturing process at which engineered nanostructures are introduced into a confining material matrix such that potential for exposure to workers and release to the environment is minimized during manufacture, and then evaluate subsequent use.

The third presenter highlighted that the CAA provides EPA with broad authority to regulate air pollutants. CAA section 108(a)(1) allows EPA to "publish . . . a list which includes each air pollutant emissions of which . . . cause or contribute to air pollution which may reasonably be anticipated to endanger public health or welfare the presence of which in the ambient air results from numerous diverse mobile or stationary sources." The questions raised by the presenter were (1) Do we know enough to say that nano-emissions may reasonably be anticipated to endanger public health or the environment? and (2) Are nano-emissions similar enough to say they result from numerous or diverse mobile or stationary sources?

The final speaker discussed the regulation of nanomaterials under the CAA's mobile source provisions. The primary issue here was the potential uses of nanomaterials such as emission control equipment (e.g. catalyst material) or fuel additives. The sections of the CAA that regulate engines and equipment (sections 202(a) and (l) and 213) and fuels and additives (202(l) and 211(a), (b), (c) and (f)) are the pertinent provisions. The speaker concluded the direct regulation of fuels is the most likely basis for regulating nanomaterials in this area.

**Cambridge Investigates Nanotechnology Regulations.** On the heels of Berkeley, California's decision last December to impose regulations on nanotechnology businesses, Cambridge, Massachusetts -- home to MIT and Harvard -- is now considering its own nanotechnology regulation. According to the Boston Globe, it appears that the

Cambridge City Council is aware of the potential for stifling nanotechnology innovation with regulation:

*We hope that nanotech is going to be a big part of new industry in Cambridge," said council member Henrietta Davis. But Davis said the city should make sure that nano-based businesses ply their trade safely. "It's not my intention to stifle it," she said. "It's more to be proactive."*

This concept of "proactive" regulation raises the question of how well municipal government regulators can strike the balance between the need for innovation and the need of safety in the absence of good information about the probability and magnitude of risks associated with a given activity. On that note, it is helpful that Cambridge has decided to invite industry representatives to the table when deciding whether to impose nano regulations:

*Igor Linkov, managing scientist at Intertox Inc., a technology consulting firm in Brookline, said there is some evidence that nanoparticles could pose health risks. He cited a study that found that rats developed scar tissue when liquid mixed with carbon nanoparticles was sprayed into their lungs. But Linkov said far more research is needed before jumping to conclusions about the safety of nanoparticles.*

*"We know that some nanomaterials, at some point during their life cycle, may pose risks," said Linkov. "We really cannot quantify how high the risk is."*

**The Perils of Preemptive Regulation.** John Monica, Michael Heintz and Patrick Lewis recently published an article in *Nature Nanotechnology* (Vol. 2, No. 2, pp. 68-70 (Feb. 2007)) entitled "The Perils of Preemptive Regulation." The lede/abstract of the article is:

*In its rush to introduce new regulations about the handling of nanomaterials, the city of Berkeley in California has made mistakes that should not be repeated elsewhere.*

In the article, the authors analyze and critique the approach that Berkeley, California has taken in its quest to become the first American jurisdiction to regulate nanomaterials. In particular, the authors question whether a "reporting requirement" that

forces nanotechnology companies to conduct comprehensive reviews of EHS literature pertaining to nanomaterials on an annual basis will significantly advance nanotechnology safety. The authors also wonder whether the de facto characterization of nanomaterials as "hazardous" by the city of Berkeley will invite unmeritorious litigation. That sort of litigation might well cripple the industry and hamper efforts to research, develop, and commercialize this revolutionary new technology.

**Nanotechnology Regulation: Where is Congress Headed?** As reported recently in a variety of publications (e.g., *Inside OSHA*, *Inside Green Business*, and the *Risk Policy Report*), possible approaches to limit liability for accidental releases of nanomaterials are currently being reviewed by key members of the Senate Commerce Committee. According to sources, the review is being spearheaded by Senator Mark Pryor (D. AR), the chairman of the Senate subcommittee having jurisdiction over consumer affairs, product safety and insurance industry issues.

This congressional interest is occurring precisely at the time that the nanotechnology industry stands poised at the threshold of significant technological advances. Some or all of those advances, however, could be stymied or substantially delayed by the possibility of major product liability litigation. At the same time, federal agencies, particularly the EPA, are looking into the potential risks associated with the unique properties found in nanomaterials, and are examining whether, and if so, what, regulatory changes may be necessary to address those risks.

One possible model for limiting liability for the accidental release of nanomaterials was advanced by David Berube, a professor at the University of South Carolina and the communications director for the International Council of Nanotechnology, in an article in the December 2006 issue of the *Nanotechnology Law & Business* journal. Professor Berube posits that Congress should consider legislation similar to the Price-Anderson Act, which protects the U.S. nuclear power industry by capping liability for nuclear accidents so long as industry members purchase all available insurance. Under, Professor Berube's approach, the liability of individual producers of nanoscale particles and nanoproductions would be capped, but injured parties could, in some cases, be awarded compensation from a group fund. The liability cap would not be permanent, but would remain in place while the EPA and other agencies evaluate the risks posed by

nanomaterials. Whether Congress adopts this approach or something similar to it remains to be seen, but pressure for Congress to enact some statutory protection to ensure that innovative uses of nanomaterials continue to be developed might be inevitable.

**UN Calls for Nanotechnology Regulation.** The 2007 United Nations Environment Program "GEO Year Book 2007" report was recently released, which explicitly calls for nanotechnology regulation on a global scale. The abstract to the Year Book contains this overview:

*The emerging scientific and policy challenges of nanotechnology are examined from an environmental perspective. Nanotechnology will bring environmental benefits but it is vital that we adopt appropriate assessment and legislative process to address the unique challenges presented by nanomaterials and their life cycles.*

The AP provides more background in a February 5th report from Nairobi, the site of this year's Global Ministerial Environment Forum, where the report was unveiled. More from the report:

*In its annual report of the global environment, the U.N.'s Environment Program said "swift action" was needed by policy makers to properly evaluate the new science of nanotechnology.*

*Although nanotechnology could transform electronics, energy industries and medicine, more research is needed to identify environmental, health and socio-economic hazards, Achim Steiner, who heads UNEP, said in the 87-page report.*

The UN is calling for cooperation between the nanotechnology industry and government, and also cooperation between developed nations and developing nations, in formulating a regulatory response to potential EHS nanomaterial concerns. On that note, the National Science Foundation's proposed 2008 budget includes a \$29 million request for a Program Component Area entitled "Societal Dimensions: Environmental Health & Safety (EHS)."

**The NNI's Research Priorities and Agenda.** In late September, the National Nanotechnology Initiative (NNI) released its priorities for risk research needs. The report has come back to the forefront of nano discussions because the NNI held meetings in January to allow other interested parties to comment. While the report is being widely criticized for either taking too long to develop, or for failing to prioritize research needs and strategies any more than listing areas where researchers lack knowledge, the report shows how much education is still needed.

However, when the report and the associated criticisms are put into a larger context, a recurring theme begins to appear. In light of the recent movement for regulating nanotechnology and nanomaterials, including the ordinance enacted by Berkeley, a similar ordinance being considered by Cambridge, MA, and most recently, the U.N. report calling for "swift action" concerning nanotechnology regulation, there is a growing disconnect between nanotechnology knowledge and nanotechnology regulation. While a precautionary principle is appropriate for new technologies that are not yet fully understood, there must be a logical connection between the risks posed by nanotechnology and the resulting regulatory efforts. To charge ahead with regulation, without an understanding of the technology being regulated, more harm than good may result. Like most intersections between industry and law, there must be a balance between allowing industry and science to develop products in a responsible manner without overburdening a budding sector with regulations that do not understand the nature of the area and the risks posed. To that end, researchers and regulators need to keep communicating with each other openly and honestly about discoveries and political movements.

### **Virginia Promotes Nanotechnology**

**Development.** If adopted, Virginia House Bill No. 1939 would establish a "Virginia Technology, Nanotechnology, and Biotechnology Investment Fund" to provide up to \$500,000 in grant money to small nanotechnology start up companies with 25 or fewer employees seeking to locate in Virginia. The bill is sponsored by Harry R. Purkey of Virginia Beach, and is currently in the appropriations process. The bill defines "nanotechnology" as "technology, research, and development at the atomic, molecular, or macromolecular levels, in the 1 – 100 nanometer range, to create and use structures, devices, and systems that have novel

properties and to integrate such structures, devices, and systems into large material components, systems, and architectures." The bill's sister legislation – Virginia House Bill No. 2275 – would establish the "Virginia Nanotechnology Authority," which would (among other things) administer the fund. Bill 2275 defines "nanotechnology" as "the manipulation of particles at the less-than-100-nanometer scale."

**Some Additional "Legal" Definitions of "Nanotechnology".** After reading Virginia's twin nanotechnology bills, we searched and located the below-listed statutory definitions of "nanotechnology."

**Arkansas:** "'Nanotechnology' means the materials and systems whose structures and components exhibit novel and significantly improved physical, chemical, and biological properties, phenomena, and processes due to their nanoscale size." A.C.A. §15-4-2103(5); and

**Oklahoma:** "'Nanotechnology' means technology development at the molecular range (1 nm to 100 nm) to create and use structures, and systems, that have novel properties because of their small size." 74 Okl St. Ann. §5060.4(12).

Additionally, Michigan uses the term in the following statute:

**Michigan:** "'Advanced automotive manufacturing, and materials technology' means any technology that involves /or more of the following . . . **'nanotechnology**, including materials, devices, or systems at the atomic, molecular, or macromolecular level with a scale measured in nanometers." M.C.L.A. 206.30 -125.2088a.

And don't forget about **Berkeley's** recent ordinance which contains the following language:

"All manufactured **nanoparticles** defined as a particle with one axis less than 100 nanometers in length . . ."

**Environmental Protection Agency's White Paper.** The long-awaited final White Paper from the United States Environmental Protection Agency (EPA) on nanotechnology and related regulatory issues was

finally issued this month. According to the Federal Register notice, the 132-page document covers "a basic description of nanotechnology, why EPA is interested in it, potential environmental benefits..., risk assessment issues..., and a discussion of responsible agency development of nanotechnology and the Agency's statutory mandates."

The White Paper, as expected, lays out the Agency's thoughts and ideas concerning nanotechnology and how it will be treated by EPA. While the Paper begins with the Agency's role in the larger government plan concerning nanotechnology, it provides many EPA-specific items as they relate to research and regulation.

The Paper explains EPA's role with regards to nanotechnology, as well as why nanotechnology is important to the Agency. It then addresses issues such as risk assessment and development of nanotechnology from EPA's perspective. Not surprisingly, EPA identifies several areas in which clear data gaps exist and must be filled in order to progress with nanotechnology. However, of particular interest to those in the regulated community, the Paper provides some of EPA's thoughts on both potential regulation of nanotechnology, as well as its possible environmental benefits.

First, with regards to possible regulation by EPA, the Paper explains that the Agency maintains the position that current environmental statutes provide it with the authority to regulate nanomaterials. This statement alone is not surprising as it is a generally accepted thought. However, the Paper fails to discuss how some of these statutes contain trigger levels that may be inappropriate measures of nanomaterials. For example, statutes such as the Clean Air Act and Resource Conservation Recovery Act contain measurable levels at which regulation begins, such as a specific concentration or weight emitted or discharged. Because nanomaterials may be a concern at vastly smaller measurements, many of these triggers that are measured in parts-per-million or pounds or tons emitted may be inapplicable; a point EPA does not fully develop. Similarly, EPA spends significant space on potential environmental harms, but also explains that nanotechnology may also provide environmental benefits, especially in terms of ground water or Superfund site remediation projects. It is important to remember that nanotechnology can be a positive in remediation efforts, not just something to regulate for protection. EPA does a good job remember this

point, and should be commended for taking a two-vision approach: understanding remediation possibilities and understanding risk possibilities.

Second, the Paper goes into great detail concerning risk assessment. EPA believes it is very important to develop sound risk assessment concerning nanomaterials before moving to the next step. The Agency then reiterates its desire to work with stakeholders to develop the necessary information to make educated decisions.

Finally, the Paper concludes with a series of recommendations directed at EPA offices and staff. If EPA holds to these recommendations, the Paper provides a good road map as to the Agency's priorities in the near future. While EPA's work in nanotechnology will be largely driven by the research of research and risk assessment projects, its overall thoughts on nanotechnology provide a well-reasoned beginning its work in the field.

**Rose Sheet Interview.** Nanotechnology Law Report's own John Monica was recently interviewed by Melina Vissat, the news editor of "The Rose Sheet," published by FDC Reports and formally known as the Toiletries, Fragrances & Skin Care on-line trade report. The interview was a followup to John's recent presentation on the perils of preemptive nanotechnology regulation at a recent conference regarding the regulation of nanotechnology in consumer products in Washington, D.C. Ms. Vissat's interview follows:

**MV: Why would Berkeley, specifically, make this a regulation? Is there a lot of handling of nanomaterials there? Or would this set precedent for California state, and/or perhaps the rest of the country?**

JCM: The short answer is Berkeley primarily wanted to be a trendsetter, and secondarily wanted a forward looking ordinance to prevent any potential future problems. Officials in Berkeley have openly criticized the federal government and the state of California for failing to enact nano-specific safety regulations. They have also openly said they enacted their own ordinance because state and federal governments failed to act first. Also, while the ordinance is not binding legal precedent, Berkeley has openly encouraged other governments -- city, state, and federal -- to follow their lead.

As for actual application, currently there are very few companies using engineered nanoscale materials in

Berkeley. (In fact, several newspapers have reported there are "none," but I do not believe this is accurate.) So, I would not say the ordinance was enacted because of any impending current safety concern.

On the other hand, University of California Berkeley labs and Lawrence Berkeley National Laboratory are both in the city limits. Both are involved in nanomaterials research. Berkeley says the ordinance was initially prompted by a lack of nanomaterials handling procedures at these two labs. The city claims to have asked the labs what nano-specific safety procedures they had in place, and the answer was "none or very few." This prompted Berkeley's original concern and ultimately the ordinance. However, Berkeley has also now stated that the ordinance does not apply to either lab because they are federally funded. The labs, on the other hand, intend to voluntarily comply with the final ordinance.

**MV: Why specifically is this legislation unnecessary? Is it because we don't yet know whether nanomaterials are actually a threat? Or because there is simply a lack of data proving either way - dangerous vs. safe?**

JCM: I believe this specific legislation is unnecessary because (i) it is virtually impossible to comply with in its current form, (ii) the federal government should take the lead in labeling any material/chemical as "hazardous," not Berkeley (iii) all "manufactured nanoparticles" - whatever that broad definition used in the ordinance implies - have not been label as "hazardous," nor is there any current scientific consensus that they all should be. There are data on both sides of the safety/hazard issue, but I do not believe any responsible scientist is dismissing the potentially negative data out of hand. It is a real concern. However, most scientists say more research is still needed and it will take several years. They also advocate the standardization of research techniques to make sure they are all talking about the same thing as they move forward with research.

**MV: Who should be doing this research to determine whether nanomaterials are safe? Companies, etc.?**

JCM: The federal government is funding nano-related environmental, health, and safety research - about \$44 million is in the 2007 budget. However, there seems to be a consensus among scientists

that federal funding should be increased to at least \$100 million annually. On the other hand, the federal government takes the position that manufacturers are primarily responsible for the research necessary to ensure the safety of their nano-products. Ultimately, product liability law imposes this same burden on manufacturers. As they must ultimately bear the social and financial burden of any liability, I believe manufacturers should plan accordingly. However, my personal belief as a policy matter is that manufacturers and the federal government have equal responsibility.

**MV: Now, regarding this regulation, who does the burden fall to to provide the required information? The companies? Will this cost companies time, money, manpower? Could you please provide more detail on how this legislation is a burden to industry?**

JCM: The burden falls on the companies to provide the required toxicology information. There are a couple of ways to answer the question depending on what the city wants, which is not crystal clear. If the city says all that is required is a literature search (most likely), then my response is that reviewing the universe of existing toxicology studies and then reporting/summarizing them to the city is a very expensive prospect. You will have to ask a toxicologist for an estimate of the actual hours this research would take. There are over 1600 EHS studies in the best nano EHS database. A lot of them, of course, might not be applicable to any individual company or situation. But if you take the Cosmetics, Toiletry and Fragrance Association's White Paper on Nanoparticles in Personal Care

Products submitted to the FDA as an example of the type/level of analysis required, it will be quite large and expensive indeed.

If new toxicology research is required (less likely), then that is a whole different (greater) level of expense. There are also additional expenses associated with implementing the materials handling plan portion of the ordinance once the toxicology issue has been resolved. Of course, this is hard to estimate without having the toxicology part nailed down.

**MV: Where else is this preemptive legislation surfacing?**

JCM: This same type of current preemptive legislation is being considered in Cambridge, Massachusetts, and there have been rumblings in Ithaca and Madison. I would look for similar efforts in nano-university communities across the country. Additionally, companies located in "top ten" states for nanotechnology development should be closely watching what is going on at the municipal level.

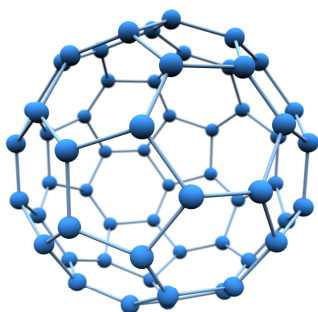
**MV: At what stage would it NOT be considered pre-emptive? Once safety data is in-hand?**

JCM: City governments are not well-equipped to analyze these issues. Thus, I would always consider municipal regulations of this specific type to be "preemptive" and ill-advised. The federal government is looking very closely at nano-EHS issues, I would leave the decision to it as to whether or not to label a nanomaterial as "hazardous" and all the burdens that come with that label.

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