Nanotechnology Law Report

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EPA Announces Nanotechnology Safety Research Grants. The EPA recently announced the award of two grants, collectively worth $600,000, to researchers at Oregon State University to study the human health impacts of nanomaterials. According to AzoNano.com, the first study is a survey of common manufactured nanomaterials to understand their interaction with biological processes. The second study looks specifically at how manufactured nanomaterials may "damage or kill cells:"

> *Dr. Alan Bakalinsky is studying the relationship between specific characteristics of nanoparticles, like shape and structure, and their effects on cells. The work is expected to lead to the development of safety guidelines for industrial and environmental exposure to nanomaterials. "We're trying to identify specific structures in manufactured nanoparticles that might cause damage to cells," said Bakalinsky. "If we can determine which shapes and structures are most dangerous to cell function, it should be possible to design the materials to avoid those shapes and minimize the risk of damage."*

EPA Explains Nanoscale Materials Are Not Necessarily "New" Chemical Substances Under TSCA. Under the Toxic Substances Control Act (TSCA) "new" chemical substances are subject to detailed premanufacturing notice and approval requirements. This is unique because "traditional" environmental statutes such as the Clean Water Act and the Clean Air Act primarily regulate "end-of-pipe" or "end-of-stack" emissions. Thus, some environmental lawyers herald TSCA as a proactive tool for EPA to regulate nanoscale materials before they are put in use, rather than simply monitoring and limiting eventual emissions/releases.

A core issue in this discussion has been whether -- because of their small size and sometimes unique properties -- EPA should treat all nanoscale materials as "new" chemicals under TSCA and subject them to the Act's premanufacturing notice and approval requirements. Some argue this is the most conservative, precautionary approach given current EHS uncertainty surrounding some nanoscale materials in certain circumstances.

In July, EPA took a large step towards clarifying its approach by publishing a paper explaining its treatment of nanoscale substances under TSCA as "new" versus "existing" chemicals. "TSCA Inventory Status of Nanoscale Substances -- General Approach." EPA's announced position is consistent with many predictions: EPA does not intend to consider nanoscale materials "new" substances just because of their diminutive size -- they must have a distinct molecular identity that is not shared with any other chemical on TSCA's existing Chemical Substance Inventory before they are considered "new."

In reaching its position, EPA explains that the term "chemical substance" is defined as “any organic or inorganic substance of a particular molecular identity," and that a "molecule" is defined as the smallest amount of matter retaining all of its same chemical properties. Therefore, EPA reasons if a nanoscale material has the same molecular identity as its bulk counterpart, it is an "existing," not "new," chemical substance.

However, EPA also indicates it is going to approach these determinations on a case-by-case basis, and “certain nanoscale substances that will be manufactured or imported for commercial purposes are expected to be new chemical substances and therefore subject to TSCA new chemical regulatory requirements. As are any other new chemical substances.”

Apparently realizing this issue may create uncertainty with nano-manufacturers, EPA encourages companies to consult EPA or submit a request for an inventory search to determine

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whether a particular nanoscale material in question should be treated as a "new" chemical under TSCA.

However, a sibling issue still remains undecided by EPA -- whether the use of nanoscale materials constitutes a "significant new use" of an existing chemical substance which also triggers TSCA's premanufacturing notice and approval requirements. This is a much tougher issue to resolve. Under the applicable statute, relevant factors in this consideration are: (i) the projected volume of manufacturing and processing of a chemical substance, (ii) the extent to which a use changes the type or form of exposure of human beings or the environment to a chemical substance, (iii) the extent to which a use increases the magnitude and duration of exposure of human beings or the environment to a chemical substance, and (iv) the reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of a chemical substance.

How EPA will resolve this issue remains to be seen. Stay tuned.

EPA Concept Paper for Nanoscale Materials Stewardship Program Under TSCA. EPA published its long awaited draft Concept Paper for Nanoscale Materials Stewardship Program Under TSCA. The paper contains a draft framework for EPA's voluntary reporting program. Public comment is invited and a public meeting will be held on August 2 here in Washington, D.C. EPA's framework is designed to collect data from manufacturers of nanoscale materials regarding the materials they make, encourage risk management practices, develop foundational scientific data for later EHS work, and promote a balance between nanotechnology's positive contributions and minimized possible EHS effects.

EPA suggests four primary categories of companies should participate in the program: manufacturers or importers of engineered nanoscale materials; companies that modify engineered nanoscale materials for subsequent use; companies that modify bulk materials producing engineered nanoscale materials; and companies that use engineered nanoscale materials in the manufacture of their products.

Participants will be asked to implement a nano-risk management program considering relevant input from EPA and to report back regarding its efficacy. EPA intends to base its nano-risk management program on the results of its October 2006 scientific consultation on nano-risk management practices, and also is encouraging additional public submissions on this specific issue.

Participants will also be asked to provide information regarding their current use of engineered nanoscale materials under two plan levels.

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. To give readers some idea of the extent of the information EPA is seeking, the draft questionnaire for this "basic" level is 25 pages long.

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. Joint research topics include: "characterizing the physical/chemical properties of the material; testing for health and environmental hazards; monitoring or estimating exposures and releases; determining fate and transport characteristics; evaluating the effectiveness of protective equipment or engineering controls; developing a model worker education program; and other evaluations agreed to under the plan of action." EPA envisions some companies taking a direct/active role in this research, while others may chose to work in loosely formed coalitions. After completing the research, there will be a final joint risk assessment for each material studied, and any additional actions/steps will be considered on a case-by-case basis.

EPA advises all of the information collected under both levels of the plan will be treated as being formally submitted under TSCA. Companies will have the opportunity to designate certain information as "confidential business information" which will be subject to all existing TSCA protections. EPA plans to use the collected information to determine "how and whether certain nanoscale materials or categories may present risks to human health and the environment," to identify any existing data gaps, prioritize nanomaterials for further research, and develop risk mitigation techniques (assuming the information warrants such measures).

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EPA believes all nano-manufacturers and importers should participate in the program in order to encourage "responsible development of nanoscale materials" and to avail themselves of enhanced informed decision making, benefiting "all stakeholders." EPA also believes the program will foster the openness and transparency many in the public and certain NGO's believe is crucial to the success of any regulatory program.

Actual participation in the voluntary program, however, remains a concern. EPA is asking the public for new ideas on providing incentives to companies to participate in the program. At the same time EPA states that participation will not "relieve or replace" existing TSCA requirements that are otherwise applicable to each specific manufacturer and nanomaterial.

The paper also has several informative attachments. Of particular interest are "Annex A" which contains a glossary of nanotechnology terms and notes substantial nomenclature gaps, and "Annex D" which identifies "issues and challenges" confronting the program.

FDA Regulation of Nanotechnology? In late July, the FDA's Nanotechnology Task Force released its report on the scientific and regulatory challenges related to the use of nanotechnology in products regulated by the FDA. The Task Force's report did not call for additional FDA regulatory authority in this area. The Task Force concluded that the use of nanomaterials in products regulated by the FDA presents challenges similar to those products using existing technologies and other emerging technologies. Further, the Task Force determined that the current science on nanotechnology does not suggest that products using nanomaterials require additional labeling.

The Task Force, however, did recognize that the unique properties of nanomaterials could at some point create challenges with respect to product safety and effectiveness. To that end, the Task Force recommended the consideration of agency guidance that would clarify what information manufacturers should provide to the FDA about products utilizing nanotechnology and would clarify the circumstances under which the use of nanomaterials would change the regulatory status of particular products. The report also recommends that the FDA assess its data needs to better regulate nanotechnology products, develop in-house expertise on nanotechnology issues, and create mechanisms that will ensure the consideration of new nanotechnology information as it becomes available. Finally, the report encouraged the FDA to evaluate the adequacy of current testing approaches to assess the safety, effectiveness, and quality of nanoscale materials.

The Task Force's report can be found at http://www.fda.gov/nanotechnology/taskforce/report2007.pdf.

A Lesson From Cambridge's rDNA Ordinance? Nanotechnology Now recently posted “Public Distrust of Science Made Cambridge the Biotech Capital of the World.” The post summarizes an article on blog.wired.com which in turn comments on the City of Cambridge, Massachusetts’ efforts to deal with the emerging science surrounding recombinant DNA back in the 1970’s. The article intimates that Cambridge’s success in attracting biotechnology companies was due in part to the extensive public discussion regarding EHS issues the City fostered back when rDNA labs were first opening in Cambridge.

Although the Nanotechnology Now post does not mention it, the City eventually passed a moratorium on rDNA research and development, followed by its own unique rDNA ordinance in 1977 which essentially adopted NIH guidelines for working with rDNA. (Both have since been amended/updated). Other nearby communities soon followed Cambridge’s lead: Newton, Bedford, Worcester, Boston, Somerville, Waltham, Woburn, and Malden. For those who are interested, Cambridge’s Director of Public Health previously published a helpful article outlining the history, intent, and implications of Cambridge’s rDNA ordinance which can be found at http://www.nanolawreport.com/Cambridge_Model.pdf.

For those watching nanotechnology related events in Cambridge, the City’s Director of Public Health is also convening a six month advisory board process to provide guidance to the City regarding whether or not to regulate nanotechnology research and development within City limits. While there are no current authoritative and comprehensive EHS guidelines for nanotechnology as there were with rDNA, it is a good possibility that Cambridge will attempt a similar approach with nanotechnology.

Please contact us directly for more information on Cambridge’s nanoregulatory efforts.

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Innovative Regulatory Approaches. It has been a little over a year since the American Bar Association published its "Innovative Regulatory Approaches" to Nanotechnology discussion paper in June 2006. During the intervening period, EPA published its White Paper and its TSCA voluntary framework. Both provide some general idea of where EPA is heading with environmental regulation, and in this context it is useful to take a glimpse back at the ABA paper.

The authors explained that the history of environmental regulation in the US has produced a regulatory system focused on controlling workplace exposures and end-of-pipe/fence line emissions, enacting management standards for hazardous wastes, and requiring increased information disclosure and risk assessment for new chemicals and pesticides. The authors also provided some insight into why they believe nanotechnology may require a different approach: the speed at which it is developing; competitive pressures; limited resources available to government regulators; difficulty in enacting new federal environmental legislation; level of scientific uncertainty and the complex risks involved in nanotechnology; difficulty in monitoring nanoscale releases; and the importance to the industry in maintaining public confidence.

The authors propose a new integrated approach to nanotechnology regulation to address these issues . Under this multifaceted approach, "[t]he goal would be to avoid the rote application of existing regulatory approaches to these 21st century technologies if a better way exists."

In order to accomplish this goal, the ABA authors suggest several environmental accountability, mechanisms: traditional regulation and enforcement; new approaches to regulations including flexible standards; enhanced monitoring and public reporting; well-defined liability standards, voluntary industry programs, improved public education, corporate social responsibility programs, and relevant stakeholders dialogues.

Looking back, with EPA's recent White Paper and TSCA voluntary stewardship papers published within the past 6 months, the latter mechanisms suggested by the ABA authors will undoubtedly take on renewed importance and deserve further development.

Nanomaterials as replacements for hazardous chemicals? CORDIS is reporting on a study funded by the European Parliament's Scientific Technology Options Assessment committee which looked into whether nanomaterials could serve as substitutes for hazardous materials.

In particular, the study focused on two areas where nanotechnology is already making inroads -- coatings and catalysts:

> *Two areas where nanotechnology is already making inroads as a substitute for hazardous chemicals are coatings and catalysts. Coatings can create anti-adhesive surfaces which resist things sticking to them, such as dirt, or have biocidal properties to prevent living organisms from sticking to them.*
>
> *Nanoparticles are also widely used in catalysts, although the authors point out that research in this field was already on the nanoscale, and so it is not clear to what extent future developments could be attributed to nanotechnologies.*

Nanoparticle Penetration Into Hair Follicles. Although it examined an uncommon nanomaterial (fluorescent food dye) of a size that is not truly nanoscale (320 nm), a recent paper looked into the ability of nanoparticles to penetrate into hair follicles for potential drug delivery purposes.

The paper used in vitro porcine skin testing to compare the penetration abilities of nano food dye against the same substance in non-nano form. The scientists found the nano food dye penetrated much deeper into hair follicles than its counterpart when a mechanical massage was applied to the porcine skin. Penetration results without massage were essentially the same for the two materials. The study concluded "movement of hairs may act as a pumping mechanism pushing the nanoparticles deep into the hair follicles."

The scientists also conducted a second experiment -- in vivo human skin -- to determine how long the nano food dye was retained in hair follicles compared to its non-nano counterpart. The scientists found the nano food dye was stored in hair follicles for 10 days, while its counterpart was stored for only 4 days. As a result, the paper concludes "hair follicles represent an efficient reservoir for topically applied substances," and noted this "reservoir" extends up to 200 nm into the underlying tissue. The scientists also explained the follicle "release" mechanism was natural sebum production.

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Combining both tests, the scientists believe hair follicles may be used as a successful reservoir for possible use in nanoscale dermal drug delivery applications. The paper concludes particle size "plays an important role in follicular penetration," and "[p]enetration into the hair follicles is a fast process in comparison to the release of the nanoparticles our of the follicles, which continues for some days."

> J. Loderman, et al., "Nanoparticles -- An efficient carrier for drug delivery into the hair follicles," EUROPEAN JOURNAL OF PHARMACEUTICALS AND BIO PHARMACEUTICS, Vol. 66, Issue 2, p. 159-164 (May 2007).

Nano-Nutraceuticals. At least one group has taken a hard look at nano-nutraceuticals to determine whether they might impact typical blood and urine tests. The writers note that 1/3 of American consume some sort of diet supplement including several "nano-based" products. They further note "the oral administration of metallic colloids, in particular colloidal silver protein, has been reported to have toxic effects." The writers tested certain nanoscale metal colloids to see if they interfered with clinical blood and urine tests. The writers found "nanoparticle nutraceuticals exhibited no major interference with the tests examined." However, they cautioned "[c]linical laboratories should remain vigilant for possible nanoparticle interferences, as these structures, with their diverse physical and chemical properties, are being used or advocated for use in a broad range of drug delivery applications and as imaging agents."

> J. Park, et al., Letter to the Editor "Nanotechnologic Nutraceuticals: Nurturing or Nefarious?" CLINICAL CHEMISTRY 52, No. 2 (2006).

Nano-composite Bootcamp. The National Composite Center's Nano-Composite Bootcamp was held in Dayton, Ohio on July 19, 2007. Dr. Phillip S. Wilson, President of Inspired Innovations, LLC, outlined the many benefits of nano-composites that use nano-fillers such as nano-platelets instead of conventional fillers and reinforcements.

Thermoplastic composites using nano-platelets have both high modulus and high impact resistance, a combination not achievable in conventional composites, with a smaller increase in resin specific gravity than conventional fillers. They also may offer enhanced isotropic performance; decreased thermal expansion, permeability, and flame spread; transparency; and UV resistance. Dr. Wilson predicts that nano-olefins will supplant engineering thermoplastics in many if not most current uses (except those requiring the higher temperature performance of engineering resins), although nano-filled engineering resins may move up to replace non-polymeric materials such as glass or metal in some applications. In addition, nano-platelets other than carbon/graphite can be produced in situ after larger clay particles have been combined with the resin or monomer, which eases handling and limits personnel exposure to nano-particles.

Thermosetting composites using nano-platelets have increased flexural modulus, which allows reduction of the wall thickness of molded parts without loss of stiffness. This results in material, energy, and process time savings during manufacturing as well as lower article weights, which in term results in packaging, shipping, and handling cost savings. In addition to property enhancements similar to those for thermoplastics, lower viscosity, improved surface finish, and reduced sagging of spray coatings have been noted.

The next Nano-Composite Bootcamp session is scheduled for October 4, 2007.

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Events and Publications

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.

NanoBiotech 2007. John Monica is speaking on "Environmental Issues of NanoBiotechnologies – FDA, EPA and the Media" at Rensselaer Polytechnic Institute on September 17, 2007.

nanoTX'07. John Monica is speaking on nanotechnology issues as part of the business session of nanoTX'07 at the Dallas Convention Center October 3, 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.

Nanotechnology Manufacturer's Forum. John Monica is speaking on nano-related EHS legal issues at the Nanotechnology Manufacturer's Forum taking places in Youngstown, Ohio on October 26, 2007.

NanoCon 2007. PWMA's nanotechnology practice group will be hosting the pre-conference workshop "Environmental, Health & Safety: Regulation Overview and Best Practices," on Tuesday, November 17, 2007 at SmallTimes Magazine's NanoCon in Santa Clara, California.

Risk 007: Agents of Analysis. John Monica will be speaking on nano-related legal issues at the 2007 Annual Meeting of the Society for Risk Analysis, December 9 – 12, 2007 in San Antonio, Texas.

EPA's Nanoscale Materials Stewardship Program. PWMA's nanotechnology practice group will be publishing a short article on EPA's proposed Nanoscale Materials Stewardship Program in the next print edition of Small Times Magazine.

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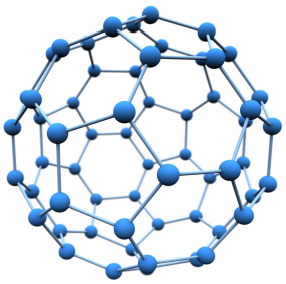

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