Legal Lookout: Nanotechnology: EPA Considers How to Proceed

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Nanotechnology is broadly defined to include technologies involving the control of materials and structures with nanoscale dimensions of 1 to 100 nanometers. Because the ratio of surface to total atoms increases exponentially with decreasing particle size, nanosized particles have uniquely large surface areas that offer special and very desirable properties for, among other characteristics, cleaning, wetability, appearance and delivery. Most technologies that are nanoparticle-based presently focus on enhancing surface modification, formulation and delivery, and light scattering properties.

These properties present significant commercial opportunity in many different business sectors. For example, because of their tremendous heat transfer and conductivity properties, certain nanostructures, namely carbon nanotubes, offer significant commercial opportunities to the electronics industry. Their small scale also has made nanostructures a compelling new component of innovative drug delivery mechanisms, among other medical applications. In the chemical manufacturing sector, nanostructured catalysts can accelerate reaction rates, offer higher selectivity for desired reaction products, and diminish the creation of unwanted byproducts, thus reducing waste and all the costs associated with disposal requirements.

Not surprisingly, much of the buzz relating to nanotechnology's promise relates to its environmental applications. Some consider nanotechnology the ultimate pollution prevention tool. Nanotubes, for example, offer superior sorbent properties for, among other substances, dioxins. Biometallic nanoparticles are reductants for polychlorinated biphenyls, some pesticides and chlorinated organic pollutants. Additionally, single-walled nanotubes (SWNT) have demonstrated efficacy when used for chemical sensing and have shown promise when used in remote, in-situ continuous monitoring devices. EPA's Office if Research and Development (ORD) and the National Center for Environmental Research are especially excited by the potential of nanotechnology in these areas. As described on its website, potential applications include "sensors for improved monitoring and detection capabilities, treatment and remediation techniques for cost-effective and specific site cleanup, green manufacturing to eliminate the generation of waste products, and green energy technology for the creation of commercially viable clean energy sources."[1]

Unanswered questions

As promising as the applications of nanosized particles, materials and structures are, there are unanswered questions relating to the potential toxicity of nanosized particles and structures, and whether their transport, potential transformation and fate in the environment could harm ecosystems. According to some researchers, the very qualities and properties that make nanosized particles so commercially attractive could make them potentially harmful under some circumstances. For example, the increased surface reactivity of nanosized particles suggests that they exhibit greater biological activity when compared with conventional bulk materials per given mass when taken up by living organisms, assuming the particles are solid. This enhanced biological activity can be beneficial, as in the case of nanosized materials being used as a drug delivery device designed to penetrate cellular barriers, or not beneficial if the biological activity

translate to enhanced toxicity that compromises cellular activity or induces some other unwanted effect.[2]

EPA and other federal agencies are engaged in research activities of varying forms to find answers to these questions. Private party research is also underway to ensure products of nanotechnology are produced responsibly.

EPA response

EPA's Office of Pollution Prevention and Toxics (OPPT) has focused its ongoing review of nanomaterials consisting of chemical substances under the Toxic Substances Control Act (TSCA) and is perhaps farther along in considering the regulatory implications of nanotechnology than other EPA program offices. The OPPT recognizes that several provisions make the Act an effective tool for assessing and managing potential risks posed by the products of nanotechnology. EPA has already made clear, for example, that nanoscale materials consisting of chemical substances not listed on the TSCA inventory would be considered new chemicals and subject to Premanufacture Notification requirements.

The more challenging area arises, however, in connection with the potential need for regulation of existing chemicals: those already in commerce and listed on the TSCA inventory. At the heart of the debate is whether existing chemicals structured as quantum dots, nanotubes, nanowires or configured in some other nanostructure to enhance specific properties for commercial value have the "same chemical molecular identity" as their conventional chemical counterparts. While EPA appears to be of the opinion that TSCA is sufficiently elastic to manage any potential risks posed by nanoscale materials consisting of chemicals, it is less clear whether and how the agency might rely upon its broad authority under the act to identify and manage potential risks posed by existing chemicals structured in nano configurations and not impose unnecessarily burdensome regulatory hurdles that could blunt innovation and commercial development.

The OPPT is scheduled to announce a public, one day meeting in Washington, D.C., to seek stakeholder views on whether and how to regulate products of nanotechnology consisting of chemical substances. EPA is also considering whether to request that developers of pertinent nanoscale materials voluntarily submit information on those materials to the agency. Such a voluntary program would provide much-needed information that would assist the agency in refining its data needs and related notification requirements, and better inform its risk assessment/risk reduction processes. How thorny issues, like confidential business information, might be addressed is unclear. EPA has, however, consistently reflected a willingness to respond quickly and sensibly to these and related issues.

Not everyone agrees that TSCA is well suited to address existing and likely forthcoming risk challenges posed by nanoscale materials and structures. Some believe, for example, that TSCA is ill-suited to address potential risks not anticipated when the law was passed in 1976. As an example, TSCA offers exemptions from Premature Notification requirements, such as the low volume exemption for those considered as low volume materials. Because of their small size, some claim that large quantities of nanoscale material could fall outside the notification requirements, despite their potential for posing precisely the types of human and environmental health risks TSCA was intended to address.

In the interim, chemical manufacturers are proceeding with their day-to-day TSCA compliance obligations independent of EPA's issuance of broader policy announcements. For example, at least one low-volume request, reportedly applicable to an SWNT, was submitted to EPA last year. Regulatory action on it is expected soon. Additionally, at least one TSCA Section 8(e) notice has been submitted on a nanoscale material.

The ORD is also preparing a public health policy statement that describes EPA's approach to nano-related research and regulation under its TSCA authority. Reportedly, the paper will be similar in structure and style to EPA's Potential Implications of Genomics for Regulatory and Risk Assessment Applications at EPA, prepared by the agency's Science Policy Council's Genomics Task Force Workgroup and issued in December 2004.[3] The paper is expected much later this year.

Air and waste offices

Work in nanotechnology from other EPA program offices is less clear. For example, while EPA's Office and Air and Radiation (OAR) has considerable expertise in fine particulate health issues given its work in the National Ambient Air Quality Standards (NAAQS) area, it is not clear whether and how this expertise has transferred into interest in applications of nanotechnology. The National Nanotechnology Initiative, the federal government's coordinating body of all things nanotechnology, has made much of the promise the technology holds for sensors and sensing devices, particularly to detect toxins and assist in discerning their source. In light of this clear interest, it is reasonable to assume that OAR is very much engaged in reviewing applications of nanotechnology and considering legal authorities that may be invoked both to expand research opportunities and to regulate applications of nanotechnology in these areas.

Similarly, EPA's Office of Solid Waste and Emergency Response (OSWER) also has a clear interest in nanotechnology's fate. A quick review of EPA's ORD Science to Achieve Results, or STAR, website confirms the obvious application of nanotechnology in contamination remediation and filtration devices.[4] Whether and how OSWER is engaged in a more comprehensive review of EPA's regulatory authority is unclear.

The regulatory implications of nanotechnology will almost certainly pose formidable scientific, regulatory and science policy challenges for regulators, risk assessors and manufacturers alike. Lawyers, risk assessors and others tasked with regulatory compliance, risk assessment, product liability and related responsibilities should monitor this area closely to ensure they remain abreast of the many diverse and important legal, regulatory and science policy developments in this area. ***PE***

REFERENCES

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