Analysis&Perspective

TOXIC SUBSTANCES

NANOTECHNOLOGY

Manipulating matter at the nanoscale is now a commercial reality. Nanoscale zinc oxides are used in sunscreen lotions and scratch-resistant glass. Digital camera displays, high resolution printer inks, and high-capacity computer hard drives are among the available products of nanoscience and nanoengineering. In this article, the authors offer general observations regarding the environmental implications of nanotechnology and whether and how existing regulatory controls are suitable to address them. When it does come, according to the authors, environmental regulation almost certainly will look first to the existing statutory framework. Unless nanotechnology confronts lawmakers with urgent and troublesome surprises, the basic set of tools will be what is available now.

The Environmental Regulatory Implications of Nanotechnology

By Lynn L. Bergeson and Bethami Auerbach

Background

As futuristic as it sounds, manipulating matter at the nanoscale is now a commercial reality. Nanoscale zinc oxides are used now in sunscreen lotions and scratch-resistant glass. Nanoscale fibers are used in stain-resistant fabrics. Digital camera displays, high resolution printer inks, and high-capacity computer hard drives are among the commercially available products of nanoscience and nanoengineering.

Demand for domestic nanomaterials in 2002 was estimated at a modest $200 million. Growth projections are an impressive 33 percent a year. The National Science Foundation has estimated that by 2015, nanotechnology applications may be valued at more than $1 trillion in the global economy.

Lynn L. Bergeson is a founding shareholder of and Bethami Auerbach is Of Counsel to Bergeson & Campbell, P.C., a Washington, D.C. law firm concentrating on industrial, agricultural, and specialty chemical and medical device product approval and regulation, product defense and litigation, and associated business issues. The views expressed herein are those solely of the authors. This article is adapted from an earlier article that appeared in The Environmental Forum, published by the Environmental Law Institute. The opinions in this article do not represent those of BNA, which welcomes other points of view.

This is the world of the truly small. The science and technology of controlling matter at the nanoscale is captured under the umbrella term "nanotechnology," and involves controlling the structure and properties of materials and systems at the scale of 10^{-9} meters—1/100,000 the width of a human hair or ten times the diameter of a hydrogen atom. To help visualize, consider that an atom is 1/10,000 the size of a bacterium, and a bacterium is 1/10,000 the size of a mosquito. An atomic nucleus is 1/100,000 the size of the atom itself.

Mindful of its tremendous commercial potential and desirous of being a leader in the race to distinguish the United States in the global nanotechnology arena, the federal government is and has been supportive of nanotechnology. To coordinate federal research and development programs in the field, a federal interagency workgroup was formed in 1996 to consider the creation of a National Nanotechnology Initiative, which was officially established in Fiscal Year 2001.

The goals of the National Nanotechnology Initiative are to conduct research and development to realize the full potential of nanotechnology; to develop the workforce necessary to advance these research and development efforts; to understand better nanotechnology's associated societal, health, environmental, and ethical considerations; and to facilitate the transfer of nanotechnologies into commercial applications.

Sixteen federal agencies, including the Environmental Protection Agency, participate in the National Nanotechnology Initiative. Ten of the agencies have a research and development budget dedicated to nanotechnology. Other federal organizations contribute to the initiative through studies and other forms of collaboration.

The Nanoscale Science, Engineering, and Technology Subcommittee is the group that provides the primary coordinating mechanism for the initiative.

At the request of the White House Economic Council and the various agencies participating in the National Nanotechnology Initiative, the National Research Council agreed to review the initiative to assess the suitability of federal investments in nanotechnology, the interagency coordinating efforts in this regard, and the initiative's research portfolio.

The National Research Council's June 2002 report on its review is overwhelmingly positive and commends the leadership and structure of the National Nanotechnology Initiative.[1] Importantly, however, the National Research Council made ten recommendations to enhance the initiative's effectiveness. Among them was the development of a ''crisp, overarching strategic plan that emphasizes long-range goals that move results out of the laboratory and into the service of society'' Other of the recommendations emphasized a strong need for inter-agency collaboration, focused research, and the development of clear metrics against which to assess the effectiveness of the National Nanotechnology Initiative in meeting its goals.

The federal government's support is illustrated by Congress's passage of S. 189, and President Bush's swift signing into law of The 21st Century Nanotechnology Research and Development Act on Dec. 3, 2003 (Public Law 108-153). The law authorizes $3.7 billion over four years in federal support for nanotechnology, funds the National Nanotechnology Initiative, creates various federal ''centers'' to coordinate and promote research, and establishes various advisory boards and review processes to set national goals and benchmarks for progress in achieving them.

The government is aware that even if the National Science Foundation's prediction that by 2015 the market for nanotech products and services is only one-third correct, this amount would represent over 3 percent of the gross domestic product of the United States. The Bush administration has increased each year the amount of money dedicated to nanotech research and has supported aggressively the National Nanotechnology Initiative, identifying it as one of the administration's highest multi-agency research and development priorities.

Environmental and Natural Resources Applications

The infusion of federal money authorized by Congress will make nanotechnology and nanoengineering research even more robust and will hasten the development of products in many market sectors. Among them, the ongoing challenges posed by the national goals of protecting human health and the environment and of managing and preserving dwindling natural resources offer promising opportunities for nanotechnology.

[1] The National Research Council's report, *Small Wonders, Endless Frontiers: A Review of the National Nanotechnology Initiative*, is available at http://books.nap.edu/books/0309084547/html/1.html#pagetop on the World Wide Web.

In the environmental and natural resource arenas, nanotechnology offers particularly attractive benefits in three key areas—new tools to detect, monitor, and reduce pollution; the availability of environmentally-benign manufacturing processes; and the production of cleaner, less expensive energy.

Nanotechnology is perhaps the ultimate sustainable development tool. Advances in the ability to manufacture products at the molecular level offer unprecedented opportunities to manipulate matter in ways that optimize the ability to engineer out of the process unwanted waste and by-product materials.

Nanotechnology offers tremendous potential in the area of ecological forecasting. According to *Ecological Forecasting*, a report prepared by the Senate Environment and Natural Resources Subcommittee on Ecological Systems, nanotechnology enhances our very ability to ''measure, monitor, and understand the complex structures and activities of living systems.''

Smart dust, for example, nanostructured particles of silicon, is composed of computerized communicating sensors the size of dust particles. Dispersed throughout the atmosphere, smart dust can relay information about weather conditions, pollutants, and chemical weapons, among many other uses. These same nanosensors may be used to understand the dynamics of the smallest elements of an ecosystem and thus help to unlock mysteries that now impede our ability to protect it.

EPA's Science to Achieve Results grants program is nurturing the development of many similar nanotechnologies and has directed $6 million to support research at 16 universities in various nanotechnology applications likely to benefit the environment. Examples of the more promising grant programs include research at the University of California/San Diego to develop nano-based sensors for real time, remote detection of certain metals to facilitate the process of tracking and treating them; research at Clemson University to explore the potential of plasmon-sensitized titanium dioxide nanoparticles to use solar energy more efficiently; research at the University of Miami to develop nanoscale sensors for the detection of destructive marine toxins; and research at Carnegie Mellon University to develop and test ''smart'' nanoparticle assemblies that are transportable in porous media and capable of identifying and degrading dense non-aqueous phase liquids. The latter are liquids denser than water and not easily mixed or dissolved in it, whose tendency to penetrate the water table and to sink into an aquifer makes them a source of persistent groundwater contamination, also capable of migrating rapidly in the subsurface due to their typically low viscosities.

Another EPA grant program, the Small Business Innovation Research program, is funding eleven projects for approximately $1 million for various nano-based products. These range from the use of nanocomposite-based filters with nanosized activated alumina to remove arsenic from drinking water to meet the new Safe Drinking Water Act standard of 10 parts per billion to the use of nanofibrous manganese dioxide to control emission of volatile organic compounds. These research initiatives are impressive in their sheer number and versatility and in the promise each holds in protecting the environment and public health.

Manufacturing at the molecular level is of critical importance to the National Nanotechnology Initiative, which considers manufacturing at the nanoscale to be a

DEN ISSN 1060-2976

prerequisite for realizing the benefits of nanotechnology. Conventional manufacturing processes require large quantities of bulk materials for production. The process necessarily generates waste and by-products, much of which typically are destined for disposal rather than beneficial reuse. This last fact is less an indictment of our ability to recycle than a consequence of the top-down machining approach to production and the inevitable generation of unwanted materials. In bottom-up manufacturing, the raw materials of the process are atoms and molecules, and only materials intended to be used in the nanofabrication process are involved. The configuration of nanoscale components in macroscale devices holds tremendous promise for green manufacturing and for the significant reduction of manufacturing waste materials.

In the environmental area, also, nanotechnology is the basis of innovative technologies that are and will be applied to treat and remediate contaminants.

Researchers at Lehigh University discovered nanoscale particles on metallic iron may remediate contaminated groundwater. They found nanoparticles injected into groundwater contaminated with trichloroethylene (TCE) degraded the TCE into more benign products when palladium or platinum was added to iron nanoparticles to enhance the rate of the degradation process. In one field study, TCE levels were reduced up to 96 percent in groundwater. Other contaminants, including chlorinated hydrocarbons, certain pesticides, perchlorate, and PCBs, all have successfully been broken down using these nanoparticles. Employing the nanotechnologies noted above to target and break down dense non-aqueous phase liquids, as well as related applications, holds out tremendous promise in advancing environmental remediation strategies.

While not as dramatic, nanotechnology applications in the world of apparel could improve significantly the ability to protect people whose livelihoods cause them to be exposed to chemicals in worst-case release scenarios and to other potentially harmful agents. Apparel manufacturers are now producing stain-resistant products that embed fabrics with hair-like fibers or ''nanowhiskers'' to prevent liquids from penetrating the fabric. Such resistance has obvious application in protecting industrial and agricultural workers, HazMat and other emergency first responders, and even in anti-terrorist and military applications of one form or another.

Nanotechnology's utility in the resources area is equally significant. The National Nanotechnology Initiative holds that nanotechnology portends significant improvements in solar energy conversion and storage, thermoelectric converters, high-performance batteries and fuel cells, and greatly enhanced electrical power transmission lines. Collectively, these advances could make energy more abundant, cleaner, and less expensive.

According to the Foresight Institute, in a scholarly white paper by Dr. Stephen L. Gillett, *Nanotechnology for Clean Energy and Resources*, molecular nanotechnology will play a ''major part of solving the issues of both sustainable resource extraction and byproduct mitigation,'' and the ''most critical'' application of molecular nanotechnology is for these uses.[2]

Two potential applications of nanotechnology in resource-related areas stand out. First, nanotechnology may hold the key to enhancing energy efficiency. In what Gillett refers to as the ''Promethean Paradigm,'' our wasteful and inefficient energy management style is largely a function of our use of energy as heat. That is, fuels are burned. Burning a fuel, however, wastes most of its energy, but the ability to utilize chemical energy without thermalizing it requires molecular restructuring. The creation and use of nanostructured devices such as fuel cells, the use of nanostructured materials to decrease transportation costs, and more effective by-product elimination through the use of molecularly tailored catalysts will all greatly increase our energy efficiency.

A second key area where nanotechnology is expected to affect resources is energy extraction and resource management. Access to subsurface information is essential when extracting materials from an underground energy source but is very difficult to obtain. Nanotechnology already is helping to retrieve and process seismic data to picture underground structures, thus facilitating efforts to locate and extract energy from subsurface sources.

Another application of nanotechnology is in the use of nanoscale sensing technologies to maximize the collection of energy from solar, tidal, surf, and related diffuse energy sources. It is well established that each of these diffuse sources potentially contains tremendous amounts of energy. The challenge has been to harness the power inexpensively and to manage it efficiently.

The large-scale fabrication of nanostructured materials has many energy-related applications, including the direct use of solar power; the use of thermoelectric materials to maximize the availability of small thermal energy sources; and the use of superstrength materials to harness the potential energy in surf, which otherwise would require, for example, log cables to reach the sea floor and to withstand turbulent weather conditions.

Professor Gillett's white paper is recommended reading for those interested in learning more about nanotechnology's potential to ensure abundant, cheap, and clean energy.

Regulatory Issues

The specific environmental, resource, and human health effects of nanotechnology, as a manufacturing process, as well as the environmental implications of using any specific product of a nanotechnology manufacturing process, are to a large extent unknown. Accordingly, any assessment of whether and how currently available environmental authorities might apply and, if so, how effectively they address these implications is necessarily speculative.

If its commercial applications are still in their early years, the environmental regulation of nanotechnology is in its infancy.

As an active participant in the National Nanotechnology Initiative, EPA's primary focus, in research dollars, has been on ''green nanotechnology,'' the pollution pre-

[2] *Nanotechnology for Clean Energy and Resources* is available at http://www.foresight.org/impact/GillettWhitePaper.txt on the World Wide Web.

vention and cleanup gains that nanotechnology holds out the promise of achieving. EPA is just beginning to fund risk studies that will be an important part of the future regulatory equation.

Even the most enthusiastic nanotechnology proponents recognize nanotechnology may have an environmental downside. It is generally recognized that the very ''nanonature'' of the substances involved, their breathtaking smallness, does not rule out their potential to be harmful to health or to the environment. From a pulmonary health standpoint, for example, small is not necessarily beautiful.

Any exploration of the health or environmental risks involved when nanotechnology comes into commercial use is complicated by the basic fact that, as with the universe of known pollutants, different nanoparticles or nanomaterials vary in their properties, in their potential to do harm, and in their amenability to existing control measures.

The modest body of early research on health effects related to the use of nanotechnology has yielded mixed results, some of them described at a symposium during the spring 2003 American Chemical Society national meeting. From a regulatory standpoint, certain of the research has been more in the province of the Food and Drug Administration than of EPA. Nanoparticles have promise in drug-delivery applications, and initial studies have shown them capable of crossing the ''blood-brain'' barrier without harming the brain in the process. Other research reviewed at the American Chemical Society meeting has shown that silica-coated nanocrystals could be incorporated safely into living cells, with no apparent harmful effects, for the purposes of studying the potential for cancer to spread at the level of the cell.

Of more pointed relevance for environmental regulation were the inhalation studies discussed at the American Chemical Society meeting.

Studies by Dr. Günter Oberdörster, a University of Rochester toxicologist and a leading proponent of the link between ultrafine particles and respiratory tract toxicity, have shown that ultrafine particles (those < 0.1 micrometer) are considerably more successful than larger particles in producing an inflammatory response in the lung. Ultrafine particles encompass nanoparticles, which are an order of magnitude smaller, at < 0.01 micrometer.

Dr. Oberdörster expressed concerns about the flipside of the ability of ultrafine particles to cross the blood-brain barrier, their potential to affect the central nervous system adversely, and called for more research in the area.

The generation of ultrafine particles, of course, is scarcely limited to applied nanotechnology. Ultrafine particles are ubiquitous in urban areas, as a product of gasoline exhaust and industrial processes, and those ultrafine particles ultimately may pose a far more substantial health threat than will the particulate byproducts of nanotechnology applications.

Researchers recommend going beyond instillation work and performing inhalation studies to try to shed more light on the operative toxicity mechanisms. Additional insight into the potential pulmonary toxicity of nanotubes will be a necessary, but not a sufficient, basis for the development of sound environmental regulatory policy. To assess the risks posed by nanotubes and other nanotechnology products, it will be essential to understand the exposure pathways as well. Without realistic means for human exposure to occur, toxicity findings become accordingly less meaningful. More research should fill in many of the blanks, but the answers will take time.

As is evidenced by the strong Bush administration support for swift passage of the 21st Century Nanotechnology Research and Development Act last December, nanomaterial research is an administration science priority. Several ongoing research initiatives provide further support for this fact. For example, the National Academies Keck Futures Initiative focuses on, among other activities, nanoscience and nanotechnology. The Future Initiatives is a 15-year effort to stimulate interdisciplinary inquiry and to enhance communication among researchers, funding agencies, universities, and the public. On April 5, 2004, the National Academies called for applications to fund researchers to attend a November 2004 conference in California that will focus on designing nanostructures at the interface between biomedical and physical systems.

Additionally, the National Toxicology Program Interagency Committee for Chemical Evaluation and Coordination last July recommended one or more types of toxicological studies for 13 substances, including nanoscale materials.[3]

Nanoscale materials were nominated to the interagency committee for study by the Rice University Center for Biological and Environmental Nanotechnology because of ''[i]ntense current and anticipated future research and development focus; further studies and development of appropriate toxicological methods are needed to adequately assess health effects.''[4] The interagency committee nominated several studies for nanoscale materials—size and composition-dependent biological disposition of nanocrystalline fluorescent semiconductor materials; toxicological characterization of high aspect ratio carbon nanomaterials; role of particle core and surface composition in the immunotoxity of the above listed materials; and phototoxity of representative metal oxide nanoparticles.

More recently, the National Toxicology Program Board of Scientific Counselors last September discussed the need to study toxic and other health effects from exposure to nanomaterials and approved the interagency committee's recommendation.[5]

The data gaps these research initiatives are intended to fill underscore the very speculative nature of any discussion of how to regulate the environmental effects of commercial nanotechnology. But some observations and projections can be made. When it does come, environmental regulation almost certainly will look first to the existing statutory framework. Amending any one of

[3] The National Toxicology Program's July 16, 2003, announcement of substances recommended for study is available at http://ntp-server.niehs.nih.gov/htdocs/liason/03JunICCECFR.pdf on the World Wide Web.

[4] Id. The nomination describes titanium dioxide as a ''potent photocatalyst[] because of the generation of OH radicals through light absorption.'' See Letter from Vicki Colvin, director of the Center for Biological and Environmental Nanotechnology, Rice University, to NTP Nominations Faculty, National Toxicology Program/NIEHS (May 19, 2003) at 6, available at http://ntp-server.niehs.nih.gov/htdocs/Chem_Background/pubNomSupport/NanoscaleNom.pdf on the World Wide Web.

[5] ''Exposure to Nanoscale Materials Considered Important for Toxicology Program Research,'' *Daily Environment Report*, Sept. 12, 2003, p. A-10.

the environmental laws, much less enacting major new legislation, can be a slow and contentious process. Unless nanotechnology confronts lawmakers with urgent and troublesome surprises, the basic set of tools will be what is available now.

Toxic Substances Control Act

The Toxic Substances Control Act (TSCA) is one of the statutes under which commercial applications of nanotechnology are likely to be regulated, in that it authorizes EPA to review and, if appropriate, to establish limits on the manufacture of new chemicals. Typically, under TSCA Section 5, the manufacturer of a new "chemical substance" (a term defined in the law) must submit a pre-manufacture notice, including toxicity and other data, to EPA at least 90 days before production of the chemical is to begin. During the prescribed 90-day review period, EPA may initiate rulemaking to regulate manufacture of the new chemical substance or may enter into an agreement with the manufacturer that imposes limits on its production. In most cases, EPA will not take such action, and the manufacturer may go ahead with production of the chemical, subject to recordkeeping, reporting, the well-known "TSCA Inventory," and other statutory requirements.

New chemicals otherwise subject to TSCA may be candidates for the exemptions provided under the law. The statutory research and development exemption, which may cover some early-stage nanotechnologies, avoids the pre-manufacture notification process without requiring EPA's approval of an exemption application. Other available exemptions from the full-scale pre-manufacture notification process, which require an application and pre-production approval by EPA, may be based on either low volume manufacture (under 10,000 kilograms/year of the chemical); low environmental releases and human exposure, together with low volume; or plans for limited test marketing.

Passing through, or by-passing, the pre-manufacture notification process and complying with applicable reporting and recordkeeping requirements do not prevent EPA from revisiting a chemical's status under TSCA, especially where the relevant information expands over time, as is likely with nanotechnology. EPA may take the position that a given nanotechnology application is a "significant new use" and, on that basis, may require test data that will enable it to explore whether the adoption of a significant new use rule is called for. Initiation of the significant new use process could result in limits on the manufacture of a chemical substance and represent another set of requirements with which to contend. The nature of nanotechnology, with its limited environmental impact database and the relative unfamiliarity of the chemicals involved, makes it possible that EPA will consider a given application to be a "new use" of an existing chemical instead of a "new chemical substance."

Ultimately, TSCA also provides EPA with the tools to respond where information comes to light that supports the finding that the manufacturing, processing, distribution, use, and/or disposal of a chemical substance will present "an unreasonable risk of injury to health or the environment." If EPA can sustain the substantial burden of proof involved, TSCA Section 6 allows it to impose one or more of an array of regulatory measures, including an outright prohibition, to "protect adequately against the risk."

The law requires EPA to use "the least burdensome requirements," however. EPA does not resort often to Section 6, and its track record has not been uniformly successful when going that route. But the Section 6 authority is available to EPA should future health or environmental data about approved nanotechnology applications warrant a greater degree of, or different, regulation under TSCA than originally determined.

The potential applicability of TSCA to nanotechnology is addressed in *Nanotechnology & Regulation: A Case Study Using the Toxic Substance Control Act*, an informative discussion paper prepared in 2003 by Ahson Wardak of the University of Virginia, with EPA input, under the auspices of the Foresight and Governance Project of the Woodrow Wilson International Center for Scholars. The paper, which uses carbon nanotubes as a test case, raises a variety of issues for consideration in the TSCA context and is helpful to those who wish to explore further how TSCA might apply to nanotechnology.[6]

EPA is keenly aware of this debate. Reportedly, decision makers in EPA's Office of Pollution, Prevention, and Toxic Substances are now considering whether and, if so how, TSCA might be applied within a broader regulatory framework to address potential risks posed by the nanoconfiguration of existing chemicals. Simply put, a key question is whether a nanoconfiguration of a chemical, carbon, for example, which is intended to impart new chemical and/or physical properties, should be considered a new chemical, a significant new use of an existing chemical, a modified but not significant new use of an existing chemical, or none of the above because the TSCA framework is ill-suited to address these issues. EPA would contend that its discretion under TSCA in these areas is broad, and the "significant new use" approach may thus hold some appeal.

That being said, however, daunting issues arise, not the least of which is managing the nomenclature of nanochemicals. The American Chemical Society's Chemical Abstract Service maintains the registry of chemical substances and assigns a CAS number to each chemically unique substance. While some nanoengineered chemicals have been assigned a CAS number, it is by no means clear the existing CAS system is the best or only system to use to inventory these chemicals and to address the challenging nomenclature issues that defining nanochemicals invites.

Occupational Safety & Health Act

A final and important point about the potential applicability of TSCA relates to the research discussed above suggesting the inhalation of nanoparticles may result in pulmonary toxicity. Where this occurs in the process of a commercial application of nanotechnology (rather than from breathing urban air), the exposures of concern are likely to be occupational ones. While the regulation of chemical exposures in the workplace are subject to regulation by the Occupational Safety and Health Administration, EPA has used TSCA as a means for exercising its own regulatory authority to minimize workplace exposures. Whether or not this is an appropriate

[6] *Nanotechnology & Regulation: A Case Study Using the Toxic Substance Control Act* is available at http://www.environmentalfutures.org/nanotech.htm on the World Wide Web.

exercise of its TSCA authority, EPA might be expected to use it again for this purpose in the future.

That said, the nascent nanotechnology industry and other interested parties should be prepared to work with OSHA in establishing air contaminant permissible exposure limits under 29 C.F.R. Section 1910, Subpart Z for nanoparticles in the workplace and such other requirements as hazard communication measures (under Section 1910.1200) and the use of suitable personal protective equipment (under Section 1910, Subpart I) to minimize risks to employees as more is learned about exposure pathways.

Similarly, non-governmental agencies, including the American Conference of Governmental Industrial Hygienists can be expected to begin to explore establishing the need to develop threshold limit values for workplace exposures to nanoparticles believed capable of posing harm.

Another key workplace issue manufacturers and others must address involves hazard communication. Potential hazards posed by nanoengineered chemicals and materials would be expected by OSHA to be disclosed on material safety data sheets under OSHA's Hazard Communication Standard.

According to Clayton Teague, director of the White House National Nanotechnology Coordination Office, guidance describing "best practices" needed to protect laboratory researchers and others who work with nanoengineered materials may be forthcoming soon. Teague spoke at the National Nanotechnology Initiative conference in Washington, D.C., in April 2004 and reported that the guidance is on a fast track.[7]

Clean Air Act

Another environmental statute under which nanotechnology eventually may be regulated is the Clean Air Act. Particulate matter is one of the "criteria pollutants" for which EPA has established national ambient air quality standards under Sections 108 and 109 of the Clean Air Act and which the states must implement under Section 110.

In 1997, EPA adopted a controversial revision to its Clean Air Act regulations, which, among other things, established an ambient air quality standard of 15 μg/m3 (annual standard) and 65 μg/m3 (daily) for fine particulates of less than 2.5 micrometers (PM2.5). After protracted litigation, including a trip to the Supreme Court on questions of constitutionality and authority, in 2002 the Court of Appeals for the District of Columbia Circuit upheld the PM2.5 standards.

Their nationwide applicability notwithstanding, the PM2.5 standards will not have a direct impact on individual industrial sources of nanotechnology products. The standards apply through the states' plans to the various air quality control districts within each state, rather than directly to individual sources. Any control measures necessary to meet the standards, which will apply only in certain geographic areas, are likelier to be aimed at larger sources of fine particulate matter. Potentially, emission controls could be translated into specific limits on individual manufacturers that employ nanotechnology —for example, in connection with the construction and operating permits required for major new and modified emissions sources—but various triggers must be met before any given nanotechnology manufacturer would become subject to such permit limits.

In a more speculative future, and one in which nanotechnology was significantly more widespread, the industry (and subgroups within it) could become subject to hazardous air pollutant standards promulgated by EPA under Section 112 of the Clean Air Act.

Section 112 standards allow EPA to target pollutants of concern on an industry-wide basis, but only after the pollutants at issue are added to a long list required by law. For a substance to be added to the Section 112 list, EPA must find it is an air pollutant and its "emissions, ambient concentrations, bioaccumulation or deposition . . . are known to cause or may reasonably be anticipated to cause adverse effects to human health or adverse environmental effects."

If identified pollutants of concern were eventually added to the list (or if production using nanotechnology generated already-listed pollutants), EPA would proceed to establish, through rulemaking, technology-based control standards, probably after dividing the industry into subcategories; later, health-based standards could kick in, if needed, to address "residual risk" remaining after a period of years. Only "major" sources would be subject to the regulatory control measures, although by the time such hypothetical measures could be in place, nanotechnology likely would be mature enough and individual production units large enough, that many of them would be "major" for Section 112 purposes.

Resource Conservation and Recovery Act

A maturing industry, along with data regarding the environmental fate of process wastes, should provide a clearer picture of how the provisions of the Resource Conservation and Recovery Act will affect nanotechnology in commercial production.

Assuming that wastes from an applied-nanotechnology facility met the criteria for a RCRA waste, either through listing or by exhibiting one of RCRA's specified hazardous waste characteristics, the facility would acquire "generator" status under Section 3002 and, as such, would be subject to the recordkeeping, reporting, manifesting, and safe handling requirements under that provision. Small generators, those that generate hazardous wastes in quantities between 100 and 999 kilograms during a calendar month, are subject to separate regulations, whereas generators that also treat, store, or dispose of hazardous wastes onsite are subject to far more extensive requirements under Section 3004. Applied nanotechnology facilities probably are likelier to be subject to the former than the latter, at least in the near term.

RCRA may well be sufficiently elastic to accommodate any new and now unknown hazards associated with "nanowaste." If, for example, nanotechnology processing waste, such as it is, poses hazards to human health and the environment when disposed, RCRA's waste identification criteria would seem well suited to apply and prevent the types of health hazards that more conventional manufacturing waste are now believed to pose when managed carelessly. It is not too much of a stretch, for example, to envision EPA designating a specific waste listing under 40 C.F.R. Section 261.32 (hazardous waste from specific sources) to capture waste

[7] "White House Says Changes to Controls May Be Needed, Not Whole New System," *Daily Environment Report*, April 2, 2004, p. A-7.

  DEN ISSN 1060-2976

from specific nanotechnology processes that are believed to pose specific and uniquely ''nanohazards.''

National Environmental Policy Act

A final environmental statute that deserves mention here is the National Environmental Policy Act. Insofar as nanotechnology research is being funded by the federal government, the projects involved can be considered, in the well-know parlance of NEPA, to be ''major Federal actions significantly affecting the quality of the human environment.'' As such, these federally-funded research projects arguably are subject to NEPA's environmental impact statement requirement before the decision to proceed with the proposed funding is made final. Whether anti-technology activists will make serious resort to NEPA as a means to impede nanotechnology research remains to be seen. NEPA litigation has the potential to hobble almost any project. Nevertheless, nanotechnology has taken off to the degree that it seems more productive to explore how best to extract its environmental benefits and to minimize its adverse impacts rather than to try to shut off a federal support effort that is well underway.

Precautionary Principle

Brief note should be made of the application of the Precautionary Principle to all of this. While not a statute, it is nonetheless an important legal concept that will have enormous application in this area. As is the case with any new technology—certainly one with as many potentially far reaching consequences as nanotechnology—there will be a chorus of advocates urging the government and the private sector to go slowly, mindful of what is unknown about any potential risk posed by the nanotechnology manufacturing process as well as any of its products. The implications of the application of the Precautionary Principle are well beyond the scope of this article. Suffice it to say its rigid application could well blunt many of the promising opportunities to enhance human health and the environment that nanotechnology offers. How, to what extent, and under what circumstances will entrepreneurs, government, and private sector stakeholders need to temper their enthusiasm in the face of caution at all costs will be a hotly debated topic for some time to come.

Conclusion

To the extent hindsight is always 20/20, we see the need for, and the wisdom of, considering now the full complement of issues that the advent of a revolution in manufacturing suggests. There are many such issues, the resolution of which will challenge even the most creative thinkers. They cover the gamut from the very general—what is the government's role; should the nanotech industry regulate itself; is regulation even necessary or appropriate; how is the Precautionary Principle applied in these circumstances; what ethical considerations should apply when developing nanotechnologies—to the specific—is an ultrafine particle subject to regulation under OSHA and the Clean Air Act; is an existing chemical that has been reengineered at the molecular level to enhance certain physical and/or chemical properties the same chemical for TSCA purposes. The commercialization of nanotechnologies soon will compel answers to these and many other questions.

EPA's Office of Research and Development is well aware of these issues and is an active participant in the international science debate involving nanotechnology. As a member of the National Nanotechnology Initiative, EPA also is actively pursuing the implications of nanotechnologies and their application in the areas of sustainable development, pollution prevention/pollution remediation strategies, and green manufacturing.

Despite these significant initiatives, the social, regulatory, ethical, scientific, and economic implications of nanotechnology are still ''flying below radar'' to a very large extent.

Greater public discourse may hasten the development of a conceptual framework for addressing the core science policy, regulatory, and ethical issues—some of which are less cerebral than they first appear—and for ensuring the public is fully aware of the significant benefits and potential risks that nanotechnology poses.

At the international level, the potential dangers of commercialized nanotechnology are more front-and-center than they are domestically, not unlike the negative hype about genetically modified organisms which has been, and remains, uniquely robust in the European Union. Lessons learned from that experience suggest that early, open, and informed communication about nanotechnology, its risks and benefits, and its considerable commercial promise is essential.

EPA and its sister agencies, the Department of the Interior and the Department of Energy, along with other stakeholders, including industry, non-government organizations, and research institutions, are well suited to foster opportunities for such debate. This will help to ensure careful and deliberate thought about the environmental, health, safety, and resource policy implications of nanotechnology keeps pace with the lightning speed of the development of nanotechnology itself.