

## No Small Task: Regulating Nanotechnology To Ensure Safety, Maximize Benefits

Anotechnology is about engineering at the same size as large molecules like DNA, which is two nanometers wide — a nanometer is a billionth of a meter — or even smaller. Smallness has its virtues. Nanoscale zinc oxide diffracts light better, making a better sunscreen. Similarly, ultrathin nanoscale films are improving the efficiency of cell phone screens and photovoltaics. In the future, moving molecules around at the nanoscale holds the hope of ultra-low-pollution energy, near-zero-waste manufacturing, and easier remediation of all kinds of problems.

But nanotech engineered materials, which can be on the same scale as viruses, enzymes, and proteins, have raised concerns that like these biological items they too can move easily into living cells. More difficult for regulators, a substance that is chemically identical can have entirely different properties when engineered at the nanoscale, compared to its bulk scale counterpart. Further, because they are tiny, nanomaterials might easily escape detection in the environment, causing damage and difficulty in cleaning up.

The problem is not necessarily easily resolved for regulators. Even though the Toxic Substances Control Act allows EPA to regulate "new" chemicals through its Pre-Manufacture Notice process, for instance, it is not immediately clear whether a substance already regulated as an "existing" chemical at the bulk scale would or should be reviewed as a new chemical if the nanoscale chemical exhibited new properties not exhibited in its bulk-scale counterpart.

How does society provide for the development of nanotechnology to reap its potential benefits, while protecting public health and the environment?

After all of our panelists had answered our question, EPA held a public meeting to solicit perspectives on how it should address potential risks of nanotechnology. The agency proposed developing, with broad stakeholder participation, a voluntary data-gathering program to facilitate its experience with reviewing and assessing nanoscale materials. Without taking a joint position on the merits of such a program, the American Chemistry Council CHEMSTAR Nanotechnology Panel and Environmental Defense submitted to EPA a Joint Statement of Principles, which states several objectives for any government or industry effort to consider in the responsible development of nanotechnology.

Copyright © 2005, The Environmental Law Institute®, Washington, D.C. Reprinted by permission from The Environmental Forum®, July/August 2005



Larry S. Andrews Chairman American Chemistry Council CHEMSTAR Nanotechnology Panel

"Our panel believes that a voluntary pilot program can generate significant information, greatly enhancing EPA's and other stakeholders' understanding of engineered nanoscale materials."



**Lynn L. Bergeson** Managing Director Bergeson & Campbell, P.C.

"If the right-to-know movement taught us anything, it is that the public's perception of safety is essential and no emerging technology will survive without broad public support."



**Richard Denison** Senior Scientist Environmental Defense

"The rapid pace of development and commercial introduction of nanomaterials is outpacing efforts to understand their implications."



**E. Donald Elliott** Chair, Environment, Health and Safety Department Willkie Farr & Gallagher LLP

"Learn the lessons of the biotech revolution and lobby the Bush administration to regulate nano now under the guidance of the National Academy of Sciences using existing EPA and FDA authority."



William H. Farland Acting Deputy Assistant Administrator for Science Environmental Protection Agency

"The challenge for environmental protection is to ensure that, as nanomaterials are developed and used, we minimize unintended consequences of exposures to humans and ecosystems."



**Kristen Kulinowski** Executive Director for Policy Rice Center for Biological and Environmental Nanotechnology "Since nanotechnology shows no signs of slowing down, dealing with potential implications of nanomaterials must not wait until a sufficient body of knowledge — whatever that might mean — is available to guide policymakers."

## ACC Panel: Realize Promise, Minimize Risk

LARRY S. ANDREWS

pplications of nanotechnology offer significant societal and sustainable. development advancements, many of which could provide direct environmental benefits. Nanotechnology products offer, for example, the potential for improved energy production, environmental remediation, solar power production, among many other benefits that could greatly enhance the quality of life. It is everyone's goal, however, to identify nanotechnology's potential risks and to ensure protection of human health and the environment.

The American Chemistry Council CHEMSTAR Nanotechnology Panel believes that responsible development and regulation of nanomaterials in an open and transparent process will best assure the public that nanomaterials are being developed in a way that identifies and minimizes potential risks to human health and the environment. The Nanotechnology Panel supports nanotechnology products and applications consistent with the Responsible Care Program to ensure that the commercialization of nanoscale materials proceeds in a way that protects workers, the public, and the environment.

The panel believes that manufacturing operations involving engineered nanoscale materials need to employ an abundance of caution while more is learned about potential human health and environmental hazards. Panel member companies have been safely manufacturing and marketing nanoscale materials for many years, and the Material Safety Data Sheets that are required by the Occupational Safety and Health Act have been the primary tool for communicating risks and how to manage them.

### THE FORUM

Additional research is today underway by a consortium of companies — many of which are panel member companies - that will greatly contribute to enhanced workplace safety. The Nanoparticle Benchmarking Occupational Health Safety and Environment Program will deliver results in three areas: a chamber test to define aerosols and monitor aerosol behavior as a function of time; a prototypical instrument to measure particle concentration in workplace ambient air in a discrete particle size range; and a means to measure penetration of nanoparticles from an air stream through filters, gloves, or protective clothing.

The panel is aware of ongoing federal regulatory agency and other organizational efforts to review the adequacy of currently used research methods and to fund needed development. Further, there are ongoing efforts to test certain engineered nanomaterials. Panel member companies are participating in many of these activities to develop recommendations and set priorities for funding. The panel supports these efforts, but believes that much more government funding must be made available for research on the environmental, health, and safety aspects of engineered nanomaterials.

The nanotechnology panel supports EPA's recent proposal (70 Fed. Reg. 24574, May 10) to establish a voluntary pilot program to collect information on existing engineered nanoscale materials. EPA seeks information that is relevant to the evaluation of potential risks from exposure to nanoscale materials. The panel believes that information that would assist EPA's assessment of potential risks from exposure to engineered nanoscale materials includes information on the manufacture, use, and disposal as well as information relevant to exposure and the potential human health and environmental hazards of these materials.

The panel believes, however, that a voluntary program should seek more than the submission of information and urges EPA to consider developing a pilot program that includes two additional components: the assessment of the information gathered as part of the voluntary reporting function, and the identification of information needs revealed by the assessment process.

The panel believes that the significant information generated through such a voluntary program would greatly enhance EPA's and other stakeholders' understanding of engineered nanoscale materials, assist in developing and refining risk assessment approaches, and provide significant comfort that engineered nanoscale materials are being developed and used safely. We support efforts to harmonize definitions, terminology, and regulation globally. In this regard, we applaud ongoing EPA and OECD efforts to engage discussion on nanotechnology. A uniform global approach to regulation that instills public confidence without unnecessarily impeding innovation will greatly facilitate its development.

The panel believes that the full value of a voluntary pilot program can only be achieved by being as inclusive as possible of all commercial entities involved in the manufacture, distribution, and import of engineered nanomaterials as well as all other interested parties. The panel has conducted outreach to other stakeholders, and is encouraged by the degree of concordance of panel goals and beliefs with those of others. The panel is committed to continuing its outreach efforts, and encourages EPA to continue its efforts to promote the identification of interested stakeholders to ensure all interested parties are engaged in these important activities.

Together we can help realize the promise of nanotechnology and at the same time minimize risk.

Larry S. Andrews is Senior Principal Toxicologist for the Rohm and Haas Company and Chairman of the American Chemistry Council CHEM-STAR Nanotechnology Panel.

## Avoid Mistakes Of Past: Develop Nano Responsibly

LYNN L. BERGESON

N anotechnology offers promising societal and economic benefits. The present global \$8 billion and growing investment of industry and governments in nanotechnology research and development confirms this. But few would challenge the fact that much more needs to be known about the human health and environmental implications of nanotechnology, including engineered nanoscale materials and nanoparticles.

What is considerably less clear, in large part because of what is not known, is how best to develop nanotechnology responsibly. There is no one answer to this question. What can comfortably be offered are a few observations about the respective roles of the key players.

The federal government has an important role in the responsible development of promising emerging technologies. That the Environmental Protection Agency, Food and Drug Administration, and Occupational Safety and Health Administration, among others, have the inherent authority to identify and address potential risks under the statutes each is charged with administrating is clear to most. Some believe, however, more laws are needed to regulate nanotechnology. A different view is that government bodies are charged with protecting human health and the environment, and the reach of current laws and regulatory infrastructures clearly extend, or can be interpreted to extend, to manage adequately any such risks. In any event, the likelihood of new legislation authorizing government authority in these areas is not high, so we better make these existing authorities work.

So how can the federal government most effectively discharge the authority it does have? At a minimum, it must do five things.

## THE FORUM

First, it must acknowledge that a laissez faire approach will work to the detriment of nanotechnology's development. The government is an essential stakeholder in the debate on how best to manage risks posed by nanotechnology, and it must engage actively in the process to legitimize in the public's eye nanotechnology products. Second, the government must commit more money toward research into the health and environmental implications of nanotechnology. Third, the government should facilitate stakeholder participation in voluntary initiatives to develop data, best practices, testing protocols, assessment methodologies, etc., as tools to secure public confidence. EPA's announced June 23 public meeting on nanoscale materials is a first step. Fourth, the government should assemble the most reliable information on the health and safety implications of nanotechnology, and work with stakeholders to validate this information and make it readily available. Finally, the government must ensure that global nomenclature, terminology, and related standardization initiatives are harmonized to the extent possible.

It is critically important that commercial interests at all levels of the value chain be able to demonstrate that their products and manufacturing operations are safe. If the right-to-know movement has taught us anything, it is that the public's perception of safety is essential and no emerging technology will survive without broad public support. This means that commercial interests must interact with all relevant constituencies — in addition to the public, downstream/upstream purchasers; the government; environmental, health care, and consumer activists; and others in the development of codes of conduct and courses of behavior that demonstrate human health and environmental safety.

This will not be easy, as commercial interests range from mature Fortune 500 companies and other sophisticated corporations to startups and other small and medium enterprises with limited appreciation of environmental health and safety law and regulation.

Finally, non-governmental organizations must be as willing as the private sector and government to engage creatively and work for the common good. The pace with which nanotechnology developments are progressing cannot be controlled, and it is both unrealistic and inappropriate to seek to do so based on the premise that findings of zero risk are predicates to progress. Reasonable precautions and risk mitigation measures are already being taken in manufacturing operations because the potential consequences of doing less are too high given the risk of litigation and other business pressures. Corporate codes of conduct, commitments to sustainable development, and other business decision drivers do not replace the need for government intervention, but cannot be overlooked when assessing precautions that are in place to ensure public health and environmental protection.

Nanotechnology's newness requires more attention from all segments of society. Business as usual is not an option. Commercial interests must work diligently to develop information, and develop new business strategies to ensure, communicate, and convince the public that their products are safe, and they must do so transparently and with the support and help of other stakeholders. The government cannot sit on the sidelines and watch it unfold. It must engage, and ensure that resources are appropriately directed, information is credible and available, and emerging global standards are harmonized to the greatest extent practical. We can avoid the mistakes of the past, but only with a firm resolve not to repeat them.

Lynn L. Bergeson is a founding shareholder of Bergeson & Campbell, P.C., a Washington, D.C., law firm focusing on chemical, pesticide, and other specialty chemical product approval and regulation; health and safety law; chemical product litigation; and associated business issues. The views expressed in this column are solely those of the author.

# Getting Nanotech Right The First Time

RICHARD DENISON

anotechnology, the design and manipulation of materials at the molecular and atomic scale, has great potential to deliver environmental as well as other benefits. The novel properties that emerge as materials reach the nano-scale — such as changes in surface chemistry, reactivity, and electrical conductivity — open the door to innovations in cleaner energy production, energy efficiency, water treatment, environmental remediation, and "lightweighting" of materials, among other applications, that provide direct environmental improvements.

At the same time, these novel properties may pose new risks to workers, consumers, the public, and the environment. The few studies now available give cause for concern: some nanomaterials have potential to damage skin, brain, and lung tissue, and to be mobile or persistent in the environment. Some of these initial studies have unearthed real surprises. For example, while individual buckyballs (spheres composed of 60 carbon atoms) do not dissolve well in water, one recent study found that they can cluster together to form aggregates that are both very water-soluble and bactericidal. Given that bacteria constitute the bottom of the food chain, this finding raises strong concerns about ecosystem impacts.

Other studies demonstrate that some nanoparticles can, when inhaled, penetrate deep into the lung, where they can cause tissue damage or cross into the circulatory system. Or they can settle in the nasal passages, from which they can be taken up by the olfactory nerve and carried past the blood-brain barrier directly into brain cells. Separate studies on fish also indicate that buckyballs can

### THE FORUM

be transported to the brain, where they cause oxidative damage.

As illustrated by asbestos, CFCs, DDT, leaded gasoline, PCBs, and numerous other substances, the fact that a product is useful does not ensure it is benign to health or the environment. And if the danger becomes known only after the product is in wide use, the consequences can go beyond human suffering and environmental harm to include lengthy regulatory battles, costly cleanup efforts, expensive litigation quagmires, and painful public-relation debacles. So far, the rapid pace of development and commercial introduction of nanomaterials in varied applications is outpacing efforts to understand their implications — let alone ensure their safety. But there is still time to learn and apply lessons from prior mistakes, by identifying risks up front, taking the necessary steps to address them, and meaningfully engaging stakeholders to help shape this technology's trajectory. In short, there is an opportunity to get nanotechnology right the first time.

There are four key components to realizing this opportunity:

Increasing risk research. Government and industry need to act now to ensure that the risks of nanomaterials are identified and addressed before such materials are incorporated into products for commercial production. Far more federal research dollars need to be spent on health and environmental implications of nanotechnology, to ensure that the critical research needed to identify potential risks is done expeditiously. Similarly, private industry needs to invest in generating data on the hazards of nanotechnology products before exposing workers, consumers, the public, and the environment.

*Improving regulatory policy.* Government needs to provide for the comprehensive management of those risks that are identified — from a full lifecycle perspective, taking into account worker safety, manufacturing releases and wastes, product use, and product disposal. Government needs first to exert its existing authority to more effectively address nanotechnology risks in the near term. An objective assessment is also needed to identify and address gaps in existing regulatory programs.

*Establishing corporate standards* of care. Because government typically moves at a slower pace than the marketplace, industry itself needs to develop and drive widespread adoption of standards of care for responsible nanotechnology development. Such standards should employ a comprehensive risk identification and management process both prior to and following commercialization of nanomaterial-containing products, and should include protective interim management standards that prevent exposure in the absence of sufficient information to demonstrate safety.

*Engaging diverse stakeholders.* Both government and industry need to do a far better job of engaging the broad array of stakeholders — labor groups, health organizations, consumer advocates, community groups and environmental NGOs — outside government and industry. These stakeholders need to be involved from the outset in helping to identify expectations and concerns, and provided a role in setting research and development priorities.

Nanotechnology's promise is impressive, but the potential risks are significant and complex, and urgently need to be addressed. The steps outlined above can help to ensure that nanotechnology is developed in a safe and responsible manner, so that its benefits are realized while appropriately identifying and managing its potential risks.

Richard Denison is a Senior Scientist in the Health Program at Environmental Defense, working in its Washington, D.C., office.

## Regulate Nano Now

E. DONALD ELLIOTT

re stand on the threshold of the next industrial revolution — the nanomaterials revolution. Those who want to commercialize nanoscale materials and maintain America's technological and economic leadership should learn the lessons of the biotech revolution and lobby the Bush administration to regulate nano now under the guidance of the National Academy of Sciences using existing EPA and FDA legal authority. A credible governmental program to protect health and the environment is crucial to public acceptance of this promising new technology.

The industrial and medical applications of nanotechnology are very exciting. Side effects of chemotherapy for cancer may become a thing of the past, for instance, as drugs can be attached to nanoparticles to kill cancer cells while leaving healthy cells alone. But some materials that are safe in ordinary sizes become toxic as nanomaterials. We already know that ordinary carbon formed into nanoparticles with spherical shapes, called buckyballs, can be toxic to fish. We currently lack techniques to find and clean up nanoscale chemical "spills" in the environment, so it is important to prevent problems before releases occur.

EPA correctly believes that it has existing statutory authority to regulate nanomaterials under the Toxic Substances Control Act by issuing a Significant New Use Rule but it has hesitated to act and instead is considering a voluntary program. Some are concerned that burdensome regulation may stifle this promising new technology. And EPA does not know how to prioritize or analyze the reams of data that might be produced if every new size or shape of par-

#### THE FORUM

ticle were considered a separate "particular molecular identity" requiring pre-market testing and clearance under TSCA.

Without government guidance, some responsible companies are doing their best to test nanomaterials on their own. The American Society of Testing and Materials is developing consensus recommendations but as yet there are no established scientific protocols for either safety or environmental compatibility testing. Meanwhile, nanomaterials are already coming onto the market. Nanoscale oxides of zinc and titanium are in some suntan lotions and nanoscale fibers are used in some stain-resistant fabrics. Many more applications of nanotechnology are just around the corner.

Those of us who favor responsible development of nanotech should learn the lessons of the biotech revolution. One reason (among many) that consumers in the United States accepted biotechnology while the same products are still rejected by many consumers in Europe was the agility of the U.S. legal system to put a credible regulatory system in place quickly. The National Academy of Sciences made recommendations for screening techniques and testing priorities for genetically modified organisms, which EPA, FDA, and other agencies quickly adopted using their *Chevron* authority to interpret existing law. We should follow the same successful course for nanotech.

Lacking government guidance, some private companies are currently making important policy decisions about how to test nanomaterials. These decisions inevitably involve policy choices about where to focus scarce resources. For example, one company has concluded that nanomaterials that do not pass through the skin are probably safer and require a lesser degree of testing. These judgments may or may not turn out to be correct, but they should not be made by the private sector alone.

In this era of deregulation, we sometimes forget that one of the purposes of regulation is not just to keep the public safe, but also to assure the public that new technologies are safe so that they will be accepted. As FDR said in 1933 when introducing the first federal law to regulate securities at the height of the Depression, "It should give impetus to honest dealing in securities and thereby bring back public confidence." A credible regulatory system can help industry win consumer acceptance of new technology. Timely and credible government regulation of biotechnology was implemented in the United States in the 1980s, but failed in Europe, leading to widespread public concern and a regulatory over-reaction by government, which is only now beginning to soften.

Like past technological revolutions, nanotechnology holds great promise, but also raises fears of possible risks to public health and the environment. Industry should not wait for the first scary headlines about a threatened nano-disaster, which are likely to lead to an over-reaction by government. Instead, industry and government should work together now to put in place a credible regulatory framework that will assure consumers that particular uses of nanotechnology are safe before they are put on the market.

É. Donald Elliott is a Partner and Chair of the Environment, Health and Safety Department of Willkie Farr & Gallagher LLP. He is a former General Counsel of EPA and an Adjunct Professor at Yale Law School and the Georgetown University Law Center, where he teaches a course comparing regulation of chemicals, biotech, and nanotech in the United States and European Union.

# Opportunities, Challenges For EPA

WILLIAM H. FARLAND

anotechnology holds great promise for creating new materials with enhanced properties and attributes. Already, nanoscale materials are being used or tested in a wide range of products, such as sunscreens, composites, medical devices, and chemical catalysts. As in consumer products and other sectors, the use of nanomaterials for environmental applications is also promising. Nanotechnology presents an opportunity to revolutionize how we measure, monitor, and manage contaminants in the environment. For example, nanomaterials have been developed that improve vehicle fuel efficiency and remove contaminants from soil and groundwater.

The challenge for environmental protection is to ensure that, as nanomaterials are developed and used, we minimize unintended consequences of exposures to humans and ecosystems. In addition, we need to understand how to best apply nanotechnology for pollution prevention, detection, monitoring, and cleanup. The key to such understanding is a strong body of scientific information, and the sources of such information are the numerous environmental research and development activities that are either currently underway or will soon be started within government agencies, academia, and the private sector.

This year approximately one billion federal dollars, and twice that amount from other U.S. sectors, will be spent on nanotechnology research and development, focused mostly on applications. This work is being coordinated through the interagency Nanoscale Science, Engineering, and Technology Subcommittee of the National Science and Technology Council.

### THE FORUM

For the past five years, EPA has played a leadership role in setting research directions for the environmental applications and, perhaps most importantly, the implications of nanotechnology, through our own research grants program. That research has already borne fruit, particularly in the use of nanomaterials for environmental cleanup and in understanding the disposition of nanoparticles in biological systems. But much work remains. With their expertise in environmental toxicology, fate and transport, exposure, risk assessment, and risk management, scientists in EPA's Office of Research and Development have identified a number of important science questions that remain to be addressed. These questions relate to the environmental consequences and health effects associated with highly reactive and bio-persistent nanomaterials; how those materials move through air, water, and soil; and how to use nanotechnology to better measure releases to water, soil, and air, as well as to enhance the effectiveness of conventional control and remediation technologies.

While these particular research questions are important for supporting EPA's statutory mandates for environmental protection, many other lines of environmental research need to be pursued by researchers throughout the scientific community if we are to ensure that society is able to reap the full benefits of nanotechnology in a manner that safeguards human health and the environment. For example, understanding potential exposure to workers involved in the manufacture of nanoparticles is important, as is the development of personal protective equipment to shield such workers from materials produced at the nanoscale. In addition, R&D in the use of nanomaterials in photovoltaics and coatings not only has high commercial potential, but also holds promise for environmentally friendly technologies such as solar power. Research into the use of nanotechnology in electronics and information technology may lead

to the development of ubiquitous wireless sensors that would drive advances in "ecological computing" and other means of remotely assessing, diagnosing, and forecasting environmental conditions.

Gaining a fuller understanding of the environmental applications and implications of nanotechnology will require the concerted efforts of scientists and policymakers across the globe. With Europe and Asia matching or exceeding the U.S. nanotechnology research budget, much opportunity exists for internationally coordinated and integrated approaches to environmental research.

As the President's Council of Advisors on Science and Technology said in May 2005, "Support for the continued advancement of nanotechnology research, and eventual integration of nanotechnology into consumer products and useful applications, will depend heavily on the public's acceptance of nanotechnology. Governments around the world must take a proactive stance to ensure that environmental, health, and safety concerns are addressed as nanotechnology research and development moves forward in order to assure the public that nanotechnology products will be safe."

We are at a point of great opportunity with nanotechnology. From EPA's perspective, that opportunity is two-fold: the potential for applying nanomaterials to preventing and solving environmental problems; and our ability — at this early juncture in nanotechnology development — to develop approaches that will allow us to produce, use, recycle, and eventually dispose of nanomaterials in a manner that protects public health and safeguards the natural environment. It is an opportunity we must grasp, and is a challenge that the environmental research community must be ready to address.

William H. Farland is Acting Deputy Assistant Administrator for Science in the Environmental Protection Agency.

# A Role For All, With Aid From Government

KRISTEN KULINOWSKI

anotechnology holds enormous promise to impact any number of technical fields, including energy, computing, environmental remediation, and medicine. Nanomaterials, broadly defined as particles or objects with at least one dimension measuring between 1-100 nanometers, constitute a subset of nanotechnology that has drawn recent attention for both its promise and its peril. The precise control that scientists wield over the size, surface properties, aspect ratio, and other characteristics is a large part of this potential, as it enables tunability of material properties that can be exploited to add value to existing products or to enable altogether new technologies.

However, the very novelty responsible for the excitement about the potential benefits of this class of materials also raises significant questions about unintended effects, including human toxicity and ecosystem impacts. If these materials have amazing properties that enable them to interact with their surroundings in new ways, then it stands to reason that not all of these interactions will be beneficial. While a few studies have demonstrated the hazards posed by certain nanomaterials to cells and specific species (bacteria, fish, rodents) in tightly controlled laboratory settings, it remains too early to draw any general conclusions about whether these particles will pose risks to human health or the environment in real-world circumstances. Moreover, what is found to apply to one type of nanoparticle may be inapplicable not only to nanoparticles of other chemical composition but even perhaps to nanoparticles of the same type with different surfaces, aspect ratios, or sizes. It will be

### THE FORUM

years before the scientific community can provide a comprehensive risk assessment of products containing nanomaterials that spans the entire lifecycle from point-ofmanufacture to ultimate disposal. Meanwhile, commercialization proceeds with a concomitant scaleup in nanoparticle production.

This leaves a cloud of uncertainty hanging over those responsible for protecting public health and the environment. Overreaction to potential risks could prevent or slow the development of the next breakthrough technology by scaring off investors or imposing onerous regulations not well supported by fundamental scientific knowledge. Underreaction could result in a risky material slipping through regulatory cracks or an undermining of public confidence in the safety of products containing these materials. Since nanotechnology shows no signs of slowing down anytime soon, dealing with potential implications of nanomaterials must not wait until a sufficient body of knowledge — whatever that might mean — is available to guide policymaking. Concerned stakeholders from government, industry, academia, and public interest groups must find a path forward.

Each of these diverse groups has a unique role to play in dealing with this issue and should also find creative ways to work together in addition to pursuing their own course. Academic and other researchers should work in multidisciplinary teams of experts in nanomaterial synthesis and characterization, toxicology, and environmental fate and transport to advance our understanding of the potential impacts of these materials. This will ensure that the body of publicly available, high-quality risk data continues to grow, preferably to where its pace approaches that of sunny-side applications research.

This will require a continued commitment on the part of government agencies to direct their funding resources toward these investigations in ways that enable multidisciplinary approaches. While industry can and should fund risk research, government support of environmental health and safety research done by those without commercial interests will enable as much of the data to end up in the public domain as possible. Companies seeking to commercialize nanomaterials must bear the responsibility for collecting and reporting comprehensive EHS data about their products and processes to regulatory agencies. Where possible, some balance should be struck between protecting proprietary business interests and adding to the collected body of publicly available knowledge.

Regulatory agencies have an essential oversight function that is challenged by the sparse body of risk research currently available. While continuing to examine the ability of existing statutes to adequately deal with this novel class of materials, these agencies should engage the broader community in exploring interim measures including voluntary guidelines. While this does not obviate the need for new regulations, it provides a path forward as the research community grows the knowledge base.

Finally, all of these groups should work together to support the development of voluntary standards for responsible manufacture, use, and disposal of nanomaterials. This task requires applying the limited information available today to a robust set of standards that can evolve over time as new data emerge. These processes must be inclusive and transparent, and should be driven by the perspectives of all affected stakeholder groups, including those often uninvolved in the standards-development process. By working together in novel ways to assess and manage the potential hazards of nanomaterials, we may be able to avoid the costly mistakes of past technologies and ensure a bright future for nanotechnology.

Kristen Kulinowski, Ph.D., is Executive Director for Policy of the Center for Biological and Environmental Nanotechnology and a faculty fellow in chemistry at Rice University.