COVER STORIES

Reading The Small Print

Industrial pollution was easy to see, and so were its effects. But what happens when the machines are microscopic, the products are smaller, and the emissions are smaller still? This is not science fiction. Nanotechnology products are already in use in cosmetics, materials, and electronic devices. Nanotech manufacturing is on the near horizon. Are our environmental laws up to the task?

LYNN L. BERGESON and BETHAMI AUERBACH

Eric Drexler stated it well almost two decades ago in his groundbreaking book *Engines of Creation: The Coming Era of Nanotechnology:* "Arranged one way, atoms make up soil, air, and water; arranged another, they make up ripe strawberries. Arranged one way, they make up homes and fresh air; arranged another, they make up ash and smoke. Our ability to arrange atoms lies at the foundation of technology. . . . For all our advances in arranging atoms, we still use primitive methods. With our present technology, we are still forced to handle atoms in unruly herds." Drexler believes, as do many others, that we stand at the cusp of truly remarkable advances in our ability to operate at the molecular level and herd those "unruly" atoms with incredible precision.

Control over matter manipulation has triumphed in certain commercial markets, as applications of nanotechnology are already in commerce. 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. This is plainly just the beginning. Demand for domestic nanomaterials in 2002 was estimated at $200 million and is projected to grow an astonishing 33 percent a year. The National Science Foundation has estimated that nanotechnology applications may be valued at more than $1 trillion in the global economy by 2015.

With such spectacular growth expected, the federal government is mindful of the regulatory implications that this "next big thing" invites, particularly in that this "big thing" is so tiny. It was easy to understand why — once environmental regulation became an accepted feature of the industrial landscape — traditional heavy manufacturing demanded controls and cleanup measures. It could be seen in the sooty skies and dead rivers. By contrast, chronic, long-term health effects and environmental contamination from manufacturing activities sometimes were not so readily discernible, at least in their earlier stages, and this tended to make them more worrisome. This was true even when the actual components of a manufacturing process — the various chemical substances and production processes themselves — were known and tangible things. The increasing commercialization of nanotechnology raises similar concerns, at a level where tangibility drops off. Minuscule in scale — which, viscerally, might make it seem tamer — its very minuteness renders the technology invisible to the naked eye and unknowable to most of us, so that it can seem sinister in its diminutive size and in its futurism. The environmental and resource implications of nanotechnology, whether and how its impacts should be regulated, and by what authorities are issues that are beginning to garner serious attention. This article considers some of those issues.

The drive to manufacture at smaller and smaller levels is by no means new. Miniaturization is as much a logical extension of ancient skills as it is a product of modern technology. Bulk technology, the term Drexler uses to refer to modern manufacturing, is big, cumbersome, and dirty, and manipulates matter containing trillions of atoms and molecules. Engineering achievements perfected over time allow the manipulation of matter to occur at smaller and smaller levels. Molecular technology, or nanotechnology, is the inevitable result of the relentless quest to control matter at its most fundamental, molecular level.

This is the world of the truly small. 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. 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 a billionth of a meter — 1/100,000 the width of a human hair, or 10 times the diameter of a hydrogen atom. A billionth of a meter is called a nanometer, which is the root of the neologism.

Nanotechnology has spawned its own lexicon. We are all familiar with a nanosecond, the speed within which we dream of accomplishing many acts in our daily lives. Other terms are less familiar. Top-down and bottom-up refer to two fundamentally different approaches to nanotechnology. Top-down is making nanoscale structures by machining techniques. Bottom-up is building organic and inorganic structures atom by atom, or molecule by molecule. As applied today, nanotechnology still is considered to be at the more nascent (and primitive) top-down stage of development. But the ability to wield a tiny tool arm and, with the aid of a highly powerful microscope, engineer in such desired qualities as strength and conductivity at the most basic level is already enhancing everyday products while providing a glimpse at new frontiers for the future. Today we have tennis rackets, strong but light, that incorporate carbon nanotubes, and we have slacks treated with a nanoengineered chemical formula so that coffee spills and red wine stains can be things of the past. Tomorrow, nano-engineered "smart dust" — tiny silicon particles — may have the ability to move through an environmental medium, sense contaminants, and warn of them by changing color.

Some of the more provocative terms associated with nanotechnology are uniquely Drexler-esque and include assemblers, programmable molecular machines capable of building molecular structures from simpler chemical building blocks; disassemblers, nanomachines designed to take apart objects at the atomic level; and replicators, entities that can make copies of themselves. These more futuristic terms, which have inspired some of the less flattering and scarier images conjured up by the thought of nanotechnology gone awry, continue to fuel the nightmare-scenario that destructive nanoids could self replicate and turn everything into a gray goo — a specter that threatens the viability of nanotechnology in much the same way the Franken-food hysteria has compromised biotechnology.

A review of existing statutes shows an array of authorities that need to be wielded in a coordinated fashion by overlapping agencies

Mindful of nanotechnology's 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. To coordinate the not insignificant 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 2001. NNI goals are to conduct R&D to realize the full potential of nanotechnology, to develop the workforce necessary to advance these R&D efforts, to understand better the associated societal, health, environmental, and ethical considerations, and to facilitate the transfer of nanotechnologies into commercial applications. Sixteen federal agencies, including EPA, participate in the Initiative, 10 of which have an R&D budget dedicated to nanotechnology. Other federal organizations contribute to the Initiative through studies and other forms of collaboration. The Nanoscale Science, Engineering, and Technology Committee is the group that provides the primary coordinating mechanism for the NNI.

At the request of the White House Economic Council and the various NNI-participating agencies, the National Research Council agreed to review the NNI to assess the suitability of federal investments in nanotech-

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.

nology, the inter-agency coordinating efforts in this regard, and the Initiative's research portfolio. The NRC's June 2002 report on its review was overwhelmingly positive and commended the leadership and structure of the NNI. Importantly, however, the NRC made 10 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 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 NNI in meeting its goals.

The promise of nanotechnology, and the federal government's support, are perhaps best illustrated by Congress's recent passage and President Bush's swift signing into law of The 21st Century Nanotechnology Research and Development Act on December 3, 2003. The law authorizes $3.7 billion in federal support for nanotechnology; authorizes and funds the NNI; creates various 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 keenly aware that even if the NSF'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 United States' gross domestic product. The Bush administration has increased each year the amount of money dedicated to nanotech research and has aggressively supported the NNI, identifying it as one of the administration's highest multi-agency R&D priorities.

Nanotechnology, at its core, is perhaps the ultimate sustainable development tool

The infusion of $847 million in federal money that Congress recently authorized 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 many promising opportunities for nanotechnology. In the environmental and natural resource arenas, nanotechnology offers particularly attractive benefits in three key areas: innovative new tools to detect, monitor, and reduce pollution; the availability of environmentally benign manufacturing processes; and the production of cleaner, less expensive energy.

Nanotechnology, at its core, 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 Committee on Environment and Natural Resources's Subcommittee on Ecological Systems, nanotechnology enhances our very ability to "measure, monitor, and understand the complex structures and activities of living systems." Consider smart dust, mentioned earlier. It is composed of computerized communicating sensors the size of dust particles. Dispersed throughout the atmosphere, smart dust can relay back 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 unlock mysteries that now impede our ability to protect it.

EPA's Science to Achieve Results — STAR — 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 exploring the potential of plasmon-sensitized titanium dioxide nanoparticles to use more efficiently solar energy; research at the University of Miami to develop nanoscale sensors for the detection of destructive marine toxins; and research

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EPA Is Aware Of Dangers, Intrigued By Social Benefits

The Environmental Protection Agency is continually in search of better ways to protect human health and the environment through the use of emerging technology. One of these, nanotechnology, has the potential to revolutionize environmental protection. EPA joined with other agencies to support the development of this innovative technology with the launch of the presidential National Nanotechnology Initiative in 1999. Our key role in planning research directions for environmental applications and implications of nanotechnology is enhanced through our participation in the interagency Nanoscale Science, Engineering, and Technology subcommittee of the White House National Science and Technology Council that coordinates implementation of the NNI.

Paul Gilman

When structures, devices or systems consist of clusters of a few hundred atoms (1-100 nanometer in dimension), the laws of quantum mechanics often cause dramatic changes in their mechanical, optical, chemical, and electronic properties. Harnessing these properties is what we call nanotechnology. By allowing us to manipulate materials on this scale, nanotechnology has the potential to make miniature analytical chemical laboratories; provide new and more effective ways to clean up environmental contaminants; and offer fundamentally new, environmentally benign ways to manufacture chemicals and pharmaceuticals. In addition, since nanotech manufacturing will potentially use much lower amounts of materials, the environmental impact from extraction, transport, use, and disposal of these products will be substantially reduced.

EPA's primary focus to date has been on research to determine how nanotechnology can be used to improve environmental protection. Nanotechnology has the potential to make an impact in three major areas — environmental sensors, treatment and remediation, and green manufacturing. At present, EPA is funding 30 academic research grants in these areas through its Science to Achieve Results extramural grants program. Sensor work funded through STAR ranges from detecting pollutants, such as toxic metals in surface waters or bacteria in drinking water, to detecting algal toxins in aquatic environments. STAR nanotechnology researchers are also developing processes to remove toxic organic pollutants from ground water, convert heavy-metal compounds in the environment to more benign forms, and prevent toxic organic materials from entering groundwater supplies. To eliminate pollution at the source, STAR-funded scientists are developing ways to manufacture nanomaterials without producing harmful wastes. They are also using nanocatalysts to synthesize chemical compounds more efficiently.

Through EPA's Small Business Innovative Research program, the private sector is developing nanocomposite plasticizers, high-efficiency catalysts, and new filter media using nanomaterials. A small number of nanotech-related research projects are also being conducted in EPA laboratories on topics such as using nanostructured photocatalysts as green alternatives for oxygenating hydrocarbons and applying nanomaterials in adsorbents and catalysts to monitor air pollutants and control emissions.

The potential environmental implications of nanotechnology have been critical issues since the inception of the NNI. Any revolutionary science and engineering approach applied to the existing infrastructure of consumer goods, manufacturing methods, and materials usage could have major environmental consequences. Understanding what these consequences are, and whether they are good or bad for the environment, is also the responsibility of those engaged in nanotechnology research and development. EPA has turned its attention to this issue in its STAR-funded research and is now reviewing research proposals that address the possible health and environmental effects of manufactured nanomaterials. This research will address the toxicity, environmental fate, transport, and transformation, exposure routes, and bioaccumulation potential of manufactured nanomaterials. STAR is also currently funding research to perform assessments on lifecycle costs and benefits as nanotech-derived manufacturing and processing techniques replace parts of current processes or products.

To encourage research sponsored by other agencies in the environmental aspects of nanotechnology, EPA works closely with the NSET committee of the NNI. We are seeking to give other federal research program managers an awareness of the environmental applications and implications of their programs. To this end, under the National Nanotechnology Coordinating Office, EPA organized an interagency conference on nanotechnology and the environment last September to foster discussion and collaboration between EPA researchers and those sponsored by other agencies whose work addresses environmental issues.

The societal implications of nanotechnology, including its possible environmental effects as well as the many benefits to environmental quality that society may be able to reap from it, have received increasing media and public attention as the technology continues to develop and products enter the marketplace. EPA is continually finding and using new information and methods that enable our research programs to work hand-in-hand with our regulatory programs. As we gain knowledge about the environmental implications of nanotechnology, we will continue to examine the regulatory implications.

Dr. Paul Gilman is Science Advisor and Assistant Administrator for Research and Development of the U.S. Environmental Protection Agency.

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(DNAPLs). The last are liquids denser than water and not easily mixed or dissolved in it, whose tendency to penetrate the water table and sink into an aquifer makes them a source of long-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 11 projects for approximately $1 million for various nano-based products. These range from the use of nanocomposite-based filters with nano-sized activated alumina to remove arsenic from drinking water to meet the new Safe Drinking Water Act standard to the use of nanofibrous manganese dioxide for emission control of volatile organic compounds. These research initiatives are impressive in their sheer number and versatility and in the promise each holds in protecting public health.

Manufacturing successfully at the molecular level is of critical importance to the NNI as a prerequirsite for realizing the benefits of nanotechnology. Current manufacturing processes require large quantities of materials for production. The process generates waste and byproducts, the bulk 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 that are intended to be used in the nanofabrication process are involved. The manufacture of nanoscale components in macroscale devices holds tremendous promise for green manufacturing and the significant reduction of manufacturing waste materials.

Manipulating matter at the molecular level could mean engineering out unwanted waste and byproducts

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 that nanoscale particles on metallic iron may remediate contaminated groundwater. They found that 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 DNAPLs, as well as related applications, promise tremendous progress in environmental remediation strategies.

While perhaps not as dramatic, nanotechnology application in the world of apparel could significantly improve the ability to protect people whose livelihoods cause them to be exposed to chemicals and 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 military personnel from occupational hazards of one form or another.

Nanotechnology's utility in the resources area is equally significant. The NNI believes 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 its thoughtful and scholarly white paper authored by Dr. Stephen L. Gillett, *Nanotechnology: Clean Energy and Resources for the Future,* 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. 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

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Regulation? Wait For Standardization, Commercialization

Control over matter at the nanometer scale provides a powerful tool for advancing industries, ranging from electronics to pharmaceuticals. The sheer breadth of the term "nanotechnology" allows scientists of every discipline to envision the far-reaching impact of nanoscale science in their own fields. In the midst of this enthusiasm, critics have emerged. Their concerns about the environmental and health effects of nanomaterials raise questions about whether and how the industry should be regulated.

Vicki Colvin

Whether to slow down the pace of a new technology is a divisive question for society. In the case of nanotechnology, the question of government regulation will be contentious, as known benefits must be balanced against an incomplete view of the risks. The imperfect cost-benefit analysis that is required is best left to policymakers. Still, I have several suggestions from a scientist's perspective that may be useful for policymakers and citizens.

The first is to hold off judgment of nanomaterials until there are pressing applications entering the market. It is difficult to determine whether "real" nanomaterials are used in commerce. In the United States no manufacturer has triggered the regulatory process for these systems, which suggests their applications are not widespread. Some industries have for years used colloidal pigments and additives in products; while these may be nanostructured, they present a different set of technical issues from the "engineered nanomaterials" that hold the true promise. These higher performance nanomaterials, which drive nanotechnology, are not yet commercialized. As the industry develops, nanotechnologists and regulators alike have a window of opportunity to evaluate the risks before products are produced. Such time will allow for an effective, measured regulatory response.

Waiting on nanomaterial regulation will also provide policymakers a more complete and coherent picture of nanomaterial risks. Right now, the toxicological studies of engineered nanomaterials can be counted on one hand, and more ambitious risk assessments are years away. However, government funding is increasing, and some industries may begin supporting such research. If so, policymakers won't have to act on the basis of only one or two studies of nanomaterial risks, but can count on a broader scientific consensus.

My next suggestion is to proceed into this new policy area with a watchful confidence in engineered nanomaterials. Engineered nanomaterials are not new substances. They are the products of chemical processes which now focus on control over nanoscale structures as opposed to molecules. The ruby red color of stained glass in Medieval churches comes from a nanoscale gold pigment, for example, and non-anthropogenic nanoparticles are widely found in nature. These materials obey the same basic chemical laws as any other manmade substance, and will be amenable to conventional risk assessment and toxicological studies. In other words, they are not unfamiliar substances to chemists, toxicologists, and environmental engineers.

This familiarity should be tempered with the recognition that engineered nanomaterials do possess features distinctive from their bulkier, molecular counterparts. It seems reasonable that the special chemical and physical properties of nanomaterials may also lead to unique biological properties. Academic research in this area is designed to test this hypothesis, and over the next few years a general understanding of these issues should develop.

Finally, I'd like to point out the limitations of drawing analogies between biotechnology and nanotechnology. In biotechnology engineered genes are the enabling component for a specific product; genes can be named precisely, detected in small amounts, and manufactured without any need for large infrastructure. Biotechnology products are thus easy to standardize, and the concrete assessments of the genetic fingerprints of products enables intellectual property to be controlled and protected.

In contrast, nanotechnology is enabled by a complex set of materials with no systematic nomenclature, and are typically challenging to manufacture with high quality. Often nanomaterial samples consist of a range of material sizes, and thus are more like a complex mixture than a pure substance. Most critically, both for regulatory issues as well as patent protection, nanomaterials are not easily detected or standardized with tabletop instruments. Although many of these problems will be overcome, most likely nanomaterials will never have a completely reliable system of fingerprinting.

While nanomaterial fingerprinting is not necessary for this industry to develop, I find it difficult to imagine any effective regulatory policy of nanomaterial-containing products with the current approaches to nomenclature and standardization and no straightforward manufacturing paradigm to follow. We nanoscientists must put our own house in order before products become available. As it now stands, there is no agreed upon standard for nanomaterial quality or purity. Additionally, we have no formal way of distinguishing among different nanomaterial classes in the technical community. With such imprecision in language, the carbon nanoparticles generated in the burning of diesel fuel are indistinguishable in the media from engineered carbon nanostructures. These housekeeping issues may not seem glamorous, but their completion ensures that the entire field of nanotechnology will survive its commercialization in one piece.

Vicki Colvin, Ph.D., is Director of the Center for Biological and Environmental Nanotechnology at Rice University in Houston, Texas.

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 byproduct elimination through the use of molecularly tailored catalysts will all greatly increase our energy efficiency.

A second key area where nanotechnology is expected to impact the resource area 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.

The ability to use fossil fuels without burning them could mean much greater energy efficiency and far less pollution

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 in harnessing the power inexpensively and managing 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 super-strength materials to harness the potential energy in surf, which otherwise would require, for example, log cables to reach the sea floor and withstand turbulent weather conditions. Professor Gillett's white paper is recommended reading for those interested in learning more about nanotechnology's potential in ensuring abundant, cheap, and clean energy.

The specific environmental and human health impacts 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.

Its commercial applications are still in their early years, and environmental regulation of nanotechnology is in its infancy too. As an active participant in the NNI, EPA's primary focus, in research dollars, has been on green nanotechnology — the pollution prevention 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.

Setting aside apocalyptic scenarios of wildly multiplying nanobots, not even the most enthusiastic nanotechnology proponents deny that it may have an environmental downside. It is generally recognized that the very "nano" nature of the substances involved — their breathtaking smallness — does not rule out their potential to be harmful to health or 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 FDA 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 ACS 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 ACS 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 UFPs (those < 0.1 micrometer) are considerably more successful than are larger particles in producing an inflammatory response in the lung. UFPs encompass nanoparticles, which are an order of magnitude smaller.

Dr. Oberdörster expressed concerns about the flip-side of the ability of UFPs to cross the blood-brain barrier — their potential to affect adversely the central nervous system — and called for more research in the area. The generation of UFPs, of course, is scarcely limited to applied nanotechnology. UFPs are ubiquitous in urban areas, as a product of gasoline exhaust and industrial processes, and those UFPs ultimately may pose a far more substantial health threat than will the particulate byproducts of nanotechnology applications.

Two other research initiatives discussed at the ACS symposium explored the pulmonary toxicity of carbon nanotubes, which are anticipated to be an early and successful application because they are extremely strong, lightweight electrical conductors, whose potential uses include semiconductors and computers. When Dr. David Warheit of DuPont and his colleagues injected nanotube and soot mixtures into the lungs of rats, they found that a startling 15 percent of the rats died within 24 hours, suffocated by the rapid clumping of the nanotubes. The rats that survived, however, showed only fleeting inflammation, apparently because the same clumping mechanism prevented the nanotubes from penetrating too deeply into the lungs. In studies under NASA auspices, when Dr. Chiu-Wing Lam and his colleagues instilled nanotubes into the trachea of mice, they also observed a clumping together of the nanotubes in granulomas, lesions that had formed as an immune response in an attempt to isolate the foreign bodies; granulomas also were observed by Dr. Warheit, although these did not correlate readily with the minimal toxicity findings in his research. When carbon nanotubes were compared with suspensions of carbon black (minimal effects) and with quartz particles (effects, at high doses, from mild to moderate), Dr. Lam concluded that the nanotubes could have the greatest toxic pulmonary impact of the three and, on this basis, cautioned about potential workplace exposures.

Drs. Oberdöster, Warheit, and Lam all recommended going beyond their instillation work and performing inhalation studies to try to reconcile the so-far inconsistent results and 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.

The yawning data gaps 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 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.

The Toxic Substances Control Act 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 (PMN), 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

Depending on how EPA might use it, TSCA allows it to review new chemicals, regulate them, and even ban them for unreasonable risks of the chemical, subject to record-keeping, 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 R&D exemption, which may cover some early-stage nanotechnologies, avoids the PMN process without requiring EPA's approval of an exemption application. Other available exemptions from the full-scale PMN process — which require an application and pre-production approval by EPA — may be based upon 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.

The Clean Air Act regulates particles, but only for large sources. OSHA workplace regulation is more likely if particles are a problem

Passing through, or bypassing, the PMN process and complying with the applicable reporting and record-keeping 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 (SNUR) is called for. Initiation of the SNUR process usually does not result in onerous, if any, limits placed on the manufacture of a chemical substance, although it does represent yet another set of requirements to contend with. The nature of nanotechnology, with its limited environmental impact database and the relative unfamiliarity of the chemicals involved, makes it very 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.

One final and important point about the potential applicability of TSCA relates to the research discussed above suggesting that 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 OSHA, EPA has used TSCA as a means for exercising its own regulatory authority to minimize workplace exposures. Whether or not this is an appropriate 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 in the workplace and such other requirements as hazard communication measures and the use of suitable personal protective equipment to minimize risks to employees as more is learned about exposure pathways.

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 and which the states must implement under Section 110. In 1997, EPA adopted a controversial revision to its CAA regulations, which, among other things, established NAAQS for fine particulates of less than 2.5 micrometers. After protracted litigation, including a trip to the Supreme Court on questions of constitutionality and authority, in 2002 the Court of Appeals for the D.C. Circuit upheld the particulates standards.

Their nationwide applicability notwithstanding, the standards will not have a direct impact on individual industrial sources of nanotechnology products. The standards apply through the state implementation plans, 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 limitations 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 CAA Section 112. 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 that it is an air pollutant and that 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.

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

If nanotech processing waste poses a threat to human health and the environment when disposed, RCRA could be invoked

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-known 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 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.

And don't forget NEPA. The federal government is funding research, and environmental impact statements at the R&D stage are a possibility

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 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.

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 ultra fine particle subject to regulation under the CAA; is an existing chemical that has been reengineered at the molecular level to enhance certain physical 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 NNI, 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, 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 and regulatory issues — some of which are less cerebral than they first appear — and for ensuring that 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 Departments of Interior and Energy, along with other stakeholders, including the Environmental Law Institute, are well suited to foster opportunities for such debate. This will help ensure that careful and deliberate thought about the environmental and resource policy implications of nanotechnology keep pace with the lightning speed of the development of nanotechnology itself. •

COVER STORIES

The Next Small Thing

Nanotechnology is not the next industrial revolution, but it will converge with ongoing revolutions in information technology and biotechnology to create it. The environmental community has a chance to guide the coming Info-Bio-Nano Revolution in ways that avoid the mistakes of the first industrial revolution — and harness this one for environmental improvement

DAVID REJESKI

A recent article in *Scientific American* contained the following statement about nanotechnology: "If the nano concept holds together, it could, in fact lay the groundwork for a new industrial revolution." That is an exciting thought. Penetrating down to a nanoscale level (one billionth of a meter or 1/100,000 the width of a human hair) is like opening up a new scientific universe, a universe where many of the basic properties of matter, from optics to chemistry, are determined. The science of nanotechnology is already here, supported in the United States by a $3.7-billion, four-year government spending plan. Dozens of other countries have launched their own national initiatives, making the nanotech boom a global phenomenon.

Nanotechnology has moved beyond arcane journals and laboratory science. Products utilizing nanotechnology are already on the market, ranging from improved sunscreens to stain-resistant fabrics to ultra-light flat panel displays for cellphones. Carbon nanotubes (an extremely high strength form of carbon discovered in 1991) are used to produce better automobile parts. The liners in Dunlop tennis balls contain clay modified at a nanoscale level to drastically reduce air leakage and maintain bounce. Use that technology in car and truck tires and we could save millions of gallons of gas a year caused by under inflated tires and lower accident rates to boot.

But remember small is not necessarily better, it is just smaller. Many of the molecules that we may end up manipulating at an atomic level are not environmentally benign and, as in all manufacturing processes, they may be manipulated to maximize other properties beside environmental characteristics, such as strength, conductivity, transparency, etc. So what exactly does smallness buy you? Solutions, maybe, if we can produce thin film photovoltaics at one tenth the present cost or find new ways to cheaply desalinate seawater or treat cancer. Problems, maybe, if nanoscale particles can be inhaled deeply into the lungs or cross the blood-brain or blood-placenta barrier. Once the production of anything ramps up, a range of familiar regulatory issues appear related to worker exposure, new chemicals, air and water emissions, and waste disposal. Separating science from science fiction is critical at this stage and it will not be easy. Ensuring that the benefits of such technologies are distributed to people in the world who need them the most will be an even more daunting task.

At the beginning of any new technological wave is what might be called the *hype bubble*, that initial burst of exuberance that is inevitably followed by the painful recognition that we mortals have not escaped the laws of unintended consequences. Remember nuclear energy (power will be too cheap to meter), or biotechnology (we will feed the world), or information technology (the paperless office)? Normally, by the time the hype bubble has passed and we recover our composure, whole new industries have been built, stock options cashed in, and environmental groups mobilized around that tiresome litany of "I told you so." The repetitive nature of this phenomenon deserves some serious attention, and it is finally receiving it thanks to the work of people like Princeton psychologist Daniel Kahneman, winner of the 2002 Nobel Prize in economics. His research has shown how optimism can undermine rational judgment and often results in wild overestimates of the benefits of projects and underestimates of their long-term costs.

The hype bubble dominates technological innovation cycles because it is easy to get people excited (and overly optimistic) about the next big thing. This kills our long-term memory, wipes out our peripheral vision (our guard against surprise), and compromises our judgment. This socially contagious affliction works regardless of whether you are a potential moviegoer, some crazed venture capitalist looking for high-return investment opportunities, a legal firm trolling for new business opportunities, or a newly minted Ph.D. searching for your first job. The problem with riding hype towards the next big thing is that people tend to forget about the last big thing and how that connected to the big things that came before. The media, the fashion industry, and the stock market reward this "art of forgetting" but public policy does not, and should not.

One way to break the hype bubble is to ask some contextual questions. The most interesting question surrounding nanotechnology is whether it will give us an industrial revolution, or just stain-resistant pants. Industrial revolutions do not happen often, so we shouldn't accept this assertion lightly (nor should it be made lightly). Answering this question forces us to view nanotechnology in a larger context and remember things we tend to comfortably obscure or avoid.

From the standpoint of the environmental community, the answer to this question (or recognition that it even exists) is important. Think about what is at stake. The modern environmental movement came into existence around thirty years ago at the tail end of the first industrial revolution. That revolution unleashed fossil energy for transportation, manufacturing, and power and created the chemical industry — a boon to society but a bane till this day because of accompanying pollution problems. If we are at the threshold of the next industrial revolution, the environmental community is facing its first opportunity to *shape* an emerging social and technological infrastructure in ways that could dramatically improve environmental conditions. This opportunity will be short-lived, given the tendency for technological systems, and their associated institutional infrastructure, to become locked in and hard to change. So if the next industrial revolution is about to happen, we will not have much time to take advantage of a new set of emerging environmental opportunities.

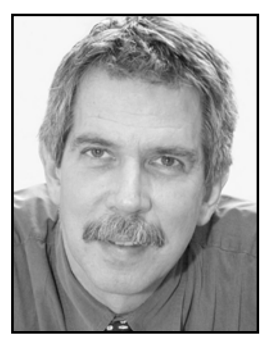
Changes already underway in industrial design and production show that regulation isn't going to be anything like it used to be

Unfortunately, there does not seem to be much excitement in the air or even the recognition of an industrial sea change in today's discourse on the environment. To be fair, many environmentalists are distracted. Given the ongoing attempts to roll back our existing environmental regulations there is not a lot of time or energy left to focus on prospective revolutions. However, the long-term costs of this distraction may be high as well as our social regrets when we wake up at some future date and gaze in amazement on a transformed industrial landscape. Now is the time to be asking three interrelated questions: First, obviously, Is there an industrial revolution taking place? Then, What are the critical implications for environmental protection and policy? And finally, How do we better prepare to shape the outcomes of this revolution? Let us address these questions one by one.

How would we know an industrial revolution if we bumped into one? Imagine if we could go back in time to the mid-1800s and pass through the last industrial revolution. What transitions — economic, social, or otherwise — would we perceive during our passage through time and are we seeing anything similar today?

Radical shifts in the means of production. The most obvious change would be the emergence of whole new ways of making things. In 1856, the search for a synthetic equivalent of quinine to treat malaria led the young English chemist William Perkins to the discovery of a purple dye and the launching of the synthetic chemical industry. Suddenly, coal went from a fuel to a feedstock for a whole new industry that quickly spread to Germany, France, and beyond. Perkins and his followers learned how to scale up laboratory-based processes to full blown manufacturing enterprises. Synthetic chemistry gave rise to synthetic plastics and then synthetic drugs and the whole synthetic world we inhabit today. Synthetic chemistry converged with other technologies such as the steam engine and electricity and electrification, which freed production from streams, coal mines, and other stationary sources of power. This story could be extended, but the point is that radi-

David Rejeski directs the Foresight and Governance Project at the Woodrow Wilson International Center for Scholars. He is a member of the EPA Science Advisory Board and was recently a Visiting Fellow at the Yale School of Forestry and Environmental Studies.



cally new means of production, based on new scientific discoveries, were a key to the last industrial revolution and will be the key to the next. Photolithography, powder metallurgy, combinatorial chemistry — these are some of the new ways of making things that have recently appeared. Nanotechnology's greatest potential, yet unrealized, will be in its ability to alter the means of production but that doesn't necessarily portend an industrial revolution. Here is why.

Environmentalism's first opportunity to shape an emerging technology in ways that could dramatically improve environmental conditions

Significant changes in communications infrastructure. We often forget that the first industrial revolution was built on radical changes in our communications infrastructure wrought by the telegraph, the telephone, and, in high-density urban areas such as New York City, pneumatic mail systems. To appreciate the extent of these changes, remember that before the advent of the telegraph, it took 10 days to carry a message from Missouri to California via pony express, two days to send a message from New York to Chicago by train, or weeks to go from America to England by ship. Within one decade (1840–1850) the time required to transmit any given word decreased by a factor of 3,000 and the cost by a factor of 100. Suddenly, the possibility of real time or near-real time communication became possible and affordable. What has changed over the last twenty years is not so much the speed of communication (we reached near speed of light rates years ago), but our connectivity, the amount of data available, processing power, and the radically decreasing cost of accessing and using that information. These changes have underpinned what we commonly refer to as the information economy. Nanotechnology may improve computing power, storage, or bandwidth, but the large disruptive changes have already occurred.

Changes in the organization and management of production. Closely associated with new ways of communicating are often new ways of organizing people, work, and commerce in a broad sense. As Peter Drucker once noted, "In a knowledge society, managers must prepare to abandon everything they know." During the last great industrial revolution, managers did abandon everything. By the early part of the 20th century, we witnessed the development and application of modern organizational and management theory. Harvard Business School was founded in 1909, new efficiency theories were applied to Fordist mass production systems, and industrial leaders such as Alfred Sloan rethought and reorganized the organizational structure underpinning business.

Pervasive changes in industrial structure have again occurred over the past decade, beginning in the computer industry and spreading to other areas in the manufacturing sector and finally into the service sector. Many of the changes are hidden behind a thick veil of jargon such as mass customization, contract manufacturing, distributed manufacturing, build-to-order, the real-time enterprise, value-chain modularity, the personalization of production, and free agent workers. Behind this gibberish, however, is the emergence of production systems built on loose, weblike networks rather than the traditional vertical hierarchies that have dominated industry in the past and shaped our past approaches to environmental law and policy. The term *supply chains* (denoting something rigid and linear) is now being replaced by the term *supply networks*. The nature and basis of competition is also in flux with an increasing premium put on speed to market, faster customer feedback loops, and the rapid re-engineering of products and processes. At this point in time, businesses in the nanotech sector have not departed from existing trends in organizational design and management. But what about impacts to the bottom-line?

Accompanying increases in productivity. A classic study by Ram Jaikumar at Harvard Business School examined the changes in labor productivity caused by shifts from the early craft system to mass production and to scientific management techniques and computer-based process control. Each of these changes in the means of production were typically accompanied by a factor of three increase in productivity. Are we seeing anything like this at this point in time? In sectors such as computers and industrial machinery, output per hour worked increased by an average of 15 percent annually between 1995 and 2001 (exceeding a factor two increase). Labor productivity has recently been running at rates of 7–8 percent, and, since the end of 2001, overall productivity has expanded at an annual rate of over 5 percent, reaching a 50-year record. Growth that appeared to be confined to discrete parts of the manufacturing sector has now spread into the service sector, defying a long held assumption attributed to economist William Baumol — that service sector productivity would lag way behind productivity in the manufacturing sector because it required activities that could not be easily mechanized. The most common explanation for this deepening in growth across multiple sectors is that organizations have finally figured out how to adapt to and optimize new technologies, especially information technologies. Nanotechnology may significantly boost industrial productivity, but is it not likely within the next five years. It is also unclear whether and when improvements will flow across sectors (into the dominant service industry, for instance) as they are doing with information technology.

So, looking backward, there were four clear signals, or patterns of signals, that an industrial revolution was upon us, starting a century and a half ago. Each of these factors — how we produce, how we communicate, how we organize production, and accompanying increases in productivity as a result of the first three — has significant environmental implications. Modify these factors and society's environmental footprint shifts, often in ways that are difficult to predict with precision. You will also notice that none of these changes has been impacted to any significant extent by nanotechnology— yet.

As the preceding section shows, an industrial revolution depends not just on the emergence of something new, but on the *convergence* of multiple innovations from multiple sectors and disciplines combined with new organizational forms and management techniques. It wasn't just the steam engine that produced the first industrial revolution, but the contemporaneous invention of the railroad, mass production, chemical engineering, telegraphy, etc. Those who declare that nanotechnology heralds a new industrial revolution are writing headlines, not making good social analysis.

However, looking at the present landscape through the same lens that history provides does show several technologies converging in the same way. We *have* entered a new industrial revolution, but not one based solely or even primarily on nanotechnology. The new industrial revolution began with information technology, which is now converging with biotechnology, and *eventually* will meld with nanotechnology. It is already upon us, and is accelerating. Nanotechology is destined to make it accelerate it even more.

The environmental community now faces a once in lifetime opportunity to get things right, but it will not happen without clarity of perception, moral conviction, and public sector leadership. We have a chance to guide an industrial revolution not only to minimize harm, but perhaps to find ways that industry can radically overhaul technologies, for environmental benefit. So let us stop here for a moment and explore this world from an environmental perspective. This is not some distant future that may appear at our local cinema, but a world at our doorsteps. The goal is to gain a better understanding of just what the hype bubble and other social distractions have obscured from view as our society has been entering, with increasing speed, the next industrial revolution.

Change accelerates. What is different about this industrial revolution versus that last is the rate of change, and this difference has broad implications for governance strategies, including environmental law. We are witnessing a shift from an economy based on long-lived technologies such as locomotives and power plants to one built increasingly on short-lived, constantly improving technologies like computers, DNA chips, or service strategies. It is not just computer processing speeds that are dramatically improving but things like the rate of process changes, the frequency of mergers, and the fundamental speed of innovation. Take, for instance, chemical synthesis, an area with significant environmental impacts. In the 1930s the largest chemical company in the world, A.G. Farber in Germany, could synthesize around 300–400 new chemicals per year. By the 1970s, a small group of chemists could achieve that rate and now, using combinatorial chemistry techniques that combine informatics and robotics, 50,000 new substances can be produced in a couple of weeks. We have moved into what Charles Fine at MIT calls a high "clockspeed" world, dominated by rapid improvements in products, processes, and organizations, all moving at rates that exceed the ability of our traditional governing institutions to adapt or shape outcomes. If you think that any existing regulatory framework can keep pace with this rate of change, think again.

An opportunity not only to minimize harm, but perhaps to find ways that industry can radically overhaul technologies, for environmental benefit

Software rules. The first industrial revolution was about hardware, the physical. It was the production, use, and disposal of this hardware that created the great environmental challenges of the past century. The new industrial revolution has created a world where hardware (atoms) and software (bits) co-exist — where the code determines the hardware. Today, a small design shop in Omaha can produce the production code for a semiconductor chip and send that code via satellite to a fabrication plant in Taiwan or Borneo. Companies are freed to focus their resources on parts of their enterprise where value creation is highest — innovation, product development, and marketing — and outsource the parts of their enterprise that manipulate the atoms — the manufacturing. This is becoming increasingly possible because of robust interfaces that allow software to create hardware (and do this almost anywhere in the world) and the increasing availability of high-quality manufacturing capabilities in low-wage markets throughout the globe. When software rules, environmental considerations will have to become embedded into the production code itself and travel with it, and that means that EPA and other environmental organizations will have to "go virtual," operating a world of simulation, production interface systems, bio-computation, etc.

> ***Environmental regulations were built on the assumption that industrial facilities and associated pollution would stay put***

The other change with potentially large environmental implications will be the increasing tendency to extract more and more economic value from the bits, not the atoms, which makes hardware less relevant. Profits will be extracted from selling information and connectivity and not from selling things. Already, companies are giving away cell phones or selling computer and peripherals under cost. Hardware will become increasingly linked to rapid software development cycles providing us with a constant flow of soon-to-be-obsolete products.

Fabrication goes mobile. As we separate bits from atoms, our ability to manipulate those atoms with ever-smaller devices is also dramatically improving. Maybe someday, as the nano prophets predict, we will be able to assemble things atom-by-atom, but long before that manufacturing will move out of big, easy-to-regulate factories and into the world around us just as computation moved from mainframes onto our desktops and into our pockets.

Take the workhorse of the industrial revolution, the hydraulic press. It used to stand many meters tall and weigh several tons. New units, based on powder metallurgy technology, are faster, more powerful, and the size of large filing cabinets. How about putting production on wheels or in cargo holds? Advances in robotics and computer-aided manufacturing now allow self-contained, turnkey manufacturing units for a variety of products, ranging from tires to bagels, to be packaged into 20 or 40-foot containers for shipment and use anywhere in the world.

Office production? Why not? Three-dimensional printers, once expensive devices used for rapid prototyping, can now be rented for under a $700 a month (Hewlett Packard is developing a unit which will sell for about $1,000). Suddenly, we will have the ability to produce "things" (not documents) in an office or workshop using a wide variety of input materials, ranging from chemical polymers to metal powders and cornstarch. But who recycles the "things" or determines the input materials? Such devices are not just gadgets for the idle classes wanting to "fax" a toy to their grandkids (though that will be possible). Researchers at the MIT Media Lab have developed sophisticated, tabletop production facilities known as FabLabs, which they have delivered (along with grad student trainers) to people around the world who would never have access to precision manufacturing. People in India, for example, have used these tabletop factories to produce devices to tune the diesel engines that provide power and water in many villages.

But it is not just the production of bulk items that will be possible with ever-smaller, adaptive systems. Chemical production modules called microreactors are now available in packages ranging in size from a postage stamp to a hockey puck. These devices open up the possibility of shipping reactors and producing, on-site, the exact amount of the substance required. This will change the industrial ecology of chemical production, shifting the routing of precursor chemicals and locations of final production. Analogous to a computer, a hundred or even thousands of microreactors connected in massively parallel arrangements would allow production to be scaled up and matched quite precisely with demand (existing units operating in parallel are already producing 30 tons of pigment annually). Uses could range from chemical synthesis to drug discovery or hydrogen production for fuel cells. A number of researchers are also developing microreactors for biotechnology applications (an area with significant implications for bioterrorism).

So long before we go from large-scale, or so-called "bulk," manufacturing to some futuristic nanoassembler, we will pass through small- and microscale production. The reason this transition is important to understand is that many of our environmental regulations were built on the assumption that industrial production and associated pollution would stay put. EPA has worked for years on the development of facility ID codes to help link data on manufacturers with stationary map coordinates and emissions data. What happens if we put production on wheels, in cargo holds, or in the mail? At that point, manufacturing becomes unteathered and from an environmental standpoint, begins to look more like a non-point, mobile source with the potential to move rapidly across geographic and administrative boundaries. How we deal with such production systems has yet to be studied by the regulatory community.

Production goes biological. Though the environmental press largely overlooked it, the biggest environmental story of the past ten years was the sequencing of the genome — the underlayment of the biotechnology revolution. But in addition to allowing us to alter basic qualities of organisms, essentially we have begun to unravel and understand the ultimate self-replicating production code, DNA, a code that operates at a nanoscale level. As this understanding grows, so does our ability to use biology for manufacturing. This industrialization of biology could radically shift the entire lifecycle of production, impacting everything from feedstocks to emissions to end-of-life strategies for products.

Nexia Biotechnologies in Quebec breeds goats with spider genes that allow the animals to produce milk containing the spider silk protein. The extracted spider silk is, in turn, used to produce a material called BioSteel, which has a tensile strength that is greater than steel and 25 percent lighter than petroleum-based polymers. In the future, we can anticipate an increase in transgenic production capabilities, which could place manufacturing in areas normally associated with livestock breeding. Transgenic modification is also not without risks, a point made in a recent report of the Pew Initiative on Food and Biotechnology.

A deeper understanding of genetics and molecular biology also provides us with a unique opportunity to replace catalytic chemistry based on nonrenewable feedstocks (such as petroleum) with enzyme-based chemistry built on renewable inputs. Polylactic acid (PLA) made from cornstarch is already replacing petroleum-based plastics such as PET, polyesters, and polystyrene, and PLA is carbon neutral and compostable. Enzymes and whole cell systems engineered from bacteria, yeasts, and plants are now being used in metal processing for leaching and refining, in drug development, textile treatment, and paper production (all processes with large environmental and energy burdens).

Finally, we may witness tectonic shifts in existing, and well regulated, production processes. One large and looming example is the production of computer logic, a process with high levels of both chemical and water use. To maintain existing exponential improvements in the per-dollar cost of computing (dictated by Moore's Law), it is highly likely that semiconductor industry will move from traditional photolithography techniques to the biological or chemical production of logic within the next decade or so. Research is already moving in this direction. Witness the work at MIT on the use of viruses to grow wires for the world's tiniest transistors or the recent development in Israel of a nanoscale transistor that assembles itself using DNA proteins. Such shifts would have far-reaching environmental implications, changing the inputs, emissions, and lifecycle management strategies of a variety of products.

Despite the game-changing nature of biological production, which includes a possibility to phase down the petroleum economy, it has received far too little attention in the environmental community, which has focused largely on its negative aspects (genetically modified crops and foods) rather than its pollution prevention potential. Once we start thinking in biological terms, it is a short step to the next major transition worth the attention of the environmental policy mavens.

> ***The industrialization of biology could radically shift the entire lifecycle of production, from feedstocks to emissions to end-of-life strategies***

Design becomes evolutionary. If we can assemble using biology why not use biology or biological principles to design? Design, after all, is the beginning of the environmental lifecycle. Before there are any environmental problems, there is a design for a factory, a product, a chemical — a design that is more or less environmentally benign. The problem with using evolution to design things is that it is normally too haphazard and time consuming. Look how many millions of years it took to design us humans.

But what if we can speed up evolution — all that messy, random sorting of traits normally done through trial-and-error and selective pressure? Well, that is exactly what is happening. In the late 1960s, Sol Spiegelman at the University of Illinois succeeded in selectively breeding particular RNA molecules to increase their replication rate by 15 times. By 1992 *Scientific American* featured its first story on what was termed "directed molecular evolution" or what we might call Darwin on steriods. Meanwhile, computer scientists have been conducting similar experiments to create computational ecosystems that breed problem-solving programs in survival of the fittest competitions. The goal is to build desktop innovation machines that will compete with humans. Such devices have already duplicated the invention of more than a dozen seminal patents in the field of electronics. Recently, researchers at Brandeis University have succeeded in selectively "breeding" simple machines in a virtual environment; machines which then "produce" themselves using the three-dimensional printing techniques mentioned earlier. So already, in the fields of biology, computing, and manufacturing, evolutionary processes are being applied to real world problems.

The speed and complexity of science and technology are exceeding the capacity of the environmental community to respond

Now comes the interesting part. If we use directed evolution to design products, molecules, or machines, how will we know if they will emerge with the right environmental characteristics? In some cases we will not. That is the nature of emergence. Many people involved in such experiments admit that they do not fully understand how an "evolved" molecule or computer program works. Essentially, understanding has been sacrificed for variety and speed. For legal scholars this raises an interesting question of who is responsible when environmental characteristics are essentially side effects of evolutionary design processes. On the other hand, one could apply directed evolution to solving environmental problems — to the design of safer chemicals, pesticides, consumer products, etc. Obviously, these scenarios sound far-reaching, yet they are as possible as any scenarios being laid out by the purveyors of nanotechnology and they are built on the last big things, the info and biotech revolutions.

If these trends hold, we are being fast forwarded into a new industrial infrastructure that is flexible, highly adaptive, increasingly based on biology, and driven more and more by evolutionary principles. To paraphrase Peter Drucker, all these developments are visible right outside our window. Waiting for nanotechnology to change this picture is a dangerous procrastination, because the picture is already changing in ways that demand our attention. The types of actions the environmental community needs to take now will prepare it to deal with the already-started industrial revolution and any that follow, nano-based or not. Here are some of the immediate challenges and some no-lose strategies:

First, the pervasiveness, speed, and complexity of the emerging science and associated technologies are exceeding the capacity of the environmental community to respond. Organizations are already being simultaneously pulled in multiple directions by disruptive changes in biology and computer science. Given the enormous public- and private-sector investments in nanotechnology we can expect extremely rapid innovation and unanticipated spillover effects, which will add to, and interact with, effects from the info and biotech realms. Especially hard hit will be the NGOs, who are otherwise occupied fighting unending battles to stop regulatory rollbacks and other stealth maneuvers by the barons of the last industrial revolution. Many local, state, and federal environmental organizations will not fare much better, as they will have to compete with the private sector for people with the skill sets to operate in these new areas or in the interstitial spaces between them (such as in biocomputation). In his 1986 science fiction novel *Count Zero*, William Gibson lays out a future where the battles are not between nations fighting for land, money, or resources, but between organizations vying for talent and creativity. The public sector needs to enter that battleground or become irrelevant. The environmental workforce in government has aged over the past thirty years and needs to be evaluated and restructured to make sure that agencies have the human, not just financial, resources to deal effectively with new challenges both in, and across, these emerging and converging disciplines.

Second, the front line of environmental protection will shift from the legal department to the science and technology functions. If we are at a critical juncture in our industrial evolution, then there is only one viable strategy in this situation, to proactively shape the future, a function that our existing regulatory infrastructure is not well suited for. This does not portend the end of environmental law. However, part of the legal profession must position itself at the front of the technological curve. There is an urgent need to carefully examine the existing regulatory framework in terms of adequacy to deal with emerging science and technology. This will require a deep, not superficial, analysis across the regulatory landscape within agencies, across agencies, and across geographic boundaries (local, state, federal, and international). The task will be made more difficult because innovation will be occurring between, rather than in, the disciplines and sectors where traditional laws and regulations have been developed and tested. Regulatory gaps need to be identified and the transparency of the regulatory system constantly improved, especially for small businesses driving innovation. The Converging Technologies Bar Association was recently launched to address some of these challenges, but more effort will be needed.

Third, agencies such as EPA, and its equivalents around the globe, will need to retool their research strategies. Too much funding is still being spent dealing with the last industrial revolution, its aftermath and byproducts, and not enough on preparatory and anticipatory research. Given the level of scientific and technological innovation taking place at this point in time, funding at EPA for so-called "exploratory" research is unacceptably low (0.8 percent or less of the total R&D budget). Funding should include a robust programs focused on societal and ethical implications in areas such as toxicogenomics.

There is also an urgent need to develop potential breakthrough technologies with R&D funding targeted directly at producing disruptive change (not a 3-percent improvement in efficiency or reduction in cost, but factor 3 or more). This is the way the Defense Advanced Research Projects Agency has traditionally functioned within the Department of Defense. That's the agency that gave us the Internet. Now is the time to create a DARPA-style office within EPA (and EPA equivalents) to tackle the really hard problems with unorthodox approaches. How much money should such an office receive? Between 1995 and 2003, DARPA's funding averaged 5.3 percent of total DOD R&D. A 5-percent figure applied to EPA's existing R&D budget would result in over $30 million devoted to the search for game-changing technologies. The driving ethos of such a project should be, as Apple computer founder Steve Jobs once said, to "put a dent in the universe." Such an office or department should become a magnet for the most creative talent in the world.

Finally, in an era of pervasive scientific change, we need pervasive scientific literacy, and that includes our public, our press, and our policymakers. We can expect the complexity of the science underpinning both environmental problems and solutions to continue to increase, demanding evermore sophisticated understanding transcending multiple disciplines. Over a decade of survey research done by Roper for the National Environmental Education and Training Foundation has shown that as complexity of environmental issues increases, public understanding drops off precipitously. A scientifically illiterate public will be extremely susceptible to various scare campaigns in the press, films, or other media. Nanotechnology has become the poster child for technohype as it creeps into the public consciousness through advertisements, TV shows, books, and films. In this environment, it will be harder for the public to separate science from science fiction. How can we possibly have a rational and informed discussion around issues such as genetic modification or nanotechnology or try to inform policy through multi-stakeholder dialogues involving the public?

Our ability to prepare society for the next industrial revolution is closely related to our ability to perceive and anticipate change and understand its implications for present actions and policies. Frankly, far too few resources in the environmental community are dedicated to understanding the changing context in which policies and strategies will be developed and implemented. Some future historian may well characterize this point in our environmental history as one of tragedy, not only because of the unenlightened attacks on our environmental laws, but also because we missed an opportunity to reshape our industrial infrastructure in ways that would make it far more environmentally benign and sustainable. In a recent interview, former Sun Microsystem's Chief Scientist Bill Joy noted that "we need to encourage the future we want, rather than try to prevent the future we fear." Too many times, environmental protection has been focused on fears rather than aspirations. We need to break that habit, and the opportunity is now. •

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