Overseeing the Unseeable

Nanotechnology — the fruit of many disciplines, involving numerous sectors of the economy — is the perfect test case for the future of environmental protection, a chance for a clean-slate approach. Oversight will require a variety of approaches — voluntary and involuntary, public and private, market-based and rules-based

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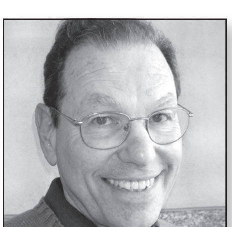
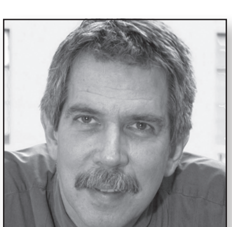

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On Earth Day 1970, protesters poured oil on the sidewalk in front of the Department of the Interior to protest the spills that were fouling the American coastline. The United Auto Workers passed a resolution stating that "a rigid timetable must be imposed upon the auto industry to develop an engine that will not pollute the air." Senator Gaylord Nelson recommended that Congress phase out the internal combustion engine unless manufacturers could develop pollution free exhausts. New York Mayor John V. Lindsay banned all automobiles from 5th Avenue, calling for the development of a "new technology of life."

The Environmental Protection Agency was born later the same year. EPA faced a daunting job, and not just from dirty motor vehicle engines and the fuel they ran on. Estimates to clean up the environment ranged upward to the hundreds of billions of dollars. While some regulations governing pollution and resource protection were already on the books, a "new technology of life" was more a motto than a mandate — new legislation was urgently needed as well as a new body of science and engineering. Almost four decades later, however, the gasoline engine, substantially cleaner but still a foul instrument, is roaring along. The agency's battle with tailpipe emissions continues.

The agency started with only a $1.4-billion budget to catch up with decades of technological advances that had neglected to take the environment into account. Ever since, EPA has been the bureaucratic tortoise racing the technological hare. Indeed, EPA has spent its entire existence in a rearguard battle to mitigate the impacts of technologies born during the Industrial Revolution. The internal combustion engine, invented in the late 19th century, was just one. The same story could be told about the basic technologies used by the chemical industry or in manufacturing or electricity generation, to name just a few.

EPA has made impressive progress in restoring clean air and clean water, but if it is to deal with new technological challenges, it will need new approaches. Nanotechnology, which utilizes materials composed of particles so small that their chemical and physical properties can sharply differ from their everyday, normal-size cousins, both illustrates why this is true and gives us some indication of what the new approaches should be.

Nanotechnology is a good test case in part because of the economic stakes. Last year, approximately $12.5 billion was invested globally in nanotech R&D by the public and private sectors. Investments are beginning to pay off, with over 500 manufacturer-identified nanotech-based consumer products on the market from 22 countries and many more to come. Nanotechnology holds immense promise for improving almost every aspect of our lives — the clothes we wear, the food we eat, the houses we live in, the medical care we receive. It will radically change many, perhaps most, industrial processes — how we transport ourselves, generate energy, synthesize chemicals, and design computers. If these promises are to be fulfilled, research and development must go hand-in-hand with development of an adequate oversight system. The current system is simply not adequate.

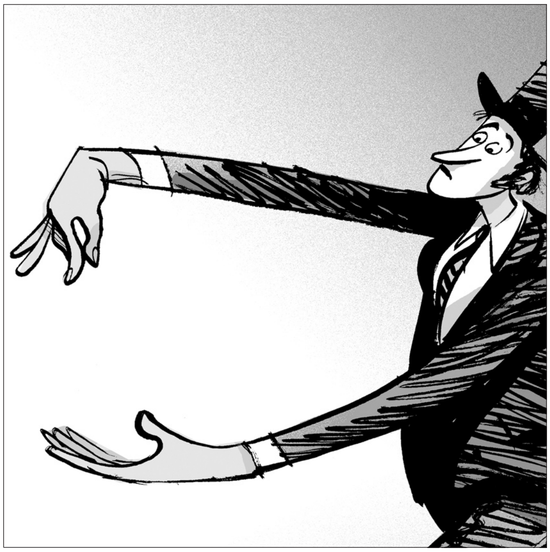
The Coming Revolution

Nanotechnology offers the opportunity for a national, and potentially global, revolution in environmental affairs — much like the 1960s revolution in business affairs, but much harder because the entire economy is involved. A revolution in environmental affairs will require EPA to re-evaluate its role, re-think its regulations, and re-invigorate its workforce. Nanotechnology provides the agency with the rationale for the revolution simultaneously with the need — the chance to emerge from its tortoise role and build an oversight system with the flexibility and efficiency to address the next hundred years of technological change, not the last hundred.

Without an adequate oversight system, people and the environment are almost entirely vulnerable to the potential adverse effects of new technologies. Without an adequate oversight system, the technologies themselves are vulnerable to public mistrust and rejection; as a result, the benefits they offer may never be realized. Recently, 40 international NGOs issued a statement calling for tighter regulation of nanotechnologies, based on the precautionary principle.

Some deficiencies of the current system are generic and have been recognized for a long time, but nanotechnology, in posing particularly daunting challenges to current oversight, highlights the magnitude of the need. The free market will not solve this problem. We need oversight precisely because the market has failed in the past to detect and prevent health and environmental problems.

The challenges posed by nanotechnology and the weaknesses of the existing statutory system are evident in almost every law that is relevant to the lifecycle of these new materials:



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- The Toxic Substances Control Act does not allow EPA to get the evidence needed to determine the risks of new chemicals, whether nano-sized or not. The act has largely been emasculated with respect to existing chemicals by the 1991 *Corrosion Proof Fittings* case, which placed restrictions on the ability of the agency to ban or limit chemical processing, distribution, or use. The most effective way for EPA to regulate nanomaterials would be under TSCA's new chemicals provisions. However, EPA recently announced that TSCA's definition of new chemical substances precludes the agency from considering particle size as a factor. This potentially emasculates the act with respect to nanomaterials. Most nanomaterials will not be categorized as new chemicals and thus will not be reviewed.
- The Clean Air Act and Clean Water Act suffer from fundamental difficulties in dealing with nanomaterials. First, the standards under the acts, especially under the CAA, are mass-based — they regulate the concentration or volume of pollutants. Such standards don't work for nano because mass is not the factor most related to their toxicity. Second, both acts are based on monitoring. We do not have good ways of monitoring for nanomaterials, especially in water. Third, both acts are premised on sources' applying controls to meet the standards, but we do not have good methods for controlling air or wa-

ter emissions of nanoparticles. Technology forcing, where Congress puts in place aspirational standards, beyond current capabilities, in the belief that such requirements will spur research and development, has been successful in the past; a good example is CAA requirements for automobile manufacturers to develop pollution controls. However, the technology for controlling nano is far more difficult to develop from a scientific and engineering standpoint — it is not simply an extension of current art. In addition, unlike carmaking, where a handful of firms dominate the industry, the nanotech industry is diffuse, involving hundreds of companies in several different sectors. It is likely that no firm would feel the responsibility to try to develop control technology.

• The two primary acts designed to deal with wastes and end-of-life issues, the Resource Conservation and Recovery Act and the Comprehensive Environmental Response, Compensation, and Liability Act, have yet to be applied to nanomaterials, though nano-engineered substances have certainly entered the wastestream. Both acts have limitations, including a focus on mass rather than size or properties arising from structure. Other issues include determining whether nanomaterials will constitute hazardous substances under these acts, whether existing test procedures for assessing risk would work (such as the Toxicity Characteristic Leaching Procedure under RCRA), and whether exemptions and exclusions would have to be modified to address nano manufacturing.

EPA recently announced that TSCA's definition of new chemical precludes consideration of particle size.

On the international front, the European Union's new chemical law, REACH — which stands for Registration, Evaluation, Authorisation, and Restriction of Chemical Substances — differs in several important respects from its U.S. counterpart, notably by putting the safety burden of proof on the manufacturer. However, it is still undecided whether REACH will cover nanomaterials, a determination that will likely be made in 2008.

The effects of nanotechnology on health and the environment are unknown, although studies have raised warning signs. Determination of these effects does not easily fit into existing risk paradigms. We are unsure which characteristics of nanomaterials correlate most closely with potential adverse effects, and the answer may differ for different types of nanomaterials or even for different products made from the same nanomaterials. Existing ways of determining risk are based on a correlation between mass (dose) and effect. Scientists are fairly sure that the biological effects of nanomaterials are more likely to depend on the surface area of a particle, the conductivity of its surface, and other factors that are not related to the weight or number of particles. The risk framework that has guided environmental policy for three decades will need to be revised.

The medium-based environmental framework that has guided most environmental law will also need to be re-thought. The limitations of the existing medium-based statutes, chiefly the CAA and CWA, means that EPA's product-based statutes, such as TSCA, will be the first line of defense. Laws like the CAA or CWA will be a last resort — once nanomaterials have escaped into air or water it is likely to be too late to effectively control them.

Nanomaterials do not fit into the traditional boxes of air or water pollutants or solid waste. An example is the Samsung Silver Wash laundry machine, which sanitizes clothes by releasing small particles of antibacterial silver into each washload. The machines are consumer products (theoretically covered by the Consumer Product Safety Act) whose primary threat is water pollution (covered by the Clean Water Act), but the only law under which they are being considered for regulation is the Federal Insecticide, Fungicide, and Rodenticide Act. Food packaging containing nanomaterials, now under development, is under the regulatory jurisdiction of three agencies — EPA, the Food and Drug Administration, and the Department of Agriculture (if used for meat or poultry). In each agency several different divisions have some role in regulating the packaging, which will raise significant challenges in terms of regulatory handoffs and the coordination of authorities.

The science of nanotechnology is expanding at a rapid pace, mobilizing chemists, physicists, medical researchers, and almost every other scientific discipline. The rollout of the science is expanding even faster. Almost every day sees a new commercial application. The government cannot deal with this rapid growth by using traditional methods of regulation. An agency that can take years to issue a rule cannot prescribe detailed behavior for a technology that changes almost daily.

Because nanotechnology, like genetic manipulation and the computer, is changing many aspects of life in important but unanticipated ways, oversight needs to consider the societal consequences of this new technology. What effect will it have on rich countries vs. poor countries? On the distribution of wealth? On health and the Social Security system? On the way military operations are conducted? At present, we do not have good ways of evaluating societal consequences, and we are handicapped by a near total inability to accurately predict what the broader consequences of new technologies will be. The National Environmental Policy Act requires analysis of physical consequences, but it has generally not been used to deal with social consequences. The NEPA analysis usually takes place at a late stage in the application of a technology, when the consequences are imminent and easier to foresee, but harder to slow down or eliminate.

RCRA and CERCLA have limitations, including a focus on mass rather than size or structure.

The challenge of safely harnessing the benefits of nanotechnology will involve both the public and private sectors in developing better ways of dealing with the interface between technology and society. It is important to note in this context that with nanotechnology, as with most of the broader new technologies — hydrogen fuel cells is another — we are not dealing with purely market-driven phenomena. The U.S. government is investing more than a billion dollars a year. Its decisions should take social consequences into account.

Nanotechnology in international trade is another formidable problem. Products containing nanomaterials are likely to be made from components from many different countries and to be marketed worldwide. The Samsung washing machines are manufactured in Korea and China and were marketed in Europe before they were sold in the United States. Research on the effects of nano products and reporting of any adverse consequences will have to involve other nations. Dealing with imports and exports will have to be an essential part of any system of oversight. Releases are likely to cause problems for many areas, not just the area where the releases take place.

A Framework for a New System

Thinking about a new oversight system should probably begin by focusing on three things: what are the functions that need to be performed, who would perform these functions, and what are the means by which they will be performed. Matching actions, actors, and tools is one way of framing the challenge of putting together an oversight system that meets the values that society holds, values that encompass both protection against adverse effects and utilization of the benefits that new technologies can bring.

The actions or functions that initially need to be considered are identification and prevention of adverse health or environmental effects. This leaves out the questions of broader societal effects, questions that need to be addressed but for which we have fewer answers and less experience.

Identifying adverse effects for products can be divided into pre-market and post-market stages; each involves collecting and analyzing data. Having identified the functions that need to be performed, we can then go on to consider who can best perform them and how. For example, developing data at the pre-market stage is probably best done by the manufacturer. To what extent test requirements should be promulgated by the government, and, if so, what the requirements would look like, are open questions.

Identifying actors involves a variety of considerations — for example, which are most likely to have the relevant information and expertise, which are most likely to have the required financial resources, which are most likely to be reliable and transparent to the public. The economic interests of corporate stakeholders will need to be considered, but so will the role and interests of state and local governments, as well as of international agencies.

The CAA and CWA function only as a last resort, after nanomaterials have already escaped into the air or water.

Analyzing the role of the public presents numerous challenges. When should citizens be involved in oversight and how? Value questions are a basic aspect of many oversight questions: How do we know the public's values and how do we incorporate them? How important is public education? How can we allow the public to educate decisionmakers? Can tools like labeling be used to allow the public to encourage good products and discourage bad ones?

It makes sense to consider a broad variety of oversight tools. (An analysis of how different tools could be used in an oversight system is featured in *EPA and Nanotechnology,* available from nanotechproject.org.) Among tools that should be explored are voluntary industry codes requiring testing and lifecycle analysis of new products; mandatory networks for observing and reporting adverse effects after a product is marketed; withholding insurance from companies that do not test adequately; and state and local regulation of manufacturing plants. Each type of tool has strengths and weaknesses.

Some Preliminary Conclusions

Given the anti-regulatory climate in the United States, it would be easy to dismiss a call for a new oversight system as overreaching and premature. However, a morality tale for nanotechnology businesses and investors appeared on the front page of the *New York Times* on July 30 titled "Without U.S. Rules, Biotech Food Lacks Investors." Worried by declining investment capital and a potential lack of public confidence in its products, the biotech industry is pushing for regulatory clarity that the administration has failed to provide. When we create a new industrial landscape, rules of the road matter.

A recent survey of nanotechnology firms in eastern New England undertaken by the University of Massachusetts/Lowell indicates that virtually every firm — large or small — lacks clear information on the environmental and health risks of nanomaterials and is suffering from a lack of guidance from regulators ("What do we test for?" "What standards do we apply?" "Where do we find research on the impacts of nano-scale materials?"). Industries operating without information and clear guidance pose risks not only to workers, consumers, and the environment, but also to their investors and shareholders. Smaller companies, often severely resource constrained, are especially vulnerable and urgently need technical assistance and clear guidelines.

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If we wait too long, regulation may not matter. Standing at the back door of this commercial dreamhouse are the ghosts of technologies past. The most recent intruder is genetically engineered food but close encounters with nuclear power, asbestos, PCBs, and CFCs have convinced many consumers that it pays to read the fine print on any so-called technological miracle. Public perception could turn against nanotech, dampen consumer enthusiasm, and generally ruin the tidy scenarios of the technophiles and their investors. The economic impacts will be real. It is estimated that public backlash against genetically modified food in Europe is costing U.S. farmers up to $300 million per year in lost revenue. Canadian exports of canola oil went from $185 million per year to just $1.5 million in 2005 because of anti-GM rules. With 70–80 percent of adult Americans largely ignorant of nanotechnology, how they learn, from whom, and with what message will be critical. Negative perceptions could easily jump across product lines and brands and from one industry sector to another.

A rapidly shifting social dynamic between business, consumers, NGOs, and the media requires that companies think through the strategic implications of their research and product development plans, including the role of government oversight in maintaining consumer confidence. Industries that overestimate their capacity to manage nanotechnology-related risks, or over-state the level of protection offered by weak or non-existent government regulation, can pass financial risks onto their shareholders and investors, a strategy that backfired with agricultural biotechnology.

Of course, all this becomes more complex as nanotechnology and biotechnology converge, a process that has already begun. When physics, chemistry, and biology collide, the potential for both profits and unintended consequences expands and the regulatory learning curve rises, placing more of a burden on already under-resourced agencies. Waiting will not make the oversight challenge any easier to solve.

Nanotechnology provides an opportunity to apply oversight while the technology is developing, to be proactive rather than reactive, to not wait until after adverse effects have occurred or the technology has been discredited. We cannot afford to lose this opportunity. We should apply our creativity to thinking through what the components of an adequate oversight system would be and how it can be made flexible enough to apply to future technological developments. Then, through dialogue and education, we should mobilize the political energy to translate thinking into action.

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As George Orwell once said, "Within any important issue, there are always aspects no one wishes to discuss." With many emerging technologies, the indiscussible is the fact that our public policies and institutions may need fundamental changes, and that we seem to lack the political will to act in the public interest. •