

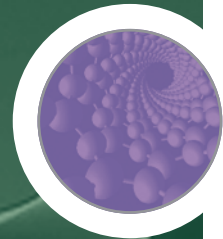


Woodrow Wilson  
International  
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*Project on Emerging  
Nanotechnologies*

# OVERSIGHT *of* NEXT GENERATION NANOTECHNOLOGY

*J. Clarence Davies*



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[Abridged from this version of the report]



## PREFACE

J. Clarence “Terry” Davies and I first became acquainted when I was appointed the first Administrator of the Environmental Protection Agency and he had just finished working on the plan that created the new agency. In the almost 40 years since then, the world has learned much about environmental problems and how to deal with them, and by many measures the environment is cleaner than it was in 1970. But, as described in Terry’s report, the challenges of the 21st century are daunting and require new approaches to oversight. We need a more effective and efficient oversight system, one that can deal with nanotechnology and other scientific advances as well as the multitude of existing problems.

In this report, Terry provides some broad and innovative suggestions about what such an oversight system might look like. He describes a new Department of Environmental and Consumer Protection that would be more of a science agency than the current regulatory ones and that would incorporate more integrated approaches to oversight and monitoring. He suggests for discussion a new law that would focus on product regulation and new tools that could be used to deal with future health and environmental problems.

These suggestions are an important contribution to the dialogue that is needed to formulate a better oversight system. As Terry says, his proposals are intended to be the beginning of a discussion, not its conclusion.

Over 20 years ago at a national conference on risk assessment, I said that I do not believe technology necessarily is going to master us. We are smart enough to take advantage of the fruits of technological advances and to minimize or eliminate risks to people and the environment. But we need to learn from past mistakes and be able to anticipate future challenges. Terry’s report uses the experience of the past to suggest the policy directions of the future. I share his hope that the report will spur the thinking and dialogue needed to deal with the problems that lie ahead.

— William D. Ruckelshaus

## ABOUT THE AUTHOR

J. Clarence “Terry” Davies, a senior advisor to the Project on Emerging Nanotechnologies and a senior fellow at Resources for the Future, is one of the foremost authorities on environmental research and policy. He helped pioneer the related fields of risk assessment, risk management, and risk communication, and his work has advanced our understanding of cross-media pollution—the tendency of pollutants to move across boundaries, from air to water to land, revealing shortcomings in the legal and regulatory framework. He has authored three previous reports on nanotechnology for the Project on Emerging Nanotechnologies.

Davies served during the first Bush administration as Assistant Administrator for Policy, Planning and Evaluation at the U.S. Environmental Protection Agency (EPA). Earlier, he was the first examiner for environmental programs at the Bureau of the Budget (now the Office of Management and Budget). In 1970, as a consultant to the President’s Advisory Council on Executive Organization, he co-authored the plan that created EPA. Dr. Davies also was Executive Vice President of the Conservation Foundation, a non-profit think tank on environmental policy; Executive Director of the National Commission on the Environment; and a senior staff member at the Council on Environmental Quality, where among other activities, he wrote the original version of what became the Toxic Substances Control Act. He has served on a number of committees of the National Research Council, chaired the council’s Committee on Decision Making for Regulating Chemicals in the Environment, chaired the EPA Administrator’s Advisory Committee on Toxic Substances and served on EPA’s Science Advisory Board. In 2000, he was elected a Fellow of the American Association for the Advancement of Science for his contributions to the use of science and analysis in environmental policy.

Davies is the author of *The Politics of Pollution*, *Neighborhood Groups and Urban Renewal*, *Pollution Control in the United States* and several other books and monographs addressing environmental policy issues. A political scientist by training, Davies received his B.A. in American government from Dartmouth College and his Ph.D. in American government from Columbia University. He taught at Princeton University and Bowdoin College, and has helped mentor a generation of environmental policy researchers.

### 3. THE FUTURE OF OVERSIGHT

This section explores what a more adequate oversight system might look like. The approach proposed is largely non-incremental because, in the author's view, the existing system is so deficient and the new challenges are so different from those of the past that it would be a mistake to try to deal with them by tinkering with the existing system. The political system operates incrementally except when faced with a crisis, and it is to be fervently hoped that no crisis arises with respect to nano or any other technology. However, over the long run, the political system also responds to models of what could or should exist. Goals and ideals, even if a sharp departure from the status quo, can influence the thinking of policy makers and the public. Many of the changes described below will take a decade or more to accomplish, but there is an urgent need to start thinking about them now.

The proposals set forth in this report are intended to be the start of a dialogue, not its conclusion. The purpose is to draw attention to the need for basic reform and to frame the magnitude and direction of the needed changes. If the proposals catalyze a serious discussion of oversight policies to deal with the problems of the coming decades, then this report will have achieved its purpose.

A new system requires a new organization, new legal authorities and new oversight tools. This section begins with a description of a new hypothetical organization, the Department of Environmental and Consumer Protection. Then, to describe the new authorities and tools that would be required and to flesh out the nature of the new organization, the paper discusses product regulation, pollution control, monitoring and technology assessment. Each

of these would be a basic function of the new agency. Finally, the section analyzes several additional important areas that require new approaches—risk assessment, enforcement, international cooperation and public involvement. Each of these functions cuts across the basic organizational building blocks described earlier in the section.

#### INSTITUTIONAL FRAMEWORK

A new oversight system is urgently needed both because of the pitiful state of the current system and because of the nature of the new challenges presented by technological change.

The characteristics of the new technology have been described above. The current oversight system was designed to deal with the problems of steam engine technology in the context of a pre-computer economy. It was based on assumptions that most problems are local, that programs can be segmented and isolated from each other, that technology changes slowly and that all the important problems have been identified. All of these concepts are no longer valid, if they ever were.

The antiquated conceptual basis of the system has been made more evident by the massive erosion of money and manpower from a system that always suffered from inadequate resources. However, resources alone are not what is needed. New concepts, new types of organizations and new tools are necessary to provide the knowledge and flexibility for effective oversight.

A new structure for 21<sup>st</sup>-century oversight requires more integrated approaches at every level. The current fragmented system was tolerable as long as the problems were limited in scope and localized in scale. This is no longer

the case. The problems of the 21st century have a potentially broad impact that is not limited to any single geographic area. They do not and will not fit into the compartments delineated by current legislation.

At the level of individual programs, fragmentation hinders effectiveness now. There are almost more pollution control programs than anyone can count, and pollution control and prevention are handicapped because current government regulations focus narrowly on air pollution, water pollution or various forms of disposal. In another area, environmental monitoring is inefficient and unsatisfactory because of the multiple agencies trying to monitor interconnected parts of the environment, each agency doing it in its own way.

At a broader level, regulation of different kinds of products can benefit from drawing on the same risk research or the same systems for monitoring adverse effects. Different types of research can benefit from a single source of monitoring data. There are many such synergisms.

Another pressing need is for scientific support that is based on high-quality research and that is relevant to the needs of oversight. In the United States, both EPA and FDA have had the advantage of in-house scientific support, but the amount of support is inadequate. A recent report by a subcommittee of the FDA Science Board stated, "The FDA cannot fulfill its mission because its scientific base has eroded and its scientific organizational structure is weak" (U.S. FDA 2007, p. 3). FDA and EPA have had problems attracting and retaining good scientists because most scientists would prefer to work for a science agency than for an oversight agency.

Unlike the current EPA and FDA, which are oversight agencies with a scientific component, the new agency would be a scientific

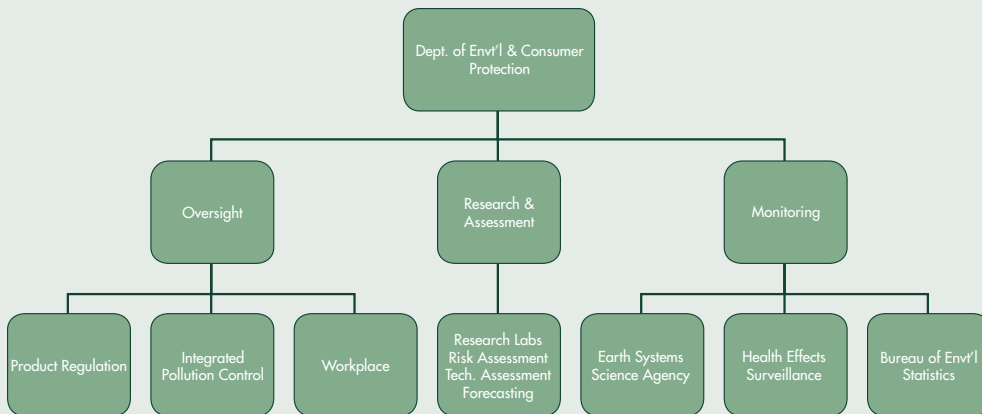
agency with an oversight component. Both the research and assessment component and the monitoring component of the new agency would focus on science, and each of these components probably would be larger than the oversight component. The scientific complexity of 21<sup>st</sup>-century problems requires oversight agencies that have strong scientific competence.

An additional need is for laws and organizations that are flexible enough to respond to the characteristics of technology described in the first part of this paper. The existing U.S. federal oversight agencies have generally been too small to have much flexibility. All their resources are devoted to survival and to the performance of the minimal required functions; they have limited ability to anticipate and respond to new problems or to consider new ways of doing things.

Meeting these needs would require both new laws and a new organization. This short paper does not cover new laws in any detail, although some suggestions are included in the discussion below. A new organization that would provide more integration, better science and more flexibility is outlined in Figure 2.

The organization depicted in Figure 2 could provide a more adequate basis for oversight than the current system does. It would focus oversight on products, pollution and the workplace, and do so in a more integrated way. In addition to an oversight function, the organization would have major components devoted to monitoring and research. The research function would also deal with technology assessment and forecasting.

A new agency would make many synergisms possible among the different functions and programs shown in Figure 2 and would facilitate integration of closely related programs. Although this paper focuses on nanotechnology,

**FIGURE 2. Hypothetical Department of Environmental and Consumer Protection**

the reorganization would improve the government's ability to handle almost all major environmental and consumer programs. For example, it would allow climate change research and modeling to be brought together under one agency (under the research and monitoring functions). The same agency would be responsible for controlling greenhouse gases (under the oversight function), and the head of the agency could formulate overall climate policy with the benefit of advice from both the scientific and regulatory components of the agency.

The new agency would incorporate six existing agencies: EPA, the U.S. Geological Survey (USGS), the National Oceanic and Atmospheric Administration (NOAA), the Occupational Safety and Health Administration (OSHA), the National Institute of Occupational Safety and Health (NIOSH) and CPSC. New units would have to be established for risk assessment, forecasting, technology assessment, health monitoring and the Bureau of Environmental Statistics.

The appendix provides some dollar and personnel estimates for the hypothetical agency. The estimates are based on the current size of the component agencies plus some additional dollars

and personnel based on estimated need. The proposed agency would be among the smaller federal cabinet departments but not the smallest. In terms of full-time equivalent (FTE) personnel, for example, it would be ten times larger than the Department of Education and four times larger than the Department of Housing and Urban Development. However, it would be half the size of the Treasury Department and a quarter the size of the Department of Homeland Security.

The new agency would be significantly larger than the current EPA or any of the other federal oversight agencies. The oversight functions should be housed in a larger organization not only because of the relationship between size and flexibility noted above but also because the current small size of the regulatory agencies makes them vulnerable to becoming even smaller. The "large getting larger" seems to be the organizational analogue of the rich getting richer. Smaller agencies have less influence and are less able to influence policy than larger agencies are. Aside from this political point, the small size of the oversight agencies prevents them from being able to devote resources to new problems, and in the 21st century new problems will arise frequently.

Large size can have the disadvantage of encouraging slow and rigid decision-making and discouraging innovation and creativity. To reduce these disadvantages, many of the components of the new agency would be allowed to operate with a good deal of independence. The success of the new organization would depend greatly on the degree to which it could strike a good balance between integration and independence of the components.

Other functions could be added to the new agency. For example, food-safety programs, currently scattered among four federal agencies, could be consolidated in the proposed department. However, this function and other functions are not included here because they are subject to other legislative proposals or other considerations beyond the scope of this paper. Consideration should be given to creating a commission to consider the composition of the new agency as well as possible new oversight laws and tools.

### PRODUCT REGULATION

A central question for oversight is whether it should focus on materials or products. The answer will determine many of the most important parameters of the oversight system. The current oversight systems focus on both materials and products. Materials are regulated by TSCA and REACH; various kinds of products, (e.g., drugs, pesticides and beef), are regulated under a variety of other laws.

*Materials* are substances with particular characteristics. TSCA defines them as substances with a particular molecular composition, although size or form should be added as a relevant defining characteristic to deal with nanotechnology. Other characteristics of a material, such as radioactivity, may also be relevant for oversight.

*Products* are items that are sold to public consumers, manufacturers or others. A product may

go through multiple stages, each stage being a separate product. For example, carbon nanotubes (one product) can be combined with plastic in a compound used for car bodies (a second product), and that compound is incorporated in a finished automobile (a third product). A material is usually a product, and the same material can be incorporated in many products.

An oversight system based only on products would be better than the current mixed system. The way in which the material is used, the way it is combined with other materials, and other factors are critical for determining whether adverse effects will occur (Royal Commission on Environmental Pollution 2008). Therefore, materials by themselves do not provide a good basis for evaluating risk. If some types of carbon nanotubes can cause asbestos-type problems, for example, these problems can be avoided by combining the nanotubes with other materials, by using them only in closed systems or by making minor changes in the form of the nanotubes. Regulation of products will capture these differences—regulation of the material will not. Whether it is possible to establish an oversight system based on products rather than materials will depend on what the system looks like.

At least two principles should underlie oversight of products. First, oversight should encompass the life cycle of the product—manufacture, use and disposal. Transportation is also part of the life cycle, but it can be regulated separately by the Department of Transportation. Second, the degree of oversight, i.e., the stringency of regulatory requirements, should be related to the anticipated harm the product will cause. This is a function of the severity of anticipated harm and the likelihood that it will occur.

The government is not likely to have detailed and current information about the

composition of a product, its intended use or its anticipated effects. Only the manufacturer will be able to know or obtain this information on a timely basis. Thus, the government inevitably must depend on the manufacturer to reliably test the product and to accurately report relevant information to the government. The penalties for distorting, concealing or failing to obtain required data must be sufficiently great to deter such behavior.

A previous report (Davies 2006, p. 19) suggested that the information required of the manufacturer be incorporated in a sustainability plan (SP) that the manufacturer would compile. A plan would be required for each product. The plan would contain a summary of known information about the components of the product, the adverse effects of the product, a life-cycle analysis of the product describing its use and manner of disposal and an explanation of why the product would not cause any undue risk. The government would define as precisely as possible what data are required and what constitutes undue risk. Risk would include mechanical risks (e.g., from chainsaws or collapsing baby cribs) as well as chemical and biological risks. It seems reasonable to require every manufacturer of a product to know this information before selling the product. The government could require additional information for particular categories of products. The SP would have to be updated if the manufacturer became aware of new information that affected the product's risk.

A number of firms have voluntarily produced statements similar to a sustainability plan. For example, Apple issued an environmental report on its MacBook Air laptop computer ([images.apple.com/environment/resources/pdf/MacBook-Air-Environmental-Report.pdf](http://images.apple.com/environment/resources/pdf/MacBook-Air-Environmental-Report.pdf)). The report includes sections on climate change, energy efficiency, material

efficiency, restricted substances and recycling. DuPont, in cooperation with Environmental Defense, developed a framework for analyzing the risks of nanomaterials ([www.nanorisk-framework.com](http://www.nanorisk-framework.com)). The framework is applied to all new DuPont nanoproducts. For many chemicals, the SP would resemble the chemical safety assessments required under REACH.

Because every product (except those exempted) would have to have an SP, manufacturers would be able to know the potential risks of components they use by requiring their suppliers to provide them with the SPs for the components. This would be a major benefit to manufacturers of complex products like automobiles. At present, auto manufacturers may be legally liable for problems caused by components they use, but they may have no practical way to find out what the risks of the components are. REACH (Article 34) requires risk information to be passed on from any actor in the supply chain to the next actor or distributor up the supply chain.

Special efforts will be needed to inform small businesses about the requirements and to provide these businesses with technical assistance to help them meet the requirements. A variety of programs can be used to do this. Small businesses should not be exempted from oversight because some of the most dangerous products are made by small manufacturers, and it is not unreasonable to expect them to assess whatever dangers their products might pose.

What would be done with the sustainability plan and what additional information, if any, it would have to contain, would depend on the harm the product might cause. A possible typology is as follows:

**Category 1:** This category would be for products that have a very low probability of having adverse effects. There would be no oversight; the SP would simply be retained by

the manufacturer, or, if there were clearly no significant risks, the product manufacturers might be exempted from the SP requirement altogether. Examples of category 1 products are books, furniture and some industrial tools—probably 70–90 percent of all products in commerce. There is always the possibility that new evidence will move a category 1 product to a different category.

**Category 2:** This category would be for products for which risk-communication measures should be sufficient to avoid adverse effects. The manufacturer would be required to use the SP as the basis for a product safety data sheet to be given to users and/or for labeling for consumers. Examples of products in this category would include some household cleaning products and industrial catalysts that are consumed in the manufacturing process.

**Category 3:** Post-market review of the SP by government. This category would consist of category 1 or 2 products suspected of causing adverse effects after having been sold. The government would be empowered to halt manufacture and/or distribution of the product pending a review of its safety.

**Category 4:** This category would be for products that have some probability of causing adverse health or environmental effects. There would be pre-market review of the product. Products in category 4 would include pesticides, fuel additives and products containing designated types of materials (e.g., persistent organic pollutants).

The government would define the categories and decide which products belong in which categories. To the extent possible, the government would assign broad classes of products to particular categories. If a manufacturer wanted to produce a product that was not included in one of the previously assigned classes, it would have to submit a request to the

government to designate which category the product belonged in.

For categories 3 and 4, the burden of proof would be on the manufacturer to demonstrate that the data in the SP were valid and adequate and that they supported the conclusion that the product would not or did not pose undue risk. The government might have to show some cause for categorizing a product as category 3.

As noted above, the major challenge in regulating products is the enormous number of products on the market at any given time. For example, CPSC oversees 15,000 types of products, and each type contains numerous individual products. Inevitably, the number of products placed in each category would, to some extent, be determined by the resources available to the government oversight agency. The first two categories would require only spot checking by government, and category 3 probably would apply to only a relatively small number of products. Category 4 would require intensive use of government resources. Consideration should be given to paying for product approval through fees, as is now done for drug registration by FDA, although steps would need to be taken to avoid some of the problems with the FDA system. Consideration should also be given to making public on a regular and timely basis whatever gap may exist between resources and oversight requirements. This could be done by requiring the agency to regularly publish the number of products that should be reviewed but for which resources were not available to do the review.

#### INTEGRATED POLLUTION CONTROL

*Pollution control* is control or prevention of harmful wastes. *Pollutants* are unwanted by-products of manufacture or use. Unlike materials or products, they have no value and the oversight goal can be to reduce pollutants to

the smallest amount possible. This goal is not applicable to materials or products because, since they have value, the benefits of the product to society must be weighed against the cost of its adverse effects. Even with respect to toxic materials it is necessary to consider the benefits they provide. Pollutants that can be recycled become, strictly speaking, products because someone will pay for them and therefore they have a value.

The dividing lines into which pollution control has been segmented are a significant handicap in dealing with present and future problems. For example, control of nanoparticles released during manufacture must be based on preventing the releases from occurring. Trying to deal with the problem by separately regulating releases to the air or the water or land, as current law does, will not work.

In Europe, integrated pollution control is a reality (U.S. EPA 2008). In 1996, the EU approved the IPPC directive. The directive mandated that each EU member nation establish a system based on an integrated pollution permit for each facility. The EU set up a mechanism to assist the countries with such a system, in particular by defining sector-specific Best Available Technology, the standard to be incorporated in each permit. The IPPC permits cover not only disposal to air, water and land, but also such matters as energy and water use, noise and odors, accidents and facility decommissioning.

As stated in a comprehensive U.S. government report on IPPC permits in the United Kingdom, “the U.S. does not have a corresponding, all-inclusive environmental statute to address emerging challenges on a comprehensive, ongoing, and straightforward basis.” (U.S. EPA 2008, p. xi). A U.S. facility typically must have dozens of environmental permits (Davies 2001). Each federal program

(air pollution control, etc.) requires several different types of permits, and in addition to the federal permits there are state and local permits. A large facility will require several filing cabinets (or many megabytes of computer space) for the contents of the different permits it holds. The system not only results in bureaucratic duplication and confusion but also makes permitting opaque to the public. Moreover, because of the fragmentation, it fails to control a significant portion of a facility’s environmental impact (*Ibid.*). Although the EU’s IPPC system operates in a political and cultural context different from that of the United States, the United States would benefit from adopting an approach more like the EU’s.

The linkage between oversight of products and control of pollution (wastes) has not been adequately explored on either side of the Atlantic. Regulation of materials and products may, in some cases, be the most effective and efficient way of preventing or reducing wastes. In the United States, the linkage is recognized—TSCA authorizes the EPA Administrator to, among other things, regulate the manufacture, use and disposal of a substance that presents or will present an unreasonable risk (TSCA sec. 6(a)). However, these authorities have rarely been used. In the 30-year history of TSCA, EPA has used these authorities to regulate a total of six existing chemicals (Schierow 2007, p. 17). It is likely that to deal with future problems, the product control laws will need to become a more significant part of environmental protection.

### TECHNOLOGY OVERSIGHT AND ASSESSMENT

A *technology* can be defined either as a body of scientific knowledge and its application or as the practical application of a particular body of scientific knowledge. To the extent that

the definition includes scientific knowledge, it probably would be impossible to regulate this kind of knowledge and, even if it were possible, it would be counterproductive. Oversight focuses on the applications of a technology. However, the line between the science and its applications may be difficult to draw, especially when dealing with the social implications of technology. Would a new material that enabled the human brain to grow additional neurons be considered science or the application of science? Focusing on particular applications may miss the overall impacts of a technology, and by the time the implications of the applications become clear it may be too late to effectively influence the direction the technology takes. With only a few exceptions (e.g., nuclear power) technology as such is not and should not be regulated in the same sense that products and wastes should be regulated. However, oversight can take forms other than regulation.

The impacts of new technologies on society in the 21st century will be huge. We can deal with these impacts to some extent by regulating products, materials and wastes. But many of the most important impacts will not be captured within these categories. When one thinks of the impacts of the automobile on society, air pollution does not seem to be among the biggest, important as it is. Three things are needed for oversight of technology: (1) an assessment of the technology's impacts, especially unintended impacts; (2) ways for the public to understand the technology's impacts and register its views; and (3) ways for the government to translate the public's views into actions. None of these requirements is being satisfactorily met.

In one sense, technology assessment is done all the time. Measuring pollution from various sources, modeling the impact of climate

change and estimating future sales of computers are all elements of technology assessment. However, what is needed is a capability to consider the overall impacts of major new technologies and to do so while there is still time to deal with the impacts. This requires a forecasting capability as well as an assessment capability. The techniques for doing forecasting and assessment have not received the attention they need. Not coincidentally, the institutions for making forecasts and conducting assessments are weak or non-existent (see Davies 2008, pp. 23-24).

Involving the public in the evaluation of new technologies poses many difficulties. It should be understood that the public *will* become involved, politically and economically, as protestors or boosters or customers. However, the involvement is mostly after the technology has become established. The future of the world's people will be shaped by new technologies, but there is usually no opportunity for people to consider which technologies should be promoted, which should be discouraged and how to deal with the consequences and impacts of any particular technology before the impacts occur.

How the government should influence the direction of new technology is also a knotty question. The government exerts a major influence now through financial support for private research and development, appropriations for defense and other science-intensive government programs and regulations (or the absence of regulations) on various activities. All these actions usually are taken piecemeal, without any coherent strategy for the overall technological future of the world or even for the future of any particular technology.

Consideration should be given to using "social impact statements" analogous to the environmental impact statements required of

government projects. The statements would provide a vehicle for the public to learn about new technologies and for both the public and the government to consider what steps, if any, should be taken to maximize the beneficial impact of the technology and to minimize its adverse effects. Who would prepare the statements, when would they be prepared, what would be their scope and level of detail and how they would be disseminated are all questions that would need to be answered.

Individual government agencies need to become more aware of their impact on technological development and of the impact of technologies on society. The foremost example is the military, which has given us a large number of significant technologies ranging from DDT to the Internet. The Department of Defense should establish a Defense Technology Review Board to weigh the civilian as well as the military consequences of new military technology. Board members would have to be privy to all aspects of defense research and development. The board would provide advice both to the military departments and to the President's Science Advisor.

### MONITORING

Monitoring is an essential part of oversight. It provides the link between government actions and the real world. The institution outlined in Figure 2 would do two types of monitoring—environmental and human.

Environmental monitoring in the United States includes a broad set of functions conducted by a number of agencies. Recently, a distinguished group of science policy experts proposed combining the two largest agencies, NOAA and USGS, into a single, independent Earth Systems Science Agency (Schaefer et al. 2008). NOAA has a budget of nearly \$4 billion and 12,000 employees. USGS has a

\$1 billion budget and 8,500 employees (*Ibid.*). The structure in Figure 2 would adopt the experts' proposal but would make the Earth Systems Science Agency a semi-independent part of the proposed Department of Environmental and Consumer Protection. The monitoring part of the department also would include the EPA monitoring functions and a Bureau of Environmental Statistics, analogous to the Bureau of Labor Statistics. The bureau proposal has been around for 20 years and has several times come close to becoming law, but has never quite made it usually because of extraneous factors.

In addition to the Earth Systems Science Agency, there should be a human-health monitoring component. Given the uncertainties of risk assessment for new technologies, some adverse consequences of new products will probably be missed when the product is first commercialized. These consequences will not be identified unless there is an extensive surveillance system that spots abnormal health phenomena such as an excess number of cases of a given disease or a spike in emergency room admissions. It is beyond the scope of this paper to provide details about such a system, but it should be coordinated with other domestic and international health reporting systems and it should be as unobtrusive as possible.

### RISK ASSESSMENT

The above discussion provides some detail about the major components shown in Figure 2. Four functions cut across most of the components: risk assessment, enforcement, international cooperation and public involvement. Each of these will be discussed in the context of 21st-century technologies.

Adequate oversight of new technologies will depend on our ability to forecast the risks the technologies pose. Forecasting the risk

involves basic scientific information about the technology, test data on specific products and risk assessment. Each of these components has a different source and different characteristics.

Basic scientific information comes primarily from university and government laboratories. The motives for developing the information include scientific curiosity, the possibility of obtaining grants and contracts and the possibility of making money through patents and/or start-up companies. Meeting societal needs, such as identifying the risks of new technologies, is often not a major consideration in setting the basic science agenda. This is one reason why it is important for government oversight agencies to have their own scientific resources.

Testing of specific products is done primarily by their manufacturers, either in-house or through contract laboratories. It is beyond the resources of government agencies to test the multitude of products and, in any case, the manufacturer will be most knowledgeable about the products it is making.

Testing for new kinds of products can be problematic. For example, it is often not known what end points (e.g., cancer, asthma, fish mortality) to look for when testing nanomaterials nor is it understood which characteristics of the material are associated with adverse effects. In the absence of testing, conclusions about the safety of a product or material are often based on analogous materials that have been tested. However, by definition, new types of materials and products do not have exact analogues that have been tested. When technologies are evolutionary, as many nanotechnologies are, analogues may help predict behavior, but they are still generally not an alternative to testing. The technology of testing is itself changing, and there has been progress in developing tests that are much faster and

cheaper than current tests that rely on laboratory animals (Service 2008).

The type of risk assessment usually done by the government has evolved into a highly sophisticated set of procedures. Risk assessment must be used if government decision makers are to make rational decisions.

Risk assessment was developed to meet the needs of decision makers. It did not grow out of any scientific questions, and assessments typically are not scientific products; they are a way of organizing and analyzing data about a particular substance or product. They are not scientific because only in unusual cases can they be empirically verified. The typical risk assessment may result in a finding that substance X will produce Y number of additional cancer cases per million people exposed. However, whether Y is zero or 1,000 in reality will never be known and typically is unknowable because there are too many other causes of cancer. Regulatory decisions almost always must be taken based on the weight of the available evidence. Conclusive scientific proof is usually not to be had, although the better the available science the easier it is to do a risk assessment and the more accurate the assessment is likely to be.

Because decisions typically must be based on balancing the available evidence, the default assumption about who has the burden of proof is critically important. Rodemeyer (2009) has observed that “in many cases information about risks of a new technology is simply unavailable or uncertain. In such cases, the regulatory decision depends upon the default policy assumptions about the inherent safety of the technology. In turn, the default policy assumption is shaped by the framing of the new technology in relation to existing technologies.” (Also see Jasanoff 2005.)

REACH primarily puts the burden on the manufacturer to prove safety, whereas TSCA

puts it on the government to prove risk. This makes REACH a more effective oversight law. Industry occasionally argues that the burden should be on the government because it is not possible to prove safety, but this is a fallacious argument. It is not possible to conclusively prove the safety of a product just as it is usually impossible to conclusively prove the risk. Risk and safety are both operationally defined by required tests, and it is equally difficult to prove either one.

### ENFORCEMENT

Enforcement has two related dimensions—incentives and compliance. The stronger the incentives the better the compliance, but the two dimensions involve different considerations.

The increasingly rapid pace of technological innovation and the diversity of the innovations have made it difficult to apply many of the older enforcement approaches. Newer approaches have emphasized economic incentives and flexibility. Liability has been used as the major incentive in one U.S. waste law (the Comprehensive Environmental Response, Compensation, and Liability Act of 1980), and it might be possible, for example, to make manufacturers legally liable for failure to develop a sustainability plan or for any adverse consequences that could reasonably have been foreseen but that were not included in the plan. A downside to using liability and litigation in implementing regulatory oversight is that government employees might have to spend large amounts of time giving testimony in court, making depositions and participating in litigation in other ways. This might seriously affect their ability to perform their primary duties (Mark Greenwood, personal communication).

Cap-and-trade programs, such as the one used in the U.S. regulation of sulfur dioxide emissions from power plants, have been proposed as a substitute for much of the existing

pollution control structure (see <http://www1.law.nyu.edu/conferences/btl/index.html>; accessed 11/11/08). Effluent fees and charges have also been used in a few situations and have been suggested as an approach that could be used more widely. It is not clear whether these kinds of approaches could be used for oversight of useful products (as contrasted with wastes) and, at the least, caution must be exercised when proposing that incentives developed for curbing wastes be applied to useful products.

Insurance is another incentive that can be important. It can be used either negatively or positively. Negatively, one insurance company has already refused to insure for any damage connected with nanotechnology (Rizzuto 2008), citing the lack of adequate risk information. If other companies follow suit, this could be a major incentive for more research and more testing of products by private firms. Insurers could deny insurance to manufacturers that did not have a sustainability plan. On the positive side, insurance could be given to manufacturers against tort suits if the manufacturer had an adequate sustainability plan and had implemented that plan, and the tort suit covered a subject that was included in the plan.

With respect to compliance, the key question probably is the extent to which voluntary compliance can be relied upon. The answer depends on the cultural context and may differ between Europe and the United States. At least for the United States, oversight in many contexts has shown voluntary compliance to be undependable. Legally enforceable requirements, vigorously implemented, are necessary to deal with the usually small, but important, percentage of firms that are not good corporate citizens.

### INTERNATIONAL COOPERATION

The combination of a worldwide economy and near-instantaneous communication among

all nations has made technology oversight an international issue. Every oversight function, from research to enforcement, now has important international dimensions. The challenge is how to embody the international dimensions in effective institutions.

A web of international organizations exists. The EU is itself an international organization. The Organization for Economic Cooperation and Development (OECD), which includes most of the industrialized nations, has taken a variety of initiatives related to new technology. It has agreed to test 14 generic nanomaterials for health and environmental effects, and has established a database for sharing research information on potential adverse effects of manufactured nanomaterials ([http://www.oecd.org/document/26/0,3343,en\\_2649\\_37015404\\_42464730\\_1\\_1\\_1\\_1,00.html](http://www.oecd.org/document/26/0,3343,en_2649_37015404_42464730_1_1_1_1,00.html)). The United Nations has several components relevant to oversight including the World Health Organization, the UN Environment Program, and the International Labor Organization. Many non-governmental international organizations, including international trade associations and mixed public-private organizations such as the International Organization for Standardization, play a part in oversight efforts.

In the long run, an international regime for product oversight may develop to match the international trade in products. At the least, the U.S. and European regulatory approaches should be made consistent (see Breggin and Falkner 2009). In the interim, the emphasis should be on information sharing.

At least three types of information should be made available internationally: (1) research results on adverse effects of a technology; (2) standards, regulations and other oversight policies and decisions applied to a product or technology; and (3) reports of any adverse health or

environmental effects that occur and that could be attributed to a product. The OECD has made a start on the first two. The third is an important function that needs to be supported, perhaps by a joint effort of the World Health Organization and the UN Environment Program. An international system for reporting adverse effects would have to draw heavily on existing surveillance systems.

As this is written, the worldwide economic crisis and the collapse of the Doha round of international trade talks have made the future of all international efforts uncertain. One outcome of the current crisis could be a stronger set of international institutions, even perhaps including the basis for an internationalized system for dealing with new technologies and products.

#### **PUBLIC INVOLVEMENT**

Transparency should be the hallmark of oversight activities. Without it, the public interest tends to get submerged beneath the interests of bureaucrats, politicians and special interests. Transparency becomes even more important in the context of new technologies because if the public senses that secrets are being kept and motives are being hidden it may reject a new technology regardless of its benefits. As the International Risk Governance Council (2007, p. 8) has noted, the new technologies will require more public involvement because their “social, economic and political consequences are expected to be more transformative.” The challenge, as expressed by the Royal Commission on Environmental Pollution (2008, p. 72), “is to find the means through which civil society can engage with the social, political and ethical dimensions of science-based technologies, and democratize their ‘license to operate’... a challenge of moving beyond the governance of risk to the governance of innovation.”

The 21st Century Nanotechnology Research and Development Act, the law governing nano research in the United States, requires the National Nanotechnology Coordination Office to provide “for public input and outreach to be integrated into the [National Nanotechnology] Program by the convening of regular and ongoing public discussions, through mechanisms such as citizens’ panels, consensus conferences, and educational events, as appropriate” (PL 108-153, sec. 2(b)(10)(D)). The National Science Foundation has experimented with some of these techniques, but overall, little effort has gone into implementing this part of the law. Other countries have also experimented with new public participation mechanisms to deal with technology (see, for example, Jones 2008).

In the context of new technology oversight, the public can be thought of as three groups: (1) the insiders—industry representatives, non-governmental organizations, academic experts, labor union representatives; (2) the somewhat informed general public; and (3) the bystanders. The majority of the population falls in the category of bystanders. They do not know about or understand the new technologies and they do not follow what the government does or says about them. However, even the bystanders may influence

oversight through their role as consumers, and the products they buy may be influenced by the opinions of the insiders.

A goal of public policy has been to move people from the bystander category to the informed category. This is consistent with a Jeffersonian view of democracy and is an important way of reducing the chances that the public will react against a technology based on propaganda or misinformation. How successful efforts to inform the public can be, what methods can be used and how to draw the line between information efforts and propaganda are important subjects that are beyond the scope of this paper.

#### THE PATH AHEAD

This is a short paper that covers a broad range of topics. A previous report (Davies 2008) laid out the steps that can be taken in the short run to improve nanotechnology oversight. This paper broadens the coverage in that the suggestions for new oversight mechanisms cover all technologies, not just nanotechnology. It also stretches the timeframe—the focus is technologies and policies over the next several decades. The paper is an exercise in both technology forecasting and policy envisioning. If the forecasts are even roughly accurate, then thinking about new policies is urgently needed.

## APPENDIX – APPROXIMATE DOLLARS AND PERSONNEL IN NEW DEPARTMENT

Agency	Oversight		Research		Monitoring		Total	
	\$s	FTEs	\$s	FTEs	\$s	FTEs	\$s	FTEs
<b>EPA</b>	6,600	14,800	600	1,900	300	600	<b>7,500</b>	<b>17,300</b>
<b>CPSC</b>	65	400					<b>65</b>	<b>400</b>
<b>OSHA</b>	500	2,000					<b>500</b>	<b>2,000</b>
<b>NOAA</b>			1,750	5,500	1,500	6,800	<b>3,250</b>	<b>12,300</b>
<b>USGS</b>			500	3,300	1,000	5,200	<b>1,500</b>	<b>8,500</b>
<b>NIOSH</b>			265	1,409			<b>265</b>	<b>1,409</b>
<b>Other</b>	1,000	1,000	3,025	500	1,050	200	<b>5,075</b>	<b>1,700</b>
<b>Total</b>	<b>\$8,165</b>	<b>18,200</b>	<b>\$6,140</b>	<b>12,609</b>	<b>\$3,850</b>	<b>12,800</b>	<b>\$18,155</b>	<b>43,609</b>

Notes: For abbreviations see list of acronyms. Dollar figures are given in millions. All figures are author's approximations based on current strength of agencies that would be included in the new department, except for the "other" category which is based on need rather than on existing agencies.

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