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*Project on Emerging
Nanotechnologies*

ROOM AT THE BOTTOM?

Potential State and Local Strategies for Managing
the Risks and Benefits of Nanotechnology



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ACRONYMS

EPA	Environmental Protection Agency
OSHA	Occupational Health and Safety Administration
FDA	Food and Drug Administration
PEN	Project on Emerging Technologies
NANO	Nanotechnologies Advancement and New Opportunities Act
TSCA	Toxic Substances Control Act
NPPTAC	National Pollution Prevention and Toxics Advisory Committee
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
DTSC	Department of Toxic Substances Control
TMD	Toxics Management Division
TURA	Toxics Use Reduction Act
CAA	Clean Air Act
RCRA	Resource Conservation and Recovery Act
CERCLA	Comprehensive Environmental Response, Compensation and Liability Act
DIMP	Di-isopropyl-methane-phosphonate
TCE	Tri-chloro-ethylene
CWA	Clean Water Act
TMDI	Total Maximum Daily Load
CAFO	Controlled Animal Feeding Operation
CSTE	Council of State and Territorial Epidemiologists
NNI	National Nanotechnology Initiative
MSDS	Material Safety Data Sheet
POTW	publicly owned treatment works
DPR	Department of Pesticide Regulation
CPSC	Consumer Product Safety Commission
UPCF	Unified Program Consolidated Form
HMBP	Hazardous Materials Business Plan
CAS	Chemical Abstract Service
PPE	personal protective equipment
ASTM	American Society for Testing and Materials
STAPPA	State and Territorial Air Pollution Program Administrators
ALAPCO	Association of Local Air Pollution Control Officials
ASWIP-CA	Association of State and Interstate Water Pollution Control Administrators

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Suellen Keiner

PEN 11 MARCH 2008

The opinions expressed in this report are those of the author and do not necessarily reflect views of the Woodrow Wilson International Center for Scholars or The Pew Charitable Trusts.

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PREFACE

This report by environmental law and policy expert Suellen Keiner presents an in-depth analysis on the role that local and state governments can play in the design and implementation of effective and forward-looking oversight systems for nanotechnology. The report makes clear that states and municipalities can serve as a “spark” for action at the federal level by illustrating which oversight practices work and can act as “laboratories for democracy” that may be more responsive and more attuned to the needs of local populations and businesses. Historically, states and municipalities have implemented oversight systems that go beyond federal mandates.

States presently are taking the lead in areas as diverse as climate change, fuel economy standards, and product labeling. Nanotechnology offers the next opportunity for these jurisdictions to continue acting as leaders and models at the cutting edge of policy-making.

This report illustrates the value of such a “bottom-up” approach. It examines how nanotechnology may fall within existing state regulatory frameworks that deal with air, water, waste, labeling, and worker safety. The report uses four short scenarios to illustrate how state and local governments may address nanotechnology and pave the way for more effective federal oversight.

This approach is not without its drawbacks. A variety of state and local regulatory strategies for nanotechnology could become difficult for companies to navigate and potentially insufficient to address the wide range of oversight challenges posed by nanotechnology. However, in the absence of substantial and timely federal government activity in this area, industry is left without clear guidance and exposed to downstream liabilities and potential public backlash. State and local governments can fill this gap, and these authorities must begin to consider how nanotechnology fits within existing and pending legislation.

—**David Rejeski**, Director, Project on Emerging Nanotechnologies

EXECUTIVE SUMMARY

Given the slow pace of federal action to oversee responsible development of nanotechnology, there is “room at the bottom” for state and local governments to move forward in pursuing regulatory and other oversight options. Certainly, this scenario is less than ideal because it creates a patchwork of different regulations across the country. However, it could serve as an interim approach until a national oversight system for the environmental, health, and safety impacts of nanotechnology is enacted into law by Congress or adopted by rules based on the existing authorities of the various federal agencies responsible for these impacts.

States and localities often have adopted their own initiatives to address environmental, health, consumer and worker safety issues that are pressing concerns for their constituents. Recent actions have addressed such issues as climate change, product labeling, and fuel economy standards. In regard to overseeing nanotechnology, Berkeley, Calif., has taken the lead in adopting an ordinance that requires handlers of nanomaterials to submit reports on the toxicology of those materials, if known, and on any measures they are taking to protect the environment, public health, or worker safety. As Berkeley’s Mayor Tom Bates put it, “If the Federal government isn’t going to do anything ... I would love for us to continue to be on the forefront and continue to put forward new and innovative ideas that allow it [nanotechnology development] to happen but does so in a way that makes sure that the public is safely protected.”¹ Cambridge, Mass., is currently considering its options for a similar ordinance.

In the absence of action at the federal level, other local and state governments may begin to explore their options for oversight of nanotechnology. Although it is difficult to track changes in state legislation and regulatory activity, research for this report has identified a number of states with laws promoting the nanotechnology industry or other initiatives encouraging research and development on nanotechnology applications. All 50 states are home to at least one company, university, government laboratory, or other type of organization working with nanomaterials.

Based on the states’ important role as “laboratories of democracy,” this report discusses possible options for states and localities to oversee the environmental, health, and worker safety impacts of nanotechnology. Existing state authorities and experiences that might be applied to nanotech oversight include:

AIR: At least 15 state agencies have adopted stringent air quality laws or regulations to fill a gap in federal standards, and at least 29 local air agencies are authorized to adopt more stringent air quality controls.

WASTE: Several states have imposed standards for regulating metals in waste that are not covered by Environmental Protection Agency (EPA) regulations.

WATER: State laws often offer substantial flexibility for regulating and controlling water discharges that may contain pollutants. At least five states have exercised their

discretion to set water quality discharge standards that are stricter than federal limits, and another five states have exceeded federal requirements in their programs for monitoring groundwater.

LABELING: States are free to adopt their own product labeling requirements, similar to those provided for toxic chemicals by California's Proposition 65.

WORKER SAFETY: The Occupational Health and Safety Administration (OSHA) has approved plans for 21 states that enable them to adopt federal safety standards for workers in private industry.

Based on the analysis presented in this report, the states that appear most able to launch initiatives for overseeing safe and responsible development of nanotechnology are California, Michigan, Massachusetts, New York, and New Jersey. These five states have both oversight authorities or historical experiences that go beyond federal requirements in two or more of the categories listed above and are already home to significant nanotechnology business activity.

Finally, this report identifies at least four scenarios for potential action by states or localities to fill gaps in federal oversight and thereby initiate their own oversight of nanotechnology's health, safety, and environmental impacts:

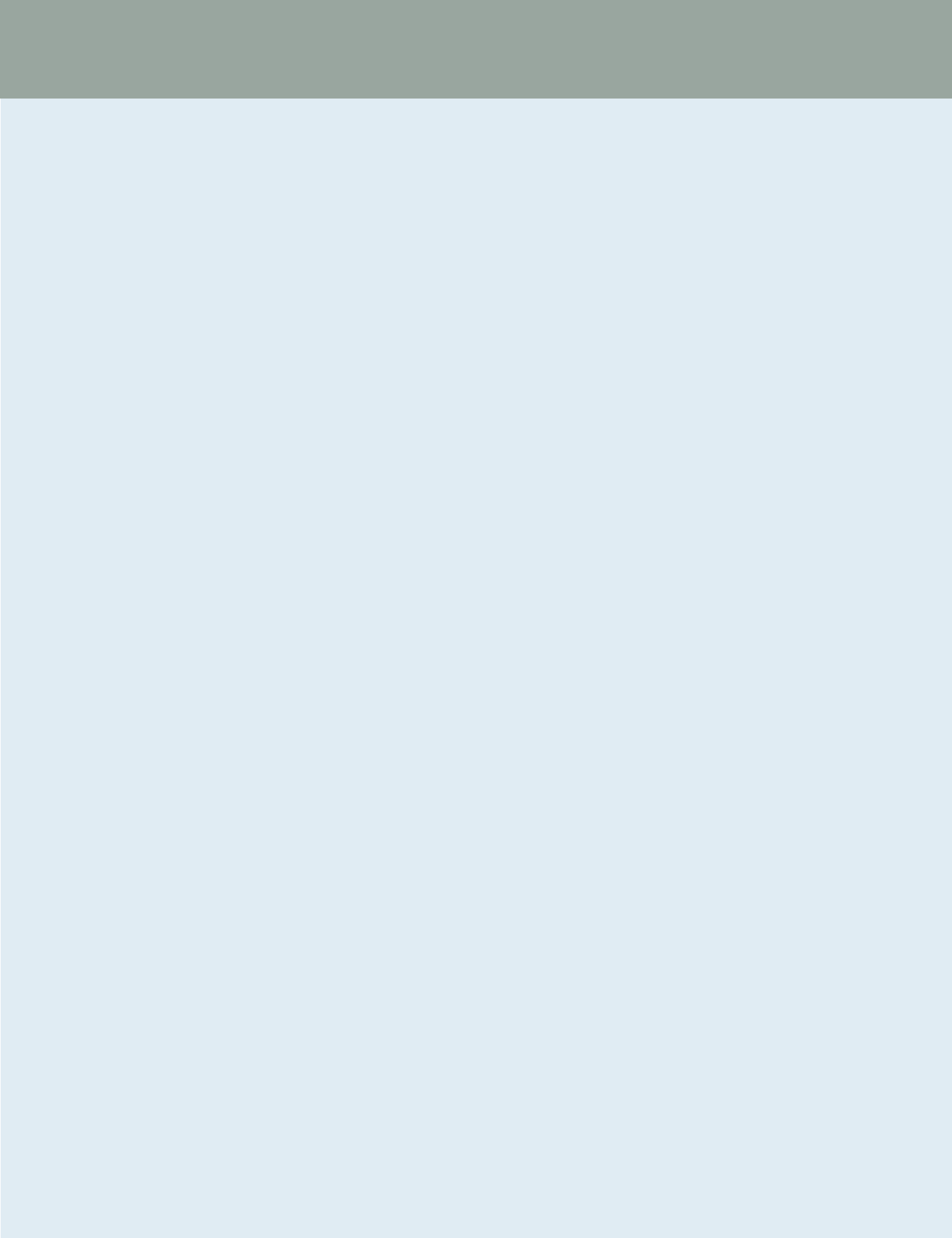
1. Localities could require disclosure of potential health, safety, or environmental hazards, as does the recently enacted ordinance in Berkeley, California;
2. States or localities may choose to adopt standards that are expert-driven, such as the nanotechnology workplace standards being developed by ASTM International, the International Organization for Standardization, or other standards bodies;
3. Stakeholders—such as state or local regulators in other programs, consumers, workers, and even nearby businesses—may play an important role in nanotechnology oversight when they exert pressure on states to control or prevent releases of nanomaterials; or
4. One or more states may choose to collaborate to establish joint regional standards or approaches for overseeing the safe development of nanotechnology.

In addition to these state-initiated approaches, there is the unlikely possibility that Congress could enact a law requiring nationally uniform standards to protect human health, worker safety, and the environment from potentially adverse impacts of nanotechnology. Such a law could either require or make it optional for states to adopt those national standards in exchange for federal grants to support their oversight programs.

Alternatively, EPA, OSHA, and the Food and Drug Administration (FDA) could choose to exert their combined authorities under various environmental, safety, worker protection, con-

sumer, and public health laws and thereby adopt nanotechnology oversight or regulatory standards that apply nationwide. But the states' and localities' own nanotechnology initiatives might still be important because they could go beyond any federal regulations that may be adopted in the future.

Interested state and local environmental or health agencies, especially those in areas where nanotech businesses and research facilities are already concentrated, could also form a coalition or working group to design a joint oversight program for nanotechnology. By drafting a model law, rule, or ordinance based on prudent precaution, state and local agencies could address concerns about responsible development of nanotechnology and fill the current gaps that leave them “room at the bottom” for effective oversight.



I. INTRODUCTION

In 1959, Nobel Prize winner Richard P. Feynman proposed that scientists begin work on the unexplored frontier at the atomic scale, which led, decades later, to the birth of nanotechnology.² At that time, he said there was “room at the bottom” to discover the “enormous number of technical applications” that can be developed by “manipulating and controlling things on a small scale”—at the atomic level—where there are “new kinds of forces and new kinds of possibilities.”³ His brilliant prediction almost 50 years ago challenged and stimulated research that led to the development of nanotechnology today.

Now the recent rapid growth in the production of materials, products, and goods based on nanotechnology⁴ has begun to raise a number of questions about how to oversee nanotech products and materials. The chemical, biological, or physical properties of nanomaterials are often unknown and quite different because of the small size of these materials and their very high ratio of surface area to volume. Compared to the same substances in larger particles, nanomaterials may thus require new approaches to ensure that public health and the environment are protected from potential adverse effects.

The need to develop government policies and oversight mechanisms for nanotechnology is becoming ever more urgent as the pace of innovation in the industry speeds up and the risk-benefit considerations of these products become increasingly complex. Moreover, unless government regulators begin to take seriously the possible hazards from nanotechnology, alarm about such risks may under-

mine the public’s confidence in businesses’ ability to handle these materials safely.⁵ This possibility of strong public opposition to a potentially beneficial new technology is what led to rejection of genetically modified organisms in many countries.

While there have been no known cases of people or the environment being harmed by nanomaterials, it would be unprecedented that, at some level or rate of exposure, some nanomaterials do not pose a risk. Already, there has been at least one recall due to concerns about the safety of a product thought to contain nanomaterials, even before a connection between nanomaterials and health problems had been established.⁶

To address the safe handling of nanotechnologies, the Project on Emerging Nanotechnologies (PEN) at the Woodrow Wilson International Center for Scholars has been publishing studies that analyze the authorities various federal agencies might be able to use for oversight of nanotechnology. See, for example, Davies, *Managing the Effects of Nanotechnology* (January 2006); Taylor, *Regulating the Products of Nanotechnology: Does FDA Have the Tools it Needs?* (October 2006); Greenwood, *Thinking Big about Things Small: Creating an Effective Oversight System for Nanotechnology* (March 2007); and Davies, *EPA and Nanotechnology: Oversight for the 21st Century* (May 2007).

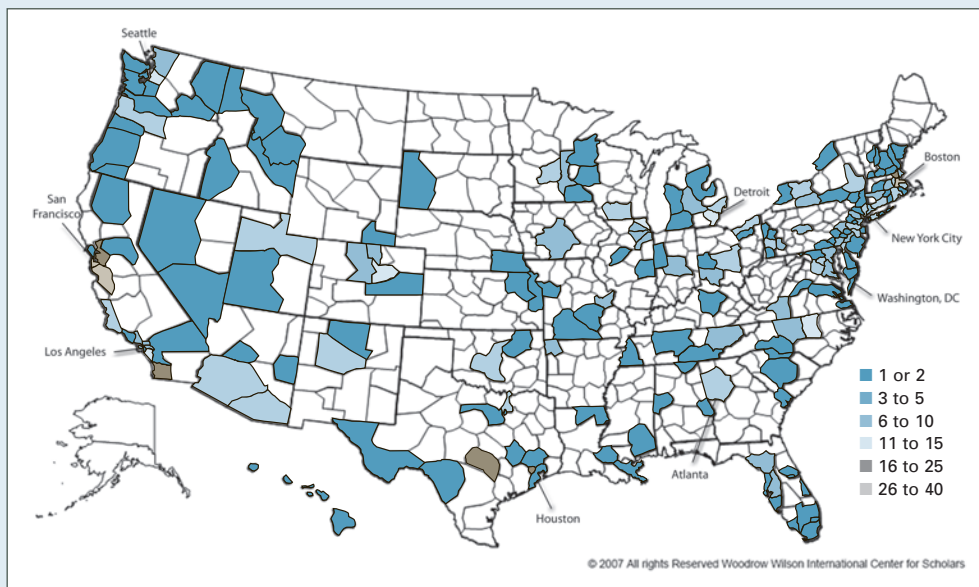
But just as there was room at the bottom to explore the science that has led to nanotechnology, there is also “room at the bottom” for states and localities to consider a variety of approaches for managing the risks and benefits

of nanotechnology. This potential may be especially interesting for communities that are now home to clusters of firms engaged in nanotechnology research and production.⁷ Work with nanomaterials is now under way in every state. As of May 2007, 47 of 50 states and the District of Columbia contained at least one of the 637 companies, 138 university and government laboratories, and 45 other types of organizations working in nanotechnology, as shown in Figure 1.⁸ These numbers are drawn from publicly available lists compiled by PEN; the actual number of companies and organizations working in nanotechnology is likely to be much higher. California (specifically San Jose, San Francisco, and Oakland), Massachusetts (specifically Boston and Middlesex-Essex), New York, and Texas contain the greatest

number of these “nano entities”. The most common sectors of nanotech activity by U.S. companies are materials, medicine and health, and tools and instruments.

Moreover, the time is ripe for states and localities to explore action for managing nanotechnology risks and benefits because there seems to be very little interest or urgency among U.S. federal agencies in initiating a nationwide approach to overseeing the potential environmental and public health impacts of nanotechnology. This lack of urgency exists despite the fact that nanotechnology was incorporated into more than \$50 billion in manufactured goods in 2006.⁹ By 2014, a projected \$2.6 trillion in global manufactured goods, or about 15 percent of total output, will incorporate nanotech.¹⁰

FIGURE 1: U.S. Nanotechnology Clusters: Number of companies, universities, government laboratories, and/or organizations working in nanotechnology and located in each three-digit zip code (820 total, as of May 2007)



Source: *Putting Nanotechnology on the Map*, Project on Emerging Nanotechnologies, Woodrow Wilson International Center for Scholars, (May 2007), Available at: <http://www.nanotechproject.org/inventories/map/> [accessed August 7, 2007].

II. CURRENT STATUS OF FEDERAL OVERSIGHT

In 2003, Congress adopted and President Bush signed the 21st Century Nanotechnology Research and Development Act (Public Law 108-153, 117 Stat. 1923), which authorized 10 federal agencies to fund research on the science, engineering, and development of nanotech products and processes. The law focuses on promoting new business opportunities based on nanotechnology and does not explicitly address the potential risks of nanomaterials to workers, consumers, or the environment. As a result, federal agencies' combined funding of more than \$1 billion annually on nanotech research has included only about \$11 million spent in 2005 on research that is highly relevant to studying potential risks of nanotech.¹¹

More recently, congressional hearings have begun to focus on the risks of nanotechnology. The House Committee on Science considered the potential environmental and safety impacts of nanotechnology at a hearing on Nov. 17, 2005; and on Sept. 21, 2006, and Oct. 31, 2007, the Committee investigated what federal agencies are doing to research those impacts. By contrast, on May 4, 2006, a hearing of the Subcommittee on Trade, Tourism and Economic Development of the Senate Committee on Commerce, Science and Transportation discussed how the government could promote economic development through nanotechnology.

During 2007, at least 20 bills somehow related to nanotechnology were introduced in the 110th Congress, but most related to stimulating development of nanotech industries rather than research or action to protect against potential risks from those processes (see

Appendix A). On July 31, 2007, Congressman Honda (D-CA) introduced HR 3235, the Nanotechnology Advancement and New Opportunities Act (NANO). The bill's stated purpose is "to ensure the development and responsible stewardship of nanotechnology." However, it contains only a small mention of stewardship, calling on the National Nanotechnology Coordination Office to develop a research strategy report with recommended agency funding levels for the development and responsible stewardship of nanotechnology, within one year of its enactment.¹²

The U.S. Environmental Protection Agency (EPA) has been resisting pressure for federal action to begin an oversight program on nanotechnology. On July 7, 2007, former EPA Administrator William Ruckelshaus and former EPA official J. Clarence Davies strongly urged EPA to "bring itself into the 21st century" by developing a research and regulatory framework for nanotechnology.¹³ If EPA followed some of the former agency officials' recommendations, it might then be possible to learn more about the effects of nanotechnology on human health, safety, and the environment. Thus, EPA could protect the public from risks while still allowing nanotechnology to develop safely and to realize its enormous potential for future advances in medicine, renewable energy, and other beneficial applications.

Rather than rise to this challenge, however, EPA has repeatedly stated that it would continue to use a case-by-case approach in deciding whether to regulate nanomaterials under the Toxic Substances Control Act (TSCA)¹⁴ if they

qualify as new, rather than existing, chemicals.¹⁵ And based on the position outlined, the agency would consider a nanoscale chemical as new only if its molecular identity differs from that of substances already listed in the TSCA Inventory,¹⁶ thereby ignoring the nano-specific properties of chemicals.

At the same time, EPA also is working to develop a voluntary program for stewardship of nanomaterials,¹⁷ a slow-moving process that began over two years ago and is still not in place.¹⁸

Over the summer of 2005, EPA's federal advisory committee, the National Pollution Prevention and Toxics Advisory Committee (NPPTAC), at EPA's request brought together a workgroup to develop a proposal for addressing potential nanomaterial risks, which included a framework for a voluntary program. At EPA's August 2, 2007 public meeting on the voluntary program, Environmental Defense's Richard Denison, who served on that NPP-TAC workgroup, stated that "had the NPP-TAC proposal been acted upon by EPA as intended, the basic [voluntary reporting] program would have been completed well before now."¹⁹ Instead, EPA is essentially starting the clock over again while public and private nanotech research and development and nanotechnology commercialization continue moving forward rapidly.

Moreover, as Davies and others have already made quite clear, TSCA is too weak to give EPA adequate authority for overseeing the many new products already containing nanoscale substances, and it does not ensure that EPA will be able to regulate the potential hazards that could result from the entirely new—and often still unknown—biological and environmental properties of these materials.²⁰

To the extent that nanomaterials—particularly metals—may have antimicrobial properties, EPA may be willing to exert its authority to regulate them as pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).²¹ In late 2006, EPA found that FIFRA registration was required for a washing machine made by Samsung Electronics that generates silver ions to kill bacteria on clothing.²² Samsung initially claimed that it used nanotechnology to produce the antimicrobial ions. In making its decision, EPA determined that the machine incorporates a substance intended to prevent, destroy, repel, or mitigate pests and thus qualifies as a pesticide. This decision was made easier, no doubt, because EPA already regulates silver as an active ingredient in a number of other registered pesticides. Even so, EPA had first declined to regulate the machine because the agency originally classified it as a "device" for which FIFRA would not require registration.²³ The *Federal Register* notice officially announcing EPA's decision on the Samsung *Silver Wash* and similar products was finally issued in September 2007;²⁴ but EPA noted that this was not a decision to regulate nanotechnology.²⁵ In the meantime, nanoscale silver is increasingly being used as an antimicrobial in a wide variety of products—from children's toys and fabric softeners to refrigerators and telephones.

In addition, the Food and Drug Administration (FDA) has begun to address the impact of nanotechnology on FDA-regulated products, including drugs, medical devices, food, cosmetics, and sunscreens. Sunscreens, in particular, have garnered a high degree of attention, as a coalition of non-governmental organizations has petitioned FDA

to re-evaluate the safety and use of nanotechnology in sunscreens,²⁶ while the agency also opened a call for comments on this subject in a recent *Federal Register* notice.²⁷ To address these multiple science, policy, and consumer confidence concerns, FDA held a public meeting in October 2006 to solicit information on nanotechnology products and medical applications, and released the report of its Nanotechnology Task Force in July 2007. The Task Force report concluded that:

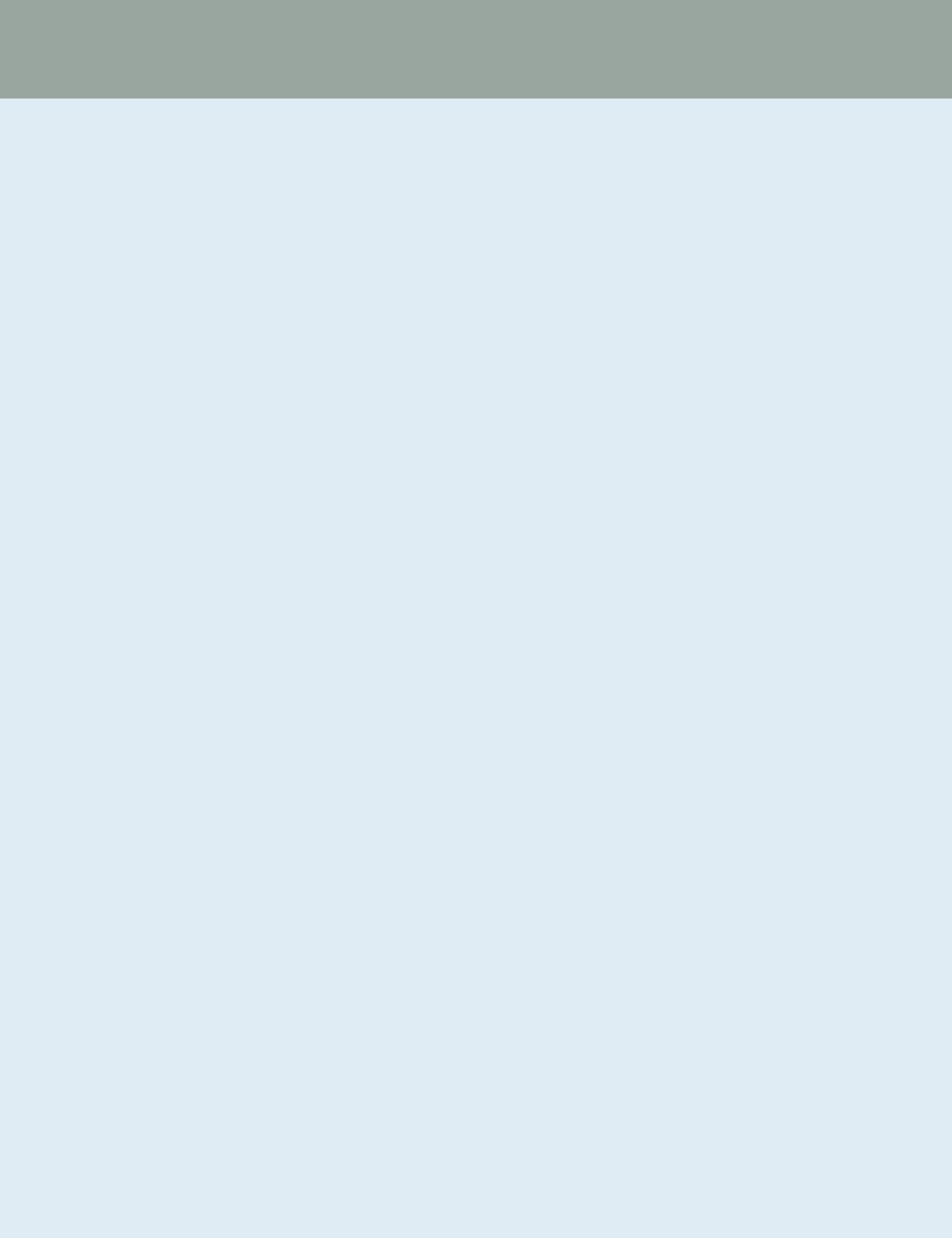
Nanoscale materials present regulatory challenges similar to those posed by products using other emerging technologies. However, these challenges may be magnified both because nanotechnology can be used in, or to make, any FDA-regulated product, and because, at this scale, properties of a material relevant to the safety and (as applicable) effectiveness of FDA-regulated products might change repeatedly as size enters into or varies within the nanoscale range.

Although this analysis is one of the most progressive to emerge on this subject from a U.S. government agency, FDA still faces a number of financial, risk research, and

human resource constraints that will continue to challenge its ability to address the impacts of nanotechnology.²⁸

As federal agencies consider if, when, and how to regulate nanotechnologies, surveys have shown that nanotech businesses are seeking greater guidance. Recent work by the University of Massachusetts-Lowell with U.S. companies in the Northeast indicated that (1) nanotechnology firms recognize potential risks, but (2) the firms (especially small firms) feel that they lack (a) information on the health and environmental risks of nanomaterials and (b) the necessary guidance from suppliers, industry, the government regulatory bodies, and others in order to manage risks associated with materials and processes.²⁹ These findings are consistent with those of other recent surveys of small and medium-sized firms in Connecticut and New York³⁰ and of nano firms around the world.³¹

These concerns arise at a time when there has been a significant increase in industry calls for regulatory clarity in the wake of public concerns over the safety of food and consumer products.³² Without clear rules, both companies and investors are exposed to potential public backlash, a collapse of consumer confidence, and product liability.



III. POTENTIAL FOR STATE OR LOCAL OVERSIGHT OF NANOTECHNOLOGY

Despite their tentative actions in the past couple of years, Congress, EPA, and FDA have made little progress in addressing the many complex policy decisions needed to formulate a comprehensive approach to overseeing the impacts of nanotechnology. With adoption of federal legislation or regulations for nanotechnology unlikely in the United States in the near future, there may now be an oversight role for states and localities. When the national level fails to act, lower levels of government have often taken the lead in policy innovation, particularly in responding to risks first identified as potentially affecting local populations, such as environmental or health hazards. The urgent nature of these risks has sometimes prompted states or localities to adopt protections despite their limited resources and the possible inefficiencies of piecemeal action.

Recently, some states have taken the initiative on environmental or health issues that have been ignored by Congress or the executive branch. These state actions include California's law to reduce global warming,³⁴ action by a consortium of 10 Northeastern and Mid-Atlantic states to establish a mandatory cap-and-trade system for carbon dioxide emissions,³⁵ and several states' requirements that electric utilities obtain power from renewable energy sources.³⁶

Sometimes, however, such state initiatives can trigger a backlash. Often under pressure by regulated industries that fear a patchwork of differing state regulations, Congress may be prompted to enact a law, or the executive

branch may adopt rules limiting or preempting state attempts to innovate in policy areas not previously addressed at the federal level. Again, state health and environmental protections are often the source of such friction, as seen in past efforts covering such issues as labeling requirements for hazards in food, making public more information about the safety or side effects of prescription drugs, and establishing fuel-economy standards for trucks.³⁷

Despite this tension in the relationship between federal and state governments, Congress has often made states explicitly responsible for implementing federal environmental, health, and safety laws as long as states agree to meet minimum federal regulatory standards for oversight and enforcement. This shared responsibility permeates our country's approach to clean air, clean water, waste disposal, worker protection, and highway safety. In return, when states meet federal standards, Congress has offered significant financial incentives in the form of grants, matching funds, contracts, and similar mechanisms to share revenues.

Such federal mandates do allow states some degree of flexibility, however. Adding to their own legal authorities and resources—combined with more direct pressures from their constituents who are concerned about exposures to nearby hazards—has sometimes enabled state governments to develop innovative approaches that can address a variety of environmental or safety challenges more quickly or more effectively than actions by federal agencies alone. By

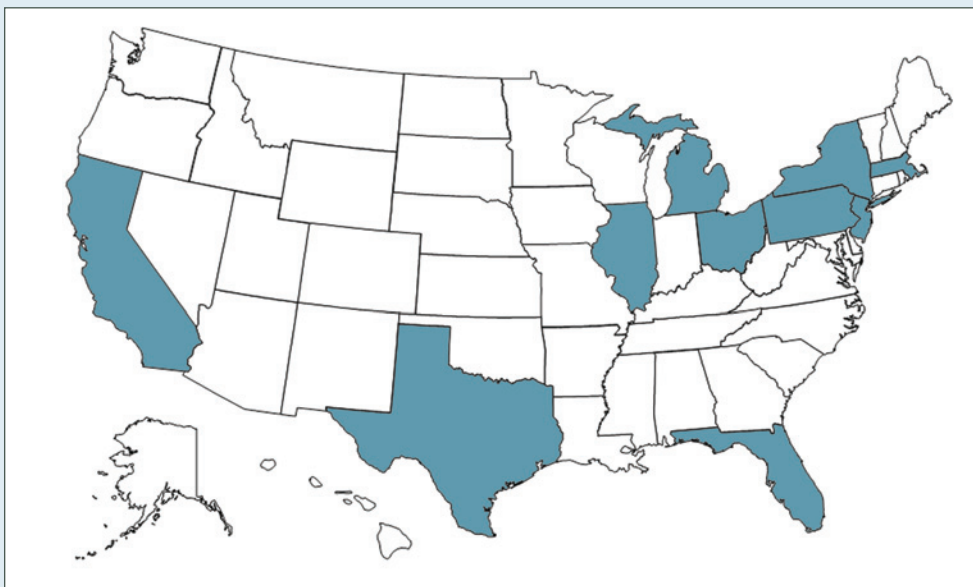
so doing, the states have demonstrated time and time again their important role as the “laboratories of democracy,” as Justice Louis Brandeis so famously described.³⁸

In turn, states sometimes delegate or devolve their own regulatory requirements to local agencies, which add other requirements and responsibilities to protect health, safety, and the environment. This pattern of decentralized governance has enabled states and localities to play a key role in finding more effective policies for many issues that concern the public; and it now offers a valuable opportunity for tackling the complex oversight challenges presented by nanotechnology, particularly in light of the inadequate action forthcoming at the federal level.

Although a number of states already have laws promoting the nanotechnology industry³⁹

and/or laws encouraging nano research and development⁴⁰ (and others may be considering such action), most current state programs are focused on developing new uses of nanomaterials designed to promote the growth of such industries, rather than on oversight of nanotech’s impacts. The top 10 states with the greatest number of companies, universities, and government labs engaged in nanotechnology activities (e.g., handling nanomaterials) include California, Massachusetts, New York, Texas, Pennsylvania, Michigan, New Jersey, Illinois, Florida, and Ohio, as shown in Figure 2. This list is based on data gathered by the Project on Emerging Nanotechnologies from a variety of sources.⁴¹ This ranking overlaps with that of other analyses, such as the *Small Times* rankings of states that “lead the nation in small tech,” according to industry, venture

FIGURE 2: Top 10 States with Nanotechnology Activity



Note: Based on the number of nanotechnology businesses, universities, and government labs in each state.

Source: *Putting Nanotechnology on the Map*, Project on Emerging Nanotechnologies, Woodrow Wilson International Center for Scholars, (May 2007).

capital, research, innovation, and workforce metrics for micro- and nanotechnologies.⁴²

The states highlighted in Figure 2, as well as other states, may be concerned that taking the initiative to address potential risks from nanomaterial use may discourage economic development within their borders; however, their environmental and worker-safety laws may offer opportunities for overseeing and reducing those potential risks. Moreover, implementing such oversight is likely to help nanotech firms—and the states or localities that want to encourage nanotechnology development—because workers, nearby residents, and consumers will then be able to understand and avoid potential risks from processes that create nanomaterials or products containing them.

At least one of these top-10 nanotechnology-development states has recently started to consider its options for oversight. In October 2007, the California Department of Toxic Substances Control (DTSC) announced that a multi-agency state team is beginning to explore ways to minimize environmental and human health risks associated with the manufacture and use of nanotechnology products.⁴³ DTSC began this process by reviewing the report of the Blue Ribbon Task Force on Nanotechnology, a multi-stakeholder group convened by California Congressman Mike Honda (D) that sought to address major areas of concern in promoting nanotechnology research, development, and commercialization.⁴⁴ The Task Force's report provided recommendations calling for "CalEPA's involvement in understanding and communicating the environmental, social, and even ethical implications of nanotechnology."⁴⁵

Meanwhile, at least two local governments have started their own processes for overseeing nanotechnology operations within their respective jurisdictions. Each local approach

serves to illustrate how other localities, or even states, might begin to implement programs for nanotech oversight. The rest of this section discusses these possible options, along with a variety of other regulatory alternatives that states or localities can consider for oversight of nanotech operations. Such alternatives include:

- setting requirements for the disclosure of nanomaterial use or storage information,
- controlling airborne fine particulates,
- cleaning up nanomaterial waste,
- monitoring water discharges containing nanoparticles,
- labeling for products that contain nanomaterials, and
- protecting worker safety.

Readers should note that changes in local and state environmental laws, ordinances, or regulations are notoriously difficult to track; thus, the examples discussed in this paper are merely representative and may evolve in the future.

A. DISCLOSING USE OR STORAGE OF NANOMATERIALS

In December 2006, Berkeley, Calif., adopted the first local regulation specifically for nanomaterials. Based on its authority under Chapter 6.95 of the California Health and Safety Code, the Berkeley City Council amended Title 15 of its Municipal Code (see Appendix B) to require that:

All facilities that manufacture or use manufactured nanoparticles shall submit a separate written disclosure of the current toxicology of the materials reported, to the extent known, and how

the facility will safely handle, monitor, contain, dispose, track inventory, prevent releases, and mitigate such materials. (Section 15.12.040, Subsection I.)

The regulation further specified that these disclosure requirements will carry no minimum threshold and will apply to “all manufactured nanoparticles, defined as a particle with one axis less than 100 nanometers in length.” (Section 15.12.050.C.7.)

Reflecting on a lack of timely and decisive federal action, Berkeley’s mayor, Tom Bates, noted that it was time for his city to step up to overseeing the safety of nanotech facilities.⁴⁶ The Berkeley City Council adopted this ordinance under its authority to implement California’s community-right-to-know law.⁴⁷ The Council made this decision after considerable research and debate and after learning from its Community Environmental Advisory Commission and its Hazardous Materials Manager that nanoparticles can be inhaled and absorbed into the skin, causing potentially toxic reactions inside cells, and that their human health and environmental impacts are complex and not well understood. The Council’s greatest concern was that people handling nanoparticles “may not know much about the materials they are handling” and that “government is not doing a good job regulating these materials.”⁴⁸ Thus, the Council determined that nanoparticles qualify under the broad definition of hazardous materials previously adopted by the state and the city:

[A]ny material, because of its quantity, concentration, or physical or chemical characteristics, poses a significant present or threatened hazard to human health and safety or to the environment

if released into the workplace or the environment.⁴⁹

Having decided that nanoparticles meet this definition, the Council then amended the disclosure requirements of its local right-to-know ordinance cover nanomaterials because they apply to all types of hazardous materials.

The city’s reporting form (OES Form 2730) requires, among other items, information on:

- the average and maximum daily amount of nanomaterials stored or
- used the physicochemical properties;
- source of the material;
- any relevant information on toxicological and ecological impacts;
- intended uses and benefits; and
- information about measures adopted by the firm to provide protections for workers and the environment.

Materials must then be categorized according to their potential for toxicity (low, moderate, high, or unknown), and reporting firms are asked to list what control measures they have adopted or propose to adopt that correspond to that potential. Low potential toxicity would require little or no control measures; moderate potential toxicity would require moderate control measures; and both high and unknown potential would require high levels of control measures.⁵⁰

To prepare these reports, the city recommends that facilities producing or handling nanomaterials conduct internal audits to evaluate the potential for exposure during the entire life cycle of the product or process and that they obtain professional advice about the materials’ potential toxicity and about appro-

appropriate measures for protecting workers and the environment. If adequate toxicological information is not available for a nanomaterial with potential for exposure or release, the city says, “A precautionary approach should be taken, which assumes that the material is toxic”; and facilities that cannot predict their inventory must still file a report based on best knowledge and document their information using a risk-based approach.⁵¹ See Appendix C for the reporting instructions to nanotechnology facilities in Berkeley.

The first disclosure reports that might contain such materials were due to be submitted to the city’s Toxics Management Division (TMD) on June 1, 2007. By early July, the TMD had received two reports and was conducting an audit to determine whether other facilities that manufactured or used nanomaterials within the city’s jurisdiction might also be required to report.⁵²

Berkeley’s ability to extend its disclosure reports to cover nanomaterials relies substantially on its authority to adopt additional, stricter requirements than those contained in California’s Health and Safety Code and the federal right-to-know law.⁵³ Thus, to the extent that other states may have authorized their localities to enact broader right-to-know ordinances or have applied their own right-to-know laws to define hazardous materials as a broader range of substances than the federal requirements, these states and localities may be able to follow Berkeley’s example.

Disclosure requirements offer some particular advantages for overseeing substances like nanomaterials that may have unknown effects on human health or the environment. The requirements provide an incentive for both businesses and their workers to find out more about those particular impacts, and they offer

an opportunity for government agencies and nearby residents to gain a better understanding of any potential risks, as well as of any plans to prevent or mitigate those risks, without unduly alarming the public or creating burdens for facilities.

Despite these advantages, Berkeley’s ordinance has been criticized as being unnecessary and ambiguous, chiefly because it does not include a definition of the nanoparticles, substances, or materials that it covers. In addition, some critics maintain that the data on potential hazards from nanomaterials are still too preliminary and that the much-needed research and investment in methods for monitoring and evaluating their toxicity, as well as development of new uses, will be impeded by unnecessary, overly broad regulation.⁵⁴ Others fear that this action will discourage nano start-up firms from locating in Berkeley. Finally, it is not clear whether the public will actually have access to data that reporting firms disclose to the city. One company that has submitted a report has requested that the city treat its submission as a trade secret.

Nevertheless, at least one other locality has expressed interest in possibly following the Berkeley model. Like Berkeley, Cambridge, Mass., is home to a number of high-tech research and manufacturing facilities that have spun off from its universities. Cambridge also is familiar with methods for overseeing technically complex operations because it was the first U.S. city to adopt regulations governing recombinant DNA (rDNA) research.

The Cambridge City Council is interested in adopting an ordinance similar to Berkeley’s because it wants the city’s growing nanotech businesses to operate safely, yet so little is known about the risks caused by nanomaterials. Contrary to criticism of Berkeley’s action,

Cambridge officials believe that adopting such regulations will encourage, not hinder, the growth of its nano-based industry, just as their rDNA regulation helped the city become a leading center for biotech research.⁵⁵

Several other states may have community-right-to-know laws that, similar to those in California, authorize reporting or disclosures broader than the federal law and thus may provide authority to require reporting when facilities use or produce nanomaterials. For example, the Toxics Use Reduction Act (TURA) of Massachusetts⁵⁶ and New Jersey's Worker and Community Right-to-Know Act⁵⁷ both contain disclosure requirements that extend beyond federal law and could possibly be applied to nanoscale substances or products even if EPA declines to regulate them at the national level.

But these broader state disclosure laws may have limitations of coverage that could exempt nanobusinesses. Such exemptions include facilities with fewer than 10 full-time employees; research laboratories, pilot plants, and start-up production units; or threshold amounts based on weight and thus likely never to be reached because nanomaterials are created and used in such small quantities.⁵⁸ Before other states or localities pursue Berkeley's approach, they will need to evaluate carefully whether their current disclosure laws or ordinances must be amended to extend their coverage or limit such exemptions so that nanotech firms will be covered.

B. CONTROLLING AIRBORNE FINE PARTICULATES

Section 116 of the federal Clean Air Act (CAA)⁵⁹ explicitly authorizes states or local air quality agencies to adopt and enforce require-

ments that are more stringent than the federal air quality standards. States and localities may therefore be interested in using their authorities to control air pollution as the basis for oversight of nanotechnologies because nanoparticles can become airborne and could potentially penetrate the human body, plants, and other natural organisms.⁶⁰ Unfortunately, however, many states have adopted laws, regulations, or policies that preclude their state or local air agencies from adopting programs, standards, or requirements that are more stringent than those of the EPA.

A survey by the National Association of Clean Air Agencies (formerly known as STAPPA/ALAPCO)⁶¹ found that 24 states are not precluded from adopting programs, standards, or requirements that are more stringent than those of the federal government.⁶² But another 24 states are at least precluded from adopting more stringent air quality programs except under certain limited conditions, and two states are precluded entirely from having more stringent requirements. Even among the 24 states that are not precluded from implementing more stringent programs, 10 states must overcome procedural barriers or prepare in-depth justifications to do so. Thus, only 14 states are entirely free to adopt requirements that go beyond those of the federal program.

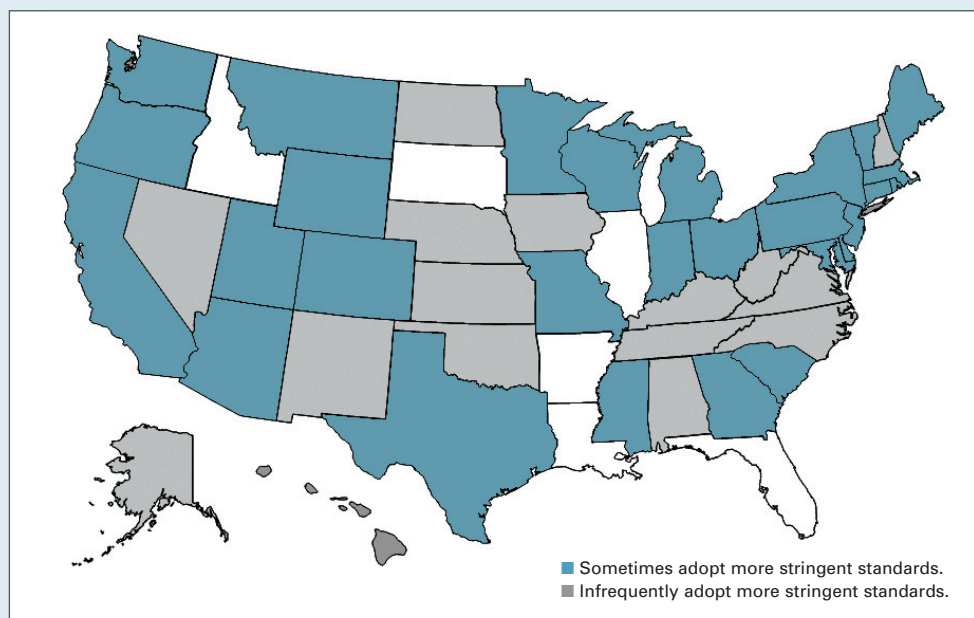
On the other hand, when there is a gap in the federal standards because there are no federal requirements—for example, the potential situation with controlling airborne nanoparticles—46 states indicated that they could adopt air quality requirements to fill that gap, and no state said it could not do so. However, eight states that said they could fill such gaps indicated they would have to overcome some barriers to do so.⁶³

As shown in Figure 3, in the past two years, at least 15 states have adopted laws or regulations that require reductions of mercury pollution, rather than participating in a proposed EPA program for trading allowances for mercury emissions.⁶⁴ As long as EPA and Congress decline to take action to make the CAA or federal air rules applicable to air emissions that contain nanoparticles, all of these states may have an opportunity to take action under their own authority to adopt more stringent air laws and regulations.

Similarly, at least 29 local air agencies are not prohibited from adopting more stringent air quality controls; but 11 of those are in California. California's air quality act, like its hazardous substances act, authorizes localities

to adopt stricter requirements when necessary to attain and maintain air quality standards.⁶⁵ Certainly, those 11 local air agencies in California have authority to exert oversight and control over airborne nanoparticles, but the other 18 local agencies may also be able to take action if they find there are nanomanufacturing facilities or research labs working with nanomaterials within their respective jurisdictions. Other than California, the 18 localities with this flexibility as of 2002 are in Colorado, Florida, Indiana, Iowa, Kansas, Kentucky, Nebraska, North Carolina, Ohio, Oregon, Pennsylvania, Tennessee, Texas, and Washington. See Figure 4, but note that the legal authorities of these local agencies may have changed since 2002.

FIGURE 3: States with Potential to Adopt More Stringent Air Quality Requirements



Note: Arkansas, Florida, Illinois, and Louisiana can be more stringent than the federal program, but have never used that authority. Idaho did not reply to this question from STAPPA/ALAPCO.

Source: STAPPA/ALAPCO, "Restrictions on State and Local Air Quality Programs" (December 17, 2002).

FIGURE 4: Localities with Potential to Adopt More Stringent Air Quality Requirements



Note: Siskiyou, Calif., and Lenexa, Kan., report they can be more stringent than the federal program, but they have never used that authority.

Source: STAPPA/ALAPCO, "Restrictions on State and Local Air Quality Programs" (December 17, 2002).

C. CLEANING UP NANOMATERIAL WASTE

Some state laws may go beyond federal requirements for cleaning up hazardous or municipal wastes; however, a few stricter states have been identified, despite the lack of a comprehensive study of the states with these stricter standards. The following examples thus illustrate some ways that states might exercise oversight to protect their landfills or hazardous waste disposal facilities from potential difficulties if or when nanomaterials from research, manufacturing, or consumer products are released into the waste stream.

As the Environmental Law Institute has documented in a recent study of "nano-

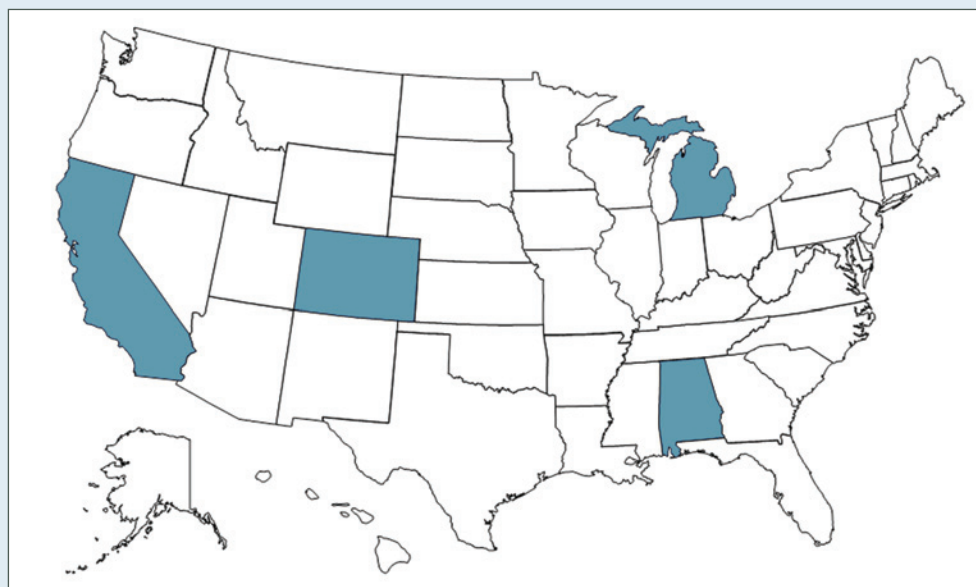
wastes,"⁶⁶ such wastes are potentially covered by the requirements of the federal waste laws (the Resource Conservation and Recovery Act [RCRA] and the Comprehensive Environmental Response, Compensation and Liability Act [CERCLA]/Superfund).⁶⁷ In turn, most states have been delegated by EPA to administer RCRA as it applies to municipal and hazardous wastes. Moreover, although Congress did not authorize states to implement CERCLA, many have adopted their own state Superfund laws to clean up abandoned waste sites that are not covered by the federal law.⁶⁸ The question then becomes which states have authority to adopt waste disposal and clean-up requirements that are stricter than the federal standards and thus could be made applicable to nanowastes.

To the extent that some important nanoparticles contain metals,⁶⁹ several states (a few of which are highlighted in Figure 5) have adopted stricter standards for metals in waste or have chosen to regulate such wastes that are not covered at all by EPA regulations. For these wastes, the state requirements might then be made applicable to the equivalent metal ions whenever they are generated as nanoparticles and later disposed as wastes. Alabama regulates organo-tin compounds,⁷⁰ and Michigan has adopted its own requirements for a number of wastes not regulated by EPA, including zinc and copper.⁷¹ Colorado has gone beyond EPA's standards to adopt water quality and clean-up standards for some chemicals, such as DIMP,⁷² which is a derivative of the nerve gases previously manufactured at the Rocky Mountain Arsenal; and

many other states have set limits more stringent than EPA's requirements for the solvent TCE⁷³ and for perchlorate, a chemical used for rocket fuel that is starting to show up in soil, water, and food. Again, California also has stricter rules for waste disposal, especially land disposal restrictions, because they cover a wider range of products and do not authorize as many exemptions as EPA allows.⁷⁴

All of these examples illustrate the possible capacity for these states—and perhaps others with similar waste treatment and/or disposal requirements that are more stringent than or cover additional materials beyond the wastes regulated by EPA—to use this authority as the basis for beginning to oversee releases from manufacturers or research facilities using nanomaterials, as well as disposal of products containing nanoparticles.

FIGURE 5: Some States with Stricter Standards for Metals in Waste



Sources: Alabama Code, Chapter 22, Sections 30-10 and 30-14; Michigan Compiled Laws, 1994 Public Act 451 (as amended), Sections 324.11101 et seq.; Michigan Rules Sections 299.9203, 299.9213, and 299.9214 (2004); California Code of Regulations, Title 22, Chapter 18, Article 10, Sections 66268.32 and 66268.100 (2005).

D. MONITORING WATER DISCHARGES CONTAINING NANOPARTICLES

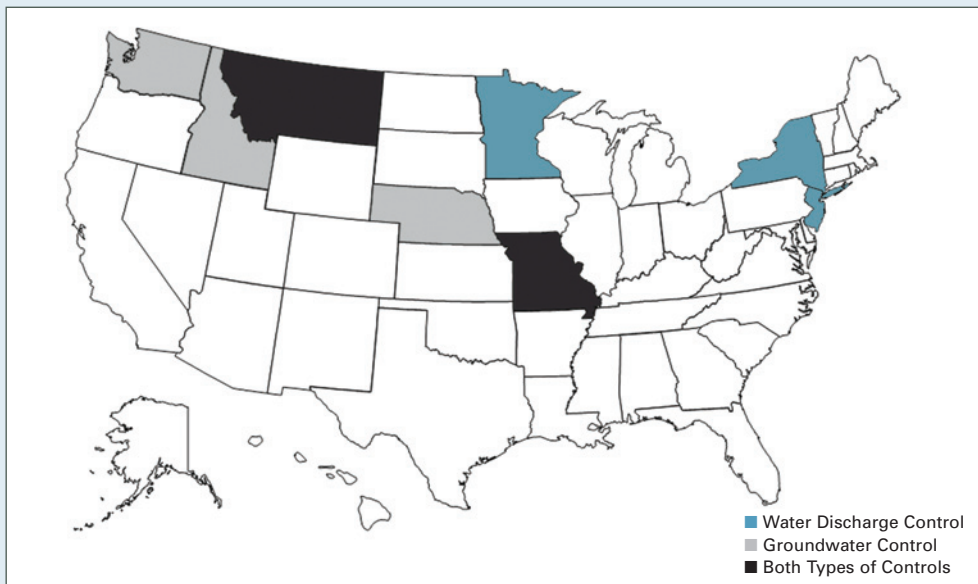
Under the federal Clean Water Act (CWA), states set their own water quality standards and are required to review them every three years.⁷⁵ EPA must approve the states' standards and, if any states adopt water quality programs that are not complete or are inconsistent with EPA's rules for implementing the CWA, EPA must promulgate standards for them and can deny them grants for water treatment facilities if they do not revise their requirements to meet EPA's standards.⁷⁶

Consequently, the CWA gives states substantial flexibility—at least in theory—to adopt statutory or regulatory provisions for controlling water discharges that contain

nanoparticles, even if EPA has not done so. Some examples of states that have exercised their discretion to set stricter water quality standards include Minnesota (toxic releases and best management practices for agriculture), Missouri (mercury), Montana (excess nutrients and algal biomass), New Jersey (zero discharge from agricultural operations), and New York (carcinogens).⁷⁷ See Figure 6. Undoubtedly, there are many more states with similar flexibility that could adopt additional discharge requirements as a way to oversee nanotechnology and protect their waters from contamination by releases of nanoparticles; but there are no recent comprehensive studies of state water quality standards.⁷⁸

Water discharges containing nanomaterials might be released in at least three ways: 1) from

FIGURE 6: States with Potential to Adopt More Stringent Water Quality Requirements



Sources: Association of State and Interstate Water Pollution Control Administrators, *Catalogue of State Innovations* (no date); *Permitting for Environmental Results: Summary of State Innovations* (August 10, 2004); Teske and Spat, "Groundwater Protection," Chapter 12 in *Regulation in the States*, Teske, ed. (2004).

pipes at “point sources” from specific facilities using or manufacturing nanomaterials; 2) from “non-point source” runoff when consumer products containing nanomaterials are washed into surface waters; or 3) from publicly owned sewage treatment facilities that are not equipped to eliminate nanoparticles released by the decomposition of products reaching the sewers from businesses or residences.

As a result of numerous lawsuits against their environmental agencies, a number of states are developing programs to improve water quality in water bodies that do not meet state or EPA standards. CWA Section 303(d)⁷⁹ requires states to identify and list these “impaired waters,” prioritize them by the severity of the pollution problem, and then establish Total Maximum Daily Loads (TMDLs) for allowable levels of discharge into those waters so they can eventually meet water quality standards.

While developing TMDL programs, many states are also upgrading their discharge standards and water monitoring requirements, especially to identify pollutants in surface runoff or groundwater that is contaminated by agricultural livestock facilities (“concentrated animal feeding operations” or “CAFOs”).⁸⁰ Both the adoption of TMDLs and the upgrading of discharge standards offer states another opportunity to consider whether TMDL standards should be established for possible discharges of nanomaterials if their impaired waters are near areas where nanotechnology firms operate.

In addition to potential state authorities for controlling direct discharges of nanomaterials into surface waters, states may be able to exercise their discretion to require additional monitoring of nanoparticles that reach groundwater. Five states—Idaho, Missouri,

Montana, Nebraska, and Washington—have gone beyond federal requirements in adopting their groundwater monitoring programs (see Figure 6), and 13 state environmental agencies have additional authorities to protect wellhead areas from contamination by developing regulatory measures that will identify sources of pollution.⁸¹

The possibility of nanomaterials becoming water pollution—or any other type of pollution that might need to be controlled—depends on whether they can be shown to have harmful effects on human health or the environment, which is not yet clear for many types of nanoparticles.⁸² On the other hand, even if some nanomaterials are shown to have potentially harmful effects, the applicability of state laws controlling water pollution may be severely limited until adequate monitoring devices have been developed to measure their presence in water, the human body, or any other environmental medium.⁸³

E. LABELING REQUIREMENTS FOR PRODUCTS THAT CONTAIN NANOMATERIALS

Labeling consumer products with a list of their contents is an oversight mechanism that could complement any state or local requirements to disclose and/or report air emissions, water discharges, or waste releases from facilities that use or manufacture nanomaterials (see section A above). Again, California is unique among the states in requiring that consumer products be labeled with warnings about any toxic chemicals they contain.⁸⁴ Neither EPA nor the Consumer Products Safety Commission has the authority to require labels on consumer products that contain toxic ingredients. FDA’s product labeling authority generally applies to

drugs, medical devices, food or color additives, and cosmetics, but it has recently declined to require consumer labels on these items even if they contain nanoparticles.⁸⁴ Thus, states are not likely to be preempted by federal nanotech labeling requirements and would be free to adopt their own warning labels similar to those provided by California's Proposition 65 for other toxic chemicals.

Under California's law, a business is prohibited from "knowingly and intentionally expos[ing] any individual to a chemical known to the state to cause cancer or reproductive toxicity without first giving clear and reasonable warning to such individual."⁸⁵ These warnings usually take the form of labels on consumer products, but they may also be issued by posting signs at workplaces or notices in restaurants, rental housing, or newspapers.⁸⁶ Every year since the law's adoption, the state has published a revised list of toxic chemicals that are covered by Proposition 65's warning requirements, so the list stays current with new findings about cancer-causing chemicals or reproductive toxins. There are currently about 750 chemicals on that list, ranging from naturally occurring to synthetic chemicals that may be additives or ingredients in common household products, foods, drinks, drugs, dyes, solvents, pesticides, or by-products of chemical processes.⁸⁷ Although Proposition 65 was enacted more than 10 years ago, it is still a landmark labeling law that can serve as a model for other states.

The most recent California list of toxic substances subject to Proposition 65 does not contain any nanomaterials, but they could be added to that list, and their appearance on labels would begin to educate consumers about potential exposures to such materials.

The key question will be whether research into the health impacts of specific types of nanoparticles or products containing them can meet the law's test for being known to cause cancer or reproductive toxicity:

[I]f in the opinion of the state's qualified experts it has been clearly shown through scientifically valid testing according to generally accepted principles to cause cancer or reproductive toxicity, or if a body considered to be authoritative by such experts has formally identified it as causing cancer or reproductive toxicity, or if an agency in the state or federal government has formally required it to be labeled or identified as causing cancer or reproductive toxicity.⁸⁸

As many commentators have pointed out and as referenced above, much research is still needed to determine the health and environmental impacts of the many types of nanoparticles and their respective, very complex characteristics and interactions. These uncertainties are the basis for FDA's recent decision not to require special labeling for products that use nanotechnology,⁸⁹ and they would doubtlessly pose a real obstacle to such materials qualifying for California's list and related warning labels under Proposition 65.

Despite the FDA's hesitancy about exerting its oversight authority through labeling requirements for nanomaterials within its jurisdiction, the Council of State and Territorial Epidemiologists (CSTE) has recently adopted a resolution urging adoption of the precautionary principle for dealing with nanotechnology due to the currently quite limited understanding of their effects on

human health, safety, and the environment.⁹⁰ CSTE further expressed concern about the lack of adequate funding for research on these impacts of nanotechnology and specifically called on FDA “to require labeling of products containing nanoparticles that are aerosolized or applied to the skin, listing the contents, intended use, and proper handling of the product.”⁹¹ Nevertheless, it does not appear that any labeling requirements will be forthcoming from the federal level.

F. PROTECTING WORKER SAFETY

In its recent resolution, CSTE further called on the U.S. Occupational Safety and Health Administration (OSHA) and EPA to “promulgate standards for the protection of workers, the general public, and the environment against known or suspected harmful effects of nanoparticles.”⁹² Such action by OSHA or EPA is unlikely to happen very soon, even though OSHA, along with EPA, FDA, and more than 20 other federal agencies, is a member of the National Nanotechnology Initiative (NNI).⁹³ This inaction at the federal level, however, presents another opportunity for states to initiate oversight that will protect the safety of workers who are handling or manufacturing nanomaterials.

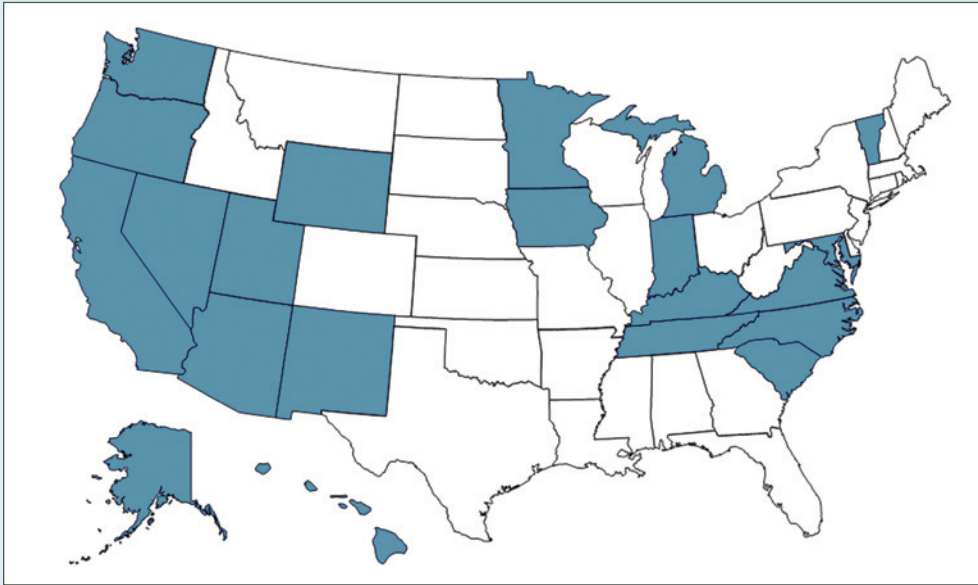
The Occupational Health and Safety Act⁹⁴ (OSH) is similar to most of the federal environmental laws in providing for worker safety programs to be implemented by states and in giving states federal grants once they adopt worker protection plans that meet federal standards.⁹⁵ Clearly, much more research is necessary in order to determine the full extent of potential health hazards for workers who use or manufacture nanomaterials. But industry experts in human resource

management in general, and workplace safety in particular, are already concerned about the need to adopt guidelines to help nanobusinesses identify and manage the possibly unique risks for workers that nanoparticles may cause.⁹⁶

These voluntary, consensus-based guidelines might then form the basis for states to extend their worker safety plans so they cover exposures to nanomaterials. The guidelines suggest a number of elements for ensuring the safety of nanotech businesses: assessments of hazards (covering toxicity, exposure limits, and potential for flammability or explosion) and both environmental emissions and fate; risk assessments and risk controls, including engineering controls and safe practices; medical monitoring; and worker training and communication, including labeling, packaging, and writing material safety data sheets (MSDS).⁹⁷

OSHA has approved plans for 21 states (plus Puerto Rico) that apply federal safety standards to workers in private industry, and at least some of those states may be able to adopt requirements for ensuring the safety of workers in nanobusinesses. Those states are Alaska, Arizona, California, Hawaii, Indiana, Iowa, Kentucky, Maryland, Michigan, Minnesota, Nevada, New Mexico, North Carolina, Oregon, South Carolina, Tennessee, Utah, Vermont, Virginia, Washington, and Wyoming (see Figure 7). Among the 21 states with approved plans, those interested in overseeing the safety of nanotech workers will need to determine whether their respective OSH laws and plans allow them sufficient flexibility and authority to take such action in the absence of federal regulation of workplace exposures to nanomaterials.

FIGURE 7: States with Potential to Adopt Safety Requirements for Nanotech Workers



Source: Occupational Safety and Health Administration, State Occupational Safety and Health Plans, Available at: <http://www.osha.gov/dcsp/osp/index.html> (accessed August 24, 2007).

IV. FOUR SCENARIOS FOR FUTURE STATE OR LOCAL OVERSIGHT OF NANOTECHNOLOGY

As the above alternative approaches illustrate, many states and some localities may have the authority to fill gaps in federal requirements for overseeing the health and environmental impacts of nanotechnology and even to go beyond any federal regulations that may be adopted in the future. The issue then becomes what might prompt or enable states and localities to take such action, particularly in the short term while the science is still developing and the risks are so uncertain. At least four scenarios for state or local action to oversee nanotechnology seem likely, based on recent events.

First, as the Berkeley ordinance demonstrates, oversight might start at the local level with localities adopting regulations to require disclosure of nanomaterial handling and potential hazards. Berkeley has been able to adopt its disclosure and reporting requirements because California's hazardous waste law places no limits on the substances or threshold particle sizes that localities can regulate, thus taking a very broad view of the potential for adverse effects on human health, worker safety, and the environment. The Berkeley model could move both sideways—to be adopted by other localities in California or used as a model for those in other states—or upward—to be adopted by state agencies.

Second, some states or localities might choose to adopt standards that are expert-driven. In the absence of federal standards, they might decide to base their regulatory programs on guidelines such as those for safety in nanotech workplaces, as described

above, or on other guidance from an authoritative source. The ASTM International and the Organization for Standardization, for example, are developing standards for workers who handle nanoparticles.⁹⁹ Consultation on a voluntary international code of conduct, called "Responsible NanoCode," for businesses and researchers working with nanotechnologies is also under way, led by Britain's Royal Society, Insight Investment, and the Nanotechnology Industries Association.¹⁰⁰ Once finalized, these standards could provide the scientific and technical support for state or local initiatives to protect people working with nanomaterials. This reliance on experts was quite successful when the city of Cambridge, Mass., adopted its ordinance on rDNA, as described previously.

Third, some state action to oversee nanotech might be initiated in response to stakeholder pressure. Regulators in other state or local programs, workers, consumers, and even nearby businesses might promote state oversight because of their concern about the potential environmental or health impacts of exposures to or releases of nanoparticles. This type of pressure played a role in EPA's recent decision to regulate the Samsung *Silver Wash*. The issue was a great concern for a number of managers from publicly owned treatment works (POTWs) because increased amounts of these ions in water could bioaccumulate in other aquatic organisms and undercut the POTWs' efforts to remove or prevent pollution from pesticides. Thus, they urged the California Department of Pesticide Regulation (DPR)

and EPA to require the registration of that machine and other products that use silver ions as a pesticide.¹⁰¹ In this way, the efforts both of state POTW managers and of the California DPR led to oversight at the federal level—though EPA stressed in its decision that its action did not represent an effort to regulate nanotechnology.

Under a fourth scenario, states could band together to establish standards for overseeing the safe development of nanotechnology. Similar joint action occurred more than 10 years ago, when a few states began to support each other by sharing research results, agreeing to streamline their respective permitting procedures, and promoting the use of new technologies for cleaning up waste sites. This effort, known as the Interstate Technology Review Committee, now includes 49 states plus the District of Columbia, and is affiliated with the Environmental Council of the States. It receives financial support from the U.S. Departments of Energy and Defense as well as from EPA. More recently, joint action has happened on the issue of climate change. Several states have sued EPA to allow them to regulate carbon dioxide emitted from vehicles,¹⁰² and seven Northeast and Mid-Atlantic states are seeking to implement a multi-state cap-and-trade program for carbon dioxide emissions from electric power generators through the Regional Greenhouse Gas Initiative. Just as many companies operating

across multiple states and countries are recognizing the many risks of inaction on climate change, so, too, are nanobusinesses starting to recognize the potential for public concern about the real and perceived risks of nanotechnology. Thus, states may decide that nanobusinesses would prefer a joint state or regional oversight program for nanotechnology while the federal agencies delay action on mandatory regulation.

At this time, an alternate possibility would be for Congress to preempt individual state action by enacting a federal law that requires nationally uniform standards to protect human health, worker safety, and the environment from potentially adverse impacts of nanotechnology. State governments would then be responsible for adopting and enforcing those standards within their jurisdictions. As we have seen, this approach probably will not happen very soon, but detailed recommendations for drafting such a law already have been proposed.¹⁰³ Nanotech oversight or regulatory standards that apply nationwide also could be adopted by EPA, OSHA, and FDA if they choose to exert their current combined authorities under the various environmental, food safety, worker protection, and public health acts. But that action also seems quite unlikely, particularly in light of EPA's and FDA's recent determinations that they would address nanotech issues only on a case-by-case basis.

IV. Conclusion

The lack of federal initiatives to begin oversight of the risks posed by nanotechnology definitely leaves “room at the bottom” for states and localities to fill this gap with regulatory action. The difficulty will be whether there is adequate scientific support for taking such action and whether state and local officials adopt a precautionary approach for dealing with the many complexities and uncertainties that surround the potential impacts of nanotechnology, as recommended by the Royal Society and Royal Academy of Engineering.¹⁰⁴ Obviously, an accident or other mishap involving nano-based products or a

nanomanufacturing facility could increase pressure for action, whether by states, localities, or federal agencies. The longer adequate oversight is delayed and the more nanotech activities increase, the greater the possibility for such a mishap. Unfortunately, many of our past environmental initiatives have been driven by reactions to damaging accidents that have galvanized public opinion in support of regulatory action. But oversight of nanotechnology need not wait for such an adverse reaction to occur.

The analysis above of existing state authorities and experiences overseeing environmental,

TABLE 1: States with Two or More of the Presented Oversight Authorities/Experiences

State	Disclosing Use or Storage of Nanomaterials	Potential to Sometimes Adopt More Stringent Air Quality Requirements	Stricter Standards for Metals in Waste	Potential to Adopt More Stringent Water Quality Requirements	Potential to Adopt Safety Requirements for Nanotech Workers
California	X	X	X		X
Michigan		X	X		X
Minnesota		X		X	X
Washington		X		X	X
Arizona		X			X
Colorado		X	X		
Indiana		X			X
Maryland		X			X
Massachusetts	X	X			
Missouri		X		X	
Montana		X		X	
New York		X		X	
New Jersey		X		X	
Oregon		X			X
South Carolina		X			X
Utah		X			X
Vermont		X			X
Wyoming		X			X

health, and safety issues that go beyond federal requirements suggests the states most likely to initiate oversight of nanotechnology's safe development may be California, Michigan, Minnesota, and Washington. These four states have oversight authorities or experiences in three or more of the categories presented (i.e., information disclosure, more stringent air quality requirements, stricter standards for metals in waste, more stringent water quality requirements, or worker safety requirements). See Table 1.

Taking into account the states with these authorities/experiences plus states that have significant nanotechnology business and research activities, five states that might be particularly likely to initiate nanotechnology over-

sight are California, Michigan, Massachusetts, New York, and New Jersey. See Table 2.

Some of these states or localities with more experience in nanotech could take the lead in forming a joint effort for designing a nanotech oversight program, as described in the fourth scenario above. A coalition of a few states and localities—perhaps those that currently house the largest concentrations of nanotech businesses and research facilities—could begin work now on drafting a model law, rule, or ordinance to adopt the precautionary principle and begin collecting information about the locations, quantities, uses, and releases of nanotech materials or products that contain them. In this way, they could put to good use their “room at the bottom.”

TABLE 2: States with Significant Nano Activity Plus Two or More of the Presented Oversight Authorities/Experiences

State	Significant Nano Activity ^a	Oversight Authority or Experience				
		Disclosing Use or Storage of Nanomaterials	Potential to Sometimes Adopt More Stringent Air Quality Requirements	Stricter Standards for Metals in Waste	Potential to Adopt More Stringent Water Quality Requirements	Potential to Adopt Safety Requirements for Nanotech Workers
California	X	X	X	X		X
Michigan	X		X	X		X
Massachusetts	X	X	X			
New York	X		X		X	
New Jersey	X		X		X	

^a Based on the states with the greatest number of nanotechnology businesses, universities, and government labs in each state.

Source: *Putting Nanotechnology on the Map*, Project on Emerging Nanotechnologies, Woodrow Wilson International Center for Scholars (May 2007).

APPENDIX A Nano-related Bill Activity During the 110th Congress

The following bills, introduced during the 110th U.S. Congress, specify actions related to nanotechnology, nanomaterial, or nanoscience activities. They are listed chronologically by last action, as of November 15, 2007. This information was obtained from: <http://www.gpo.access.gov/bills/index.html> and <http://www.govtrack.us>.

S. 339: Dependence Reduction through Innovation in Vehicles and Energy Act.

To promote the national security and stability of the United States economy by reducing the dependence of the United States on oil through the use of alternative fuels and new technology, and for other purposes. - Introduced in Senate January 18, 2007

H.R. 670: Dependence Reduction through Innovation in Vehicles and Energy Act.

To promote the national security and stability of the United States economy by reducing the dependence of the United States on foreign oil through the use of alternative fuels and new vehicle technologies, and for other purposes. - Introduced in House January 24, 2007

H.R. 828: Math and Science Incentive Act of 2007.

To preserve mathematics- and science-based industries in the United States. - Introduced in House February 5, 2007

S. 1055: American Automobile Industry Promotion Act of 2007.

To promote the future of the American automobile industry, and for other purposes. - Introduced in Senate March 29, 2007

S. 1115: Energy Efficiency Promotion Act of 2007.

To promote the efficient use of oil, natural gas, and electricity, reduce oil consumption, and heighten energy efficiency standards for consumer products and industrial equipment, and for other purposes. - Introduced in Senate April 16, 2007

H.R. 1915: American Automobile Industry Promotion Act of 2007.

To promote the future of the American automobile industry, and for other purposes. - Introduced in House April 18, 2007

S. 1199: Nanotechnology in the Schools Act.

To strengthen the capacity of eligible institutions to provide instruction in nanotechnology. - Introduced in Senate April 24, 2007

S. 761: America COMPETES Act.

To invest in innovation and education to improve the competitiveness of the United States in the global economy. - Passed Senate April 25, 2007

H.R. 2144: Farm, Nutrition, and Community Investment Act of 2007.

To extend and enhance farm, nutrition, and community development programs of the

Department of Agriculture, and for other purposes. - Introduced in House May 3, 2007

H.R. 1867: National Science Foundation Authorization Act of 2007. To authorize appropriations for fiscal years 2008, 2009, and 2010 for the National Science Foundation, and for other purposes. - Passed House May 2, 2007; Placed on Senate Calendar May 7, 2007

S. 1321: Energy Savings Act of 2007. To enhance the energy security of the United States by promoting biofuels, energy efficiency, and carbon capture and storage, and for other purposes. - Introduced in Senate May 7, 2007

S. 1372: Nanotechnology Infrastructure Enhancement Act. To provide for a Center for Nanotechnology Research and Engineering. - Introduced in Senate May 11, 2007

S. 1419: Renewable Fuels, Consumer Protection, and Energy Efficiency Act of 2007. To move the United States toward greater energy independence and security, to increase the production of clean renewable fuels, to protect consumers from price gouging, to increase the energy efficiency of products, buildings, and vehicles, to promote research on and deploy greenhouse gas capture and storage options, and to improve the energy performance of the Federal Government, and for other purposes. - Introduced in Senate May 17, 2007

S. 1424: Farm, Nutrition, and Community Investment Act of 2007. To provide for the continuation of agricultural programs through fiscal year 2013, and for

other purposes. - Introduced in Senate May 17, 2007

S. 1425: To enhance the defense nanotechnology research and development program. - Introduced in Senate May 17, 2007

H.R. 2436: Nanotechnology in the Schools Act. To strengthen the capacity of eligible institutions to provide instruction in nanotechnology. - Introduced in House May 22, 2007

H.R. 2556: Energy Savings Act of 2007. To enhance the energy security of the United States by promoting biofuels, energy efficiency, and carbon capture and storage, and for other purposes. - Introduced in House May 24, 2007

H.R. 2950: Renewable Fuels, Consumer Protection, and Energy Efficiency Act of 2007. To reduce our Nation's dependency on foreign oil by investing in clean, renewable, and alternative energy resources, promoting new emerging energy technologies, developing greater efficiency, and creating a Strategic Energy Efficiency and Renewables Reserve to invest in alternative energy, and for other purposes. - Introduced in House June 28, 2007

S. 1548: Department of Defense Authorization Act for Fiscal Year 2008. To authorize appropriations for fiscal year 2008 for military activities of the Department of Defense, to prescribe military personnel strengths for such fiscal year, and for other purposes. - Reported with amendments June 29, 2007; Placed on Senate Calendar June 29, 2007

H.R. 2900: Food and Drug Administration Amendments Act of 2007. To amend the Federal Food, Drug, and Cosmetic Act to revise and extend. - Passed House July 11, 2007; Placed on Senate Calendar July 16, 2007

H.R. 3235: Nanotechnology Advancement and New Opportunities Act (NANO). To ensure the development and responsible stewardship of nanotechnology. - Introduced in House July 31, 2007

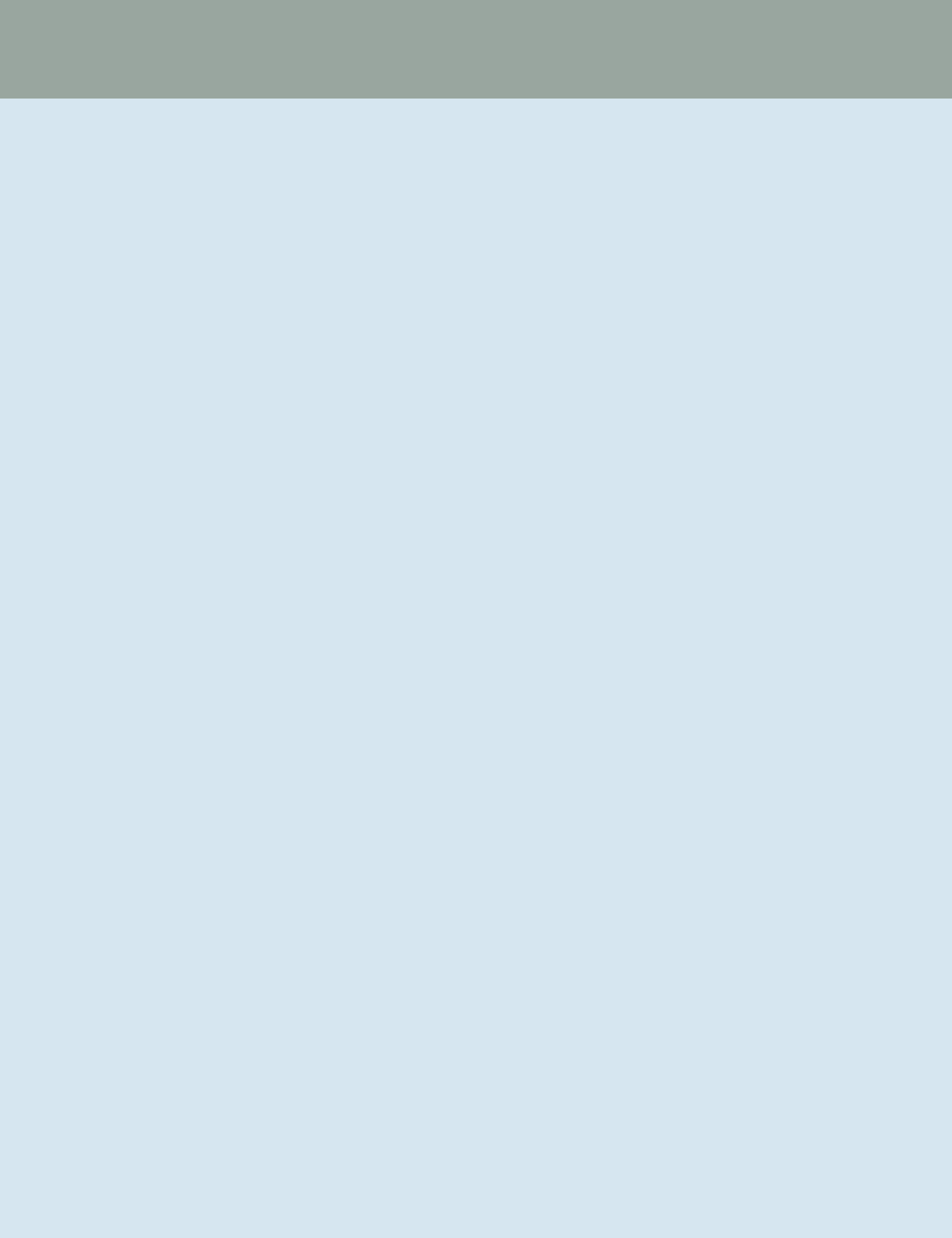
H.R. 2272: 21st Century Competitiveness Act of 2007. To invest in innovation through research and development, and to improve the competitiveness of the United States. - Became Law August 9, 2007

S. 2045: CPSC Reform Act of 2007. To reform the Consumer Product Safety Commission to provide greater protection for children's products, to improve the screening of noncompliant consumer products, to improve the effectiveness of consumer product recall programs, and for other purposes. - Introduced in Senate September 12, 2007

H.R. 3580: Food and Drug Administration Amendments Act of 2007. To amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs and for medical devices, to enhance the post-market authorities of the Food and Drug Administration with respect to the safety of drugs, and for other purposes. - Passed House September 19, 2007; Received in Senate September 19, 2007

H.R. 1585: National Defense Authorization Act for Fiscal Year 2008. To authorize appropriations for fiscal year 2008 for military activities of the Department of Defense, for military construction, and for defense activities of the Department of Energy, to prescribe military personnel strengths for such fiscal year, and for other purposes. - Passed Senate with amendment October 4, 2007

S. 2302: Food and Energy Security Act of 2007. To provide for the continuation of agricultural programs through fiscal year 2012, and for other purposes. - Placed on Senate Calendar November 2, 2007



APPENDIX B Berkeley Ordinance for Nanoparticle Disclosure

The following text contains the two relevant sections of the Berkeley Municipal Code that were amended by the Council of the City of Berkeley, through Ordinance No. 6,960-N.S in January 2007, to include manufactured nanoparticle health and safety disclosure requirements. The amended subsections, highlighted below, are 15.12.040.I and 15.12.050.C.7.

SECTION 15.12.040 FILING OF DISCLOSURE INFORMATION.

A. Each handler, or facility under the jurisdiction of the City of Berkeley, that handles hazardous material or waste in a quantity subject to disclosure under the provisions of Section 15.12.050 at any time must submit the following information at the time it begins operations, or at the time it first begins to handle a hazardous material or waste that must be disclosed:

1. Unified Program Consolidated Form (UPCF), including additional information required under this chapter; and
2. All information required to be submitted under the authority of Health and Safety Code Sections 25503, 25503.3, 25503.5, 25504, 25504.1, 25509 and 25509.3.

B. In addition, each handler shall submit annually either a completed certification, signed under penalty of perjury, that previously filed information remains accurate, or revised information.

C. A handler shall file a revised UPCF, including additional information required under this chapter, at least once every three years or as specified by the hazardous materials manager. In addition, a handler shall file a revised UPCF within 30 days after any of the following:

1. Introduction of a new hazardous material or waste, or an increase in the total quantity handled of any previously disclosed hazardous material or waste by 100% or more above the quantity previously disclosed, unless the material or waste is exempted from disclosure by any of the exemptions set forth in Section 15.12.050;
2. Change of business address;
3. Change of business ownership; or
4. Change of business name.

D. The hazardous materials manager shall review each UPCF and shall accept the form if it conforms to the requirements of subsection A of this section, and provides complete and adequate information

needed for the protection of safety and health and of the environment, or shall require the handler to submit additional information to be included in the form before it may be accepted.

E. A handler shall supply upon request to the hazardous materials manager additional information determined by the hazardous materials manager to be necessary to protect health and safety or the environment.

F. All filings shall be made on the City's most current version of the applicable form. If a state form is used, a handler must comply with all additional stricter local requirements in this chapter.

G. A short form hazardous materials management plan may be required at the discretion of the hazardous materials manager or Fire Chief if the quantity of each hazardous material stored in one or more storage facilities in an aggregate quantity for the facility is 500 pounds or less for solids, 55 gallons or less for liquids, or 200 cubic feet or less at standard temperature and pressure for compressed gases. Such a plan shall include the following components:

1. General facility information;
2. A simple line drawing of the facility showing the location of the storage facilities and indicating the hazard class or classes and physical state of the hazardous materials and wastes being stored and whether any of the material is a waste;

3. Information describing that the hazardous materials and wastes will be stored and handled in a safe manner and will be appropriately contained, separated and monitored;

4. Assurance that security precautions have been taken, employees have been appropriately trained to handle the hazardous materials and wastes and react to emergency situations, adequate labeling and warning signs are posted, adequate emergency equipment is maintained, and the disposal of hazardous materials and wastes will be in an appropriate manner.

H. Each handler, or facility under the jurisdiction of the City of Berkeley, that is subject to the disclosure requirements under the provisions of Section 15.12.050(C)(5) shall file a hazardous waste generator reporting packet in lieu of the requirements of Section 15.12.040(A). The hazardous waste generator reporting packet will include forms to identify the generator, the waste streams, an Emergency Response Plan/Contingency Plan per Health and Safety Code Section 25504(b), and any additional information as required by the hazardous materials manager.

I. All facilities that manufacture or use manufactured nanoparticles shall submit a separate written disclosure of the current toxicology of the materials reported, to the extent known, and how the facility will safely handle, monitor, contain, dispose, track inventory, prevent releases and mitigate such materials. (Ord. 6960-NS § 1 (part), 2006; Ord. 6824-NS § 3, 2004)

**SECTION 15.12.050 QUANTITIES
REQUIRING DISCLOSURE.**

A. Except as provided in the following subsections of this section, each handler who handles the following aggregate quantities of all hazardous materials and wastes at any time during a year shall disclose all such handling: 500 pounds or more of all solid hazardous materials and wastes; 55 gallons or more of all liquid hazardous materials and wastes; or 200 cubic feet or more at standard temperature and pressure of all gaseous hazardous materials.

B. Hazardous materials contained solely in consumer products packaged for distribution to, and use by, the general public shall be exempt from disclosure under this chapter unless the hazardous materials manager has notified the handler in writing that the handling of certain quantities of specified consumer products requires disclosure under this chapter in response to health and safety concerns.

C. The following disclosure requirements shall apply in addition to those in subsections A and B of this section:

1. The handler shall disclose handling of any extremely hazardous substance in quantities that require disclosure under the provisions of Section 25532(j) of Division 20 of Chapter 6.95 of the California Health and Safety Code.
2. The handler shall disclose the handling of any quantity of a material or waste that is or contains a material

subject to regulation by the Nuclear Regulatory Commission in Title 10 of the Code of Federal Regulations, including any by-product, licensed, source, or special material. Disclosure is not required for manufactured products, such as tritium exit signs, smoke detectors, china, and similar products that are in use by the consumer, as well as naturally occurring radioactive materials, provided that these items are properly disposed of at the end of consumer use. Facilities may petition the hazardous materials manager for exemption of low risk or short lived radiological materials, wastes, or products.

3. The handler shall disclose the handling of any quantity of an etiologic agent, as defined in subsection D of Section 15.08.060 of this title. Vaccines are exempt from disclosure requirements.
4. The handler shall disclose the handling or generation of any hazardous waste as defined in this title.
5. As required by the Fire Chief or hazardous materials manager, the handler shall disclose the handling of any hazardous material, as defined by the Uniform Fire Code, in a quantity at least equal to the permit quantity threshold established in the Uniform Fire Code, if that quantity is less than the applicable quantity set forth in subsection A. Permits under Section 105 of the Uniform Fire Code are under the jurisdiction of the Berkeley Fire

Department. Submission of the inventory does not constitute meeting the requirements of UFC Section 105.

6. Each laboratory shall identify separately in its disclosure each hazardous material or waste handled at any time during a year in the following quantity: 500 pounds or more of any solid hazardous material or waste; 55 gallons or more of any liquid hazardous material or waste; or 200 cubic feet or more at standard temperature and pressure of any gaseous hazardous material or waste. In addition, each laboratory shall report all other hazardous materials and wastes handled during a year, but may do so by hazard class.
7. **All manufactured nanoparticles, defined as a particle with one axis less than 100 nanometers in length, shall be reported in the disclosure plan. (Ord. 6960-NS § 2 (part), 2006; Ord. 6824-NS § 3, 2004)**

APPENDIX C Berkeley Nanotech Facility Reporting Instruction

Planning and Development Department
Toxics Management Division

August 2007

MANUFACTURED NANOSCALE MATERIALS HEALTH & SAFETY DISCLOSURE

The City of Berkeley recently adopted a manufactured nanoscale material disclosure ordinance that has been incorporated into the hazardous materials business plan HMBP requirements (Title 15, Berkeley Municipal Code and by reference, Chapter 6.95 Division 20 of California Health & Safety Code). Facilities that produce or handle manufactured nanoscale materials (defined as manufactured chemicals that are engineered and which have one dimension less than 100 nanometers) are required to submit a report (incorporating the items listed on pages 2 and 3) to the Toxics Management Division (TMD) by June 1, of each year.

We have received much input from industry, legal firms, consultants, members of the public and regulators during the drafting of this reporting requirement. Our goal was to allow flexibility in reporting yet still require the facility to address the potential risks to its workers and the environment. It is our hope that the reporting requirements will change with time as we gather additional knowledge about safe handling of manufactured nanomaterials.

In an effort to contain costs of reporting, we adopted a system of prioritizing risk activities into control bands as listed in the guidance below. This requires a review of the available toxicological information for materials handled or you intend to handle and an exposure pathway study. An internal audit should be conducted to evaluate exposure potentials of your nanoscale materials throughout its lifecycle; from the point of generation or receipt to disposal. If an exposure potential is determined to exist, you must review the published data on the toxicity of the nanoscale materials in question. We recommend you use health professionals for this task. Based on the band of risk you identify in this evaluation, you should take appropriate measures to protect workers and the environment. If an exposure potential is present but insufficient toxicological information is available, a precautionary approach should be taken which assumes that the material is toxic.

Facilities that cannot predict their inventory for the reporting period should submit this report based on your best knowledge of the inventory for the year. You should use a risk-based approach and document your findings in the same manner as reported materials. However, you are not required to submit updated information unless specifically requested.

Please note that there is important information at the end of these instructions that you should read.

For additional information please contact:

Nabil Al-Hadithy PhD – Hazardous Materials Manager:
Toxics@ci.berkeley.ca.us

Drew Lerer – Hazardous Materials Specialist: Dlerer@ci.berkeley.ca.us

A. GENERAL INFORMATION

1. By June 1 of each year, provide a cover letter signed by senior member of the staff indicating the information in the report is accurate and precautions therein will be adhered to.
2. Fill out the company information (California OES Form 2730) unless you have already submitted this form in your Hazardous Materials Business Plan (HMBP).
3. Provide the common name of the nanoscale material or class of materials.
4. Where available, provide the Chemical Abstract Service (CAS) number. For mixtures, enter the CAS number of the individual chemicals. If there is no CAS number assigned to this material please indicate.
5. Provide the average and the maximum daily amount of the material stored onsite at any one time during the year.

Specify the units used (use metric units where possible).

6. Provide the physicochemical properties of the nanoscale material. Include available information about the following: chemical form (e.g., solid, liquid), purity, particle dimensions, prediction of surface area with approximate mass, shape, aggregation potential, water solubility, flammability, flash point, and reactivity.
7. Provide the source of the material if it is not produced on site. Please provide the address and contact information for the site from which the material was obtained
8. Indicate the type of substrate used if any and any relevant toxicological information that may be important about the substrate.
9. Indicate the use within the site, intended downstream use, and information about the benefits of the applications.

B. TOXICOLOGY

10. Provide toxicological information about the nanoscale material. If available, include information regarding inhalation toxicity, dermal penetration and/or toxicity, and oral toxicity, mutagenicity/genotoxicity, and reproductive toxicity.
11. Provide ecological information about the nanoscale material, which may include: effects on organisms, degra-

dation/biopersistence, and bioaccumulation potential.

C. OCCUPATIONAL AND ENVIRONMENTAL PROTECTION

12. Provide safe handling information for the nanoscale material
13. Provide information about the potential exposure pathways and likelihood of exposure via these pathways.
14. Provide a list of personal protective equipment (PPE) used in production and handling of the nanoscale equipment
15. Provide descriptions of engineering and administrative controls, such as local exhaust ventilation or job rotation, that are used to reduce employee exposures.
16. Provide a training plan for employees who may come into contact with nanoscale material. Include safe handling procedures, release prevention, release mitigation and disposal methods
17. Provide the clean up methods and procedures for accidental spills or releases
18. Provide the container type that the nanoscale material is stored in. Please indicate if the material is stored in more than one type of container.

19. Provide a site map indicating safety equipment, spill mitigation equipment, engineering control equipment, storage areas, and process areas.

D. CONTROL BAND MEASURES

Review the data gathered and identify the chemicals by one of the Bands below. The list of Bands is not exhaustive and you should use best judgment for your reporting.

List the control measures adopted or proposed to be adopted that are commensurate with the Band Level you have identified for the nanoscale materials. If you intend to adopt control levels in the future, please indicate the timeline for adopting such control measures. Examples of control banding:

Band 1: Low potential toxicity and no exposure pathway. Little or no control measures.

Band 2: Moderate potential toxicity and exposure pathways. Moderate levels of control measures

Band 3: High potential for toxicity and possible exposure pathways. High levels of control measures.

Band 4: Unknown toxicity and possible exposure pathways. High levels of controls measures.

IMPORTANT NOTES:

- Where information is not available, please indicate this in the disclosure.
- For the purpose of efficiency you may

refer to multiple manufactured nanoscale material as a single category in your submittal if they show similar behavior.

- Trade Secret: Please print "TRADE SECRET" on the top right of each page of the disclosure, which is subject to trade secret clause per California Health and Safety Code Section 25538. Trade secret status does not preclude you from submitting required information.
- If you have an internal procedure that addresses all the analyses indicated above, you can make a request to TMD to submit your report using your individual process.

ENDNOTES

1. Berkeley City Council Meeting, Discussion on Manufactured Nanoparticle Health and Safety Disclosure (December 5, 2006). Video archive available at: <http://www.ci.berkeley.ca.us/city-council/2006citycouncil/agendaindex.htm>
2. Federal agencies have not yet offered any official definitions of terms like *nanotechnology*, *nanoscale*, *nanomaterials*, or *engineered nanoscale material*, but *nanotechnology* has been defined by the National Nanotechnology Initiative (NNI), the International Standards Organization (ISO), and the American Society for Testing and Materials (ASTM). Those three definitions vary slightly but, for purposes of this paper, the NNI definition should suffice. It defines nanotechnology as “the understanding and control of matter at dimensions roughly 1 to 100 nanometers, where unique phenomena enable novel applications. Encompassing nanoscale science, engineering and technology, nanotechnology involves imaging, measuring, modeling, and manipulating matter at this length scale.” See <http://nano.gov/html/facts/whatIsNano.html>. A nanometer is one-billionth of a meter, a human hair is about 80,000 nanometers wide, and a sheet of paper is about 100,000 nanometers thick.
3. Feynman, “There Is Plenty of Room at the Bottom: An Invitation to Enter a New Field of Physics,” Lecture at the American Physical Society (December 29, 1959).
4. By the end of 2006, the U.S. Environmental Protection Agency (EPA) estimated there were “over 600 raw materials, intermediate components and industrial equipment items” being used by makers of nanotech materials. U.S. EPA, *U.S. Environmental Protection Agency Nanotechnology White Paper*, EPA 100/B-07/001, U.S. Environmental Protection Agency (2007). As of August 2007, the Consumer Products Inventory, compiled by the Project on Emerging Nanotechnologies at the Woodrow Wilson International Center for Scholars, already included over 500 products for which the manufacturers claimed some nanocomponent. *A Nanotechnology Consumer Products Inventory*, Project on Emerging Nanotechnologies, Woodrow Wilson International Center for Scholars, Available at: <http://nanotech-project.org/44> (accessed August 7, 2007). Lux Research estimates that global growth in the value of nanotech goods will reach \$2.6 trillion by 2014. Lux Research, *The Nanotech Report™: Investment Overview and Market Research for Nanotechnology*, 4th edition, volume 1. Lux Research Inc. (2006).
5. Maynard et al., “Safe Handling of Nanotechnology,” *Nature*, Vol. 444, no. 16, pp. 267–269 (November 2006).
6. Thayer, “Nanotech Consumer Product Recalled in Germany,” *Chemical & Engineering News* (April 7, 2006), reporting that the German Federal Institute for Risk Assessment issued a warning against using a household spray called “Magic Nano” after German poison control centers “received about 80 reports of people coughing or complaining of fever and headache, and several people were hospitalized with pulmonary edema.” As it turned out, the spray did not contain any nanoparticles, but this incident illustrates the confusion and panic that can result from unknown or misunderstood product ingredients.
7. See *Putting Nanotechnology on the Map*, Project on Emerging Nanotechnologies, Woodrow Wilson International Center for Scholars (May 2007), Available at: <http://www.penmedia.org/maps/mappage.html> (accessed August 7, 2007). Also see “State Rankings Part Six: The all-category summary,” *Small Times Magazine*, Vol. 7, Issue 4 (July/August 2007).
8. Based on *Putting Nanotechnology on the Map*, Project on Emerging Nanotechnologies, Woodrow Wilson International Center for Scholars (May 2007), Available at:

- <http://www.penmedia.org/maps/mappage.html> (accessed November 16, 2007). By the fall of 2007, every state was home to at least one company, university or government lab, or other type of organization working in nanotechnology.
9. Lux Research, "Profiting from International Nanotechnology, Report Press Release: Top nations see their lead erode." Lux Research Inc. (2007)
 10. Lux Research, *The Nanotech Report™: Investment Overview and Market Research for Nanotechnology*. 4th edition, volume 1. Lux Research Inc., New York, NY. (2006)
 11. See Maynard, *Nanotechnology: A Research Strategy for Addressing Risk*, Project on Emerging Nanotechnologies, Woodrow Wilson International Center for Scholars (July 2006); Maynard, *International Risk Research Strategy and Funding Needed for Nanotech Safety* (March 27, 2007).
 12. See <http://thomas.loc.gov/cgi-bin/query/z?c110:H.R.3235> (accessed November 21, 2007).
 13. Ruckelshaus and Davies, "An EPA for the 21st century," *The Boston Globe* (July 7, 2007).
 14. 15 U.S.C. 2601 *et seq.*
 15. U.S. EPA, "TSCA Inventory Status of Nanoscale Substances—General Approach," Office of Pollution Prevention and Toxics, U.S. Environmental Protection Agency (July 12, 2007), Available at: <http://www.epa.gov/oppt/nano/nmspfr.htm> (accessed August 8, 2007).
 16. *Ibid.*
 17. U.S. EPA, "Nanoscale Program Approach for Comment," Office of Pollution Prevention and Toxics, U.S. Environmental Protection Agency (July 12, 2007), Available at: <http://www.epa.gov/oppt/nano/nmspfr.htm> (accessed August 8, 2007). Notice of Availability posted in *Federal Register*, Vol. 72, No. 133 (July 12, 2007).
 18. Fed. Reg. "Nanoscale Materials; Notice of Public Meeting," EPA-HQ-OPPT-2004-0122-0001, *Federal Register*, Vol. 70, No. 89 (May 10, 2005).
 19. Denison, "Statement of Richard A. Denison, Ph.D., Senior Scientist on USEPA's Public Meeting on the Development of a Voluntary Nanoscale Materials Stewardship Program," Environmental Defense (August 2, 2007). Available at: <http://www.environmentaldefense.org/article.cfm?ContentID=6748> (accessed August 28, 2007).
 20. Davies, *Managing the Effects of Nanotechnology*, Project on Emerging Nanotechnologies, Woodrow Wilson International Center for Scholars (January 2006); Greenwood, *Thinking Big about Things Small: Creating an Effective Oversight System for Nanotechnology*, Project on Emerging Nanotechnologies, Woodrow Wilson International Center for Scholars (March 2007); Davies, *EPA and Nanotechnology: Oversight for the 21st Century*, Project on Emerging Nanotechnologies, Woodrow Wilson International Center for Scholars (May 2007); and Breggin and Carothers, "An Agenda for the Nano Revolution," *The Environmental Forum* (July/August 2007).
 21. 7 U.S.C. Sections 136 to 136y.
 22. "Antimicrobial Nanomaterials Meet Increased Regulatory Scrutiny," *Environmental Science & Technology Policy News* (January 3, 2007).
 23. "EPA to Regulate Nanoscale Silver Used in Washing Machines to Kill Bacteria," *Daily Environment* (November 21, 2006).
 24. Fed. Reg. "Pesticide Registration; Clarification for Ion-Generating Equipment." EPA-HQ-OPP-2007-0949, *Federal Register*, Vol. 72, No. 183 (September 21, 2007).
 25. U.S. EPA, "Pesticide Registration: Clarification for Ion Generating Equipment." U.S. Environmental Protection Agency Web site, http://www.epa.gov/oppad001/ion_gen equip.htm (September 21, 2007)
 26. ITCA, "Petition Requesting FDA Amend its Regulations for Products Composed of Engineered Nanoparticles Generally and Sunscreen Drug Products Composed of Engineered Nanoparticles Specifically," International Center for Technology Assessment (2006).

27. U.S. FDA, "Sunscreen Drug Products for Over-the-Counter Human Use; Proposed Amendment of Final Monograph," U.S. Food and Drug Administration, 21 CFR Parts 347 and 352 (August 2007).
28. U.S. FDA, *Nanotechnology: A Report of the U.S. Food and Drug Administration Nanotechnology Task Force*, U.S. Food and Drug Administration (July 25, 2007). Available at: <http://www.fda.gov/nanotechnology/taskforce/report2007.html> (accessed September 4, 2007).
29. Taylor, *Regulating the Products of Nanotechnology? Does FDA Have the Tools It Needs?*, Project on Emerging Nanotechnologies, Woodrow Wilson International Center for Scholars (October 2006).
30. Lindberg and Quinn, "A Survey of Environmental, Health and Risk Information Needs and Practices among Nanotechnology Firms in the Massachusetts Region," Research Brief, Project on Emerging Nanotechnologies, Woodrow Wilson International Center for Scholars (December 2007).
31. Lekas, Lifset, and Rejeski, "Nanotech Startup Concerns, Information Needs, and Opportunities to Proactively Address Environmental, Health, and Social Issues: Focus on Firms in Connecticut and New York," Master's project completed at Yale's School of Forestry and Environmental Studies (July 2006), Available at: www.nanotechproject.org/file_download/87.
32. Gerritzen, Huang, Killpack, Mircheva, and Conti. *A Survey of Current Practices in the Nanotechnology Workplace*, produced for the International Council on Nanotechnology by University of California Santa Barbara (November 13, 2006).
33. See: Pollack, "Without U.S. Rules, Biotech Food Lacks Investors," *New York Times* (July 30, 2007); Lipton and Harris, "In Turnaround, Industries Seek U.S. Regulations," *New York Times* (September 16, 2007); Zhang, "Food Makers Get Appetite for Regulation," *Wall Street Journal* (September 17, 2007); Waldmeir, "The brave new risks of nanotechnology," *Financial Times* (September 19, 2007).
34. Global Warming Solutions Act of 2006, Assembly Bill 32 (signed into law September 27, 2006).
35. Regional Greenhouse Gas Initiative, see <http://www.rggi.org>.
36. Oregon's governor has recently signed two laws requiring electric utilities to use renewable sources for 25% of their energy by 2025 and creating a renewable fuel standard and tax incentives to increase the use of biodiesel and ethanol in gasoline. Senate Bill 838 (June 6, 2007) and House Bill 2210 (July 3, 2007); Minnesota has adopted the Next Generation Energy Act to increase energy efficiency while also mandating that 25% of the state's power must come from renewable sources by 2025; and New Hampshire has adopted the Renewable Energy Act (HB 873, May 11, 2007) requiring that electricity providers begin using renewable sources in 2008 and increase their renewable power every year until they, too, reach 25% by 2025.
37. Mendelson, "Bullies Along the Potomac," *The New York Times* (July 2006).
38. *New State Ice Co. v. Liebmann*, 285 U.S. 262, 311 (1932) (dissenting opinion).
39. These states include Arkansas, California, Illinois, Massachusetts, New York, Oklahoma, Oregon, Pennsylvania, South Carolina, Texas, Virginia. See Environmental Law Institute, *Securing the Promise of Nanotechnology: Is U.S. Environmental Law Up to the Job?*, Appendix 2 (2005), Available at: <http://www2.eli.org/pdf/research/nanotech/issue.paper.appendix2.pdf> (accessed August 7, 2007); Illinois legislation information from National Conference of State Legislatures, Nanotechnology: 2006 State Legislation, Available at <http://www.ncsl.org/programs/lis/legislation/NanoLegislation2006.htm>.
40. National Conference of State Legislatures, Nanotechnology: 2006 State Legislation, Available at: <http://www.ncsl.org/>

- programs/lis/legislation/NanoLegislation 2006.htm.
41. See: *Putting Nanotechnology on the Map*, Project on Emerging Nanotechnologies, Woodrow Wilson International Center for Scholars (May 2007), Available at: <http://www.penmedia.org/maps/map page.html> (accessed November 16, 2007).
 42. *Small Times* found that the following 10 states ranked highest across the five areas of industry, venture capital, research, innovation, and workforce in small tech: California, Massachusetts, New Mexico, New York, Michigan, Texas, Maryland, Illinois, Pennsylvania, and Ohio. See *Small Times*, “State Rankings Part Six: The all-category summary,” *Small Times*, Vol. 7, Issue 4 (July/August 2007); in the industry-only ranking, California, Massachusetts, New York, New Mexico, Connecticut, Michigan, Delaware, New Jersey, Pennsylvania, and Texas came to the top. See Forman, “State Rankings,” *Small Times*, Vol. 6, Issue 5 (September/October 2006).
 43. “California Department of Toxic Substances Control to Examine Risks of Manufacturing and Using Nanotechnology-Related Products,” News release posted at: <http://www.azonano.com/News.asp?NewsID=5053> (October 3, 2007).
 44. Blue Ribbon Task Force on Nanotechnology. “Thinking Big About Thinking Small: An Action Agenda for California” (December 19, 2005).
 45. California Department of Toxic Substances Control Nanotechnology Website, Available at: <http://www.dtsc.ca.gov/Technology Development/Nanotechnology/> (accessed October 5, 2007).
 46. See *supra* note 1.
 47. California Health and Safety Code, Chapter 6.95, Division 20, Section 25500 *et seq.*
 48. Office of the City Clerk, City of Berkeley, “Manufactured Nanoparticle Health and Safety Disclosure,” Action Calendar (December 5, 2006).
 49. California Health and Safety Code, Section 25501(o); Berkeley Municipal Code, Section 15.12.050.
 50. City of Berkeley, Toxics Materials Division, “Introduction to Manufactured Nanoscale Material Health & Safety Disclosure” (Appendix C).
 51. *Ibid.*
 52. Communication with Drew Lerer, Hazardous Materials Specialist, TMD (July 2, 2007). Some laboratories at the University of California-Berkeley are known to be working with nanomaterials but are exempt from the city’s disclosure requirements because they are state entities.
 53. Emergency Planning and Community Right-to-Know Act (EPCRA), 42 U.S.C. Section 11001 *et seq.*
 54. Monica Heintz, and Lewis, “The Perils of Pre-emptive Regulation,” *Nature Nanotechnology*, Vol. 2, 68–70 (2007).
 55. See, for example: Bray, “Cambridge Considers Nanotech Curbs,” *The New York Times* (January 26, 2007); Lipson, “The Cambridge Model: How public oversight of biotech is good for everyone—even business,” *GeneWatch*, Vol. 16, Number 5 (Sep–Oct 2003), Available at: http://www.nanolaw report.com/Cambridge_Model.pdf
 56. Massachusetts General Laws, Chapter 211.
 57. New Jersey Statutes Annotated, Sections 34:5A *et seq.* (Public Law 1983, chapter 315, adopted August 29, 1984, as amended through July 1, 2003).
 58. TURA, Section 10 (D); NJSA, Section 34:5A-34:5A-3(m). Although the New Jersey disclosure law, like California, allows for reporting of potentially many more substances than the federal EPCRA, New Jersey explicitly forbids any municipality or county from enacting a law or ordinance requiring disclosure of information about hazardous substances and supersedes any future municipal or county enactment for this purpose. NJSA, Section 34:5A-27. By contrast, California’s law explicitly states that it “does not intend to preempt

- any local actions, ordinances, or regulations that impose additional or more stringent requirements on businesses which handle hazardous materials.” California Health and Safety Code, Section 25500.
59. 42 U.S.C. Section 7416.
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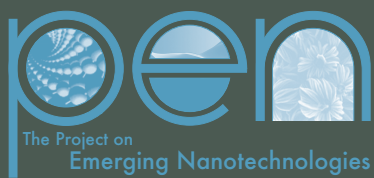
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