HARVARD Kennedy School
MOSSAVAR-RAHMANI CENTER
for Business and Government 30 YEARS

The Massachusetts Toxics Use Reduction Act: A Model for Nanomaterials Regulation?

Jennifer Nash
Harvard Kennedy School

July 2012

M-RCBG Associate Working Paper Series | No. 9

The Massachusetts Toxics Use Reduction Act: A Model for Nanomaterials Regulation?

Jennifer Nash
Executive Director
Regulatory Policy Program
Harvard Kennedy School
jennifer_nash@harvard.edu
617.495.9379

Abstract

Nanomaterials exemplify a new class of emerging technologies that have significant economic and social value, pose uncertain health and environmental risks, and are entering the marketplace at a rapid pace. Effective regimes for regulating emerging technologies generate information about known or suspected hazards and draw on private sector expertise to guide managers' behavior toward risk reduction, even in the absence of clear evidence of harm. This paper considers the extent to which the federal Toxic Substances Control Act (TSCA) accomplishes those objectives. It offers the approach of the Massachusetts Toxics Use Reduction Act (TURA) as a possible supplement to TSCA, filling gaps in agency knowledge and private sector capacities. TURA is notable for its focus on chemicals use and hazard and its emphasis on strengthening firms' internal management systems. Given the current deadlock in Congressional efforts to modernize federal laws such as TSCA, the role of state laws like TURA merit attention. Absent definitive information about risk, a governance strategy that generates information and focuses management attention on reducing hazards is worth considering.

Forthcoming in the *Journal of Nanoparticle Research*, DOI 10.1007/s11051-012-1070-7
The final publication is available at www.springerlink.com

The Massachusetts Toxics Use Reduction Act: A Model for Nanomaterials Regulation?

Jennifer Nash
Executive Director
Regulatory Policy Program
Harvard Kennedy School
jennifer_nash@harvard.edu
617.495.9379

Nanomaterials exemplify a new class of emerging technologies that have significant economic and social value, pose uncertain health and environmental risks, and are entering the marketplace at a rapid pace. What regulatory approaches are appropriate for mitigating health and environmental risks from technologies with such characteristics? The US Toxic Substances Control Act (TSCA) is one of the primary frameworks for regulating nanomaterials at the federal level (Wardak 2003, Mandel 2008, Rudd 2008, Bomkamp 2010, Bergeson 2010). This statute, more than any other federal law, attempts to address the risks from new chemicals and materials before they enter the marketplace. Particular features in the way that TSCA was written and has been implemented have limited its effectiveness, however, leading US Environmental Protection Agency (US EPA) Administrator Lisa Jackson to conclude that this law "has fallen behind the industry it's supposed to regulate" (Jackson 2009). Given the ongoing deadlock in Congressional efforts to amend TSCA to address its deficiencies, the role of state laws merits attention. This paper examines the Massachusetts Toxics Use Reduction Act (TURA), enacted in 1989, as a potential framework for supplementing federal environmental protection laws.

The paper begins with an overview of the health and environmental risks posed by nanotechnologies, underscoring significant gaps in existing knowledge. It summarizes key features of TSCA and TURA: the events and conditions that motivated lawmakers to act and the major goals and provisions of these laws. It argues that a regulatory regime for emerging technologies should increase the information available to regulators about health and environmental risks posed by new technologies and draw on private sector managers' expertise about their products and processes. The paper considers how TSCA and TURA meet those characteristics, emphasizing the strengths and weaknesses of each approach. Finally, it envisions what a regulatory regime for nanomaterials might look like under a TURA-like approach. It concludes that, given the unlikelihood of action at the federal level, state approaches like TURA offer important, although limited benefits.

I. Risks from Nanotechnologies

The term "nanotechnology" refers to "the understanding and control of matter at dimensions between approximately 1 and 100 nanometers" (NNI 2007). Nanoparticles (particles with at least one dimension in the size range of 1 to 100 nm) are commonly found in nature, for example in volcanic ash and sea salt. Only recently, however, have humans had the ability to engineer nanoparticles for defined uses (Lok 2010).

Today, research laboratories and universities, small start-up firms, and large diversified manufacturing businesses are rapidly developing and commercializing engineered nanoparticles and nanoenabled products. The Project on Emerging Nanotechnologies at the Woodrow Wilson International Center currently lists more than 1,300 nanoenabled products on the market, a 521 percent increase since 2006 when the Center first began tracking the development of these products (PEN 2011). Nanotechnologies enter the market as bulk products such as carbon nanotubes (CNTs), as intermediaries with nanoscale features (such as fabricated sheets of CNTs woven together), and as nanoenabled products (such as body armor made from CNT fabricated sheets). They already are critical components in automobiles, construction materials, cosmetics, human protective equipment, computers, food, medical devices, and pharmaceuticals. Many nanomaterial applications—such carbon nanotubes that increase the electrical storage capacity of lithium ion rechargeable batteries—are associated with significant environmental benefits.

The novel properties that make nanoparticles particularly valuable to business and society also make them potentially hazardous: their small size, relatively large surface area, shape, and reactivity with other chemicals. Because they are so small, nanoparticles are easily respirable. Toxicologists compare them to ultrafine diesel particles, long considered carcinogenetic due to their surface area, reactivity, and ability to penetrate deep within the lung (Ellenbecker and Tsai, 2010; Seaton et al. 2009). Once inhaled, nanoparticles may penetrate cell walls, passing through the lungs to blood, the brain, and other organs (GAO 2010). For their mass, nanoparticles have large surface areas where chemical reactions can occur. That reactivity means that nanoparticles do not tend to remain passive in living tissues; they interact in ways that are potentially harmful.

Moreover, engineered nanoparticles may be produced in a variety of shapes, such as tubes, spheres, and threads. Some are similar in size and shape to asbestos fibers, a known human carcinogen that can remain in the lung for decades. While inhalation is the most common route of exposure (NIOSH 2009), nanoparticles may also be ingested or absorbed through the skin. For example, nanoenabled

sunscreens are designed for direct application to the skin, maximizing the potential for absorption, while nanosilver deodorizers are designed to disperse to clothing where they come into contact with the skin.

Little is currently understood about the fate and transport of engineered nanoparticles in the environment. Due to their small size, nanoparticles may have the tendency to disperse. Alternatively, they may agglomerate to form larger particles, break down, or react with other materials (GAO 2010). Because these materials vary so much, findings from the study of one nanoparticle may not be applicable to others. While nanomaterials such as silica nanoparticles and carbon black have received substantial scrutiny, others have not (GAO 2010). In sum, much is still not known about the health and environmental implications of these novel technologies.

II. TSCA and TURA: Motivations, Goals, and Key Features

The Toxic Substances Control Act and the Toxics Use Reduction Act (TURA) offer contrasting approaches to regulating emerging technologies. TSCA is a federal statute, while TURA is Massachusetts-based and only affects actions within that single state. TSCA authorizes US EPA to require manufacturers to conduct tests to determine chemical risks, while TURA establishes no testing mandates. TSCA attempts to prevent businesses from introducing dangerous chemicals into the marketplace, while TURA encourages firms to reduce their use of toxics by preparing toxics use reduction plans. TSCA allows companies to limit information disclosure on the basis of claims of confidentiality. TURA includes broad information disclosure requirements. TSCA has proven to be remarkably resistant to change and many people view it as ineffective. TURA is more adaptable to new concerns.

While notably different in jurisdiction, purpose, and approach, the two laws share important similarities. Both attempt to address the health and environmental impacts of toxic chemicals. Both generate information about chemicals. Both attempt to shape core business activities—the products businesses make and materials they use. Both attempt to prevent environmental problems at their source rather than shift problems from in-plant workers to external communities or from water to air. Similarities and differences in the two laws are summarized in Table 1.

Table 1: Comparison of Selected Features of TSCA and TURA

Feature	*TSCA*	*TURA*
Jurisdiction; year enacted and amended (if applicable)	Federal statute enacted in 1976	Massachusetts statute enacted in 1989 and amended in 2006
Goal	To develop information about the health and environmental impacts of toxic chemicals; regulate chemicals that present an "unreasonable risk;" promote innovation and economic development	To reduce toxic waste by 50% by 1997 using toxics use reduction; establish toxics use reduction as the preferred means for compliance with federal and state laws pertaining to toxics; safeguard and promote competitive advantage of MA firms; promote reductions in production and use of toxic substances
Definition of substances covered	"Any organic or inorganic substance of a particular molecular identity"	Chemicals listed under EPCRA and CERCLA. Authorizes the Massachusetts Administrative Council on Toxics Use Reduction to list additional chemicals (or delist)
Trigger for regulatory action	"Unreasonable risk"	Hazard
Nature of regulatory action	Authorizes government to require firms to conduct chemical testing, label products, restrict uses, and ban chemicals	Authorizes government to require firms to disclose use of listed chemicals and to prepare Toxics Use Reduction Plans
Role of risk assessment and management	Authorizes US EPA to require risk assessment and management	Decisions are based on hazard rather than risk
Type of policy tool	Performance-based	Management-based

Lawmakers' motivations for implementing TSCA can be traced to the early 1970s as the public first became aware of pervasive and persistent toxics in the environment. As kepone was discovered in the James River, polychlorinated biphenols in the Hudson, and mercury in swordfish, Congress began to investigate opportunities for "preventive medicine legislation" that could stop the introduction of toxic chemicals into the economy before they became health and environmental problems (Markell 2010: 337). Lawmakers sought to avoid the "after-the-fact" quality of most environmental statutes in place at the time (Markell 2010: 344). With statutes such as the Clean Air and Clean Water Acts, Congress attempted to address the unintended byproducts of manufacturing processes that went up smokestacks, down drains, and out the back doors of plants. With TSCA, Congress instead focused on

core business decisions: the products managers choose to develop and sell. A 1977 report by the Council on Environmental Quality summarized Congressional intent in enacting TSCA:

> "Unhappily, the toxicity and persistence of chemicals have often been discovered after their widespread use and after they have become important to jobs, commerce, or agriculture… [T]he major accomplishment of the new law is that it gives the government broad authority to control the production, distribution, and use of all potentially hazardous chemicals. It provides for testing of suspect chemicals before they become widely used and economically important. It emphasizes collection of information and freedom of access to research data so that the scientific community can note and assess potential problems" (CEQ 1977: 1-3).

The three main goals of TSCA are to develop information about the health and environmental impacts of toxic chemicals, regulate chemicals that present an "unreasonable risk," and promote innovation and economic development. The law provides US EPA with authority to require manufacturers to test new or existing chemicals for their impacts on human health and the environment (Section 4); regulate new chemicals prior to manufacture and existing chemicals for significant new uses (Section 5); regulate existing chemicals or mixtures (Section 6); and report information to US EPA about chemical production and environmental, health, and safety studies (Section 8). Using this authority, US EPA can restrict chemical uses and even ban chemicals.

Unlike TSCA, TURA is not "preventive medicine legislation" aimed at keeping dangerous chemicals from entering commerce in the first place. While an early draft of the TURA authorized the Massachusetts Department of Environmental Quality Engineering—now called the Massachusetts Department of Environmental Protection (MassDEP)—to ban and phase out toxic chemicals, the version of TURA signed into law did not include that provision. As a result, TURA takes as given that thousands of toxic chemicals are in commerce; its goal is to encourage firms to use less of them and to transition to less toxic or nontoxic alternatives.

TURA was the product of a compromise hammered out in 1989 among leaders from industry, environmental advocacy groups, and representatives of the legislative and executive branches of Massachusetts state government. Government and business at that time were concerned about the diminishing availability of places to dispose of growing quantities of hazardous wastes generated by Massachusetts businesses. Establishing new disposal facilities had proven impossible, despite the state's passage of an innovative hazardous waste facility siting law in 1980. Policymakers, business people, and environmental advocates started calling for policies to encourage firms to reduce the amount of waste they generated, thereby lessening the need for more disposal capacity, reducing environmental risks, and saving firms money. An influential study published by the Congressional Office of Technology Assessment at this time, *Serious Reduction of Hazardous Waste*, made the case that waste reduction

was “the most certain means” to reduce environmental risks overall (US Congress 1986: 19). The study found, however, that most managers did “not know how to start or … how to move beyond the simplest [waste reduction] measures” (US Congress 1986: 33). Those who drafted TURA sought to encourage private sector managers to understand where and why they used toxic substances that created waste and to foster a process whereby they systematically considered alternatives.

TURA’s goal is toxics use reduction, which the law defines as changes to production processes or raw materials that reduce or eliminate toxics use without shifting risks to workers or communities. Firms in specified industry sectors that use materials the law designates as toxic and employ ten or more full-time employees must annually submit a report to the MassDEP detailing the types and quantities of toxics they use. They must also prepare a Toxics Use Reduction Plan according to guidelines developed by the state and have plans certified by a registered Toxics Use Reduction Planner. TURA supports, through fees assessed on firms subject to the law, a range of non-regulatory services to help firms identify and use alternatives to toxics.

III. Characteristics of a Regulatory Regime for Emerging Technologies

What is the best way to regulate technologies that have significant societal value, are widely used, and that pose uncertain health and environmental hazards? Others have made the case that environmental regulatory regimes should be enforceable (Esty & Porter 2005), performance-based (Fiorino 2006), cost-effective (Stavins 1997), and distribute costs and benefits equitably (Stavins 1997). While those characteristics are important, they may be insufficient for regulating technologies already in use and about which uncertainty abounds.

A regulatory regime for emerging technologies should further two objectives. First, it should increase the information available for regulatory decisionmaking. Since the health and environmental impacts of nanomaterials are largely unknown, an effective governance system should make available to regulators all relevant human health-related testing and environmental studies and compel new testing and studies where the necessary information does not exist. It should also establish standards for decision-making that acknowledge the incomplete nature of available information and be adaptable to new information as it emerges.

Second, a regulatory regime for emerging technologies should draw on private sector expertise and guide private sector behavior toward risk reduction even in the absence of clear evidence of harm. In the regulation of toxic chemicals generally and nanomaterials in particular, private firms enjoy an information advantage compared to government (Coglianese 2010). Those developing these materials

are often in the best position to know how they will be used, the types of exposures most likely to occur, and what similar products might provide a frame of reference for assessing risks. Public policies should tap that expertise.

To what extent do TSCA and TURA advance those objectives?

Accessing Information

TSCA's drafters believed that generating more information about toxics was key to preventing the introduction of harmful toxics into the marketplace. In a 1976 press release, then-US EPA Administrator Russell Train described the agency's information needs:

> [W]e know so little—so abysmally little—about these chemicals. We know little about their health effects . . .. We know little about how many humans are exposed, and how and to what degree. We do not even know precisely how many—much less precisely which—new chemical compounds are made and marketed every year (US EPA 1976).

According to those responsible for TSCA's passage, the successful regulation of toxics depended in large measure on regulators' ability to fill the "abysmal" state of agency knowledge about chemical risks. Consequently, TSCA authorizes US EPA to require manufacturers or importers to conduct tests of chemicals to determine their potentially harmful effects. Under Section 4 of the law, US EPA must require such testing if the manufacture, distribution, use, or disposal of the chemical presents an "unreasonable risk" of injury to health or the environment and data to assess the impacts of the chemical are not otherwise available. TSCA does not define "unreasonable risk," however. Congress intended US EPA to evaluate the risks posed by each chemical on a case-by-case basis, weighing its hazard and potential exposure against its economic and social value through risk assessments and cost-benefit analyses (Applegate 1991: 269).

Many commentators argue that Section 4 poses a "Catch 22" for regulators since in order to make the case that more testing is required, US EPA must first demonstrate that the chemical poses an unreasonable risk, a determination that cannot be made without first having substantial information about the health and environmental impacts of the chemical (EDF 1997). Since TSCA was signed into law in 1976, US EPA has issued Section 4 rules or entered into consent agreements requiring testing for only about 200 of the more than 80,000 chemicals in commerce (GAO 2009). The fact that Congress has consistently underfunded US EPA's office for TSCA implementation has contributed significantly to the agency's slow progress (Greenwood 2009). According to a US EPA advisory committee, that low number indicates not how much information is needed, but rather "the administrative challenges of mounting an information request" (US EPA 1999). Typically it takes US EPA two to ten years to finalize a testing

rule (GAO 2009). In its Unified Regulatory Agenda for 2011, the US EPA announced plans to propose a test rule under TSCA Section 4 for several multiwalled carbon nanotubes as well as certain clays, bentonite, alumina, and spray-applied nanomaterials (US EPA 2010). Time will tell how much information US EPA is able to generate through this process and how long it will take. The fact that Congress has consistently underfunded US EPA's TSCA program has contributed significantly to the agency's slow progress (Greenwood 2006).

TSCA's Section 5 also authorizes US EPA to impose important information-generating requirements on chemical manufacturers and users. TSCA Section 5 includes two provisions, for new chemicals (Section 5(a)(1)) and for significant new uses of existing chemicals (Section 5(a)(2)). For new chemicals, manufacturers must submit a Pre-Manufacture Notice (PMN) to EPA. The PMN form asks for information about a new chemical's "identity, production volume, uses, exposures, and environmental fate" (Bergeson et al 2000: 6). While US EPA cannot require a manufacturer to undertake new testing under Section 5, manufacturers must submit to US EPA any environmental or health information in their possession at that time. Only about 15 percent of PMNs submitted by manufacturers include any health and safety information, however (GAO 2009).

Businesses seeking to use existing chemicals in significantly new ways are subject to TSCA Section 5(a)(2). This section is of particular importance for the regulation of nanotechnologies. TSCA defines a "chemical" as "any organic or inorganic substance of a particular molecular identity." For the most part, nanomaterials are distinguished by unique features at the *sub*-molecular scale. If a nanomaterial has the same molecular identify as an existing chemical, US EPA does not consider it new. Its *use* may be new, however, making its manufacturers, processors, and users subject to Section 5(a)(2). US EPA has to date issued several Significant New Use Rules (SNURs) for nanomaterials under Section 5(a)(2) of TSCA, in June 2009, September 2010, and May 2011. Each rule addresses specific carbon nanotube applications, identified in the *Federal Register* by numbers such as PMN P-08-117, PMN P-08-328, and PMN P-08-199. Manufacturers' confidentiality claims prevent US EPA from describing the nanomaterials in more detail. The rules require firms that intend to manufacture, import, or process these particular carbon nanotubes to notify the US EPA at least 90 days in advance. US EPA will then "evaluate the intended use and, if necessary, … prohibit or limit that activity before it occurs" (EPA 2011). One factor that has inhibited US EPA from using Section 5(a)(2) more effectively is the way it has defined "new use." US EPA has consistently maintained that nanomaterials already in use when the agency proposes a SNUR are not, in fact, "new" (Bergeson 2010: 24). Given the fast pace of

nanomaterials development, this position is likely to exempt many nanomaterials from this important TSCA section.

TSCA's Section 8 also imposes important information-generating requirements on firms. Under Section 8(a), US EPA has promulgated the Preliminary Assessment Information Rule (PAIR) requiring manufacturers to submit information on chemicals they manufacture, use, distribute, and release to the environment. Under Section 8(d), US EPA has promulgated a rule for health and safety data reporting, requiring manufacturers and distributors to submit unpublished health and safety studies (Gold & Warshaw 2010). Section 8(e) requires manufacturers to notify the agency of information that reasonably supports the conclusion that their product presents a substantial risk of injury to health or the environment. US EPA has applied these rules inconsistently, however (Applegate 2008). Manufacturers routinely request that US EPA consider their Section 8(e) submittals as confidential business information, restricting the public's access (US EPA 2010a).

Recognizing TSCA's limitations in generating a free flow of information about chemical risks, in 1998 the US EPA initiated the High Production Volume (HPV) Challenge program, a voluntary effort in which chemical manufacturing firms sign up to provide US EPA with toxicity test results for specific chemicals or test chemicals that have not yet been tested. Through the HPV Challenge, chemical manufacturers provided data on more than 2,200 chemicals based largely on studies that were not publicly available before the start of the program (Fiorino 2010). This initiative, and its successor program known as "CHAMP" under which the US EPA enrolls manufacturers to test high and moderate volume chemicals, has proven more effective, less time-consuming, and less costly than TSCA's Section 4 requirements in generating information required for regulation. Still, most chemicals lack toxicity testing (Schierow 2007). Citing over-reliance on indirect testing methods and poor quality of many submissions, the Environmental Defense Fund gave the chemicals industry the grade of "D" for its implementation of the HPV Challenge (Denison 2007).

In 2005, the US EPA initiated the Nanoscale Materials Stewardship Program, a voluntary program to collect information about private sector production and use of nanomaterials. As of December 31, 2008, 29 companies had submitted information about 123 nanomaterials, only about 10 percent of the nanomaterials that were commercially available at that time. More telling, only a few submissions addressed the toxicity of nanomaterials or their environmental fate (US EPA 2009). In sum, under TSCA neither regulatory nor voluntary approaches have worked well to generate information about chemical hazards in general, and nanomaterials in particular.

Does TURA do a better job informing regulators about chemical hazards? Nothing in the TURA statute authorizes the Commonwealth of Massachusetts to command private firms to test chemicals or disclose health and environmental studies they may have conducted or have access to. However, while TURA does not generate *new* information on chemical risks for regulators, it offers a process whereby regulators can marshal the information that is available to inform decision-making. That process is most clear in the state's recent decisions to add or delete chemicals to or from the list of covered toxics and designate chemicals as higher or lower hazard. TURA defines "toxic" as any of the approximately 1400 chemicals that the US EPA lists under the Emergency Planning and Community Right-to-Know Act (EPCRA) and the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA, better known as Superfund) (US EPA 2010). In general, TURA uses the same reporting thresholds stipulated by federal law. Amendments to TURA in 2006 allow the Administrative Council to designate lower thresholds for very dangerous chemicals. This new authority fits the requirements of a nanotechnology governance regime.

TURA allows anyone—representatives from industry, government agencies, or citizen groups—to initiate a process to add or subtract chemicals from the TURA list and raise or lower the thresholds for chemicals already listed. A Science Advisory Board (SAB), comprised of toxicologists and other experts appointed by the Governor, is responsible for considering and issuing recommendations on all such requests to the Toxics Use Reduction Institute (TURI), the organization created by the TURA statute responsible for policy analysis, education, and training in toxics use reduction. SAB meetings are announced on the Massachusetts state government website and are open to the public.

The SAB's role is to determine a chemical's intrinsic hazard. Policy guidance from the Administrative Council directs the SAB *not* to undertake risk assessment or cost benefit analysis—the analytical approaches required under TSCA—but to focus instead on understanding a chemical's inherent properties. The SAB bases its review on published studies about the health and environmental impacts of the chemical including exposure limits that OSHA, US EPA, or other organizations may set; environmental and ecosystem hazards; safety and physical hazards; global environmental impacts; and chemical information and physical characteristics (TURI 2010). When scientific information is missing or uncertain, SAB members are to use their best judgment given information at hand. SAB members are instructed to fill data gaps by using "modeled data, structure activity relationships, data on similar chemicals, and expert judgment" (TURI 2010: 8). The SAB's prioritization decision process is based on the Delphi Method, which, according to Massachusetts policymakers, is appropriate when "accurate information is unavailable or expensive to obtain" (TURI 2010: 17).

Following SAB recommendations, the Administrative Council has added two chemicals to the TURA list—crystalline silica for particle sizes less than 10 microns and n-propyl bromide. In addition, the Council has designated four higher hazard chemicals—trichloroethylene, cadmium, cadmium compounds, and perchloroethylene—and it has designated nine lower hazard substances—isobutyl alcohol, sec-butyl alcohol, n-butyl alcohol, ferric chloride, ferrous chloride, ferric sulfate, ferrous sulfate, butyl acetate, and iso-butyl acetate.

In addition to compiling and using available information on chemical hazards, TURA requires firms to disclose information on the toxic chemicals they use. TURA's role in generating information on toxic chemical use stands in stark contrast to TSCA's. Managers of firms subject to TURA must report to the state how much of each listed chemical they manufacture, process, otherwise use, generate as byproduct, or ship as or in product. They must explain where in their facilities they use each chemical, estimate how much by-product or emissions they generate, and compare those amounts to what they generated in the previous year. They must detail the techniques they currently employ to reduce toxics use.

TURA's information disclosure requirements allow state agencies to know which firms are using which toxic chemicals for what purposes. For example, in a recent deliberation about whether Massachusetts should designate formaldehyde as a higher hazard chemical under TURA, thereby reducing the reporting threshold, the Administrative Council drew upon information concerning names and locations of firms that currently used that chemical. That information was available because the US EPA already listed formaldehyde under EPCRA, which means that Massachusetts firms covered by TURA must report their use of this chemical to MassDEP. Information about which firms are using particular chemicals is of significant interest to environmental regulators. It allows them to identify higher-hazard facilities and provides information that could inform the development of future regulations. It also allows them to track the extent to which facilities subject to the law are reducing their use of toxics. Since 1996 MassDEP has annually published an analysis of the amounts and types of toxic chemicals Massachusetts facilities are using, releasing, storing, and shipping and has made data supporting that analysis available to the public (MassDEP 2010).

Drawing on Private Sector Capacity

Effective approaches for governing emerging technologies should draw on private sector expertise about the hazards associated with the chemicals they use, likely exposure routes, and the best ways to minimize hazards and exposures. In essence, effective approaches engage regulated entities in

co-producing governance. However, the "command and control" approach used in many federal and state environmental laws may do little to leverage private sector expertise (Coglianese 2010). Instead, this approach imposes government's view of the most appropriate way to protect the environment upon private sector firms. It may work best when government enjoys an information advantage compared to firms about how to control environmental problems. However, when attempting to regulate emerging technologies, government often enjoys no such information advantage.

TSCA and TURA are alike in that they do not regulate means. Neither statute specifies technologies or devices firms must employ to mitigate the impacts of their activities. Instead, TSCA attempts to regulate the health and environmental *performance* of the chemicals that firms produce, focusing on risk. TURA, by contrast, attempts to regulate the *management systems* firms use to set goals, collect information, monitor progress, and report results. Performance-based and management-based approaches, exemplified by TSCA and TURA respectively, tend to work best in situations where government finds itself at an information disadvantage compared to firms about how to characterize and control environmental risks (Coglianese 2010). These approaches leverage private sector knowledge and resources—at least in theory.

A performance-based standard specifies the level of performance a firm must meet without specifying how it must do so. The performance standard at the heart of TSCA is "unreasonable risk." A manufacturer that proposes to produce a chemical that poses an unreasonable risk is subject to US EPA controls. At least in theory, TSCA's "unreasonable risk" performance standard encourages firms to use their expert knowledge about chemical hazards, potential uses, and likely exposures to produce safer, more beneficial chemicals. Ideally, TSCA encourages manufacturers to use their R&D budgets and testing capabilities to undertake careful, comprehensive studies of chemicals' hazardous properties before considering commercial development. Manufacturers rationally would choose not to develop chemicals that posed risks that exceeded the "unreasonable" threshold.

The problem is that as currently implemented TSCA offers firms no incentives to undertake chemical testing that could determine the level of risk a chemical posed, or to otherwise engage in the types of rational activities designed to lessen the likelihood of unreasonable risk. In fact, TSCA creates *disincentives* for manufacturers to conduct tests and to flag chemicals they know to be particularly hazardous (Denison 2008). After all, why do so when the result is greater scrutiny? Furthermore, neither firms nor US EPA knows precisely what "unreasonable risk" means in practice. The standard is too vague to offer clear guidance as to the level of performance US EPA requires. In short, performance-based standards tend to be ineffective when performance cannot be clearly specified and when government

cannot monitor firms' performance independently (Coglianese 2010). Those problems are endemic to TSCA.

Is TURA's management-based approach more promising? TURA requires managers of facilities covered by the law to prepare toxics use reduction plans, to be updated every two years. TURA does not require managers to implement their plans or reduce their use of toxics. Instead, it requires managers to figure out where and why they use toxics, consider available alternatives, decide whether to substitute any non-toxic alternatives, and justify their decisions. TURA draws on facility managers' expertise about which toxic chemicals they use, for what purposes and at what costs, and whether alternatives might be substituted. Rather than restrict or ban the use of particularly hazardous chemicals, TURA requires managers to consider whether a different, less toxic chemical could be used instead. It requires managers to use their best judgment to answer the questions, "how much contamination can be avoided and what alternatives exist to a product or activity" (O'Rourke & Lee 2004: 186)?

How effective has TURA been in achieving its goals? On an annual basis, MassDEP publishes an assessment of the program based on information that a Core Group of facilities subject to the law submits to the state. The most recent report finds that from 2000 to 2009 facilities in this Core Group reduced their use of covered toxic chemicals by 21%, taking into account changes in production. Core Group facilities also reduced toxic byproducts by 38%, toxics shipped in products by 21%, on-site releases of toxics to the environment by 56%, and transfers of toxics off-site by 23% (MassDEP 2011). The Core Group is comprised of facilities in industry sectors that have been subject to TURA reporting requirements since 2000. It should be noted, however, that MassDEP has not investigated whether facilities in other states achieved similar reductions, a result that could indicate that factors other than TURA were responsible for the change. (While other states do not collect comparable information on facilities' use of toxics, comparable waste and emissions data are available through the federal Toxics Release Inventory.)

Assessments of TURA implementation offer insights to the law's applicability to nanotechnology. More than half (55%) of the managers who participated in a 2008 assessment commissioned by TURI and conducted by Abt Associates felt that implementing toxic use reduction projects in the period 2000-2006 had resulted in "increased management attention to environmental practices" (Massey 2009: 5). Fifty-one percent reported that implementing toxic use reduction projects had resulted in "improved worker health and safety" (Massey 2009: 43). The challenge noted by the largest number of respondents (62%) was finding "technically feasible alternatives that work for both the facility and its

clients" (Massey 2009: 48). In essence, TURA encourages firms to manage what they measure without requiring them to change their products or processes. Where managers deem changes infeasible for technical or cost reasons, they may reject them. A TURA approach would require managers to weigh the benefits of a particular nanotechnology application in terms of energy savings, improved functionality, or performance against known or unknown health and environmental damage. It would not require managers to curtail use of a listed nanomaterial, but it would require them to go through a series of defined steps to consider whether continued use was their interest, taking into account a range of environmental and economic considerations.

IV. Envisioning the Regulation of Nanomaterials under a TURA Approach

What would the regulation of nanomaterials under a TURA approach look like? Would such a system be desirable? The process might begin with the MassDEP, TURI, or other agency or organization petitioning the Administrative Council to consider listing a particular type of nanomaterial under the Act. One potential candidate might be carbon nanotubes, flagged as a concern due to their structural similarity to asbestos, a potent human carcinogen. Massachusetts is one of the top US states for nanotechnology investment, second only to California (Lindberg & Quinn 2007). In 2007, the last year such data are available, approximately 180 Massachusetts firms were developing or using nanoscale technologies (Lindberg & Quinn 2007; see also PEN 2011).

The Administrative Council would refer the petition to list carbon nanotubes under TURA to the Science Advisory Board. Researchers at the Toxics Use Reduction Institute would gather information about the health and environmental hazards posed by carbon nanotubes, drawing on information developed by the US Environmental Protection Agency, National Institute for Occupational Safety and Health, and the European Chemicals Agency and published in peer-reviewed scientific journals such as the *Journal of Nanoparticle Research* and *ACS Nano*, among other sources. The SAB would likely meet several times to discuss the information and consider the significance of data gaps. Since SAB meetings are open to the public, representatives of firms that manufacture, process, or otherwise use the nanomaterial proposed for listing would likely come to present their views. Taking all of this information into account, SAB members would vote as to whether to recommend the material for listing.

If the SAB voted in support of including carbon nanotubes on the TURA list, TURI would prepare a policy analysis. An Advisory Committee comprised of representatives of environmental advocacy organizations, labor organizations, business, and the general public, established under TURA and appointed by the chair of the Administrative Council, would consider that analysis and send its

recommendation to the Administrative Council. The Administrative Council would consider the science and policy implications of listing the chemical, including the number of firms likely to be affected by the decision, the types of regulations they are already subject to, and whether they are already covered under TURA. It would also consider state environmental agencies' experience working with affected firms and their ability to provide technical assistance. TURI would prepare the analysis, which would include a summary of the SAB findings.

Once listed, firms would be required to report to the MassDEP about their use of the specified nanomaterials and prepare plans to reduce or otherwise manage that material. As firms that manufactured or used carbon nanotubes began reporting to MassDEP, the state would gain a fuller understanding of which firms are using these materials, for what purposes. Listing specific nanomaterials under TURA could achieve many of the information benefits that Berkeley, California, sought to derive from its Ordinance for Nanoparticle Disclosure. That ordinance, enacted in 2007, requires firms to report to city government information about how they use nanoparticles onsite and in downstream applications (Berkeley 2007 §A6). The Berkeley Ordinance requires managers of firms using nanoparticles to submit to the City information about how they will "safely handle, monitor, contain, dispose, track inventory, prevent releases and mitigate such materials" (Berkeley 2007 Municipal Code §15.12.040). TURA, in contrast, requires managers to develop plans to *reduce* their use of listed chemicals. TSCA does neither.

Information on where and how firms were using nanomaterials would help the TURA program, in particular TURI and the Massachusetts Office Technical Assistance and Technology (OTA), assess the technical assistance needs of these firms as well as the risks currently posed to workers and communities. OTA is a non-regulatory agency within the Massachusetts Executive Office of Energy and Environmental Affairs that provides technical assistance to firms seeking to improve their environmental performance. OTA assistance could be significant: a study of nanotechnology development in Massachusetts found that many firms lack information about the nature of health and environmental impacts from nanotechnology and methods for controlling associated risks (Lindberg and Quinn 2007). OTA could partner with materials development companies to share available information about nanomaterials hazards, potential exposure pathways, and appropriate controls. Given the wide range of nanomaterials that firms are developing, for a diversity of applications, OTA's capacity to provide advice tailored to individual firms' needs could be of considerable importance (Morose 2010). OTA has already developed a guidance document, "Nanotechnology—Considerations for Safe Development" and is well-positioned to advise firms on how best to adopt that guidance (OTA 2010).

Still, aspects of TURA could be problematic. The purpose of the law's information disclosure and planning requirements is to encourage managers progressively to reduce their use of toxics. MassDEP planning guidance instructs managers to identify and reflect on options for reducing their use of listed toxics through input substitution, product reformulation, production unit redesign or modification, production unit modernization, improved operation and maintenance, and recycling or reuse. MassDEP tells managers to analyze the feasibility of each strategy and include in their Toxics Use Reduction Plan a description of their analysis process—the employees they spoke with, the sources of information they consulted, the ways they collected information—as well as a list of all the options they considered (MassDEP 2009). Many of the Massachusetts firms that might be covered are in the business of developing nanomaterials for commercial application. Phasing out these materials would be contrary to their business interest. The planning process mandated under the law could be an empty exercise.

Several additional issues raise questions about the applicability of a TURA approach to emerging technologies. TURA regulates toxics that are "manufactured, processed, or otherwise used" by Massachusetts firms. It does not regulate toxics that are "present in an article" (Chapter 21I § 2). Firms that distribute, process, or sell products containing nanomaterials imported to Massachusetts from other states would not be covered. In addition, TURA applies to "Large Quantity Toxics Users" employing ten or more full-time people in the manufacturing, mining, transportation, wholesale, and certain business and repair sectors. Small firms, research laboratories, and universities are excluded, yet small establishments in those sectors often engage in significant nanotechnology development.

V. Conclusion

TSCA provides the US EPA with exceptionally broad authority, but in many ways ties the agency's hands when it comes to using it. Envisioned by its drafters as "preventive medicine legislation" powerful enough to avert the sale and use of high-risk chemicals, TSCA has proven to be exceedingly difficult to implement. In recent years, the US EPA has taken steps to regulate carbon nanotubes under TSCA's Section 4 (proposing a rule to require testing) and Section 5(a)(2) (finalizing rules requiring firms to notify US EPA in advance of their manufacture or use of particular nanomaterials for particular uses). But the law is riddled with conundrums that will likely marginalize the significance of these initiatives. The effective governance of emerging technologies authorizes environmental regulators to access new information about chemical risks and draw on private sector expertise. TSCA falls short with respect to both characteristics. Similarly, the US EPA's program to encourage firms voluntarily to submit information about their manufacture and use of nanotechnologies has failed to generate meaningful

results. How can government best regulate emerging materials without sufficient information to understand their potential harm?

TSCA has been remarkably resistant to change, despite calls for reform from the Environmental Defense Fund, American Chemistry Council, and US EPA alike. TSCA is widely viewed as a "serious under-performer" (Applegate 2008: 723), a law that both regulators and firms must work "over, under, and around" to achieve results (Roberts 2010). The fact that US EPA has relied on voluntary programs such as HPV Challenge and CHAMP to inform its regulation of chemicals is a powerful indictment of TSCA's failings. While Congress over time substantially amended other major environmental statutes enacted in the 1970s including the Clean Air Act and Clean Water Act to address emerging problems (such as acid rain) and incorporate new policy approaches (such as market-based instruments), attempts to amend TSCA consistently fail. Hearings were held on House and Senate bills to amend TSCA introduced in 2010, but any hopes for further action ebbed away after the mid-term elections. Neither party seems ready to open debate that could on the one hand allow government to control toxic chemicals as TSCA's drafters intended, or on the other to undercut that authority further.

Today, states are active players in many areas of environmental policy. Given the failure of national leaders to address the problems of climate change, for example, local, state, and regional governments are experimenting with their own approaches (Hoffman 2010). While these efforts do not substitute for federal action, they can supplement, inform, and motivate it. A TURA approach could help to achieve those objectives for the regulation of emerging technologies. In the face of Congressional stalemate in enacting changes to TSCA, a TURA-like approach merits consideration as a supplementary strategy.

Still, TURA does not offer all the answers. It is based on the premise that managers should reduce their use of listed materials, yet emerging technologies may offer significant societal benefits as well as hazards. It relies on the discretion of private sector managers to strike the appropriate balance between developing and using an emerging technology or finding non-toxic alternatives. The effectiveness of TURA's management-based approach has not been tested in a context of substantial uncertainty about health and environmental impacts.

TURA establishes a process whereby states can identify and address new hazards even in the face of substantial uncertainty. While TURA relies on federal statutes to define what is and is not toxic, the law allows state-level decision-makers to add or delete chemicals from federal lists of covered substances based on their own determination of what constitutes a significant hazard. Recent decisions by the Administrative Council offer guidance about how to regulate in the face of scientific uncertainty

and data gaps. By generating information on chemicals use, TURA allows regulators to know where and how firms are developing and using emerging technologies. TURA draws on the capabilities of private sector managers to decide where and how they should reduce their use of emerging technologies. Absent definitive information about risk, a governance strategy that generates information and focuses management attention on reducing hazards is worth considering.

Acknowledgements

This research was made possible with support from the National Science Foundation, NSF grant #SES 0609078, Christopher J. Bosso, PI, and the Mossavar-Rahmani Center for Business and Government, Harvard Kennedy School. Thanks to Christopher J. Bosso and anonymous reviewers for comments on an earlier draft. Any mistakes and omissions are the author's.

References

Applegate JS (2008) Synthesizing TSCA and REACH: Practical principles for chemical regulation reform. Ecol Law Quart 35: 721-769

Applegate JS (1991) The perils of unreasonable risk: information, regulatory policy, and toxic substances control. Colum L Rev 91: 261-333

Berkeley Municipal Ordinance (2007) Ordinance for nanoparticle disclosure. http://www.calcupa.net/civica/filebank/blobdload.asp?BlobID=2305. Accessed 29 December 2010

Bergeson LL (2010) Nanotechnology: environmental law, policy, and business considerations. American Bar Association Section of Environment, Energy, and Resources, Chicago

Bergeson LL, Campbell L, Rothenberg L (2000) TSCA and the future of chemical regulation. EPA Admin Law Rep 15(4): 1-23

Bomkamp S (2010) Beyond chemicals: the lessons that toxic substance regulatory reform can learn from nanotechnology. Ind. L.J. Supp 85: 24-37

Coglianese C (2010) Engaging business in the regulation of nanotechnology. In: Bosso CJ (ed) Governing uncertainty: environmental regulation in the age of nanotechnology. Resources for the Future Press, Washington, DC: 46-79

Council on Environmental Quality (CEQ) (1997). Environmental quality: the eighth annual report of the council on environmental quality. Government printing office, Washington, DC.

Denison RA (2007) High hopes low marks: a final report card on the high production volume chemical challenge. Environmental defense, New York

Denison RA (2008) Policy options for generating information about sound chemicals management. In: Tichner J (ed) Options for state chemicals policy reform: a resource guide. University of Massachusetts Lowell Center for Sustainable Production, Lowell, MA: 35-68

Ellenbecker M, Tsai S (2010) Engineered nanoparticles: safer substitutes for toxic materials, or new hazard? J Clean Prod 19(5): 1-5

Environmental Defense Fund (EDF) (1997) Toxic ignorance: the continuing absence of basic health testing for top-selling chemicals in the United States. Environmental Defense Fund, Washington, DC

Esty DC, Porter ME (2005) National environmental performance: an empirical analysis of policy results and determinants. Environ. Devel. Econ.10: 391-434

Fiorino DJ (2010) Voluntary initiatives, regulation, and nanotechnology oversight: charting a path. Project on Emerging Nanotechnologies No. 19. Woodrow Wilson Center for Scholars, Washington, DC

Fiorino DJ (2006) The new environmental regulation. MIT Press, Cambridge, MA

Gold MV, Warshaw J (2010) The toxics substances control act: a practical guide. Oxford University Press, New York

Greenwood, MA (2009) TSCA reform: building a program that can work. 39 Envtl L Rpt News & Analysis: 10034-10041

Hoffman MJ (2010) Climate governance at the crossroads. Oxford University Press, New York

Jackson LP (2009) Remarks to the commonwealth club of San Francisco, 29 September 2009. http://yosemite.epa.gov/opa/admpress.nsf/a883dc3da7094f97852572a00065d7d8/fc4e2a8c05343b3285257640007081c5!OpenDocument. Accessed 9 August 2011

Lindberg JE, Quinn MM (2007) A survey of environmental, health and safety risk management information needs and practices among nanotechnology firms in the Massachusetts region. Project on Emerging Nanotechnologies Brief No. 1. Woodrow Wilson Center for Scholars, Washington, DC

Lok C (2010) Small wonders. Nature 467 (September 2): 18-21

Mandel G (2008) Nanotechnology governance. Ala L Rev 59: 1323-1384

Markel D (2010) An overview of TSCA, its history and key underlying assumptions, and its place in environmental regulation. J.L. & Pol'y 32: 333-375

Massey R (2009) Toxics use reduction act program assessment. Toxics use reduction institute methods and policy report #26. Toxics Use Reduction Institute, Lowell, MA

Massachusetts Department of Environmental Protection (MassDEP) (2011). 2009 toxics use reduction information release. July 2011. Commonwealth of Massachusetts Department of Environmental Protection, Boston

Massachusetts Department of Environmental Protection (MassDEP) (2010) Toxics use reduction act data and results. http://www.mass.gov/dep/toxics/tura/turadata.htm. Accessed 12 September 2010

Massachusetts Department of Environmental Protection (MassDEP) (2009) Toxics use reduction planning and plan update guidance. Commonwealth of Massachusetts Department of Environmental Protection, Boston

Massachusetts Office of Technical Assistance & Technology (OTA) (2010) OTA technology guidance document: nanotechnology—considerations for safe development. OTA, Boston

Morose G (2010) The 5 principles of "Design for Safer Nanotechnology." J Clean Prod 18: 285-289

National Institute for Occupational Safety and Health (NIOSH) (2009) Approaches to safe nanotechnology: managing the health and safety concerns associated with engineered nanomaterials. http://www.cdc.gov/niosh/topics/nanotech/safenano/. Accessed 21 December 2010

National Nanotechnology Initiative (NNI) (2007) Strategic plan. http://www.nano.gov/sites/default/files/pub_resource/nni_strategic_plan_2007.pdf. Accessed 22 November 2011

O'Rourke D, Lee E (2004) Mandatory planning for environmental innovation: evaluating regulatory mechanisms for toxics use reduction. J Environ Plann Man 47(2): 181-200

Project on Emerging Nanotechnologies (PEN). (2011). Woodrow Wilson International Center. Consumer products inventory of nanotechnology products. http://www.nanotechproject.org/inventories/consumer/browse/. Accessed 21 December 2010

Project on Emerging Nanotechnologies (PEN) (2010) Woodrow Wilson International Center. Nanotechnology map. http://www.nanotechproject.org/inventories/map/. Accessed 30 December 2010

Roberts JA (2010) From inception to reform: an oral history project of the toxic substances control act. Center for Contemporary History and Policy, Chemical Heritage Foundation. Webinar. 8 December 2010

Rudd J (2008) Regulating the impacts of engineered nanoparticles under TSCA: shifting authority from industry to government. Colum. J. Envtl. L. 33: 215-282

Schierow L-J (2007) Toxic substances control act (TSCA): implementation and new challenges. Congressional Research Service, Washington, DC

Seaton A, Tran L, Aitken R, Donaldson K (2009) Nanoparticles, human health hazard, and regulation. R J Soc Interface. http://rsif.royalsocietypublishing.org/content/7/Suppl_1/S119.full. Accessed 22 November 2011

Stavins RN (1997) Economic incentives for environmental regulation. The new palgrave dictionary of economics and the aaw.. Available at SSRN: http://ssrn.com/abstract=11487. Accessed 7 June 2012

Toxics Use Reduction Institute (TURI) (2010) Decision-making under TURA: process overview and reference guide. Methods and policy report No. 28. University of Massachusetts Lowell, Lowell, MA

United States Environmental Protection Agency (US EPA) (2011) Multi-walled carbon nanotubes: significant new use rule. 76 FR 26186. 6 May 2011

United States Environmental Protection Agency (US EPA) (2010) Title III consolidated list of lists - May 2010 version. http://www.epa.gov/emergencies/tools.htm#lol**.** Accessed 11 September 2010

United States Environmental Protection Agency (US EPA) (2010a) EPA needs a coordinated plan to oversee its toxic substances control act responsibilities. Report no. 10-P-0066. US Environmental Protection Agency, Washington, DC

United States Environmental Protection Agency (US EPA)(2009) Nanoscale materials stewardship report. Interim report. US Environmental Protection Agency, Washington, DC

United States Environmental Protection Agency (US EPA)(2008) TSCA inventory status of nanoscale substances – general approach. US Environmental Protection Agency, Washington, DC

United States Environmental Protection Agency (US EPA) (1999) Endocrine disrupter screening and testing advisory committee, final report 2-11. US Environmental Protection Agency, Washington, DC

United States Environmental Protection Agency (US EPA) (1976) Train sees new toxics substances law as preventive medicine. http://www.epa.gov/history/topics/tsca/03.html. Accessed 9 August 2011

US Congress, Office of Technology Assessment (1986) Serious reduction of hazardous waste. Government Printing Office, Washington, DC

US Government Accountability Office (GAO) (2010) Nanotechnology: nanomaterials are widely used in commerce, but EPA faces challenges in regulating risk. Report to the chairman, committee on environment and public works, US Senate. GAO-10-549. US GAO, Washington, DC

US Government Accountability Office (GAO) (2009) Chemical regulation: options for enhancing the effectiveness of the toxic substances control act. Statement of John Stephenson, director, natural resources and the environment, before the subcommittee on commerce, trade, and consumer protection, house of representatives. GAO-09-428T. US GAO, Washington, DC

Wardak A (2003) Nanotechnology & regulation: a case study using the toxic substances control act (TSCA). Discussion paper 2003-6. Woodrow Wilson International Center for Scholars, Washington, DC