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PROJECT ON EMERGING NANOTECHNOLOGIES RESEARCH BRIEF

Application of the Toxics Release Inventory to Nanomaterials

by Linda K. Breggin and Read D. Porter

Background

This research brief examines whether the legal authorities that establish the Toxics Release Inventory (TRI) in the Emergency Planning and Community-Right-to-Know Act (EPCRA)¹ could be applied to nanomaterials. Although several organizations have published analyses of whether specific environmental laws could be used to regulate nanomaterials,² none of these reviews has examined EPCRA or TRI in any detail.

Examination of the principal federal right-to-know law seems opportune for several reasons. First, the only law that specifically addresses environmental, health, and safety of nanomaterials, enacted in 2006 by the City of Berkeley, California, takes a "right-to-know" approach that requires facilities that manufacture or use "manufactured nanoparticles" to disclose both the known toxicology of those materials and the facility's plan for material handling, monitoring, containment, disposal, inventory tracking, release prevention, and mitigation. The City's reporting guidance document expands on the ordinance by requiring disclosure of inhalation, dermal, oral, geno-, and reproductive toxicity information, as expressed through published research.³ The City of Cambridge, Massachusetts is currently considering the adoption of a similar ordinance.⁴

Second, several non-profit groups have called for various forms of regulation of nanomaterials, including some types of disclosure. Most recently, a broad coalition of 40 environmental, consumers, labor; and other groups called for regulation and

Nanotechnology—the ability to observe and engineer matter within the general size range of 1 to 100 nanometers—is creating a set of materials that have properties that differ in fundamental ways from those of larger forms of the same material, and that make them useful for a variety of applications. It is estimated that there are more than 500 nanotechnology consumer products, as well as increasing numbers of industrial products, already on the market.

AUTHORS/ACKNOWLEDGMENTS

Linda K. Breggin joined the Environmental Law Institute (ELI) in 1997 as a Senior Attorney. She is also Director of Southeast Environmental Programs for the Institute and directs its Nanotechnology Initiative. Ms. Breggin previously served as an Associate Director in the White House Office on Environmental Policy and as a Special Assistant to the Assistant Administrator for Enforcement at the U.S. Environmental Protection Agency. Prior to joining ELI, she was in private practice. Ms. Breggin has worked on a wide range of environmental law issues over the past 20 years. She is the author or co-author of numerous reports and articles, including a recent article in the *Columbia Journal of Environmental Law* entitled "Governing Uncertainty: The Nanotechnology Environmental, Health, and Safety Challenge" and an ELI report on a dialogue convened in 2005 entitled *Securing the Promise of Nanotechnology: Is U.S. Environmental Law Up to the Job?* Ms. Breggin is a graduate of the University of Chicago Law School. She formerly served as Co-Chair of the District of Columbia Bar Association's Section on Environment and Natural Resources and as a Vice Chair of the American Bar Association's Section of Environment, Energy and Resources, Committee on Innovation, Management Systems and Trading. **Read D. Porter** joined the Environmental Law Institute as a Staff Attorney in 2006. He also directs ELI's Invasive Species Project, for which he oversees numerous projects designed to improve invasive species prevention, control, and management on federal and state levels. His research and writing has focused on invasive species and ocean governance in addition to nanotechnology. Prior to joining ELI, Mr. Porter served as a law clerk to the Honorable Julia Smith Gibbons of the United States Court of Appeals for the Sixth Circuit. He is a graduate of Harvard Law School, where he was the Editor in Chief of the *Harvard Environmental Law Review*, and received a B.A. from Amherst College.

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Valuable research assistance was provided by ELI Intern James Partridge. The authors would like to thank Lynn Bergeson, Natalie Chin, and John Pendergrass for their valuable comments and input. Any inaccuracies or omissions are solely the responsibility of the authors. disclosure, including labeling of products containing nanomaterials.⁵ Similarly, a coalition of organizations in the United Kingdom, led by the Royal Academy, have begun to develop a code of conduct for businesses involved in manufacturing and using nanomaterials.⁶ Another group in the United Kingdom, Corporate Watch, recently issued a report criticizing the European Union for lack of regulation and labeling of nanomaterials.⁷ Thus, there is stakeholder interest in adoption of right-to-know or disclosure-based regulation for nanomaterials.

Third, recent hearings and proposed legislation in the United States (U.S.) Congress address amendments to TRI. Much of this legislative activity has been in response, in part, to recent, widely-criticized regulatory changes under TRI, which are discussed further below.⁸ In addition, bills are pending that would expand TRI to cover greenhouse gas emissions.⁹ Although currently proposed legislation does not address nanomaterials, a public dialogue about the benefits and costs of TRI is underway that could allow for at least tangential discussion of the program's application to nanomaterials.

Prior to examining TRI, however, it is important to recognize that several additional right-to-know or disclosure-related laws and initiatives also should be explored for purposes of determining their effectiveness as a means of addressing environmental, health, and safety (EHS) risks that could be associated with nanomaterials. This Research Brief examines TRI primarily because it is the principal federal right-to-know law and one of the only major federal environmental laws not yet analyzed for purposes of its application to nanomaterials. It is quite possible, however, that other mechanisms would be preferable to TRI as a vehicle for disclosures about nanomaterials.

These additional disclosure or right-to-know laws and initiatives are outlined briefly in Appendix 1 and include:

- Emergency planning provisions of EPCRA;
- Risk management plans required under Section 112 (r) of the Clean Air Act;
- Facility-based disclosure initiatives, including the potential use of facility-based permits under the Clean Water Act and other environmental laws;
- State environmental disclosure laws;
- Local right-to-know laws;
- · Labeling of products containing nanomaterials; and
- Public and private voluntary initiatives.

In summary, the purpose of examining TRI is not to suggest that it should be a primary vehicle for regulating nanomaterials or even that it is the preferable disclosurebased approach. Rather, the objective is to make a preliminary determination about whether the TRI statutory authorities could be applied to nanomaterials and whether amendments to the law would be needed.

Overview of EPCRA/TRI

EPCRA was enacted in 1986 to provide information to citizens about hazardous chemicals in their communities. In part, the statute was adopted in response to two

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particularly high profile and deadly chemical spills at Union Carbide facilities in Bhopal, India and Kanawha Valley, West Virginia. These spills generated demands from workers, environmental groups, and community activists for information about chemicals to which they could be exposed.

A key aspect of EPCRA is the establishment of the TRI.¹⁰ Section 313 of the Act requires owners and operators of certain facilities to complete and submit to Environmental Protection Agency (EPA) "Form R," which summarizes the release of certain toxic chemicals from a facility into the environment. Covered releases include any method by which a facility allows toxic chemicals to enter an environmental medium (air, water, soil), such as accidental spills, transfers to off-site landfills or treatment facilities, discharges to municipal sewer systems, direct air emissions, underground injection, and surface water discharges. In addition, in 1990, Congress enacted the Pollution Prevention Act, which amends EPCRA to require the reporting of additional data on waste management and source reduction activities.

EPCRA further requires EPA to establish and maintain a computer database that contains the TRI data collected and to make that database available to the public. In practice, EPA does this through several data access tools, including the TRI Explorer and Envirofacts. Other organizations also have programs that make the data available to the public over the Internet, including OMB Watch's "RTKNet" and Environmental Defense's "Scorecard."

EPA describes the influence of TRI as follows:

Armed with TRI data, communities have more power to hold companies accountable and make informed decisions about how toxic chemicals are to be managed. The data often spurs companies to focus on their chemical management practices since they are being measured and made public. In addition, the data serves as a rough indicator of environmental progress over time.¹¹

This positive perspective generally is shared by the broader stakeholder community. TRI has been characterized as the "most successful environmental regulation of the last ten years" due to consistent decreases in the releases of reportable chemicals and the use of reported data by a broad spectrum of stakeholders.¹² The decreases in the amounts of pollutant releases are surprisingly high, given that TRI solely requires reporting without any performance requirements. The basis or reasons for TRI's purported success have been the topic of much debate and discussion in the legal academy.¹³

Nevertheless, not all commentators agree that TRI has been a success. Critics assert, for example, that TRI data is incomplete and inaccurate and that the reporting methodologies and chemicals reported obscure the relative risks, leading to consumer confusion and misallocation of resources.¹⁴ Furthermore, even TRI's champions recognize its compliance and enforcement shortcomings, as well as limitations in required disclosures.¹⁵

In any event, it is important to recognize that even if the law could be applied to nanomaterials, this does not necessarily mean that TRI would produce the same effects as it has for the conventional chemicals it now covers or that those effects would be adequate, even if they occurred. For example, if the statute is applied to materials that involve new technologies that are unfamiliar to the public, it is possible that TRI will not have the same influence on private sector behavior or that public reaction may differ. Similarly, even if TRI-type disclosure exerted some pressure to reduce releases of nanomaterials, that pressure alone may be inadequate to reduce some important risks.

TRI and Nanomaterials

The TRI statutory requirements are straightforward: the owners and operators of certain *facilities* are required annually to complete a toxic chemical *release* form for each listed *toxic chemical* that was *manufactured*, *processed*, *or otherwise used* in a certain *quantity* in the preceding year. The following discussion examines how some of these requirements may apply to nanomaterials.

Facilities: The statute defines the term "facility" broadly to include buildings, equipment, structures, and other stationary items.¹⁶To be subject to TRI, however, a facility must have 10 or more full-time employees. In addition, facility eligibility for reporting is determined by reference to the North American Industry Classification System (NAICS), which is used by various regulatory agencies to identify the industry(ies) in which a given facility is active. The regulations previously referred to, and observers continue to rely on, a parallel classification system known as Standard Industrial Classifications (SIC); for simplicity, this Research Brief refers to SIC codes in analyzing the potential influence of TRI on nanomaterials. Although the initial law covered only manufacturing Standard Industrial Classification, or SIC codes, in 1997, EPA added seven new industry sectors, including certain mining, electric utility, and hazardous waste treatment and disposal facilities, among others.¹⁷

Although further research is needed, a preliminary analysis suggests that most known *commercial* nanomaterial facilities would be eligible for reporting under TRI on the basis of their SIC codes. Based on data previously collected by the Project on Emerging Nanotechnologies at the Woodrow Wilson Center, a preliminary effort was made to assign a SIC code to 587 known commercial nanomaterial facilities. The resultant facility categorization was then compared to the codes subject to TRI reporting in order to determine the approximate percentage of nanomaterial facilities that could be covered by TRI. This preliminary analysis indicates that the vast majority of nanotechnology facilities are engaged in manufacturing. The three most common facility types appear to be: production of chemicals and allied products (43 percent); production of measuring, analyzing, and controlling instruments and photographic, medical, and optical goods (33 percent); and production of electronic equipment and components other than computer equipment (14 percent). Together, these three manufacturing categories appear to fall under the SIC codes subject to TRI reporting almost

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without exception; only seven of 587 facilities appear likely to fall under SIC codes that are exempt from reporting.

The results of this preliminary effort suggest that industrial classifications for commercial nanomaterial facilities accommodate the application of TRI in the nanomaterial context. Several facility exemptions and special considerations, however, merit consideration for non-commercial facilities.

Laboratories: The TRI regulations contain certain exemptions from the reporting requirements including, with certain exceptions, an exemption for chemicals manufactured, used, or processed in a laboratory setting. This exemption is narrowly drawn and does not cover all laboratories. It could influence reporting of nanomaterial releases in certain circumstances, however, as it is aimed at exempting research and development work in laboratories, as opposed to work that produces commercial products.

Universities: TRI does not apply to SIC Code 61, which covers universities. As a result, educational institutions that are manufacturing, processing, or using nanomaterials are not required to report under TRI, unless required to do so for another reason. For example, universities hypothetically could be subject to reporting if they:

- fall under multiple industrial classifications, including a listed category that is their primary SIC code;
- qualify as federal agency facilities; or
- are required to report by state law.¹⁸

Federal Facilities: Because of the considerable work on nanomaterials conducted by federal agencies, it is notable that, as originally enacted, TRI did not require federal facilities to report their releases of covered chemicals. While the statutory language has not changed, federal facilities have been required to comply with TRI reporting since 1993, pursuant to executive order.¹⁹ In January 2007, the Bush Administration caused significant uncertainty as to federal facility reporting by revoking several Clinton-era executive orders, including the executive order that applied TRI to federal facilities. Although the Administration did issue a replacement order (Executive Order 13,423 issued January 27, 2007), that order is silent with respect to the reporting issue. As a result, the legal basis for requiring federal TRI disclosures became unclear, with some commentators speculating that reporting was no longer required. The situation was clarified in March 2007, when the Council on Environmental Quality (CEQ) issued interpretive guidance that explicitly states that federal facilities must continue to comply with the EPCRA reporting requirements.²⁰

Thus, although it appears that many commercial and federal nanotechnology facilities could be covered by TRI, an interesting question is whether EPA could or would use the authority provided to it in the statute to add SIC codes that would include additional facilities that manufacture, process, or use nanomaterials. The statute states that this authority may be used "only to the extent necessary" to provide that each SIC covered is "relevant to the purposes" of the TRI law.

Finally, the statute also provides EPA with authority to apply TRI requirements to particular facilities that use a toxic chemical if warranted on the basis of the toxicity of the chemical, proximity to other facilities that release the toxic chemical or to population centers, the history of the releases of the chemical at the facility, or other factors the Environmental Protection Agency (EPA) deems appropriate to consider.²¹ Further research is needed to determine whether and how this authority could be used to apply TRI to nanotechnology facilities.

Toxic Chemicals: The statute specifies the numerous chemicals it covers. In addition, the law provides that EPA may, by rule, add certain types and numbers of chemicals to the list. The standard that governs EPA's decision to add a chemical to the list is detailed in the statute but focuses on whether there is "sufficient evidence" to establish that the chemical is "known to cause or can reasonably be anticipated to cause significant adverse" acute or chronic human health or environmental effects. The statute also specifies that the determination to add a chemical must be based on "generally accepted scientific principles or laboratory tests, or appropriately designed and conducted epidemiological or other population studies" available to EPA. These same standards apply to citizen and state government petitions to add a chemical to the list.

According to EPA, of the approximately 650 chemicals on the list, the Agency added roughly half of them subsequent to enactment of the statute, including many pesticides and dioxin-like compounds. For example, in 1999, EPA added a category of dioxin and dioxin-like compounds. The list of current TRI chemicals and chemical categories does not include any specific nanomaterials, but it does include chemicals that are currently manufactured at the nanoscale. In fact, according to EPA in its Nanotechnology White Paper:

Some producers of nanomaterials containing materials listed in the TRI may be subject to reporting under the TRI Program.... Of the nearly 650 toxic chemicals and chemical compounds on the TRI, a number are metals and compounds containing these metals, including cadmium, chromium, copper, cobalt and antimony. Such compounds may be produced as nanomaterials and some are commonly used in quantum dots.²²

A key issue requiring confirmation is whether EPA considers a nanomaterial to be a toxic chemical under TRI when the bulk material is listed, as is the case with selenium and cadmium, which are on the TRI list and currently are manufactured at the nanoscale for use in quantum dots. Conversely, it is important to determine whether EPA will evaluate a nanoscale chemical separately for purposes of TRI listing, even if the bulk chemical is not listed as a toxic chemical. Assuming, however, that nanomaterials are evaluated separate from their bulk counterparts, or that their distinctive chemical and physical properties are considered when evaluating the bulk chemical, the principal question is whether or when there will be sufficient evidence to establish the required human health or environmental effects for adding the nanomaterial to the TRI list. This question would

6 6 A key issue requiring confirmation is whether EPA considers a nanomaterial to be a toxic chemical under TRI when the bulk material is listed. **9 9** **6 6** [EPCRA] reporting is only required if a certain threshold amount of a toxic chemical is "manufactured," "processed," or "otherwise used" at a facility....Threshold amounts, however, may need to be amended to apply effectively to nanomaterials. **9 9** apply equally to chemicals that EPA considers on its own initiative and those that it is petitioned to consider.

It is also interesting that, in some cases, EPA lists only a certain form of a chemical. For example, phosphorus is covered by TRI only in its yellow or white state, hydrochloric acid is covered only in its acid aerosol forms, "including mists, vapors, gas, fog, and other airborne forms of any particle size," and zinc is covered only to the extent it is used in a fume or a dust state.²³ Whether this is relevant precedent for future agency decisions about nanomaterials would require further investigation.

Threshold Amounts: The statute and regulations provide that reporting is only required if a certain threshold amount of a toxic chemical is "manufactured," "processed," or "otherwise used" at a facility. The definitions of these terms are broad and inclusive and they do not appear to present any particular problems in the context of nanomaterials. The threshold amounts, however, may require statutory or regulatory amendments to apply effectively to nanomaterials since production quantities of nano-engineered substances may be orders of magnitude below those traditionally associated with the bulk chemical industry that TRI was orginally designed to address. In fact, the model for nano-manufacturing may not be the chemical industry at all, but the pharmaceutical or semiconductor industries with a focus on precision manufacturing of small quantities of highly engineered materials.

Under TRI, the threshold amounts vary depending on whether the chemical is "otherwise used" (10,000 pounds) or "manufactured or processed" (25,000 pounds). The statute authorizes EPA to lower the reporting threshold under certain circumstances for classes of chemicals or categories of facilities, an action it has taken on occasion. For example, in 1999, EPA reduced the reporting threshold for persistent and bioaccumulative toxic (PBT) chemicals to 100 pounds and for highly persistent and highly bioacumulative toxic chemicals to 10 pounds. Similarly, the reporting threshold for dioxin and dioxin-like compounds is 0.1 grams. EPA's rationale for revising the thresholds for these chemicals potentially could apply in the nanomaterial context as well. An EPA Fact Sheet notes that, "relatively small releases of PBT chemicals can pose human and environmental health threats and consequently releases of these chemicals warrant recognition by communities."²⁴ Accordingly, an issue for further examination is whether it would be appropriate to reduce the reporting threshold for some or all nanomaterials that are determined to be toxic chemicals.

In addition, it is important to note that there are additional quantity-based considerations for reporting that may have a bearing on nanomaterials:

Alternate reporting: An alternate reporting form, Form A, provides certain facilities the option of submitting a substantially shorter form with a reduced reporting burden under certain circumstances. Specifically, the regulations allow facilities to use Form A in lieu of Form R for a non-PBT chemical when: 1) the facility's total annual amount of the chemical released, recycled, combusted for energy recovery, and/or treated for destruction does not exceed 5,000 pounds; 2) the facility's total

annual releases of the chemical do not exceed 2,000 pounds; and 3) the facility has not manufactured, processed, or otherwise used more than one million pounds of the non-PBT chemical. The alternate threshold also may be used for PBT chemicals if: 1) total waste management of the PBT chemical does not exceed 500 pounds; 2) there are *zero* releases (both on- and off-site) into the environment of the PBT chemical; and 3) the facility has not manufactured, processed, or otherwise used more than one million pounds of the PBT chemical. Form A cannot be used for reporting dioxin and dioxin-related compounds.²⁵

Whereas Form R provides details about releases and other waste management information (e.g., total quantity of releases to air, water, and land, and on- and off-site recycling, treatment, and combustion for energy recovery), Form A provides the name of the chemical and certain facility identification information. The TRI regulations were recently amended to expand the number of facilities that could opt for alternate reporting. Further research would be needed to assess the implications of applying the current alternate reporting threshold to nanomaterials.

Chemical mixtures: The regulations contain an exemption for *de minimis* concentrations (typically less than one percent, but 0.1 percent for some chemicals) of a non-PBT toxic chemical in a mixture of chemicals.²⁶ Further examination of how nanomaterials are used in chemical mixtures and in what percentage would be needed to determine if any special concerns are raised in the context of nanomaterials.

The remainder of the statutory and regulatory exemptions that carve out certain uses or forms of toxic chemicals from the calculation of whether a facility manufactures, processes, or uses a toxic chemical above threshold amounts do not appear to raise special concerns for nanomaterials. These include, for example, exemptions for toxic chemicals used as structural components of a facility, in routine grounds maintenance, in food and cosmetics for personal use, and contained in "articles" or manufactured items.²⁷ As more is learned about the toxicity of nanomaterials and new uses emerge, however, these exceptions may need to be reconsidered.

Information Reported: The statute requires that covered facilities report the following information:

- Whether the toxic chemical at the facility is manufactured, processed, or otherwise used, and the general category or categories of use of the chemical;
- An estimate of the maximum amounts (in ranges) of the toxic chemical present at the facility at any time during the preceding calendar year;
- For each waste stream, the waste treatment or disposal methods employed, and an estimate of the treatment efficiency typically achieved by such methods for that waste stream; and
- The annual quantity of the toxic chemical entering each environmental medium.²⁸

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C An additional consideration in the context of nanomaterials is whether effective tools and methodologies exist for measuring and estimating releases.

6 6 This initial review of TRI authorities indicates that, in theory, the statute could be applied to nanomaterials. The key question is whether any nanomaterials are or will be considered by EPA to be toxic chemicals under TRI. **9 9** It is noteworthy that TRI only requires facilities to report specific amounts released (i.e., chemicals "entering each environmental medium") – not the amounts manufactured, processed, or otherwise used. The estimated maximum inventory and treatment efficiency allow for an imperfect calculation of the amounts of the chemical used but not released.

Monitoring under other laws: The statute states that it does not require the monitoring or measurement of quantities of any toxic chemical released into the environment beyond the monitoring and measurement required under other laws or regulations. This provision requires further analysis to determine whether and to what extent it presents an impediment to applying TRI to nanomaterials, due to lack of regulation of nanomaterials under laws other than EPCRA. It appears, however, that facilities often use estimates to determine releases when monitoring data are not collected pursuant to other statutory requirements. EPA's regulations provide that, "when relevant monitoring data or emission measurements are not readily available, reasonable estimates of the amounts released must be made using published emission factors, material balance calculations, or engineering calculations."²⁹ An additional consideration in the context of nanomaterials is whether effective tools and methodologies exist for measuring and estimating releases.

Supplier notification: With certain exceptions, the TRI regulations require suppliers in certain SIC codes that manufacture a toxic chemical and sell or supply a mixture or trade name product containing the chemical to a facility covered by TRI (or to someone who ultimately will supply the facility with the chemical) to provide written notification to each person who will be supplied with the mixture or product.³⁰

Miscelloneous Authorities: The statute also addresses protection of trade secrets, as well as enforcement and citizen suits. In theory, these authorities do not appear to raise any particular concerns with respect to nanomaterials.

Summary and Next Steps

This initial review of TRI authorities indicates that, in theory, the statute could be applied to nanomaterials. The key question is whether any nanomaterials are or will be considered by EPA to be toxic chemicals under TRI. These decisions will rest, in part, on the development of additional toxicological data but also on EPA's approach to administering the statute. It also may be necessary to amend certain aspects of the regulations to address reporting thresholds that may not be effective in the context of nanomaterials and, to a lesser extent, to add SIC codes that would cover additional nanomaterial facilities. Additional research is required, however, including qualitative interviews with key stakeholders, to determine whether application of TRI to nanomaterials should be pursued as a policy priority in the near term.

Endnotes

1.42 U.S.C. §116 (2005).

- 2. See, e.g., J. Clarence Davies, EPA and Nanotechnology: Oversight for the 21st Century, Project on Emerging Nanotechnologies, Woodrow Wilson International Center for Scholars, Washington, DC, May 2007, available at http://www.nanotechproject.org/file_download/197; Linda K. Breggin and John Pendergrass, Where Does the Nano Go? End-of-life Regulation of Nanotechnologies, Project on Emerging Nanotechnologies, Woodrow Wilson International Center for Scholars, Washington, DC, July 2007, available at http://www.nanotechproject.org/file_download/208; Mary Ellen Ternes, ABA SEER CAA Nanotechnology Briefing Paper, American Bar Association Section of Environment, Energy, and Resources, June 2006, available at http://www.abanet.org/environ/nanotech/pdf/CAA.pdf.
- 3. City of Berkeley, "Introduction to Manufactured Nanoscale Material Health & Safety Disclosure," 2007 available at http://www.ci.berkeley.ca.us/toxics/Manufactured%20Nanoparticle%20Reporting%20 Final.pdf. The guidelines note that "information is not available" is an appropriate response. Using this toxicity information, the guidance requires users to indicate the "control band" into which each material falls based on its risk profile and to list the applicable control measures for each control band. Facilities are instructed to take a "precautionary approach" to all materials without known toxicities, including instituting control measures consistent with those adopted for materials of high known toxicity.
- 4. The city council of Cambridge, Massachusetts ordered its department of public health to study the issue and recommend action. See City Manager's Agenda, Cambridge Civic Journal 4, 6, January 8, 2007.
- 5. Acción Ecológica, *et al.*, "Principles for the Oversight of Nanotechnologies and Nanomaterials," July 2007, *available at* http://www.icta.org/doc/Principles%20for%20the%20Oversight%20of%20 Nanotechnologies% 20and%20Nanomaterials_final.pdf.
- 6. The Responsible NanoCode, which will be introduced in February 2008, is a "voluntary, principlesbased Code of Conduct" that aims to signal the consensus of what constitutes good practice in the nanotechnology industry. Responsible Nano Code, Responsible Nanotechnologies Code Consultation Draft, *available at* http://www.responsiblenanocode.org/pages/progress/index.html.
- Olaf Bayer, "Nanomaterials: Undersized, Unregulated and Already Here," Corporate Watch, 2007, available at http://www.corporatewatch.org/download.php?id=63.
- 8.The Toxic Right-to-Know Protection Act, S. 595, 110th Congress, 2007 [introduced by Sen. Frank Lautenberg (D-N.J.), repealed December 2006 EPA rule that increased Toxics Release Inventory reporting threshold to 5,000 pounds per year from 500 pounds per year in certain cases, and reduced the reporting frequency to every other year from every year].
- 9. The National Greenhouse Gas Registry Act of 2007, S. 1387, 110th Congress, 2007.
- 10. The statute establishes TRI, the subject of this research brief, but also requires businesses to report the locations and quantities of chemicals stored on-site to state and local governments in order to help communities prepare to respond to chemical spills and similar emergencies. These requirements may merit further study to determine whether and how they could apply to nanomaterials and are discussed briefly in an appendix to this research brief. They are not the focus of this research brief; however, because the requirements primarily are intended to provide disclosures to state and local bodies to assist them in preparing for and responding to chemical emergencies; whereas, TRI disclosures are more readily available to the public.
- 11. Environmental Protection Agency, What is the Toxics Release Inventory (TRI) Program, *available at* http://www.epa.gov/tri/whatis.htm.
- See, e.g., Archong Fung & Dara O'Rourke, Reinventing Environmental Regulation from the Grassroots Up: Explaining and Expanding the Success of the Toxics Release Inventory, 25 Environmental Management, 2007, 115; Bradley Karkkainen, "Information as Environmental Regulation: TRI and Performance Benchmarking, Precursor to a New Paradigm?", 89 Georgetown Law Journal, 2001, 257.
- 13. These include the assessment that stakeholders can use TRI information to affect future releases through an array of potential mechanisms, including: self-analysis; industry-wide regulation/peer-review; governmental regulation as a response to newly-disclosed information; public pressure; and market pressure through capital markets, reputational harm, and other means. *See, e.g.*, Fung & O'Rourke, *supra* note 12; Karkkainen, *supra* note 12; see also Mark A. Cohen, Information as a Policy Instrument in Protecting the Environment: What Have We Learned?, 10 *Environmental Law Report*, 2001, 10,425 (noting the need for empirical research on the causes of TRI-related environmental benefits).

- 14. See David W. Case, "Corporate Environmental Reporting as Informational Regulation: A Law and Economics Perspective," 76 University of Colorado Law Review 379, 385 n.32 (2005) (collecting sources); Alexander Volokh, "The Pitfalls of the Environmental Right-to-Know," 2002 Utah Law Review 805 (2002); Tom Tietenberg & David Wheeler, Empowering the Community: Information Strategies for Pollution Control 13 (1998).
- 15. See Fung & O'Rourke, *supra* note 12 (noting success of TRI despite "lackadaisical" enforcement, undercompliance, and limited scope of regulated chemicals); Karkkainen, *supra* note 12 (characterizing TRI as "crude" due to its reliance on narrow, incomplete, and unreliable data).
- 16. 42 U.S.C. 11049(4). 17. 40 C.F.R. § 372.22.
- 18. Many universities enter into research contracts with federal agencies such as the Department of Defense (DOD), the Department of Energy (DOE), and EPA. Contractors, including universities, are not subject to TRI reporting under Executive Order 13,423 and its predecessors unless the contractor is operating a federally-owned facility for an agency. See EPA, Toxics Release Inventory (TRI), *available at* http://www.epa.gov/enviro/html/tris/column/federal_fac_ind.html. Some universities operate federal facilities in this manner, such as DOE National Laboratories. For example, Berkeley Laboratory, which is operated by the University of California, has acknowledged its TRI reporting responsibility. *See, e.g.* Berkeley Lab, Site Environmental Report for 2000, *available at* http://www.lbl.gov/ehs/esg/00ser/00serchp3.html (listing releases but noting that reporting was not required because releases did not exceed reporting thresholds). Finally, some state laws extend TRI reporting to educational institutions. In Wisconsin, for example, state law requires both public and private educational institutions to comply with TRI reporting standards. Wis. Stat. § 166.20.
- 19. Executive Order No. 12,856, issued August 6, 1993 (President Clinton replaced this TRI-specific executive order in 2000 with a more general order requiring a broad array of requirements for federal facility environmental management. Executive Order 13,148 retained the federal facility EPCRA-reporting requirements, however, and strengthened them by specifically clarifying, with reference to EPCRA's provisions, the legal requirements applicable to federal facilities).
- 20. Council on Envtl. Quality, Instructions for Implementing Executive Order 13,423 at 21 (Mar. 29, 2007).
- 21.According to EPA: "[T]he Senate-passed TRI bill encompassed reporting by only those facilities within SIC codes 20 through 39, whereas the House legislation contemplated that any facilities handling above-threshold amounts of reportable chemicals would be subject to the reporting requirements. The Conference Committee that developed the language eventually enacted into law stated as follows: The conference substitute combines elements of the Senate and House amendments. Coverage of facilities is based on SIC Codes 20–39, except that [EPA] may add or delete SIC Codes to the extent necessary to achieve the purposes of this section..."Addition of Facilities in Certain Industry Sectors; Revised Interpretation of Otherwise Use; Toxic Release Inventory Reporting; Community Right-to-Know, Federal Register: May 1, 1997 (Volume 62, Number 84), available at http://www.epa.gov/EPA-TRI/1997/May/Day-01/tri11154.
- 22. Nanotechnology Workgroup, Science Policy Council, Environmental Protection Agency, Nanotechnology White Paper at 68 (February 2007), *available at* http://www.epa.gov/osa/pdfs/nanotech/epa-nanotechnology-whitepaper-0207.pdf (last visited Aug. 14, 2007).
- 23.40 C.F.R. § 372.65.
- Environmental Protection Agency, Fact Sheet on EPCRA Section 313 Rulemaking: Persistent Bioaccumulative Toxic Chemicals, *available at* http://www.epa.gov/tri/lawsandregs/pbt/pbtrule-fs.pdf (last visited August 14, 2007).
- 25.40 C.F.R. § 372.27.
- 26. "The *de minimis* exemption allows facilities to disregard certain minimal concentrations of non-PBT chemicals in mixtures or other trade name products when making threshold determinations and release and other waste management calculations. The *de minimis* exemption does not apply to the manufacture of an EPCRA section 313 chemical except if that EPCRA section 313 chemical is manufactured as an impurity and remains in the product distributed in commerce, or if the EPCRA section 313 chemical is imported below the appropriate *de minimis* level. The *de minimis* exemption does not apply to a byproduct manufactured coincidentally as a result of manufacturing, processing, otherwise use, or any waste management activities. The *de minimis* exemption does not apply to any PBT chemical (except lead when it is contained in stainless steel, brass or bronze alloy) or PBT chemical category." Environmental Protection Agency, Toxic Chemical Release Inventory Reporting Forms and Instructions, (2006), at 19, available at http://www.epa.gov/tri/report/TRI_RFI_2006.pdf.

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- 27. Specifically, this exemption covers TRI chemicals present within a manufactured item, which is (1) "formed to a specific shape or design during manufacture, (2) which has end use functions dependent in whole or in part upon its shape or design during end use, and (3) which does not release a toxic chemical under normal conditions of processing or otherwise use of the item at the facility." For the purposes of criteria (3), releases totaling less than 0.5 pounds from all such products are rounded down to zero. This quantity does not include releases during manufacture. *Supra* note 26, at 18.
- 28.42 U.S.C. § 11023(g)(1).
- 29. U.S. Envtl. Prot. Agency, Toxics Chemical Release Inventory Reporting Forms and Instructions for Reporting Year 2001 EPA Document Number: 260 B 02 001 (also noting that "you may not use emission factors or calculations to estimate releases if more accurate data are available. No additional monitoring or measurement of the quantities or concentrations of any EPCRA section 313 chemical released into the environment, or of the frequency of such releases, beyond that required under other provisions of law or regulation or as part of routine plant operations, is required for the purpose of completing Form R."); EPA, Economic Incentives for Pollution Control: 9.2.1. Trends in Toxics Release Inventory (TRI) Data (2004) *available at* http://yosemite1.epa.gov/ee/epalib/incent.nsf/c7950cb0634d42808525634e00438a4a/05367 2865827906e852564f60054662e!OpenDocument (companies usually determine TRI release amounts by estimate rather than monitoring).

30.40 C.F.R. § 372.45.



In addition to further examination of TRI as a vehicle for disclosure-based regulation of nanomaterials, several additional disclosure-related laws and initiatives should be evaluated:

Federal Disclosure and Right-to-Know Laws: Several federal laws either provide broad permitting authority or include disclosure components that should be evaluated for purposes of application to nanomaterials. These include, but are not limited to:

EPCRA: In addition to the TRI program, EPCRA includes an array of additional provisions intended to promote state and local emergency planning. These provisions require that facilities disclose a variety of types of information relating to their use of potentially harmful chemicals. Whereas TRI reports are made to EPA in order to inform the public about historic releases and potentially to affect practices at reporting facilities, these other EPCRA disclosures primarily are intended to mitigate the harm caused by chemical accidents after they happen. Thus, EPCRA emergency-planning disclosures are made to state and local bodies—not EPA—and are tailored to aid those bodies in their preparations for future chemical emergencies.

Section 112(r) of the Clean Air Act:¹ Section 112 requires stationary sources that use threshold amounts of certain chemicals to: identify hazards resulting from chemical production, processing, handling, or storage; prevent chemical releases through provisions for safe facility design and operation; and establish an emergency response plan that minimizes the consequences of releases should they occur. To implement these requirements, covered facilities must create risk management plans (RMPs) that include the facility's five-year accident history and its off-site consequences analysis, accident prevention plan, and emergency response plan. These RMPs must be submitted to EPA for use in emergency planning and must be available to the public. RMP disclosure, however, has been limited due to national security concerns.² As a result, the only remaining federally-disclosed internet-based source of RMP data is the Vulnerable Zone Indicator System (VZIS), which identifies only whether a given address could be affected by a toxic chemical release from a reporting facility. Despite these limitations, RMP executive summaries remain available from nongovernmental sources. OMBWatch, a non-profit advocacy group, maintains an RMP database that is based on information requests made pursuant to the Freedom of Information Act. A review is needed to determine whether and how Section 112 could apply to nanomaterials.

Additional Facility-Based Disclosure Programs: An evaluation is needed of potential facility-based disclosure initiatives, including the use of permit requirements to seek information from nanotechnology facilities permitted under the Clean Water Act, Clean Air Act, and other federal laws. For example, permit requirements or facility-specific initiatives could require disclosure to the public of information about air emissions, water discharges, and waste disposal practices.

State Disclosure Laws: Many states have enacted laws that require some type of information disclosure from regulated entities. These laws should be evaluated as possible vehicles for regulation of nanomaterials.

Local Right-to-Know Lows: The first EHS law to address nanotechnologies, as discussed above, is a local right-to-know law. The implementation of this law provides ample opportunities to evaluate the effectiveness of such laws through review of data and information submitted by covered facilities, as well as through qualitative interviews with stakeholders, such as environmental and community groups, businesses, investors, and regulators.

Labeling: The potential effectiveness and pros and cons of labeling products that contain nanomaterials should be evaluated. Consideration should be given to the form and content of labeling and whether educational information should be provided in conjunction with a labeling initiative.

Voluntary Disclosure Programs: An analysis is needed of private sector and public sector voluntary disclosure programs and how they could augment traditional regulatory tools. For example, the review should consider the types of weaknesses or gaps that are likely to exist in these programs and how voluntary and mandatory disclosure programs could work together as part of the governance structure for nanotechnologies.

ENDNOTES

1.42 U.S.C. § 7412(r).

2. See, e.g. Evan M. Slavitt et al., National Security vs. Public Disclosure: The War on Terrorism's Implications Upon Federal Emergency Planning and Right to Know Laws (2003).

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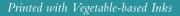
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Woodrow Wilson International Center for Scholars 1300 Pennsylvania Ave., N.W. Washington, DC 20004-3027

T 202.691.4000 F 202.691.4001 nano@wilsoncenter.org www.nanotechproject.org

