



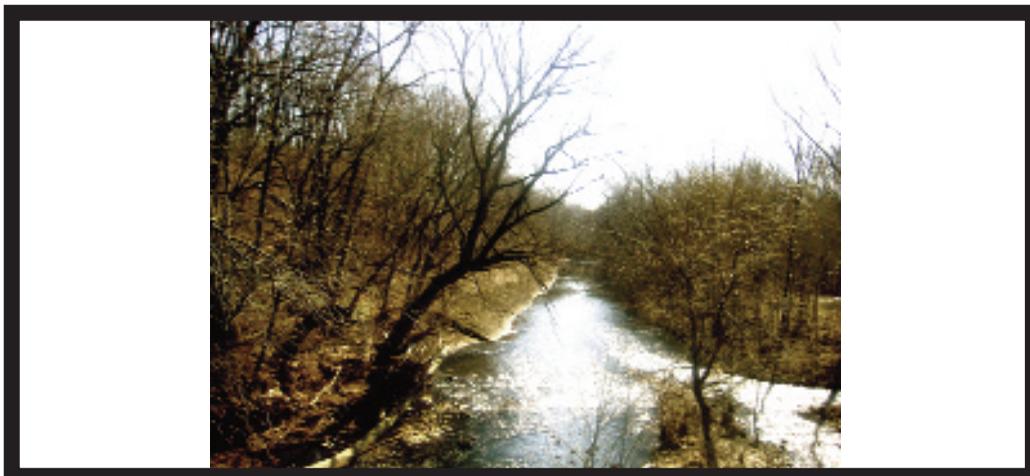
**Center for
Contemporary
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STUDIES IN SUSTAINABILITY

Nanotechnology Regulation:

Policies Proposed by Three
Organizations for the Reform of the
Toxic Substances Control Act



ANNA LAMPROU



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C h e m i c a l H e r i t a g e F o u n d a t i o n

Anna Lamprou

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EXECUTIVE SUMMARY

Nanotechnology involves the act of manipulating matter at the molecular level. Having the capacity to work at this scale has generated a lot of excitement: researchers have imagined using nanotechnology for a wide range of applications in disparate fields, from medicine and cosmetics to food packaging and environmental filters.¹ This surge of interest has attracted enormous investments toward development while simultaneously producing significant anxieties over the potential harmful effects of nanomaterials.² In particular, critics are concerned that the properties exhibited by nanomaterials are not fully known, and these groups advocate for a framework that regulates production.³ This paper discusses the current primary law governing nanotechnology in the United States and addresses its limitations as identified by three interest organizations. Also discussed are different policy recommendations that these organizations have suggested in regard to nanotechnology regulation.

¹ Los Alamos National Laboratory, “What Is Nanotechnology?” Nanotechnology at Los Alamos National Laboratory, 25 June 2002, www.lanl.gov/mst/nano/definition.html (accessed 5 Apr. 2009).

² The National Nanotechnology Initiative, “Research and Development Leading to a Revolution in Technology and Industry,” May 2009, nano.gov/NNI_2010_budget_supplement.pdf (accessed 20 Oct. 2009).

³ See J. Clarence Davies’s 2006–2009 reports on nanotechnology <http://www.nanotechproject.org/publications/>; e.g., Davies, “Managing the Effects of Nanotechnology,” Woodrow Wilson International Center for Scholars, Project on Emerging Nanotechnologies, Washington, DC, Jan. 2006, www.nanotechproject.org/publications/archive/managing_effects_nanotechnology/ (accessed 19 Jun. 2009).

INTRODUCTION

Nanotechnology is formally defined as “the creation of functional materials, devices, and systems through control of matter on the nanometer (1 to 100 nm) length scale and the exploitation of real properties and phenomena developed at that scale.”⁴ Research on nanostructures and at the nanoscale is not entirely new; most biological processes take place at the nanoscale. The difference today is that scientists possess more sophisticated techniques that are necessary to isolate, synthesize, and manipulate matter at this scale. From the perspective of a molecular composition many of these materials are the same (or very nearly the same) as other bulk materials. Their scale and size, however, mean that these materials can exhibit unique physical and chemical properties. A quandary results: how do we acknowledge both sameness and difference in dealing with nanomaterials?

This situation makes the regulation of nanotechnology under the long-existent framework of the Toxic Substances Control Act (TSCA), the primary law governing nanomaterials, a complicated issue. According to TSCA a chemical substance is characterized by its molecular identity, for example, the type, number, and arrangement of the atoms that constitute a molecule. Since nano and bulk forms have the same molecular identity under TSCA, they are considered the same substance, which subsequently causes many difficulties in regulatory procedures. Recently, the Environmental Protection Agency (EPA) issued a report addressing how nanomaterials fall under the regulatory framework of TSCA and how engineering nanomaterials might be handled by the same framework.⁵ In addition, congressional hearings have been held to discuss and decide on further reforms of TSCA in relation

⁴ Los Alamos National Laboratory, “What Is Nanotechnology?”

⁵ U.S. Environmental Protection Agency, “TSCA Inventory Status of Nanoscale Substances—General Approach,” Washington, DC, 23 Jan. 2008, www.epa.gov/oppt/nano/nmsp-inventorypaper2008.pdf (accessed 9 Apr. 2009).

to nanomaterials.⁶ EPA has already used existing tools to regulate certain nanomaterials⁷ and has developed voluntary programs for the same purpose.⁸ EPA's activities are not adequate according to various interest organizations, including environmental organizations and think tanks, which argue that regulatory reform must take place as soon as possible for both the public and the environment to be protected.

Previous research on the role played by reform organizations in policy debates over nanotechnology allows for an exploration of regulatory policy reforms, as suggested by three interest organizations, concerning the regulation of nanotechnology and the subsequent reform of TSCA in the United States.⁹ These organizations are the Project on Emerging Nanotechnologies (PEN), the Environmental Defense Fund (EDF), and Friends of the Earth (FoE). They represent the larger category of interest-based organizations active in nanotechnology regulation, as well as the diversity present in such organizations' advocacy styles and missions. The following questions are to be addressed and answered:

- * *How do different interest organizations position themselves on the issue of nanotechnology regulation?*
- * *How do these organizations position themselves on the issue of TSCA reform?*
- * *What regulatory frameworks or solutions does each propose?*
- * *How do these organizations try to achieve their goals?*

A comparative analysis suggests that while there is a general consensus among the three groups on the nature of the problematic issues presented by TSCA, each organization proposes solutions and approaches that reflect the different organizational cultures.

⁶ For examples, see Clarence Davies's testimony, U.S. Senate Committee on Commerce, Science, and Transportation, hearing on "Developments in Nanotechnology," Washington DC, 15 Feb. 2006, commerce.senate.gov/pdf/davies-021506.pdf (accessed 19 Jun. 2009); Davies's testimony, U.S. House of Representatives, Subcommittee on Commerce, Trade, and Consumer Protection, Committee of Energy and Commerce, Washington DC, 26 Feb. 2009. http://energycommerce.house.gov/Press_111/20090226/testimony_davies.pdf (accessed 19 Jun. 2009).

⁷ Jim Alwood, "Nanotechnology Update," GlobalChem 2009, 8 Apr. 2009, www.socma.com/assets/File/socma1/PDFfiles/gcrc/2009/jim-alwood-globalchem-nano-update-0320.pdf (accessed 26 Nov. 2009).

⁸ U.S. Environmental Protection Agency, Office of Pollution Prevention and Toxics, "Nanoscale Materials Stewardship Program: Interim Report," Washington, DC, Jan. 2009, www.epa.gov/oppt/nano/nmsp-interim-report-final.pdf (accessed 19 Jun. 2009).

⁹ David Hess, "The Environmental, Health, and Safety Implications of Nanotechnology: Environmental Organizations and Undone Science in the United States," *Science as Culture*, 2010 (in press).

THE ORGANIZATIONS

Various types of interest organizations have staked claims in the debates involving nanomaterials. For the purposes of this study only those looking specifically at the regulation of nanomaterials were examined. From this smaller subset three organizations were chosen to reflect organizational differences, with particular attention paid to audience, advocacy style, and mission. As a result this study includes discussions of the positions taken by a think tank and two environmental organizations: the Project on Emerging Nanotechnologies (PEN), the Environmental Defense Fund (EDF), and Friends of the Earth (FoE).

Project on Emerging Nanotechnologies

PEN was first established in April 2005 as a partnership between the Woodrow Wilson International Center for Scholars and The Pew Charitable Trusts. Chartered by Congress and administered by the Smithsonian Institution, PEN is a think tank of experts fueled by a common interest in transparency and better regulatory policy. It does not have a public base like the other two organizations, EDF and FoE. PEN supports its mission—proposing strategies for responsible research and development of nanotechnology and its regulation, and informing a public already knowledgeable about these issues, such as policy makers and scientists—through the creation of reports and publicly available search tools.¹⁰

In comparison with other organizations PEN's scope is narrowly focused on issues surrounding nanotechnology oversight, and more specifically, on policy and responsible research and development for nanotechnology. PEN is not an advocate either for or against particular nanotechnologies; rather it seeks to ensure that as these technologies are developed, the potential human health and environmental risks are anticipated, properly understood, and effectively managed. The goal is to generate objective knowledge about nanotechnology and to propose objective policy

¹⁰ Project on Emerging Nanotechnologies, 2009, www.nanotechproject.org/about/mission (accessed 15 Jun. 2009).

solutions, as well to inform the public on the same issues. Since May 2005 PEN has published seventy-seven reports concerning nanotechnologies and nanomaterials.¹¹

J. Clarence “Terry” Davies, one of PEN’s senior advisers, wrote the PEN reports used for the development of this paper. As a think tank, PEN relies on outside assistance from such experts as Davies to help construct materials that fulfill the institution’s mission to provide thoughtful and useful tools for policy. While PEN has published scores of papers on nanotechnology, only Davies’s explicitly address the issue of TSCA reform and nanotechnology regulation.

E n v i r o n m e n t a l D e f e n s e F u n d

EDF is an environmental organization that was founded by scientists in 1967 and that currently has a public base and a history of successes in environmental and chemical regulation. EDF activities cover a broad spectrum of environmental and health issues, including nanotechnology regulation, with a mission aimed at “finding the ways that work.” While litigation provided the main vehicle for action in the early years of EDF, its staff now works to develop partnerships with industry and the government. EDF staff members have Ph.D.s in science and law: consequently, they hold positions on many expert and policy boards and participate in a broad range of activities that encompass both environmental and health issues, as well as nanomaterials.¹²

EDF argues that nanotechnology is a very promising field but that it must be regulated for environmental and health risks. Owing to this argument EDF urged both EPA and the U.S. Food and Drug Administration (FDA) to use their existing authority to regulate nanomaterials through letters cosigned with members of industry. Nearly two years ago EDF representatives also helped initiate, and participated in, an EPA Federal Advisory Committee that proposed an overall approach for the agency to address potential risks of nanomaterials.¹³ EDF also issued a joint statement of principles with the American Chemistry Council.¹⁴ The most controversial of EDF’s activities, however, was its partnership with DuPont in June 2007 and the development of a six-step nano-risk framework.¹⁵

11 Ibid.

12 Environmental Defense Fund, 2009, www.edf.org/home.cfm (accessed 5 Jun. 2009).

13 Environmental Defense Fund, “Environmental Defense’s Activities on Nanotechnology,” Jun. 2007, www.edf.org/documents/6594_nano_summary.pdf (accessed 30 Jun. 2009).

14 Environmental Defense and American Chemistry Council Nanotechnology Panel, “Joint Statement of Principles,” 23 June 2005, www.edf.org/documents/4857_ACC-ED_nanotech.pdf (accessed 2 Jul. 2009).

15 Nano Risk Framework. “A Partnership of Environmental Defend Fund and DuPont” http://www.edf.org/documents/6496_Nano%20Risk%20Framework.pdf 2007 (accessed 2 Jul. 2009)

F r i e n d s o f t h e E a r t h

Friends of the Earth (FoE) is a grassroots environmental organization that works directly with the public. FoE has been fighting for a broad range of environmental issues for more than forty years, within a web of seventy-seven national member organizations and five thousand local organizations. FoE is typically involved with food and agricultural issues, but they have also taken a keen interest in nanotechnology policy development. Unlike PEN and EDF, FoE is an international organization, and so it often coordinates activities in the United States with those in the European Union. FoE advocacy uses direct action involving the public and is the only one of the three organizations discussed here that has requested a moratorium on the manufacture of products containing nanomaterials.¹⁶ Since 2006 FoE United States has published three reports in cooperation with FoE Australia and FoE Europe.¹⁷

With respect to nanotechnologies FoE argues that “the failure of government regulators to take seriously the early warning signs surrounding nanotoxicity suggests that they have learned nothing from any of the long list of disasters that resulted from the failure to respond to early warning signs about previous perceived ‘wonder’ materials (like asbestos, DDT, and PCBs).”¹⁸ FoE has joined a broad coalition of civil society, public interest, environmental, and labor organizations for the development of reports and has filed petitions to EPA and the FDA asking for regulation of nanomaterials.¹⁹

The selection of these different approaches allows for a comparison of the unique methods of three distinct interest-based organizations. Together they provide a set of diverse case studies to explore nanotechnology, TSCA, and the role of interest organizations in regulatory reform.

16 Friends of the Earth, 2009, www.foe.org (accessed 2 Jun. 2009).

17 Friends of the Earth, “Nanomaterials, Sunscreens, and Cosmetics: Small Ingredients, Big Risks,” FoE Australia and United States, May 2006, www.foeeurope.org/activities/nanotechnology/nanocosmetics.pdf (accessed 19 Jun. 2009); Friends of the Earth, “Out of the Laboratory and onto Our Plates: Nanotechnology in Food and Agriculture,” FoE Australia, Europe, and United States, Mar. 2008, www.foeeurope.org/activities/nanotechnology/Documents/Nano_food_report.pdf (accessed 19 Jun. 2009); Rye Senjen and Ian Illuminato, “Nano and Biocidal Silver: Extreme Germ Killers Present a Growing Threat to Public Health,” FoE Australia and United States, 2009, www.foe.org/sites/default/files/Nano-silverReport_US.pdf (accessed 19 Jun. 2009).

18 Friends of the Earth, “Nanomaterials, Sunscreens,” p. 3.

19 International Center for Technology Assessment, “Citizen Petition to the United States Food and Drug Administration,” 2006, www.icta.org/doc/Nano%20FDA%20petition%20final.pdf (accessed 15 Mar. 2010); International Center for Technology Assessment, “Citizen Petition for Rulemaking to the United States Environmental Protection Agency,” 2008, www.icta.org/nanoaction/doc/CTA_nano-silver%20petition__final_5_1_08.pdf (accessed 19 Jun. 2009).

1. CASE BACKGROUND

The regulation of most nanomaterials in the United States falls under the jurisdiction of TSCA;²⁰ TSCA is also the framework in place for regulating bulk chemical substances. Because of their size and unique properties, nanomaterials have presented a regulatory challenge in the United States and in the rest of the world, resulting in the initiation of discussions regarding TSCA reform procedures by the EPA to include nanomaterials.²¹

Under TSCA, chemicals are classified as either existing or new substances.²² Existing substances are identified as those that already exist in the EPA inventory; they account for almost 99 percent of all chemicals in the market and are grandfathered under TSCA. Therefore, these substances are not subject to TSCA pre-manufacture or pre-market review, though exceptions to that rule may occur by applying the significant new use rule (SNUR). This regulatory tool gives permission to EPA to reassess existing substances for risks if their use has changed. As a result the SNUR allows EPA to prevent or limit possible exposure and effects from the new use of these substances.²³ For new chemicals a pre-manufacture notification (PMN) is required. The PMN requires manufacturers to provide EPA with any known or reasonably accessible data concerning the new chemical they want to produce. Using these data, the agency assesses whether the substance poses unreasonable risks. If no unreasonable risks are detected, permission is granted for the manufacture of the substance.²⁴

Most nanomaterials are not currently subject to EPA review. The existing regulatory frameworks, TSCA included, are not scale-based. They have been developed to regulate bulk chemical substances using existing scientific knowledge and classifications which do not necessarily apply to nanomaterials. TSCA does not distinguish on the basis of scale (one of the main issues for substances in nano form) but rather on molecular identity. Consequently, nanoscale and non-nanoscale

²⁰ Other regulatory frameworks also regulate chemicals but in more specific contexts or applications.

²¹ U.S. Environmental Protection Agency, “TSCA Inventory Status of Nanoscale Substances—General Approach, Washington, DC, 2008, www.epa.gov/oppt/nano/nmsp-inventorypaper.pdf (accessed 19 Jun. 2009).

²² U.S. Environmental Protection Agency, “Summary of the Toxic Substances Control Act,” Washington, DC, 2008, www.epa.gov/lawsregs/laws/tsca.html (accessed 9 Apr. 2009).

²³ U.S. Environmental Protection Agency, “Consent Orders and Significant New Use Rules (SNURS),” Washington, DC, 2009, www.epa.gov/oppt/newchems/pubs/cnosnurs.htm (accessed 2 Dec. 2009).

²⁴ U.S. Environmental Protection Agency, “Instruction Manual for Reporting under the TSCA New Chemical Program (PMN),” Washington, DC, 2005, www.epa.gov/opptintr/newchems/pubs/tscaman2.pdf (accessed 2 Oct. 2009).

forms, because they have the same or similar molecular identities, are considered to be the same chemical substances. In addition, since most of the chemicals with these identities already exist in the database, they are not considered new substances. As existing substances, most nanomaterials are grandfathered and are not subject to pre-manufacture or pre-market review.

Currently, even though TSCA does not discuss in depth the importance of additional data for the classification of nanomaterials, case-by-case regulation might be possible for certain nanoscale substances.²⁵ However, such regulation can happen only through the issuance of a SNUR, for certain nanomaterials and for certain uses. The result is that currently, most nanomaterials enter into commercial applications without government oversight.

2. INTEREST ORGANIZATIONS, TSCA, and NANOMATERIALS

Since most nanomaterials are considered existing substances under TSCA, different interest organizations are raising questions about the ability of existing frameworks, such as TSCA, to regulate nanotechnology adequately.

The following two sections explore the perceived problems and proposed solutions from the perspective of each of the three interest organizations. Through this exploration two observations are made: 1) all three organizations identify the same problems with TSCA, but they propose different solutions; and 2) the policies proposed by each organization are connected to the basic differences that the three exhibit as a result of audience, mission, and advocacy style.

One of the main questions at the root of this investigation explores whether TSCA is a good regulatory framework for nanomaterials. According to Richard Denison, a senior scientist with EDF, for EPA to take any regulatory action under TSCA, the agency must first prove that a chemical “presents or will present an unreasonable risk or injury to health or the environment. Since 1976 EPA has done that for only five substances.”²⁶ All three organizations identify the same problems with TSCA and EPA: the first refers to three exemptions that give manufacturers the right not to disclose information to EPA. These exemptions make the regulation of nanomaterials

²⁵ U.S. Environmental Protection Agency, “TSCA Inventory Status of Nanoscale Substances.”

²⁶ Richard Denison, “EPA Nano Authority under TSCA, Part 4: Can EPA Get Industry Data on ‘Existing’ Nanomaterials?” Environmental Defense Fund, 1 Jul. 2008, blogs.edf.org/nanotechnology/2008/07/01/epa-nano-authority-under-tsca-part-4-can-epa-get-industry-data-on-%E2%80%9Cexisting%E2%80%9D-nanomaterials/ (accessed 15 Jun. 2009).

especially difficult and include:

- * *The low-volume exemption (LVE) (this is the main issue with nanomaterials since it applies to chemical substances manufactured in quantities equal to or less than 22,000 pounds; nanomaterials are not manufactured in such big quantities);*
- * *The low-release/low-exposure exemption (LOREX) (manufacturers can argue that the substances they produce and use are maintained under circumstances of low release and exposure);²⁷ and*
- * *The confidential business information exemption (CBI) (manufacturers can argue that certain information is CBI, and therefore they do not have to submit it to the EPA).*

The second issue refers to the way new substances are regulated under TSCA. Even if nanomaterials are considered new substances, a PMN for a new substance does not have to contain any hazard data: only a few PMNs contain such data. In addition, the model currently used to estimate hazard is based on traditional chemistry that may or may not apply to nanomaterials; EPA also has only ninety days of opportunity to review a substance after a PMN has been submitted, which creates important time and data limitations. At the moment data for nanomaterials are not available, and EPA cannot prove that a substance poses unreasonable risk, since under TSCA, no data is interpreted to mean no risk.²⁸

The third issue concerns the way existing substances are regulated under TSCA. While the burden for EPA to regulate new substances is large, the burden for regulating existing materials is larger. The obstacles are greater since all the existing substances in the United States are grandfathered and are not subject to pre-manufacture or pre-market review: most nanomaterials are considered to be existing substances. What burdens must EPA meet to actually regulate the production, use, or disposal of an existing nanomaterial under TSCA? The Inventory Update Reporting program is the source of basic screening-level and exposure-related information on chemicals available to EPA, which EPA then uses to develop risk assessments on chemicals. Inventory Update Reporting takes place every five years and only for substances produced in amounts of more than 25,000 pounds;²⁹

27 Richard Denison, "EPA Nano Authority under TSCA, Part 2: 'New' Isn't Necessarily All That Better," Environmental Defense Fund, 27 May 2008, blogs.edf.org/nanotechnology/2008/05/27/epa-nano-authority-under-tsca-part-2-%E2%80%9Cnew%E2%80%9D-isn%E2%80%99t-necessarily-all-that-better/ (accessed 15 Jun. 2009); Davies, 2006 "Managing the Effects of Nanotechnology." Woodrow Wilson International Center for Scholars: PEN, 2006., http://www.nanotechproject.org/process/assets/files/2708/30_pen2_mngeffects.pdf (accessed 19 Jun. 2009)

28 Denison, "EPA Nano Authority under TSCA, Part 2."

29 U.S. Environmental Protection Agency, "Inventory Update Reporting (IUR)," www.epa.gov/oppt/iur/ (accessed 2 Oct. 2009).

nanomaterials are not produced in such large quantities. At the same time, all of the previously mentioned exemptions (LVE, LOREX, and CBI) apply.

As a result most nanomaterials will be missed by TSCA's current reporting mechanisms.³⁰

In order to fill in these regulatory gaps EPA established a working group in 2005 to address the risk issues posed by nanomaterials, with Richard Denison representing EDF. The group's proposal was a framework for a voluntary program known as the Nanoscale Materials Stewardship Program (NMSP), which the EDF supported as a temporary measure until mandatory regulations were in place but now no longer supports.³¹ NMSP encourages manufacturers to submit and develop information, including risk-management practices for nanoscale materials, so EPA can make firmer regulatory decisions for nanomaterials.³²

In 2007, however, EDF was disappointed with NMSP's regulatory ability; according to EDF the program established no deadlines and no regulatory backstop. By this point it was too late for voluntary programs to be helpful because EPA had developed them without any intention of backing them up with mandatory rules.³³ As a result of NMSP's deficiency Denison argued in 2008 that "we are nowhere near having even a basic understanding of the nature and extent of nanomaterial-related activity in the U.S."³⁴

FoE representatives also argued that NMSP fell short of the expectations for regulating nanomaterials.³⁵ The program lacked deadlines for participation, launch, and evaluation, and failed to require concurrent development of mandatory TSCA oversight measures. According to FoE, enforcing the NMSP as mandatory under TSCA will better ensure compliance from all nano industries and will work toward achieving the urgent goals outlined by EPA in the program concept paper.³⁶

³⁰ Richard Denison, "EPA Nano Authority under TSCA, Part 3: Can EPA Track 'Existing' Nanomaterials?" Environmental Defense Fund, 27 June 2008, blogs.edf.org/nanotechnology/2008/06/27/epa-nano-authority-under-tsca-part-3-can-epa-track-existing-nanomaterials/ (accessed 15 Jun. 2009).

³¹ Richard Denison, "Comments on EPA's 'Concept Paper for the Nanoscale Materials Stewardship Program under TSCA' and 'TSCA Inventory Status of Nanoscale Substances - General Approach,' in Response to the U.S. Environmental Protection Agency's Request for Comments Published in the Federal Register on 12 Jul. 2007 (72 FR 38083)," Environmental Defense Fund, 7 Sep. 2007, www.edf.org/documents/7010_ED_WrittenCommentsonEPANanoDoc09072007.pdf (accessed 19 Jun. 2009).

³² U.S. Environmental Protection Agency, "Nanoscale Materials Stewardship Program. Interim Report."

³³ Denison, "Comments on EPA's 'Concept Paper.'"

³⁴ Denison, "EPA Nano Authority under TSCA, Part 4."

³⁵ Friends of the Earth, "Out of the Laboratory and onto Our Plates."

³⁶ International Center for Technology Assessment and Friends of the Earth, 'Joint ICTA-FoE Comments on EPA's 'Concept Paper for Nanoscale Materials Stewardship Program (NMSP) under TSCA' and 'TSCA Inventory Status of Nanoscale Substances - General Approach,' Federal Register notice, 12 Jul. 2007, http://www.icta.org/doc/Joint%20Comments%20on%20EPA%20TSCA%20voluntary%20program_9_10_07_FINAL.pdf. (accessed 19 Jun. 2009).

PEN, however, advocates some voluntary frameworks, such as the EDF-DuPont framework. But in the case of NMSP, PEN appeared as disappointed as the other two organizations. In an article titled “Too Small to Overlook,” published in *Nature* in 2009, PEN’s director, David Rejeski, and its chief science adviser, Andrew Maynard, state the failure of NMSP quantitatively. By the end of 2008 the NMSP had received only 29 submissions, covering 123 different nanoscale materials. This number of nanomaterials covers only 10 percent of the nanomaterials in commerce.³⁷

According to all three organizations TSCA has serious deficiencies that make it almost impossible for the framework to regulate nanomaterials and ultimately toxic chemicals in general. Further, the EPA has offered inadequate solutions for overcoming these deficiencies. Not only the law (TSCA) falls short in regard to the U.S. regulation of nanomaterials, but EPA does as well. Even though TSCA has some useful tools, like the SNUR, for regulating nanomaterials, EPA either has limited authority or a limited desire to use those tools. In addition, to overcome these regulatory deficiencies EPA has proposed and developed voluntary programs, but they fall short of resolving the problems.

3. REGULATORY GOALS and TSCA REFORM

All three organizations argue that TSCA does not regulate nanomaterials adequately and that beyond the first step of recognizing nanomaterials as new substances, further reform is needed. Viewpoints differ, however, on how to classify which chemicals count as “nano.”

EDF uses the broadly accepted definition for nanomaterials: particles with the size of 1 to 100 nanometers. Even though PEN and FoE mention the same definition in their posts and reports, both seek to modify and expand that definition.

In a 2007 PEN report Davies points out the complexity of classifying nanomaterials: “For single-walled carbon nanotubes (and there are other types of nanotubes), there are 20 different structural types, and their lengths can vary from 5 to 300 nanometers.”³⁸ Therefore, classifying nanomaterials simply as being 1 to 100 nanometers in size does not work. And FoE claims that when it comes to regulation, “all particles up to 300 nm in size must be considered to be ‘nanomaterials’ for the

³⁷ U.S. Environmental Protection Agency, “Nanoscale Materials Stewardship Program: Interim Report”; Andrew Maynard and David Rejeski, “Too Small to Overlook,” *Nature* 460:9 (2009), 174.

³⁸ Clarence Davies, “EPA and Nanotechnology: Oversight for the 21st Century,” Woodrow Wilson Center for Scholars, Project on Emerging Technologies, 2007, p. 23, www.nanotechproject.org/publications/archive/epa_nanotechnology_oversight_for_21st/ (accessed 19 Jun. 2009).

purposes of health and environmental assessment, given the early evidence that they pose similar health risks as particles less than 100 nm in size which have to date been defined as ‘nano.’”³⁹ Beyond the issue of nano classification, however, the three organizations differ in the solutions they propose with regard to nanotechnology regulation and TSCA reform. So how do the different organizations frame potential solutions?

P r o j e c t o n E m e r g i n g N a n o t e c h n o l o g i e s

In PEN’s four published reports on nanotechnology regulation Davies suggests a multi-agency approach that would involve a new law and specific provision for nano: a framework where more than one agency coordinates policies and responsibilities in order to regulate nanotechnology research and products.⁴⁰ Although this kind of framework might work, nanotechnology poses greater challenges, as it applies to a broader range of product types. For example, the Nanoscale Science, Engineering, and Technology subcommittee, as part of the National Science and Technology Council’s Committee on Technology, could include regulatory and policy issues in their R&D framework, but according to Davies, “it would be easier, politically and substantively, to draft and enact a new law focused on nanotechnology.”⁴¹ Davies, however, does not advocate a new law focused specifically on nanomaterials in his later reports.

Instead, since TSCA is currently the most meaningful of the existing laws that can apply to nanomaterials, the first steps in regulating nanomaterials, according to Davies’s more recent reports, should involve changes to accommodate the regulatory capability of TSCA and EPA. Thus, under TSCA, nanomaterials should be considered new chemical substances, and EPA should develop a SNUR that covers all nanomaterials. In regard to voluntary programs Davies states they can be useful in including small manufacturers that would otherwise be excluded in regulatory procedures.⁴²

At the same time, there must be internal and external cooperation with EPA and other agencies, such as the FDA, the Occupational Safety and Health Administration, the Consumer Product Safety Commission, and the U.S. Department of Agriculture.⁴³ For example, EPA should have the power to require testing of substances in order to clarify that absence of data is sufficient evidence that the substance may present an

³⁹ Friends of the Earth, “Out of the Laboratory and onto our Plates.”

⁴⁰ Davies, “Managing the Effects of Nanotechnology.”

⁴¹ *Ibid.*, p. 17.

⁴² Davies, “EPA and Nanotechnology: Oversight for the 21st Century”; C. Davies, “Nanotechnology Oversight: An Agenda for the Next Administration,” Woodrow Wilson Center for Scholars, Project for Emerging Technologies, 2008, www.nanotechproject.org/publications/archive/pen13/ (accessed 19 Jun. 2009).

⁴³ Davies, “EPA and Nanotechnology: Oversight for the 21st Century.”

unreasonable risk. More specifically, manufacturers should “report on the uses, risks, amount manufactured, by-products, and other information about a chemical or a category of chemicals.”⁴⁴ In addition, EPA should have greater power to share CBI.⁴⁵

For the future, Davies continues to support the idea of a new law that would provide an adequate oversight of nanotechnology. This new law should be focused on products, “because the same substance will have widely different impacts depending on the products in which it is used.”⁴⁶

According to Davies a law focused on products would be more effective than the current system because such a law would increase the focus on the way a material will be used and how it will be combined with other materials. ⁴⁷

Davies also states that a product law is an effective solution for the future for all chemicals because it could lead to more efficient risk assessments.⁴⁸ As for TSCA, he argues that the law is a valuable tool if it is reformed, but that regardless TSCA is deficient and even a rewritten TSCA will not be able to regulate efficiently.⁴⁹ In addition, even though he recognizes that TSCA needs to be reformed for all chemicals, Davies argued in a 2009 congressional hearing that the problem is that “the United States is trying to deal with 21st century problems using mid-20th-century tools.”⁵⁰ One of the reasons why TSCA is falling short in regulating nanomaterials is that the law was not developed with nanotechnology in mind.⁵¹ As a result a new regulatory framework focused on products might be the best solution to oversee nanomaterials and protect the public and the environment.

E n v i r o n m e n t a l D e f e n s e F u n d

EDF takes a broader approach to TSCA reform by stating that the United States is the only western country that has failed to ban chemicals already banned elsewhere,

44 Ibid., Davies, “Nanotechnology Oversight: An Agenda for the Next Administration,” p. 62.

45 Davies, “EPA and Nanotechnology: Oversight for the 21st Century.”

46 Clarence Davies, “Oversight of Next Generation Nanotechnology,” Woodrow Wilson International Center for Scholars, Project on Emerging Technologies, 28 Apr. 2009 p. 22, www.nanotechproject.org/publications/archive/pen18/ (accessed 19 Jun. 2009).

47 Clarence Davies, “Oversight of Next Generation Nanotechnology.”

48 Clarence Davies, phone interview with the author, 1 Jul. 2009, CHF Philadelphia, PA.

49 Davies, “Nanotechnology Oversight: An Agenda for the Next Administration”; Davies, interview.

50 Clarence Davies, “Testimony: Subcommittee of Commerce, Trade, and Consumer Protection, Committee of Energy and Commerce. Washington, DC: U.S. House of Representatives, 26 Feb. 2009 http://energycommerce.house.gov/Press_111/20090226/testimony_davies.pdf (accessed 19 Jun. 2009).

51 Davies, testimony to U.S. Senate Committee on Commerce, Science, and Transportation, hearing on “Developments in Nanotechnology,” Washington DC, 15 Feb. 2006, p. 4 <http://www.rff.org/RFF/Documents/davies-senate-nanotech-testimony.pdf> (accessed 19 Jun. 2009).

such as in China, and that continues to regulate substances under a law more than thirty years old.⁵² The problem with nanotechnology regulation, according to EDF, is not that the law was developed without nanotechnology in mind but that the law is not efficiently regulating toxic chemicals in general. EDF does not advocate a nano-specific law but instead argues for a careful consideration of the special features of nanomaterials and the provision for incorporating their appropriate regulation into the broader process of bringing TSCA into the twenty-first century.⁵³

Among EDF's main recommendations is the identification of chemicals based on their hazard or exposure characteristics and not just on risk.⁵⁴

EDF also asserts that EPA should have more power to initiate action in cases presenting less than absolute evidence of harm and should not have to prove potential or actual risk to require data on certain substances from industry. Further, according to Denison, EPA “should be able to impose controls that address potential harm as well as uncertain, but potentially significant, harm.”⁵⁵ EDF suggests that chemical manufacturers be responsible for demonstrating that their products are safe in order to introduce and maintain them in the market. At the same time, EPA should have the authority to request submission of minimum data sets of all chemicals, both new and existing.

As a first step toward better regulation for nanomaterials, EDF argues that nanomaterials should be considered new chemicals under TSCA and that until and unless the exemptions mentioned previously (LVE and LOREX) are appropriately revised, nanomaterials should be ineligible for such exemptions.⁵⁶ Beyond that, however, Denison and EDF argue for a broader scope that goes beyond the need to reform TSCA for nanomaterials: they demand reform for all chemicals. While EDF thinks that other environmental organizations’ proposals are excellent, it argues that there is no point in forgetting the other chemicals. A better regulatory framework for all toxic chemicals, developed on the principles of transparency and data collection, will be enough to regulate nanotechnology if some of the specific characteristics of

⁵² Richard Denison, testimony at hearing on “Revisiting the Toxic Substances Control Act of 1976,” U.S. House of Representatives, Committee on Energy and Commerce, Subcommittee of Commerce, Trade, and Consumer Protection, Washington, DC, 26 Feb. 2009, www.edf.org/documents/9295_Denison_testimony_Toxics_Act.pdf (accessed 19 Jun. 2009).

⁵³ Richard Denison, “EPA Nano Authority under TSCA, Part 5: Can EPA Regulate ‘Existing’ Nanomaterials?” Environmental Defense Fund, 2 July 2008, blogs.edf.org/nanotechnology/2008/07/02/epa-nano-authority-under-tscA-part-5-can-epa-regulate-%E2%80%9Cexisting%E2%80%9D-nanomaterials/ (accessed 15 Jun. 2009).

⁵⁴ Richard Denison, “Ten Essential Elements in TSCA Reform,” *Environmental Law Reporter* 39 (2009), 10,020–10,028.

⁵⁵ Denison, testimony, “Revisiting the Toxic Substances Control Act of 1976.”

⁵⁶ Denison, “EPA Nano Authority under TSCA, Part 2.”

nanomaterials are included.

REACH (Regulation, Evaluation, Authorization, and Restriction of Chemicals), for example, is the new regulatory framework for bulk chemicals that was implemented in the European Union in 2007. This framework, which uses the precautionary principle as a foundation, requires action to be taken when chemicals pose possible threats to human health and the environment instead of waiting for complete scientific proof of cause and effect. REACH also shifts the burden of proof to manufacturers, who have to demonstrate to the best of their ability the safety of their products before they can be released to the market.

In structuring REACH in this way the European Commission acknowledges that industry has not only the burden but also the ability to generate data to ensure the safety of their products.⁵⁷ According to Denison, REACH was not developed with nanotechnology in mind but can regulate it more effectively.⁵⁸

In contrast to TSCA, under REACH, chemical substances are classified as “phase-in” and “non-phase-in.” Phase-in substances are already listed in the European Inventory of Existing Commercial Chemical Substances. Non-phase-in substances can be broadly defined as the “new” substances, meaning they have not been manufactured, placed on the market, or used in the European Union before 1 June 2008. Both phase-in and non-phase-in substances are evaluated for risk assessment. In this way the law achieves the regulation of existing chemicals that did not receive attention under the previous law or under TSCA in the United States.⁵⁹

With regard to nanomaterials, in the case of REACH, as in TSCA, scale has not been used to characterize chemical substances. Additionally, the fact that a substance has different properties cannot be used as the only factor to decide whether or not a chemical is a new substance.⁶⁰ Currently, most nanomaterials are considered phase-in substances under REACH. EDF seems to support the development of a regulatory framework like REACH and proposed the Kids-Safe Chemicals Act of 2008 as a first step toward that style of regulation.⁶¹ In brief, the Kids-Safe Chemicals Act is both

⁵⁷ European Commission Environment DG, “Reach in Brief,” European Commission, Oct. 2007, ec.europa.eu/environment/chemicals/reach/pdf/2007_02_reach_in_brief.pdf (accessed 9 Apr. 2009).

⁵⁸ Richard Denison, “Fixing TSCA for Nano: Don’t Forget All the Other Chemicals!” Environmental Defense Fund, 28 July 2008, blogs.edf.org/nanotechnology/2008/07/28/fixing-tsca-for-nano-dont-forget-all-the-other-chemicals/ (accessed 30 Jun. 2009).

⁵⁹ *Ibid.*

⁶⁰ European Commission, “Follow-Up to the 6th Meeting of the REACH Competent Authorities for the implementation of Regulation (EC) 1907/2006 (REACH),” European Commission, Brussels, 15–16 Dec. 2008, ec.europa.eu/environment/chemicals/reach/pdf/nanomaterials.pdf (accessed 12 Apr. 2009).

⁶¹ Kids-Safe Chemicals Act, 110th Congress, 2nd Session, S. 3040, U.S. Senate, Washington, DC, 20 May 2008, www.govtrack.us/congress/billtext.xpd?bill=s110-3040 (accessed 19 Jun. 2009).

an addition and a reform to TSCA: the bill proposed the development of a stricter safety standard that takes into account the fact that children, workers, and consumers are most sensitive to chemical exposure. The bill is much stricter than TSCA and gives EPA power to request comprehensive risk, hazard, and life-cycle information for both new and existing substances. EDF believes that by controlling all chemicals effectively, the United States will be able to better regulate nanomaterials as well.⁶²

F r i e n d s o f t h e E a r t h

FoE, unlike the other two organizations, requests partial moratoria on products containing nanomaterials, according to Ian Illuminato, the organization's health and environment campaigner.⁶³ FoE believes that TSCA should authorize EPA to prevent the release of nanomaterials into the environment until more is known.⁶⁴ More specifically, in the case of nanosilver, a substance regulated by the Federal Insecticide, Fungicide, and Rodenticide Act, the organization argues that "in the interim and the long-term the precautionary principle should be applied and all products containing nanosilver should be removed from the market for the time being."⁶⁵ Beyond that, using the reports developed by Davies for PEN,⁶⁶ FoE argues that even if NMSP, the voluntary program developed by EPA to help regulate nanomaterials, is made mandatory, "without further statutory or regulatory change the amount of oversight EPA can provide is limited due to the inherent weaknesses and outdated nature of the law."⁶⁷

FoE also argues that EPA should develop a nanomaterial inventory and tracking system.⁶⁸ FoE agrees with PEN and EDF that all nanomaterials should be declared "new" chemical substances under TSCA and as a result should require a pre-manufacture notification (PMN) and review accompanied by toxicity testing for nanomaterials intended for commercial use. FoE also argues that "EPA has legal powers to compel nano-agrochemical manufacturers to provide toxicity data and to demonstrate product safety—that is, to place the burden of proof on the manufacturers."⁶⁹

⁶² Denison, "Fixing TSCA for Nano: Don't Forget All the Other Chemicals!"

⁶³ Ian Illuminato, phone interview with the author, 28 July 2009 CHF Philadelphia, PA.

⁶⁴ International Center for Technology Assessment and Friends of the Earth, "Joint ICTA-FoE Comments."

⁶⁵ Senjen and Illuminato, "Nano and Biocidal Silver."

⁶⁶ Davies, "EPA and Nanotechnology: Oversight for the 21st Century."

⁶⁷ Senjen and Illuminato, "Nano and Biocidal Silver."

⁶⁸ International Center for Technology Assessment and Friends of the Earth, "Joint ICTA-FoE Comments."

⁶⁹ Davies, "EPA and Nanotechnology: Oversight for the 21st Century"; Friends of the Earth, "Out of the Laboratory and onto our Plates," p. 43.

FoE also suggests that EPA must act in accordance with the principles of oversight for nanotechnologies and nanomaterials.⁷⁰ These principles include

*1) a precautionary foundation, 2) mandatory nanospecific regulations, 3) health and safety of the public and workers, 4) environmental protection, 5) transparency, 6) public participation, 7) inclusion of broader impacts, and 8) manufacturer liability.*⁷¹

Further, oversight of nanomaterials must be based on an open and full assessment of the adequacy of current regulatory mechanisms and the adoption—with meaningful public participation—of a more comprehensive, mandatory, and robust regulatory system based on producer responsibility for the life-cycle impacts of nanomaterials.⁷²

But FoE also believes that TSCA, even if reformed, cannot regulate nanomaterials efficiently. Consequently, FoE reports focus more on products and materials that fall under other agencies and acts. FoE representatives also argue that these very novel technologies should be assessed in new ways and that currently TSCA has neither the technical nor the technological abilities to provide assessment resources. FoE argues that ultimately a new framework has to move away from TSCA. In a recent interview Illuminato asserts that parts of TSCA are still usable, but a completely new regulatory package and a restructuring of the regulatory agencies are necessary. Currently the agencies do not have the expertise or the budget to truly assess these products.⁷³

⁷⁰ International Center for Technology Assessment and Friends of the Earth, “Joint ICTA-FoE Comments.”

⁷¹ International Center for Technology Assessment, “Declaration: Principles for the Oversight of Nanotechnologies and Nanomaterials,” Washington, DC, 2008, www.nanoaction.org/nanoaction/page.cfm?id=223 (accessed 19 Jun. 2009).

⁷² International Center for Technology Assessment and Friends of the Earth, “Joint ICTA-FoE Comments.”

⁷³ Illuminato, interview.

CONCLUSIONS

According to the three interest organizations, TSCA must be reformed in order to adequately regulate nanomaterials. Even though these organizations identify the same problems with the present form of TSCA, they propose different solutions for resolving these issues, and their positions on nanotechnology regulation and TSCA reform differ according to each organization's audience, mission, and style of advocacy.

FoE is a grassroots organization and needs the public's support to achieve its goals of regulatory reform. As the most radical of the three organizations, FoE requests partial moratoria of nano-products until more is known about the posed risks and until adequate regulations are in place. According to FoE, TSCA does not cover nanomaterials and, even when reformed, will not protect the public. REACH is not the most appropriate model either because it is neither strict nor specific enough for nanomaterials; as a result a new product law is necessary for the adequate protection of the public and the environment.⁷⁴ This framework, however, should also be free of voluntary programs and be based on a broader definition of the size of the materials to be considered nano.⁷⁵

EDF is not a grassroots organization; it has a public base but does not engage the public in its activities. Instead EDF works through partnerships with the government and industry, such as DuPont, to achieve reform for the regulation of nanomaterials and all chemicals.⁷⁶ EDF believes that TSCA reforms could use REACH as a model and does not advocate a new nano-specific law. EDF also argues that the reform of TSCA should be for all chemicals, bulk and nano.⁷⁷ This kind of reform should be

⁷⁴ Illuminato, interview.

⁷⁵ International Center for Technology Assessment and Friends of the Earth, "Joint ICTA-FoE Comments"; Friends of the Earth, "Out of the Laboratory and onto our Plates."

⁷⁶ Denison, "Fixing TSCA for Nano: Don't Forget All the Other Chemicals!"

⁷⁷ Denison, "EPA Nano Authority under TSCA, Part 5."

accommodated by a mutual trust between the government and the industry: a trust that can be built through voluntary frameworks, such as the six-step framework with DuPont, which addresses the potential risks of nanomaterials in order for industry to engage in safer practices.⁷⁸

PEN does not have a public base but rather a team of experts focusing primarily on responsible research and the development of nanotechnology. The organization advocates a new, product-oriented law as the best solution, so that the public can benefit from the uses of nanotechnology. A reform of TSCA that includes nanomaterials might serve as a starting point.⁷⁹ Toward that goal PEN, unlike EDF, believes that REACH may not be the best example to follow as a starting point for a reformed or a new law. The precautionary principle on which it is based is a vague idea and may not serve the purposes of regulating and developing nanotechnology adequately. Even though PEN argues that voluntary programs do not seem to work, these programs might serve some purpose in developing a relationship of trust between the industry and the government and in including small manufacturers that otherwise would not be included in the regulatory procedures.⁸⁰

The three organizational approaches to nanotechnology regulation differ according to their distinct origins, cultures, and missions. EDF is an environmental organization with a long history in chemical regulation-advocacy activities and with successes in this area. It has the expertise and the power to expand the debate for the reform of TSCA for nanomaterials to a reform for all chemicals. FoE, however, is a grassroots organization with a long history in environmental-protection activities but not in chemical regulation.

FoE has no strong connections to political or governmental regimes but has a strong public base from which its power springs. By including the public FoE makes a strong case for the protection of the public health and the environment; this is an important regulatory issue that has been the focus of governments, industries, and scientists. Finally, PEN is a think tank, developed for facilitating and promoting responsible research and development for nanotechnologies. As a result activities focus on creative scientific development for nanomaterials that will protect the public health and the environment but at the same time can be mutually beneficial.

Discussions on the reform of TSCA for nanomaterials were ongoing before 2008, though the kinds of reform that will take place have yet to be seen. All proposals for TSCA reform suggested by the three interest organizations, however, are equally valid

⁷⁸ Nano Risk Framework. "A Partnership of Environmental Defense Fund and DuPont."

⁷⁹ Davies, "Oversight of Next Generation Nanotechnology"; Davies, interview.

⁸⁰ Davies, interview.

and important, and they keep the critical debate on regulation open. Between the

** partial moratoria for products containing nanomaterials (until more is known about the posed risks) that FoE advocates,⁸¹*

** the need for responsible research and development of nanotechnology that PEN advocates,⁸²*

** and the need to readdress the issue of TSCA's deficiency to regulate all chemicals through the nanotechnology regulation debate that EDF advocates,⁸³*

there is a strong chance that the regulation of nanomaterials and the reform of TSCA will lead to a framework that will successfully provide oversight for nanotechnology research and development and can ultimately protect the public health and the environment.

⁸¹ Illuminato, interview.

⁸² Project on Emerging Nanotechnologies, 2009.

⁸³ Denison, "Fixing TSCA for Nano: Don't Forget All the Other Chemicals!"

REFERENCES

- Alwood, Jim. "Nanotechnology Update." GlobalChem 2009, 8 Apr. 2009. jim-alwood-globalchem-nano-update-0320.pdf (accessed 26 Nov. 2009).
- Davies, J. Clarence. "EPA and Nanotechnology: Oversight for the 21st Century." Woodrow Wilson International Center for Scholars, Project on Emerging Technologies, 2007. www.nanotechproject.org/publications/archive/epa_nanotechnology_oversight_for_21st/ (accessed 19 Jun. 2009).
- . Phone Interview with the author. 1 July 2009 CHF Philadelphia, PA.
- . "Managing the Effects of Nanotechnology." Woodrow Wilson International Center for Scholars, Project on Emerging Technologies, Washington, DC, Jan. 2006. www.nanotechproject.org/publications/archive/managing_effects_nanotechnology/ (accessed 19 Jun. 2009).
- . "Nanotechnology Oversight: An Agenda for the Next Administration." Woodrow Wilson International Center for Scholars, Project on Emerging Technologies, 2008. www.nanotechproject.org/publications/archive/pen13/ (accessed 19 Jun. 2009).
- . "Oversight of Next Generation Nanotechnology." Woodrow Wilson International Center for Scholars, Project on Emerging Technologies, 28 Apr. 2009. www.nanotechproject.org/publications/archive/pen18/ (accessed 19 Jun. 2009).
- . Testimony to U.S. House of Representatives, Committee of Energy and Commerce, Subcommittee of Commerce, Trade, and Consumer Protection. Washington, DC, 26 Feb. 2009. <http://www.rff.org/RFF/Documents/davies-senate-nanotech-testimony.pdf> (accessed 19 Jun. 2009).
- . Testimony to U.S. Senate Committee on Commerce, Science and Transportation. Hearing on "Developments in Nanotechnology," Washington DC, 15 Feb. 2006. <http://www.rff.org/RFF/Documents/davies-senate-nanotech-testimony.pdf> 19 Jun. 2009. (accessed 19 Jun. 2009)
- Denison, Richard. "Comments on EPA's 'Concept Paper for the Nanoscale Materials Stewardship Program under TSCA' and 'TSCA Inventory Status of Nanoscale Substances—General Approach,' in Response to the U.S. Environmental Protection Agency's Request for Comments Published in the Federal Register on 12 July 2007 (72 FR 38083)." Environmental Defense Fund, 7 Sept. 2007. www.edf.org/documents/7010_ED_WrittenCommentsonEPANanoDocs09072007.pdf (accessed 19 Jun. 2009).
- . "EPA Nano Authority under TSCA, Part 2: 'New' Isn't Necessarily All That Better." Environmental Defense Fund, 27 May 2008. blogs.edf.org/nanotechnology/2008/05/27/epa-nano-authority-under-tsca-part-2-%E2%80%9Cnew%E2%80%9D-isn%E2%80%99t-necessarily-all-that-better/ (accessed 15 Jun. 2009).

- . “EPA Nano Authority under TSCA, Part 3: Can EPA Track ‘Existing’ Nanomaterials?” Environmental Defense Fund, 27 June 2008. blogs.edf.org/nanotechnology/2008/06/27/epa-nano-authority-under-tsca-part-3-can-epa-track-existing-nanomaterials/ (accessed 15 Jun. 2009).
- . “EPA Nano Authority under TSCA, Part 4: Can EPA Get Industry Data on ‘Existing’ Nanomaterials?” Environmental Defense Fund, 1 July 2008. blogs.edf.org/nanotechnology/2008/07/01/epa-nano-authority-under-tsca-part-4-can-epa-get-industry-data-on-existing-nanomaterials/ (accessed 15 Jun. 2009).
- . “EPA Nano Authority under TSCA, Part 5: Can EPA Regulate ‘Existing’ Nanomaterials?” Environmental Defense Fund, 2 July 2008. <http://blogs.edf.org/nanotechnology/2008/07/02/epa-nano-authority-under-tsca-part-5-can-epa-regulate-existing-nanomaterials/> (accessed 15 Jun. 2009).
- . “Ten Essential Elements in TSCA Reform.” *Environmental Law Reporter* 39 (2009), 10,020–10,028.
- . Testimony at hearing on “Revisiting the Toxic Substances Control Act of 1976.” U.S. House of Representatives, Committee on Energy and Commerce, Subcommittee of Commerce, Trade, and Consumer Protection. Washington, DC, 26 Feb. 2009. www.edf.org/documents/9295_Denison_testimony_Toxics_Act.pdf (accessed 19 Jun. 2009).
- . “Fixing TSCA for Nano: Don’t Forget All the Other Chemicals!” Environmental Defense Fund, 28 July 2008. [/2008/07/28/fixing-tsca-for-nano-dont-forget-all-the-other-chemicals/](http://www.edf.org/documents/2008/07/28/fixing-tsca-for-nano-dont-forget-all-the-other-chemicals/) (accessed 30 Jun. 2009).
- Environmental Defense Fund. <http://www.edf.org/home.cfm> (accessed 5 Jun. 2009).
- . June 2007. “Environmental Defense’s Activities on Nanotechnology.” http://www.edf.org/documents/6594_nano_summary.pdf (accessed 30 Jun. 2009).
- Environmental Defense and American Chemistry Council Nanotechnology Panel. 23 June 2005. “Joint Statement of Principles.” www.edf.org/documents/4857_ACC-ED_nanotech.pdf (accessed 2 Jul. 2009).
- European Commission. “Follow-up to the 6th Meeting of the REACH Competent Authorities for the implementation of Regulation (EC) 1907/2006 (REACH).” European Commission, 15–16 Dec. 2008. ec.europa.eu/environment/chemicals/reach/pdf/nanomaterials.pdf (accessed 12 Apr. 2009).
- European Commission Environment DG. “REACH in Brief.” European Commission, Oct. 2007. ec.europa.eu/environment/chemicals/reach/pdf/2007_02_reach_in_brief.pdf (accessed 9 Apr. 2009).
- Friends of the Earth. 2009. www.foe.org (accessed 2 Jun. 2009).
- . “Nanomaterials, Sunscreens, and Cosmetics: Small Ingredients, Big Risks.” FoE Australia and United States, May 2006. www.foeeurope.org/activities/nanotechnology/nanocosmetics.pdf (accessed 19 Jun. 2009).
- . “Out of the Laboratory and onto Our Plates: Nanotechnology in Food and Agriculture.” FoE Australia, Europe, and United States, Mar. 2008. www.foeeurope.org/activities/nanotechnology/Documents/Nano_food_report.pdf (accessed 19 Jun. 2009).
- Hess, David. “The Environmental, Health, and Safety Implications of Nanotechnology: Environmental Organizations and Undone Science in the United States.” *Science as Culture* 2010 (in press).
- Illuminato, Ian. Interview with the author. 28 July 2009 CHF Philadelphia, PA.

- International Center for Technology Assessment (ICTA). "Citizen Petition to the United States Food and Drug Administration." Washington, DC, 2006. www.icta.org/doc/Nano%20FDA%20petition%20final.pdf (accessed 19 Jun. 2009).
- . "Citizen Petition for Rulemaking to the United States Environmental Protection Agency." Washington, DC, 2008. www.icta.org/nanoaction/doc/CTA_nano-silver%20petition__final_5_1_08.pdf (accessed 19 Jun. 2009).
- . "Declaration: Principles for the Oversight of Nanotechnologies and Nanomaterials." Washington, DC, 2008. www.nanoaction.org/nanoaction/page.cfm?id=223 (accessed 19 Jun. 2009).
- International Center for Technology Assessment and Friends of the Earth (ICTA-FoE). Joint ICTA-FoE "Comments on EPA's 'Concept Paper for Nanoscale Materials Stewardship Program (NMSP) under TSCA' and 'TSCA Inventory Status of Nanoscale Substances—General Approach,'" Federal Register notice, 12 July 2007, http://www.icta.org/doc/Joint%20Comments%20on%20EPA%20TSCA%20voluntary%20program_9_10_07_FINAL.pdf (accessed 19 Jun. 2009).
- Kids-Safe Chemicals Act. 110th Congress, 2nd Session, S. 3040. U.S. Senate, Washington, DC, 20 May 2008. www.govtrack.us/congress/billtext.xpd?bill=s110-3040 (accessed 19 Jun. 2009).
- Los Alamos National Laboratory. "What Is Nanotechnology?" Nanotechnology at Los Alamos National Laboratory, 25 June 2002. www.lanl.gov/mst/nano/definition.html (accessed 5 Apr. 2009).
- Maynard, Andrew, and David Rejeski. "Too Small to Overlook." *Nature* 460:9 (2009), 174.
- Nano Risk Framework. "A Partnership of Environmental Defense Fund and DuPont." 2007. www.edf.org/documents/6496_Nano%20Risk%20Framework.pdf (accessed 2 Jul. 2009).
- National Nanotechnology Initiative. "Research and Development Leading to a Revolution in Technology and Industry." May 2009. http://nano.gov/NNI_2010_budget_supplement.pdf (accessed 20 Oct. 2009).
- Project on Emerging Nanotechnologies. 2009. www.nanotechproject.org/about/mission/ (accessed 15 Jun. 2009).
- Senjen, Rye, and Ian Illuminato. "Nano and Biocidal Silver: Extreme Germ Killers Present a Growing Threat to Public Health." FoE Australia and United States, June 2009. www.foe.org/sites/default/files/Nano-silverReport_US.pdf (accessed 19 Jun. 2009).
- U.S. Environmental Protection Agency. "Consent Orders and Significant New Use Rules (SNURS)." Washington, DC, 1 Oct. 2009. www.epa.gov/oppt/newchems/pubs/cnosnurs.htm (accessed 2 Dec. 2009).
- . "Instruction Manual for Reporting under the TSCA New Chemical Program (PMN)." Washington, DC, Feb. 2005. www.epa.gov/opptintr/newchems/pubs/tscaman2.pdf (accessed 2 Oct. 2009).
- . "Inventory Update Reporting (IUR)." Washington, DC. www.epa.gov/oppt/iur/ (accessed 2 Oct. 2009).
- . Office of Pollution Prevention and Toxics. "Nanoscale Materials Stewardship Program: Interim Report." Washington, DC, Jan. 2009. www.epa.gov/oppt/nano/nmsp-interim-report-final.pdf (accessed 19 Jun. 2009).
- . "Summary of the Toxic Substances Control Act." Washington, DC, 23 March 2008. www.epa.gov/lawsregs/laws/tsca.html (accessed 9 Apr. 2009).
- . "TSCA Inventory Status of Nanoscale Substances—General Approach." Washington, DC, 23 Jan. 2008. www.epa.gov/oppt/nano/nmsp-inventorypaper.pdf (accessed 9 Apr. 2009).

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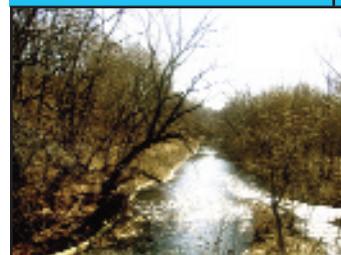
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