TSCA and Engineered Nanoscale Substances

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Introduction

Nanotechnology is now the subject of much excitement and attention, with applications proliferating quickly. Thus, engineered nanoscale materials' ("ENM") implications for human health and the environment, and the critical need for governments throughout the world to get the policy and regulatory framework right has garnered much attention. Most would agree that the ultimate goal for society is to enable nanotechnology to realize its potential while effectively addressing the pertinent environment, health, and safety ("EHS") issues associated with ENM.

Domestically, the Toxic Substances Control Act ("TSCA") is the federal environmental law most often mentioned in connection with regulating ENM. It provides the framework for the U.S. Environmental Protection Agency ("EPA") to manage new and existing chemical substances throughout their production, use, and disposal.[2] This Article considers several issues in connection with the application of TSCA to ENM. It does not propose comprehensive resolutions, but rather seeks to raise awareness and promote further discussion of these issues.

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Background on Nanotechnology

Nanotechnology, the "understanding and control of matter at dimensions of roughly 1 to 100 nanometers, where unique phenomena enable novel applications,"[3] is expanding rapidly. It is viewed broadly as encompassing many technologies that over time will generate many new products and applications. Lux Research, a nanotechnology research and advocacy firm, predicts that by 2014, products incorporating nanotechnology will constitute fifteen percent of global manufacturing output and will total $2.6 trillion.[4]

One of the key reasons governments and inter-governmental organizations around the world are focusing on nanotechnology is the lack of understanding in all cases regarding the EHS effects of exposure to ENM. Some believe that the information that exists warrants caution. The small size of certain nanoparticles facilitates their biological uptake into cells and their movement in the body more readily than is the case with their macro/bulk counterparts.[5] Other factors about nanoparticles contribute to a general sense of uncertainty regarding the health and environmental effects of exposure to ENM. ENM can have properties that do not conform to conventional physics and chemistry, potentially increasing risk.[6]

Set forth below is an overview of TSCA—the statute and EPA's implementing regulations—followed by a discussion of the key issues that have arisen regarding the application of TSCA to ENM and a review of EPA's TSCA-related nanotechnology initiatives to date.

TSCA Overview

Congress enacted TSCA in 1976 to protect human health and the environment from potentially harmful chemical substances and mixtures. The statute authorizes EPA to regulate "chemical substances,"[7] defined to mean "any organic or inorganic substance of a particular molecular identity."[8] EPA has explained that ENM "which meet the TSCA definition of 'chemical substance[]' are subject to TSCA."[9]

TSCA Section 8(b)(1) directs EPA to "compile, keep current, and publish a list of each chemical substance which is manufactured or processed in the United States."[10] This list is known as the TSCA Chemical Substance Inventory ("Inventory"). Chemical substances included on the Inventory are considered existing chemical substances for purposes of TSCA, while the statute expressly defines "any chemical substance which is not included [on the Inventory]" as a "new chemical substance."[11] Therefore, under TSCA, the government considers a chemical substance as an existing chemical substance or a new chemical substance. For ENM, this distinction is significant.

EPA published the initial Inventory in 1979 and continually updates it. EPA adds new chemical substances to the Inventory after a Premanufacture Notice ("PMN") and subsequent Notice of Commencement of Manufacture or Import ("NOC") have been submitted pursuant to TSCA Section 5.[12] As of early 2007, the Inventory listed approximately 83,000 chemical substances.[13]

EPA's PMN Authority

TSCA Section 5 governs the manufacture and import into the United States of new chemical substances, in addition to the

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manufacture, import, and processing of existing chemical substances for a use that the EPA determines to be a "significant new use."[14] New, but not existing, chemical substances are subject to the PMN requirement set forth in TSCA Section 5(a)(1)(A).[15] Unless a PMN exemption applies, a company must submit a completed PMN form to the EPA at least ninety days before commencing the manufacture or import of any new chemical substance.[16] Through the PMN review process, EPA assesses the new chemical and determines whether its manufacture, importation, processing, and/or distribution in commerce may present an unreasonable risk of injury to health or the environment.[17]

Exemptions from the PMN process are either "self-executing" or require prior EPA approval. Self-executing exemptions are those that take effect once an entity determines that the exemption applies, and the company can manufacture the new chemical substance in the United States without the need for a PMN, provided that they comply with any recordkeeping or other applicable requirements for the particular exemption. Self-executing PMN exemptions include the exemption for chemical substances with no separate commercial purpose,[18] the polymer exemption,[19] and the research and development ("R&D") exemption.[20]

Other exemptions from the PMN requirement require prior EPA approval. In those situations, entities must submit, and EPA must approve, an exemption application before the entity can commence manufacture of the new chemical, subject to compliance with any recordkeeping or other applicable requirements. PMN exemptions that require prior EPA approval include the low volume exemption ("LVE"),[21] the low release and low exposure exemption ("LoREX"),[22] and the test marketing exemption ("TME").[23]

The PMN exemptions of greatest importance to the emerging nanotechnology industry include the LVE, the LoREX, and the R&D exemption,[24] which appears to be uniquely well-suited for nanotechnology R&D undertaken by start-up companies, research laboratories, universities, and others. As noted above, the LVE and the LoREX require prior EPA review and approval.

The EPA bases eligibility for an LVE on the manufacture of a new chemical in quantities of 10,000 kilograms—approximately 22,000 pounds—or less per year, while it bases eligibility for a LoREX on meeting several regulatory criteria for release and exposure throughout the manufacture, processing, distribution, use, and disposal of the chemical.[25] Once EPA notifies an applicant that it granted the LVE or LoREX application, or if the thirty-day review period expires without notice from EPA, manufacture or import of the chemical substance may commence, consistent with the terms of the exemption.[26]

TSCA Section 5(e) authorizes EPA to issue administrative orders controlling new chemical substances when it finds, after review of a PMN, that insufficient information exists to permit a reasoned evaluation of the risk, and either the chemical may present an unreasonable risk to health or the environment, or it will be produced in substantial quantities that will enter the environment or to which there will be substantial or significant human exposure.[27] In an order, the EPA may ban or limit the manufacture, processing, distribution, use, or disposal of the chemical.[28] EPA must propose a Section 5(e) order prior to the expiration of the ninety-day PMN review period.[29] As a matter of practice, rather than acting unilaterally under Section 5(e), EPA typically enters into a consent order with a PMN submitter, under which the latter agrees to restrict the manufacture, processing, distribution, use, or disposal of the new chemical substance pending the development of data necessary to evaluate the potential hazards.

EPA's "Significant New Use" Authority

TSCA Section 5 authorizes EPA to review and assess the potential risks posed by significant new uses of existing chemical substances.[30] A significant new use rule ("SNUR") determines that a use is significant and new. [31] A Significant New Use Notice ("SNUN") is the form an entity must submit to EPA at least ninety days prior to any manufacture, import, or processing for that use.[32] Some have suggested that the co-location of EPA's SNUR authority and PMN requirement in the same statutory section is a clear indication that Congress intended EPA to regulate new chemicals and significant new uses of existing chemicals similarly.[33] In fact, the TSCA legislative history reveals that EPA's SNUR authority complements its PMN authority.[34]

A key distinction between EPA's PMN authority and its SNUR authority is that under the latter, EPA first must issue a SNUR, whereas with the former, both the statute and a generic implementing rule already mandate the submission of a PMN.[35] Once EPA issues a SNUR, the two provisions operate in much the same way, and a SNUN is submitted on the same form and contains virtually the same information as a PMN.

In promulgating a SNUR, EPA must explain how it considered all relevant factors, including the following factors specifically mentioned in the statute: "the projected volume of manufacturing and processing . . . the extent to which a use changes the type or form of exposure to human beings or the environment . . . the extent to which a use increases the magnitude and duration of exposure of human beings or the environment . . . and . . . the reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal."[36] EPA need not make a legal finding with respect to the potential harm that the existing chemical may pose, but rather, EPA need only consider the relevant factors.[37]

Importantly for present purposes, EPA is authorized to issue SNURs for categories of chemical substances.[38] The term "category of chemical substances" is defined as "a group of chemical substances the members of which are similar in molecular structure, in physical, chemical, or biological properties, in use, or in a mode of entrance into the human body or into the environment, or the members of which are in some other way suitable for classification as such for purposes of [TSCA]."[39] Thus, the criteria for qualifying as a category are extremely broad.

EPA's Authority under TSCA Section 8

TSCA Section 8 gives EPA broad information-gathering powers. These powers include the ability to impose recordkeep-

ing and reporting requirements for production, use, and exposure-related information under Section 8(a),[40] and requirements for the submission of "health and safety study" data under Section 8(d).[41] Pursuant to regulations issued by EPA under Section 8(c), manufacturers, importers, and processors of chemical substances must create and maintain records of allegations—whether written or oral—that a particular chemical "caused a significant adverse reaction to health or the environment."[42] A company must make its Section 8(c) records available for inspection by EPA at any time and submit them to EPA upon request.[43]

Section 8(e), the self-executing "substantial risk" reporting provision of TSCA, obligates manufacturers, processors, and distributors as follows:

> Any person who manufactures, processes, or distributes in commerce a chemical substance . . . and who obtains information which reasonably supports the conclusion that such substance . . . presents a substantial risk of injury to health or the environment shall immediately inform [EPA] of such information unless such person has actual knowledge that [EPA] has been adequately informed of such information.[44]

This reporting requirement is important and may have special significance for companies working with ENM. Historically, penalties for non-compliance with the Section 8(e)'s substantial risk reporting obligation have been severe, and the EPA collected its largest civil administrative penalty ever from alleged Section 8(e) reporting violations.[45]

Applicability of TSCA to ENM

Several of the key TSCA issues raised in connection with the application of TSCA to ENM include whether TSCA should regulate ENM consisting of Inventory-listed chemicals as "new chemical substances;" whether certain PMN exemptions are appropriate when applied to ENM; and whether TSCA's information-gathering and reporting provisions are sufficiently robust to address issues arising in connection with ENM.

ENM Consisting of Inventory-Listed Chemicals

Several well-respected organizations, including Environmental Defense ("ED") and the Natural Resources Defense Council ("NRDC"), have questioned whether TSCA is well-suited to manage potential EHS risks believed to be posed by ENM. These organizations have recommended that nanoscale versions of Inventory-listed chemicals be considered new chemical substances for purposes of TSCA Section 5.[46] As stated by ED, "engineered nanomaterials are 'new' substances under TSCA (and thus subject to PMN review), even where a material has a chemical structure that is identical to a substance already included on the Inventory, unless the nanomaterial's chemical and physical properties are demonstrably identical to an existing conventional substance with the same chemical structure."[47] In short, the argument is that because nanoscale versions of existing macro-scaled chemicals are designed to have novel and enhanced properties and/or characteristics that differ from the macro-sized counterparts, it is reasonable to conclude that the nanoscale versions may pose risks not associated with their conventional counterparts, such that the nanoscale versions should be considered new chemicals and thus subject to PMN review.

TSCA applies to ENM that meet the broad statutory definition of "chemical substance." Conceding that ENM, which are chemical substances, are subject to TSCA, the issue really is which TSCA provisions apply. Proponents of the argument that nanoscale versions of existing chemicals should be regulated as new substances claim this interpretation of TSCA is good public policy and could prevent any unintended adverse human health and environmental consequences that may be associated with ENM. They also assert that ENM are of interest precisely because they are new and special. Because these materials are believed to offer new features and added value, they should be subject to TSCA's new chemical review provisions.[48] A third argument offered is that the TSCA definition of "chemical substance" encompasses more than just a substance's molecular structure. ED, for example, claims nothing in TSCA expressly precludes the definition of "chemical substance" from including physical and chemical properties.[49]

The American Chemistry Council ("ACC") Nanotechnology Panel, on the other hand, claims that nanoscale versions of Inventory-listed substances are not new chemical substances for TSCA purposes and cannot be considered new based on the very definition of "chemical substance."[50] A "chemical substance" is defined by its "particular molecular identity," and the definition makes no mention of a substance's physical and chemical properties.[51] In ascertaining whether a particular substance appears on the Inventory, all that matters legally, according to the ACC Nanotechnology Panel, is whether, based on the substance's molecular identity, it is or is not listed on the Inventory.[52]

Additionally, the Panel claims that EPA's historic course of conduct has been to consider only a chemical substance's molecular identity, not its physical or chemical properties. This argument finds support in the ABA SEER Paper, which asserts "EPA's emphasis on molecular structure is reflected in the PMN review process."[53] The ABA SEER Paper continues:

> The initial steps of the PMN review process involve EPA establishing a complete and accurate chemical name for the substance and determining whether the chemical is already on the Inventory. If EPA determines, based on the chemical identity of the substance, that it is already on the Inventory, the PMN review ceases and the submitter is notified that the chemical can be manufactured in the U.S. This determination is made without any reference to the physical or chemical properties of the chemical.[54]

The ABA SEER Paper acknowledges that the statutory term "particular molecular identity" is "sufficiently flexible as to take into account physical properties or other defining characteristics in addition to molecular structure, at least to a limited degree," but it concludes "molecular structure is the definitive characteristic in most instances."[55]

Even if EPA announced that nanoscale versions of Inventory-listed chemicals are existing and not new chemicals for TSCA purposes (and as will be seen below, EPA is leaning

strongly in this direction), EPA nonetheless has broad authority under TSCA to consider any potential risks posed by nanoscale substances. The ABA SEER Paper emphasizes that, beyond the PMN requirement, EPA has broad authority under other provisions of TSCA to address potential risks posed by ENM.[56]

Key among the other provisions is EPA's SNUR authority. As indicated above, EPA can issue a SNUR, thereby triggering the need for companies to submit a SNUN.[57] TSCA Sections 5(a)(1)(B) and 5(a)(2) thus enable EPA to perform the same risk assessment and implement the same risk management controls on existing chemical substances engineered at the nanoscale that can be applied to new chemical substances through the PMN process.[58] SNUNs and PMNs use the same submission form, EPA Form 7710-25,[59] and both notices "undergo the same review process."[60] Notably, EPA is authorized to issue a Section 5(e) (or Section 5(f)) order for any chemical substance "with respect to which notice is required by [Section 5(a)]," and that notice can be either a PMN under Section 5(a)(1)(A) or a SNUN under Section 5(a)(1)(B).[61]

In promulgating a SNUR, EPA must consider all relevant factors, including the four factors listed in the statute. Of the four statutory factors discussed above, the latter three appear to be especially relevant to ENM.[62] EPA, however, is not restricted to the four statutory factors, and in fact "construes the statute to allow consideration of any other relevant factors."[63]

The ABA SEER Paper also points out that EPA is not limited to issuing SNURs for individual ENM. Given the great diversity that reportedly characterizes these materials, EPA's authority to issue a SNUR for a category or categories of existing ENM is important, particularly as the criteria for qualifying as a category are broad and may mean merely being "in some . . . way suitable for classification as such for purposes of [TSCA]."[64]

EPA nonetheless has broad authority under TSCA to consider any potential risks posed by nanoscale substances.

Appropriateness of Certain PMN Exemptions

The appropriateness of several of the PMN exemptions is also debated. ED, for example, has urged the EPA "not to apply mass-based, or other exemptions in the PMN program, unless the underlying scientific rationale is appropriate when applied to nanomaterials."[65] A key issue is the relevance of mass-based and volume-based criteria as applied to ENM, and whether these criteria could ever apply to ENM, which are in many cases unlikely to be produced in substantial quantities.

The appropriateness of the LVE in particular has been questioned on the grounds that the threshold level of 10,000 kilograms is too high, especially considering that few companies are expected in the near term to be producing ENM in amounts even approaching that level.[66] At first glance, the suitability of this PMN exemption may seem questionable, but a closer review may suggest otherwise. Because the exemption requires prior EPA approval, EPA's consideration of any potential risks posed by the ENM at issue can be expected to be comprehensive. In fact, EPA's review of a PMN exemption for a carbon nanotube, originally submitted as a LVE, but later converted to a LoREX, took approximately one year and likely consumed considerable EPA resources and generated no small amount of deliberation and scrutiny.[67]

Although the LVE allows certain new chemicals, including those falling into the category of ENM, to avoid the full panoply of PMN review, this does not mean EPA does not consider carefully the EHS implications of the candidate substance. Indeed, the level of scrutiny the EPA reportedly devoted to the LVE/LoREX application likely exceeded the degree of scrutiny typically reserved for conventional new chemicals reviewed under the PMN program.

Appropriateness of Reporting Obligations under TSCA Section 8

Whether certain TSCA information-gathering and reporting obligations, particularly Section 8(e), apply to ENM is another debated issue. EPA, however, has made it clear that the Section 8(e)'s substantial risk reporting obligation applies to all chemicals, including nanoscale materials consisting of chemical substances.[68] Hence, if a person learns that a nanoscale-sized version of an existing chemical substance poses hazards different from those associated with its bulk counterpart, and if that information reasonably supports the conclusion that the nanoscale-sized version presents a substantial risk of injury, then TSCA Section 8(e) requires reporting.[69]

Similarly, TSCA Section 8(c) reporting obligations apply to persons manufacturing, importing, processing, or distributing ENM in commerce. Such persons must maintain, and make available to the EPA for inspection, records of significant adverse reactions alleged to have been caused by the particular ENM. Under EPA's implementing regulations, this means that if anyone, including a company's employees, customers, or neighbors, makes a written or oral statement to the effect that an ENM caused a significant adverse effect, the company must maintain a record of that allegation.

EPA Nanotechnology Initiatives To Date

EPA is to be commended for its leadership, vision, and energy in exploring early and creatively the application of TSCA to ENM. Two regulatory initiatives are worthy of discussion.

TSCA PMN Decision Logic—EPA's Office of Pollution Prevention and Toxics ("OPPT") developed a decision logic that its staff applies in assessing ENM submitted to EPA for PMN review under TSCA Section 5, or as part of PMN exemption applications. Use of the logic is resulting in EPA's identifica-

tion of specific areas of inquiry unique to ENM. Primary among these areas are potential routes of exposure to workers and potential environmental releases. EPA is assessing the adequacy of personal protective equipment to prevent potential exposures to ENM during the manufacturing, processing, and/or distribution and use of these materials. EPA's decision logic is believed to distinguish between true ENM, meaning those materials that meet the criteria set out by the NNI, and those materials that fall within the size range of 1-100 nanometers, but are not specifically engineered with the intent to enable novel, size-dependent properties. According to published sources, EPA has, as of August 2006, reviewed fifteen new chemicals that were deemed to fall within the nanoscale size range, one of which, a carbon nanotube, possessed properties deemed unique and resulted in EPA's approval of a LoREX application in 2005.[70]

Now, the Inventory includes at least two new ENM. On June 9, 2006, and August 14, 2006, EPA issued *Federal Register* notices acknowledging the receipt of NOCs of siloxane-coated silica and siloxane-coated alumina nanoparticles.[71]

Nanoscale Materials Stewardship Program—In 2005, OPPT announced its interest in considering how best to obtain much-needed information on existing ENM, and convened a public meeting to discuss various options in June 2005.[72] The discussion at the public meeting yielded a consensus that a voluntary program on existing ENM would have significant value. Shortly thereafter, EPA created an Interim *Ad Hoc* Work Group on Nanoscale Materials ("Work Group") as part of the National Pollution Prevention and Toxics Advisory Committee ("NPPTAC"), a federal advisory group tasked with advising OPPT on TSCA and pollution prevention matters.[73] On November 22, 2005, after the Work Group had met several times, NPPTAC submitted to the EPA Administrator its *Overview Document on Nanoscale Materials*, which outlined a framework for an EPA approach to a voluntary program for ENM and a complementary approach to new chemical nanoscale requirements under TSCA, and addressed various other issues pertinent to ENM.[74]

On October 18, 2006, EPA Assistant Administrator James Gulliford sent a letter to stakeholders formally announcing the development of the Nanoscale Materials Stewardship Program ("NMSP") and inviting stakeholder participation in it.[75] Several months later, EPA simultaneously published three *Federal Register* notices related to the NMSP.[76] The first notice solicited public comment on EPA's proposed Information Collection Request under the Paperwork Reduction Act, including a draft form that NMSP participants could use to submit data to EPA;[77] the second announced a public meeting on the NMSP;[78] and the third solicited public comment on two draft documents: the "Concept Paper for the Nanoscale Materials Stewardship Program under TSCA" ("NMSP Concept Paper") and the "TSCA Inventory Status of Nanoscale Substances—General Approach" ("TSCA Inventory Paper").[79]

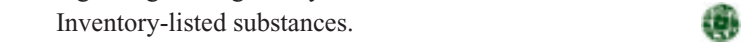
The draft NMSP Concept Paper outlined EPA's "initial thinking on the design and development" of the NMSP and explained that the program, in keeping with the Work Group's recommendations, would consist of two parts, a "Basic Program" and an "In-Depth Program."[80] The draft TSCA Inventory Paper "inform[ed] the public of the approach EPA has historically taken under TSCA in evaluating whether chemical substances are new, and further inform[ed] the public of EPA's intention to follow [the same] approach for nanomaterials that are chemical substances."[81] In the draft TSCA Inventory Paper, EPA explained that if a particular ENM has the same molecular identity as a non-nanoscale (*i.e.*, macro) substance that is listed on the TSCA Inventory, then the ENM is an existing chemical irrespective of its particle size and physical/chemical properties.[82] Thus, the TSCA Inventory Paper runs counter to the view expressed by ED, NRDC, and others, that nanoscale versions of Inventory-listed chemicals should be deemed new for purposes of TSCA Section 5.

The comment period for the NMSP documents closed on September 10, 2007, and EPA is now reviewing the various comments submitted.[83] It is clear that EPA intends to proceed with the NMSP, and EPA hopes to launch the program by the end of 2007. EPA has indicated that regulatory efforts under TSCA are unlikely to happen until after the NMSP is well underway, but a TSCA Section 8(a) information-gathering rule is possible, and perhaps even likely.

Conclusion

The debate over TSCA's application to ENM will continue for some time. The discussion above demonstrates that EPA has broad authority under TSCA, and that new legislation intended to address any potential risks that ENM might pose is unnecessary. EPA can review ENM under TSCA Section 5(a), either as new chemicals or as significant new uses of existing chemicals. EPA can conduct a comprehensive review of the exemptions from the PMN requirement. EPA can also collect information on and compel and enforce reporting obligations with respect to ENM.

EPA's stated commitment to issue final guidance on these issues will greatly assist the regulated community in understanding EPA's expectations regarding the submission of PMN and exemption applications for ENM and thus better prepare industry to undertake its TSCA compliance obligations consistently. In the interim, chemical manufacturers would be wise to consider carefully their TSCA compliance obligations, obtain legal advice when necessary, and seek EPA's thoughts early and often regarding the regulatory status of ENM believed to consist of Inventory-listed substances.



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[11] Corrosion Proof Fittings v. EPA, 947 F.2d 1201 (5th Cir. 1991).

[12] *Hearing before the U.S. Sen. Committee on Public Works*, 109th Cong. (Aug. 2, 2006) (testimony of William Rawson) ("TSCA is a well-crafted statute that has stood the test of time quite well.")

[13] Ernie Rosenberg, Presentation at the Bureau of National Affairs Teleconference: State Toxics Control Programs: Reaching Beyond TSCA (Dec. 18, 2006).

[14] SARA JANSSEN, HEALTHCARE WITHOUT HARM, BROMINATED FLAME RETARDANTS: RISING LEVELS OF CONCERN (June, 2005), *available at* http://www.noharm.org/details.cfm?ID=1095 (last visited Oct. 9, 2007).

[15] Council Directive 2002/95/EC, 2003 O.J. (L 037) 19 (EC).

[16] NATIONAL CAUCUS OF ENVIRONMENTAL LEGISLATORS, ENACTED LAWS, EXECUTIVE ORDERS, AND 2007 INTRODUCED BILLS: PBDE LEGISLATION (Aug. 13, 2007) [hereinafter NCEL].

[17] NCEL, *id.* (showing that in 2007 legislation to restrict deca-BDE was introduced in California, Connecticut, Hawaii, Illinois, Michigan, Minnesota, Montana, and New York).

[18] The Safer Alternatives Bill (H. 783/S. 558) focuses initially on ten chemicals or groups: lead, formaldehyde, trichloroethylene (TCE), perchloroethylene ("perc"), dioxins and furans, hexavalent chromium, organophosphate pesticides, 2,4-D herbicide, polybrominated diphenyl ethers (PBDEs), and diethylhexylphthalate (DEHP).

[19] ALLIANCE FOR A CLEAN AND HEALTHY MAINE, BODY OF EVIDENCE: A STUDY OF POLLUTION IN MAINE PEOPLE (June 2007), *available at* http://www.cleanandhealthyme.org/BodyofEvidence.pdf (last visited Nov. 17, 2007); JANE HOULIHAN ET AL., ENVIRONMENTAL WORKING GROUP, BODYBURDEN: THE POLLUTION IN NEWBORNS (July 14, 2005), *available at* http://archive.ewg.org/reports_content/bodyburden2/pdf/bodyburden2_final-r2.pdf (last visited Nov. 17, 2007).

[20] NCEL. (National Caucus of Environmental Legislators), Biomonitoring in the States, http://www.ncel.net/newsmanager/news_article.cgi?news_id=164 (last visited Nov. 17, 2007).

[21] Memorandum from Linda Adams, Secretary for Environmental Protection, California Environmental Protection Agency to California Chairpersons and Directors (Apr. 20, 2007), *available at* http://www.dtsc.ca.gov/PollutionPrevention/GreenChemistryInitiative/upload/CalEPA_Green_Chemistry_Initiative_Memo.pdf (last visited Oct. 9, 2007) [hereinafter Memorandum from Linda Adams].

[22] Memorandum from Linda Adams, *supra id.*

[23] MICHAEL P. WILSON ET AL., CALIFORNIA POLICY RESEARCH CENTER, GREEN CHEMISTRY IN CALIFORNIA: A FRAMEWORK FOR LEADERSHIP IN CHEMICALS POLICY AND INNOVATION (Mar. 2006), *available at* http://www.ucop.edu/cprc/documents/greenchemistryrpt.pdf (last visited Oct. 9, 2007).

[24] Henrik Selin & Stacy D. VanDeveer, *Raising Global Standards: Hazardous Substances and e-Waste Management in the European Union*, ENV'T, Dec. 2006, at 10, 15, *available at* http://www.brown.edu/Administration/News_Bureau/2006-07/06-074.pdf (last visited Nov. 17, 2007).

[25] Stockholm Convention on Persistent Organic Pollutants, May 22, 2001, UNEP/POPS/CONF/4, *available at* http://www.pops.int/documents/convtext/convtext_en.pdf (last visited Oct. 9, 2007) [hereinafter Stockholm Convention].

[26] KAREN PERRY STILLERMAN, CENTER FOR INTERNATIONAL ENVIRONMENTAL LAW, U.S. STATES AND THE GLOBAL POPS TREATY: PARALLEL PROGRESS IN THE FIGHT AGAINST TOXIC POLLUTION (May, 2005), *available at* http://www.ciel.org/Publications/States_POPs_May05.pdf (last visited Oct. 9, 2007).

[27] CENTER FOR INTERNATIONAL ENVIRONMENTAL LAW, U.S. RATIFICATION OF THE STOCKHOLM CONVENTION: ANALYSIS OF PENDING POPS LEGISLATION (Mar. 13, 2006), *available at* http://www.ciel.org/Publications/POPs_Bills_28Feb2006.pdf (last visited Oct. 9, 2007).

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[29] MARK SCHAPIRO, EXPOSED: THE TOXIC CHEMISTRY OF EVERYDAY PRODUCTS AND WHAT'S AT STAKE FOR AMERICAN POWER (Chelsea Green Publishing 2007).

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[33] GUNNAR LIND, REACH - WHAT HAPPENED AND WHY: THE ONLY PLANET GUIDE TO THE SECRETS OF CHEMICAL POLICY IN THE EU, (Apr. 2004) *available at* http://www.besafenet.com/ppc/docs/toxic_chemicals/chemical_regulation/CH_RPLA.pdf (last visited Nov. 18, 2007).

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[35] Louisville Charter, *supra* note 32.

[36] DARYL DITZ, CENTER FOR INTERNATIONAL ENVIRONMENTAL LAW, CLOUDY SKIES, CHANCE OF SUN: A FORECAST FOR U.S. REFORM OF CHEMICALS POLICY (May 2006), *available at* http://www.ciel.org/Publications/Cloudy_Skies_9May06.pdf (last visited Oct. 9, 2007).

[37] Child, Worker, and Consumer-Safe Chemicals Act of 2005, S. 1391 109th Cong. (2005).

ENDNOTES: TSCA AND ENGINEERED NANOSCALE SUBSTANCES *continued from page 35*

[1] An earlier version of this Article was published in *Nanotechnology Law & Business*, Vol. 4 No. 1 (Mar. 2007).

[2] Toxic Substances Control Act, 15 U.S.C. §§ 2601-92 (2006) (only Subchapter I of TSCA is relevant to nanotechnology, and will be discussed here).

[3] National Nanotechnology Initiative ("NNI"), *What is Nanotechnology?*, http://www.nano.gov/html/facts/whatIsNano.html (last visited Oct. 12, 2007).

[4] *See* LUX RESEARCH, THE NANOTECH REPORT™, 4TH EDITION iii (2006), *available at* http://www.luxresearchinc.com/pdf/TNR4_TOC.pdf (last visited Oct. 12, 2007).

[5] *See* Günter Oberdörster, Eva Oberdörster & Jan Oberdörster, *Nanotechnology: An Emerging Discipline Evolving from Studies of Ultrafine Particles*, 113 ENVTL. HEALTH PERSPS. 823, 823 (2005).

[6] *See* Torsten Hansen et al., *Biological Tolerance of Different Materials in Bulk and Nanoparticulate Form in a Rat Model: Sarcoma Development by Nanoparticles*, 3 J. ROYAL SOC'Y INTERFACE 767, 767 (2006), *available at* http://www.journals.royalsoc.ac.uk/content/r20g806u0881u1r4/fulltext.pdf (last visited Oct. 12, 2007).

[7] *See* 15 U.S.C. § 2601(b)(3) (2000) (extending TSCA jurisdiction to "mixtures").

[8] 15 U.S.C. § 2602(2)(A); 40 C.F.R. §§ 710.3(d), 720.3(e) (2007). *But see* 15 U.S.C. § 2602(2)(B) (excluding various materials regulated under other federal law from the TSCA definition of "chemical substance").

[9] Nanoscale Materials Stewardship Program, 72 Fed. Reg. 38,081, 38,082 (July 12, 2007).

[10] 15 U.S.C. § 2607(b)(1).

[11] 15 U.S.C. § 2602(9).

[12] *See* EPA New Chemical Program, *What is the TSCA Chemical Substance Inventory?*, http://www.epa.gov/opptintr/newchems/pubs/invntory.htm (last visited Oct. 13, 2007).

[13] EPA, *U.S. Toxic Substances Control Act Chemical Substance Inventory* slide 6 (Chemical Inventory Workshop Sept. 2007), http://www.ine.gob.mx/dgicurg/sqre/download/taller_inv_sq/16_tw_en.pdf (last visited Oct. 13, 2007).

[14] *See* 15 U.S.C. § 2604(a).

[15] 15 U.S.C. § 2604(a)(1)(A); *see*, *e.g.*, 40 C.F.R. §§ 720, 723 (containing EPA's PMN regulations and several exemptions).

[16] *See* 15 U.S.C. § 2604(a)(1); *see also* EPA Design for the Environment, *Section E. Toxic Substances Control Act*, *available at* http://www.epa.gov/dfe/pubs/pwb/tech_rep/fedregs/regsecte.htm (last visited Oct. 14, 2007).

[17] *See* 15 U.S.C. 2604(h)(4).

[18] 40 C.F.R. § 720.30(h).

[19] *See* 40 C.F.R. § 723.250.

[20] *See* 15 U.S.C. § 2604(h)(3); 40 C.F.R § 720.36

[21] *See* 15 U.S.C. § 2604; 40 C.F.R. § 723.50.

[22] *See* 15 U.S.C. § 2604(h)(4); *see also* EPA New Chemical Program, *Background on the LoREX exemption*, http://www.epa.gov/oppt/newchems/pubs/lorexemp.htm (last visited Oct. 14, 2007).

[23] *See* 15 U.S.C. § 2604(h)(1); 40 C.F.R. § 720.38.

[24] *See* 15 U.S.C. § 2604(h)(3); 40 C.F.R. § 720.36.

[25] *See* 40 C.F.R. §§ 723.50(a), (c).

[26] 40 C.F.R. § 723.50(g)(2).

[27] *See* 15 U.S.C. § 2604(e)(1)(A).

[28] *Id*.

[29] *See* 15 U.S.C. § 2604(e)(1)(C).

[30] *See* 15 U.S.C. §§ 2604(a)(1)(B).

[31] *See* 15 U.S.C. § 2604(a)(2).

[32] *See* 15 U.S.C. § 2604(a)(1)(B).

[33] *See* American Bar Association Section of Environment, Energy, & Resources, Regulation of Nanoscale Materials under the Toxic Substances Control Act 11 (June 2006), *available at* http://www.abanet.org/environ/nanotech/pdf/TSCA.pdf (last visited Oct. 14, 2007) [hereinafter ABA SEER Paper].

[34] *See* S. Rep. No. 94-698, at 19 (1976) ("If a new use of an existing substance has been specified by the Administrator in accordance with this subsection [Section 5(a)(2)], all of the premarket notification procedures and authority during the premarket notification period apply to such new use of an existing substance.")

[35] *See* 40 C.F.R. § 720.22.

[36] 15 U.S.C. § 2604(a)(2).

[37] *See* EPA, EPA Authorities Under TSCA 14 (July 11, 2005), *available at* http://www.epa.gov/oppt/npptac/pubs/tscaauthorities71105.pdf (last visited Oct. 14, 2007) [hereinafter EPA Authorities Under TSCA].

[38] *See* 15 U.S.C. § 2625(c)(1).

[39] 15 U.S.C. § 2625(c)(2)(A).

[40] *See* 15 U.S.C. § 2607(a).

[41] *See* 15 U.S.C. § 2607(d).

[42] 40 C.F.R. § 717.3(a).

[43] 40 C.F.R. § 717.17(a)-(b).

[44] 15 U.S.C. § 2607(e).

[45] *See* Press Release, EPA, EPA Settles PFOA Case Against DuPont for Largest Environmental Administrative Penalty in Agency History (Dec. 14, 2005), *available at* http://yosemite.epa.gov/opa/admpress.nsf/d9bf8d9315e942578525701c005e573c/fdcb2f665cac66bb852570d7005d6665!OpenDocument (last visited Oct. 14, 2007).

[46] *See* Letter from Richard A. Denison & Karen Florini, Environmental Defense, to Susan B. Hazen, Acting Assistant Administrator, Office of Prevention, Pesticides & Toxic Substances, EPA (Sept. 2, 2004) [hereinafter Sept. 2004 ED Letter] (attached to Letter from Richard A. Denison & Karen Florini, Environmental Defense, to Ann R. Klee, General Counsel Environmental Protection Agency (May 22, 2006) [hereinafter May 22, 2006 ED Letter]), *available at* http://www.environmentaldefense.org/ documents/5265_StatusofNMsUnderTSCA.pdf (last visited Oct. 14, 2007). Comment from Natural Resources Defense Council et al., in response to EPA Proposal to Regulate Nanomaterials Through a Voluntary Pilot Program 11-12 (July 5, 2005), *available at* http://www.regulations.gov (Select "Search For Dockets" and select EPA as "Agency" and enter "EPA-HQ-OPPT-2004-0122" as "Docket ID" for a link to the document "EPA-HQ-OPPT-2004-0122-0013") (last visited Oct. 23, 2007).

[47] May 22, 2006 ED Letter *supra*, note 46 at 1 (emphasis in original).

[48] *See id.*

[49] *See id.* at 3-4.

[50] *See id.* at 1; *see generally* American Chemistry Council, Nanotechnology Panel, http://www.americanchemistry.com/s_acc/sec_statistics.asp?CID=654&DID=2564 (provides information about the Panel's goals, views, etc.) (last visited Oct. 14, 2007).

[51] *See generally* 40 C.F.R. § 710.3.

[52] *See* TSCA Inventory Nomenclature for Enzymes and Proteins, 69 Fed. Reg. 65565, 65567 (Nov. 15, 2004) (stating "the only way to determine if a substance is new or existing is by consulting the TSCA Inventory").

[53] ABA SEER Paper, *supra* note 33, at 8.

[54] ABA SEER Paper, *supra* note 33, at 8.

[55] ABA SEER Paper, *supra* note 33, at 9.

[56] ABA SEER Paper, *supra* note 33, at 12-13.

[57] *See* 15 U.S.C. § 2604(a)(1)-(2).

[58] *See* 15 U.S.C. § 2604(a)(1)(B)-(2).

[59] *See* 40 C.F.R. §§ 720.40(a)(2)721.25(a) (regulating PMN and SNUN).

[60] EPA Authorities Under TSCA, *supra* note 37, at 12.

[61] 15 U.S.C. § 2604(e)(1)(A)(i), (f)(1).

[62] 15 U.S.C. § 2604(a)(2)(B)-(D).

[63] Perfluoroalkyl Sulfonates; Proposed Significant New Use Rule, 71 Fed. Reg. 12311, 12314 (Mar. 10, 2006) (to be codified at 40 C.F.R. §721.9582).

[64] 15 U.S.C. § 2625(c)(2)(A); *see* ABA SEER Paper, *supra* note 33, at 16.

[65] *See* Karen Florini et al., *Nanotechnology: Getting It Right the First Time*, Sustainable Dev. L. & Pol'y, Spring 2006, at 51.

[66] ED Letter, *supra* note 46, at 4-4.

[67] *See* Pat Phibbs, *Manufacture of New Carbon Nanotube Approved by EPA Under an Exemption*, BNA Daily Env't Rep., Oct. 21, 2005, at A-1.

[68] *See* James Alwood, EPA, Presentation at American Chemistry Council/SOCMA Global Chemical Regulations Conference (Mar. 22, 2005) (noting that Section 8(e) reporting applies to nanoscale materials) (unpublished); *see also* EPA, Concept Paper for the Nanoscale Materials Stewardship Program under TSCA, Annex C, (including discussion of Section 8(e)), *available at* http://www.regulations.gov/fdmspublic/component/main?main=DocumentDetail&d=EPA-HQ-OPPT-2004-0122-0058 (last visited Nov. 1, 2007) [hereinafter Concept Paper].

[69] To date, EPA has received at least one Section 8(e) submission (8EHQ-0403-15319 (Apr. 10, 2003)) addressing an engineered nanoscale material, although it is not clear from the submission whether the nanoscale material was existing or new. *See generally* OPPT Accomplishments Report, New Nanotechnology Products *available at* http://www.epa.gov/oppt/ar/20052006/managing/new_nano.htm (last visited Nov. 1, 2007).

[70] *See* Pat Phibbs-Rizzuto, *EPA Reviews 15 New Nanoscale Chemicals, But Finds Only One With Unique Properties*, BNA Daily Env't Rep., Aug. 16, 2006, at A-7.

[71] Notice of Certain New Chemicals, Receipt & Status Information, 71 Fed. Reg. 33449, 33451 (June 9, 2006); Notice of Certain New Chemicals, Receipt & Status Information, 71 Fed. Reg. 46475, 46480 (Aug. 14, 2006).

[72] *See* Meeting Notice, 70 Fed. Reg. 24574 (May 10, 2005).

[73] *See* Nat'l Pollution Prevention & Toxics Advisory Comm., Overview Document on Nanoscale Materials (Nov. 22, 2005) (acknowledging the formation of the Ad Hoc Work Group prior to the Oct. 2005 meeting), *available at* http://www.epa.gov/opptintr/npptac/pubs/nanowgoverviewdocument20051125.pdf (last visited Nov. 1, 2007) [hereinafter NPPTAC Overview Document].

[74] *Id.*

[75] Letter from James B. Gulliford, Assistant Administrator for Prevention, Pesticides & Toxic Substances, to Stakeholders (Oct. 18, 2006) (laying out EPA's goal "to implement TSCA in a way that enables responsible development of nanotechnology and realizes its potential environmental benefits, while applying sound science to assess and, where appropriate, manage potential risks to human health and the environment presented by nanoscale materials"), *available at* http://www.epa.gov/oppt/nano/nano-letter.pdf (last visited Oct. 14, 2007).

[76] *See* Nanocale Materials Stewardship Program, 72 Fed. Reg. 38079-38081, 38083-38085 4 (July 12, 2007), *available at* http://www.epa.gov/opptintr/nano/nmspfr.htm (last visited Oct. 14, 2007).

[77] Information Collection Activities on Nanoscale Materials Stewardship Program, 72 Fed. Reg. 38079 (July 12, 2007).

[78] Meeting Notice, 72 Fed. Reg. 38081 (July 12, 2007).

[79] Comment Notice, Nanoscale Materials Stewardship Program & Inventory Status of Nanoscale Substances under TSCA, 72 Fed. Reg. 38083 (July 12, 2007).

[80] Concept Paper, *supra* note 68, at 3.

[81] EPA, TSCA Inventory Status of Nanoscale Substances at 2, *available at* http://www.regulations.gov/fdmspublic/component/main?main=DocumentDetail&d=EPA-HQ-OPPT-2004-0122-0057 (last visited Oct. 14, 2007) [hereinafter TSCA Inventory Paper].

[82] *See* TSCA Inventory Paper, *id.* at 6.

[83] *See* Comment Notice, Nanoscale Materials Stewardship Program & Inventory Status of Nanoscale Substances under TSCA, 72 Fed. Reg. 38083 (July 12, 2007).

Endnotes: Environmental Standards in U.S. Free Trade Agreements *continued from page 36*

[6] *Sun Belt Water, Inc. v. Canada*, Notice of Claim and Demand for Arbitration (Oct. 12, 1999), *available at* http://naftaclaims.com/Disputes/Canada/Sunbelt/SunBeltNoticeClaimDemandArbitration.pdf (last visited Nov. 19, 2007).

[7] U.S. Dep't of State, Office of the Legal Advisor, *Bayview Irrigation Dist. v. Mexico*, *available at* http://www.state.gov/s/l/c20028.htm (last visited Oct. 17, 2007) [hereinafter *Bayview*].

[8] *Bayview, id.*

[9] *See* Bayview Irrigation Dist. v. Mexico (U.S. v. Mex.), ICSID ARB(AF)/05/1, Award (June 21, 2007), *available at* http://www.naftaclaims.com/Disputes/Mexico/Texas/Bayview_Jursdictional_Award_19-05-07.pdf (last visited Nov. 19, 2007) [hereinafter *Bayview award*].

[10] *See Bayview award, id.*

Endnotes: Minneapolis Bridge Collapse *continued from page 37*

[1] U.S. Dep't of Transp. Office of Public Affairs, *I-35W Bridge Collapse*, *Minneapolis, MN*, http://www.dot.gov/affairs/factsheet080207.htm (last visited Oct. 18, 2007) [hereinafter *I-35W Bridge Collapse*].

[2] Reason Foundation, State-by-State Ranking of Deficient Bridges, *available at* http://www.reason.org/news/deficient_bridges_by_state_080307.shtml (last visited Oct. 18, 2007).

[3] *I-35W Bridge Collapse*, *supra* note 1.

[4] Minneapolis I-35W Bridge Collapse Information, *Vision for a New Bridge*, http://www.ci.minneapolis.mn.us/minneapolisrebuilds/vision.asp (last visited Oct. 18, 2007).

[5] Lauren R. Hunt, Development of a Rating System for Sustainable Bridges 6 (May 31, 2005) (unpublished M.S. thesis, Massachusetts Institute of Technology), *available at* http://dspace.mit.edu/bitstream/1721.1/31115/1/61146095.pdf (last visited Oct. 18, 2007).

[6] U.S. Dep't of Transp. Federal Highway Administration, *High-Performance Materials: A Step Toward Sustainable Transportation*, http://www.tfhrc.gov/pubrds/spring97/high.htm (last visited Oct. 18, 2007).

[7] Hunt, *supra* note 5, at 8.

[8] U.S. Dep't of Transp., Federal Highway Administration website, http://www.fhwa.dot.gov/ (last visited Oct. 18, 2007)

[9] U.S. Dep't of Transp. Federal Highway Administration, *Celebrating 50 Years: The Eisenhower Interstate Highway System*, http://www.fhwa.dot.gov/interstate/homepage.cfm (last visited Nov. 2, 2007).

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[34] 40 C.F.R. § 1500.1(b).

[35] Robertson v. Methow Valley Citizens Council, 490 U.S. 332, 349 (1989).

[36] Treasury and General Government Appropriations Act for Fiscal Year 2001, Pub.L.No. 106-554, § 515; *see also* Bureau of Land Management, Information Quality Guidelines, *available at* http://www.blm.gov/nhp/efoia/data_quality/guidelines.pdf (last visited Nov. 3, 2007).

[37] 40 C.F.R. § 1502.22.

[38] The scope of an EIS is relatively wide and requires the agency to "discuss the purpose and need for the proposed action, environmental impacts resulting from the actions, unavoidable adverse environmental impacts, alternatives to the proposed action, the relationship between short-term uses and long-term productivity, and the amount of resources that must be devoted to the proposed action." Citizens' Comm. to Save Our Canyons v. U.S. Forest Serv., 297 F.3d 1012, 1022 (10th Cir. 2002); 42 U.S.C. §4332(2)(C)(i)-(v); 40 C.F.R. § 1502.10.

[39] Council on Environmental Quality, *supra* note 5.

[40] National Environmental Policy Act, 42 U.S.C. § 4331(a) (2007).

[41] 40 C.F.R. § 1508.8.

[42] 40 C.F.R. § 1508.7.

[43] Neighbors of Cuddy Mountain v. U.S. Forest Serv., 137 F.3d 1372, 1379-80 (9th Cir. 1998).

[44] *See* Ocean Advocates v. U.S. Army Corps of Eng'rs, 361 F.3d 1108, 1129 (9th Cir. 2004); Muckleshoot Indian Tribe v. U.S. Forest Serv., 177 F.3d 800, 811 (9th Cir. 1999) (holding that the cumulative impact statements that are provided in the EIS are far too general and one-sided to meet the NEPA requirements); *see also* High Sierra Hikers Ass'n v. Blackwell, 390 F.3d 630, 645-46 (9th Cir. 2004); Klamath-Siskiyou Wildlands Ctr. v. Bureau of Land Mgmt., 387 F.3d 989, 991-92 (9th Cir. 2004) (asserting that the analyses performed by the BLM do not sufficiently consider the cumulative impacts posed by the timber sales); Wyoming Outdoor Council Powder River Basin Res. Council v. United States, 351 F. Supp. 2d 1232, 1238 (D. Wyo. 2005); Defenders of Wildlife v. Ballard, 73 F. Supp. 2d 1094, 1114 (D. Ariz. 1999).

[45] *See* Kleppe v. Sierra Club, 427 U.S. 390, 410 (1976); Northcoast Envtl. Ctr. v. Glickman, 136 F.3d 660, 688 (9th Cir. 1998). (holding that the preparation of a programmatic EIS, will permit agency to assess the environmental consequences of "an entire policy initiative rather than performing a piecemeal analysis").

[46] Bartell, *supra* note 4, at 848.

[47] Bartell, *supra* note 4, at 848.

[48] James L. Connaughton, *Modernizing the National Environmental Policy Act: Back to the Future*, 12 N.Y.U. Envtl. L.J. 1, 9 (2003) (writing about the possibilities of using ERAs to improve the NEPA process, and saying, "[t]he question we must find an answer to now is how to pull environmental and risk assessments together in such a way to create a more programmatic view of planning and development").

[49] Bartell, *supra* note 4, at 848.

[50] 40 C.F.R. § 1502.22.

[51] Seattle Audubon Soc'y v. Espy, 998 F.2d 699, 704 (9th Cir. 1993).

[52] *Seattle Audubon Soc'y*, *id.*; *see also* Ecology Ctr., Inc. v. Austin, 430 F.3d 1057, 1065 (9th Cir. 2005).