TSCA and Engineered Nanoscale Substances

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ABSTRACT

The federal law that regulates new and existing chemical substances, including engineered nanoscale chemical substances, is the Toxic Substances Control Act (TSCA). While there is much debate over how the U.S. Environmental Protection Agency (EPA) should deploy its significant TSCA authority to address potential risks to human health and the environment posed by engineered nanoscale materials, there is no doubt that EPA is already doing so. This article provides a general overview of TSCA as it relates to new and existing chemical substances, and discusses how EPA may go about discharging its significant TSCA authority with respect to engineered nanoscale substances.

I. TSCA AND ENGINEERED NANOSCALE SUBSTANCES

Nanotechnology is the subject of considerable excitement and attention these days. The many articles appearing in technical journals, trade and mainstream publications, and in other contexts make it impossible to be unaware of the immense commercial promise offered by nanotechnology. Applications are proliferating quickly in diverse economic sectors, including chemical manufacturing, medical device applications, energy production, and transportation, among many others. Considerable attention likewise has been devoted to the implications for human health and the environment posed by engineered nanoscale materials and the critical need that governments globally get the policy and regulatory framework "right" to enable nanotechnology to realize its full societal value

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while at the same time effectively addressing pertinent health, safety, and environmental issues posed by this transformative technology.

In the United States, the federal law most often mentioned in connection with regulating engineered nanoscale substances is the Toxic Substances Control Act (TSCA), the federal law that regulates new and existing chemical substances and provides a regulatory framework to address chemicals throughout their production, use, and disposal. This article considers several issues in connection with the application of TSCA to engineered nanoscale materials,[1] and it focuses on nanoscale materials that are intentionally manipulated by human activity and not on naturally occurring nanoscale particles (volcanic ash) or incidental nanoscale materials (combustion byproducts). This article is not intended to propose comprehensive resolutions to these issues under TSCA, but rather to raise awareness of, and to facilitate constructive debate on, them.

The debate over TSCA's application to engineered nanoscale materials will continue for some time. This debate is interesting and challenging. The U.S. Environmental Protection Agency (EPA) has robust authority under TSCA to review engineered nanoscale materials considered new under TSCA Section 5(a), to review under TSCA uses of existing chemical substances considered by EPA "new," to review comprehensively exemptions from full premanufacture notification (PMN) requirements, and to collect information on and compel and enforce reporting obligations with respect to engineered nanoscale materials.

EPA's stated commitment to issue guidance on these issues will greatly assist the regulated community in understanding EPA's expectations regarding the submission of PMN and exemption applications for engineered nanoscale materials and thus better prepare industry to undertake consistently its TSCA compliance obligations. 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 often and early regarding the regulatory status of engineered nanoscale materials believed to consist of TSCA Inventory-listed substances, either though a pre-submission meeting with EPA, or the submission of a *bona fide* intent to commence manufacture.

II. BACKGROUND ON NANOTECHNOLOGY

Nanotechnology, the "understanding and control of matter at dimensions of roughly 1 to 100 nanometers, where unique phenomena enable novel applications,"[2] according to the National Nanotechnology Initiative (NNI), is expanding rapidly. Nanotechnology is viewed broadly as many technologies that will over time generate many new products and applications. Lux Research, Inc., the New York-based nanotechnology research and advocacy firm, predicts that by 2014, products that incorporate nanotechnology will constitute 15 percent of global manufacturing output and will total $2.6 trillion. Global demand for engineered nanomaterial, nanoparticles, and nano-intermediates was $1 billion in 2004, and is expected to be $40 billion in 2008. Worldwide investment in nanoscience and

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[1] Other articles on this subject include: Lynn Bergeson & Bethami Auerbach, *Reading the Small Print*, 21 ENV'T FORUM 30 (2004); Linda K. Breggin, *Securing the Promise of Nanotechnology: Is the U.S. Environmental Law up to the Job? A Dialogue*, ENVTL. LAW. INST. (Woodrow Wilson Int'l Ctr. for Scholars Project on Emerging Nanotech.), Oct. 2005, *available at* http://www.elistore.org/reports detail.asp?ID=11116.; Peter J. Tomasco, *Manufactured Nanomaterials: Avoiding TSCA and OSHA Violations for Potentially Hazardous Substances*, 33 B.C. ENVTL. AFF. L. REV. 205 (2006); Ahson Wardak, *Nanotechnology & Regulation: A Case Study Using the Toxic Substance [sic] Control Act (TSCA)*, INT'L ASS'N OF NANOTECH. (Woodrow Wilson Int'l Ctr. for Scholars), 2003, *available at* http://www.ianano.org/Nanotech-Regulation.pdf.

[2] National Nanotechnology Initiative, What is Nanotechnology?, http://www.nano.gov/html/facts/whatIsNano.html (last visited Feb. 7, 2007).

nanotechnology development exceeds tens of billions of dollars, and public spending globally was estimated in 2003 to be over $3 billion.[3]

One of the key reasons governments around the world are focusing on nanotechnology is the lack of understanding in all cases regarding the health, safety, and environmental effects of exposure to engineered nanoscale materials. Some believe sufficient information exists to suggest caution is needed. The small size of certain nanoparticles facilitates uptake into cells and movement through the body more readily than their macro counterparts.[4] In addition to size, however, other factors contribute to a general sense of uncertainty as to the biological and environmental effects of exposure to engineered nanoscale materials biologically and in the environment. The complexity of engineered nanomaterials means that their impact will depend on more than chemistry alone. Size, shape, surface chemistry, and surface coating, for example, can all influence how these materials behave. As noted, in some cases, the tiny size alone of nanoparticles might allow them to more easily enter and affect living organs. In other instances, the fact that nanoscale materials can have unusual properties—properties that do not conform to "conventional" physics and chemistry—may increase the potential for risk.[5]

Many federal agencies are engaged in the active review of applications of nanotechnology as well as of the environmental, health, and safety implications of nanotechnologies.[6] These include EPA, the Food and Drug Administration (FDA), the Occupational Safety and Health Administration (OSHA), the National Institute for Occupational Safety and Health (NIOSH), the National Toxicology Program (NTP), and the Department of Defense (DOD), among others. Regulatory and health agencies globally are similarly engaged.[7] EPA is most prominently involved in the review of the environmental, health, and safety implications of nanotechnologies, and in identifying and funding research initiatives regarding the beneficial environmental applications of nanotechnologies in a wide variety of areas.

III. EPA NANOTECHNOLOGY INITIATIVES

EPA is to be commended for its leadership, vision, and energy in exploring early and creatively the application of existing environmental regulatory programs under TSCA to address the safety and health implications of engineered nanoscale materials. Three regulatory initiatives are pertinent: 1) the

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[3] M.C. Roco, *Government Nanotechnology Funding: An International Outlook*, NAT'L SCI. FOUND., June 30, 2003, http://www.nano.gov/html/res/IntlFundingRoco.htm (last visited Feb. 7, 2007).

[4] Günter Oberdörster, Eva Oberdörster & Jan Oberdörster, *Nanotechnology: An Emerging Discipline Evolving from Studies of Ultrafine Particles*, 113 ENVTL. HEALTH PERSPECTIVES, 823 (2005). *See also* Jennifer Sass, Patrice Simms & Elliott Negin, *Nanotechnologies: The Promise and the Peril*, 6 SUSTAINABLE DEV. L. & POL'Y 11 (2006) (single-walled carbon nanotubes (SWCNTS) have been reported by five different research groups to be associated with lung toxicity). The authors recognize that there is considerable debate over the definitions of nanoparticle and particulate nanomaterial. We make no attempt to define these terms more than we have in the article, and use the terms interchangeably throughout the article.

[5] 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. INTERFACE 767 (2006) (toxicity of certain nanoparticles *in vitro* found cytotoxic effects in some nanoparticles), *available at* http://www.journals.royalsoc.ac.uk/media/p8lhtpxwwrjmgc6uhqrl/contributions/r/2/0/g/r20g806u0881u1r4.pdf (free registration required).

[6] *See* Nat'l Sci. & Tech. Council. *The National Nanotechnology Initiative Research and Development Leading to a Revolution in Technology and Industry*, (Supplement to the President's 2007 Budget), NAT'S NANOTECH. INITIATIVE, July 2006, *available at* http://www.nano.gov/NNI_07Budget.pdf.

[7] Most notably, the U.K. Department of Environment, Food & Rural Affairs (DEFRA) launched a Voluntary Reporting Scheme for Engineered Nanoscale Materials in September 2006, which will run until September 2008. *See* DEFRA, *Voluntary Reporting Scheme for engineered nanoscale materials*, Nov. 2006, http://www.defra.gov.uk/environment/nanotech/policy/index.htm.

NPPTAC Overview of Issues Document, 2) the Nanotechnology White Paper, and 3) the TSCA PMN Decision Logic.

1. NPPTAC Overview of Issues Document

EPA's Office of Pollution Prevention and Toxics (OPPT) announced in 2005 its interest in considering how best to obtain much needed information on existing engineered nanoscale materials, and convened a public meeting to discuss various options in June 2005.[8] The discussion at the public meeting yielded a consensus that a voluntary program designed to obtain existing information and new information and data on engineered nanoscale substances has significant value. EPA shortly thereafter decided to create an Interim *Ad Hoc* Work Group on Nanoscale Materials as part of the National Pollution Prevention and Toxics Advisory Committee (NPPTAC), a federal advisory group tasked with advising OPPT on TSCA and related pollution prevention matters. The Work Group was formed to provide input to the NPPTAC on the need for, and design of, a voluntary program for reporting information pertaining to existing chemicals that are engineered nanoscale materials, and the information needed to inform adequately the conduct of such a program. On November 22, 2005, the NPPTAC issued its *Overview Document on Nanoscale Materials*, which outlines a framework for an EPA approach to a voluntary program for engineered nanoscale materials, a complementary approach to new chemical nanoscale requirements under TSCA, and various other relevant issues pertinent to nanoscale materials that are chemical substances.[9]

EPA is now considering what types of information to collect. Reportedly, EPA is preparing an Information Collection Request (ICR) to submit to the Office of Management and Budget (OMB) for review and convened the first of several public scientific peer consultations on October 19-20, 2006, to consider the elements of what is now referred to as the Nanoscale Materials Stewardship Program (NMSP). In October, Office of Prevention, Pesticides, and Toxic Substances (OPPTS) Assistant Administrator Jim Gulliford sent a letter to stakeholders inviting them to participate in the NMSP, which is a voluntary program that EPA will manage under its TSCA authority. According to the letter, EPA's goal is "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."

As of this writing, EPA still intends to roll out the NMSP in 2007, but has yet to announce when it intends to convene the stakeholder meetings that are needed to help define the elements of the program. Similarly, it is unclear whether OMB has received the ICR noted above and if so, whether it has approved it.

2. Nanotechnology White Paper

EPA's Science Policy Council (SPC) Nanotechnology Workgroup issued on February 15, 2007, its final *Nanotechnology White Paper*. The White Paper is intended "to inform EPA management of the science needs associated with nanotechnology, to support related EPA program office needs, and to communicate these nanotechnology science issues to stakeholders and the public."[10] The draft *White*

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[8] *See* Nanoscale Materials; Notice of Public Meeting, 70 Fed. Reg. 24,574 (May 10, 2005).

[9] NAT'L POLLUTION PREVENTION & TOXICS ADVISORY COMM., EPA, OVERVIEW DOCUMENT ON NANOSCALE MATERIALS (Nov. 22, 2005), http://www.epa.gov/opptintr/ npptac/pubs/nanowgoverviewdocument20051125.pdf. *See* Lynn l. Bergeson, *Nanotechnology and TSCA*, 6 ABA PESTICIDE, CHEM. REG. & RIGHT-TO-KNOW COMM. NEWSLETTER 11 (ABA Section for Env't, Energy, & Res.), Apr. 2005, at 11, http://www.abanet.org/environ/committees/pesticides/newsletter/apr05/pesticides0405.pdf.

[10] Science Policy Council: Nanotechnology Workgroup, *Nanotechnology White Paper*, EPA, 1 (Feb. 15, 2007), *available at* http://www.epa.gov/osa (EPA White Paper).

Paper was released in December 2005. EPA convened an expert peer review meeting in Washington, D.C. on April 19-20, 2006, to conduct an independent expert external peer review of the White Paper.[11] The SPC approved the final report on September 25, 2006, and, as noted, issued the final document in mid-February 2007. Importantly, the document includes EPA staff recommendations for addressing science issues and research needs, and includes prioritized research needs within key risk assessment topic areas such as human health effects research and fate and transport research. The final *White Paper* also includes a new Appendix C, "EPA's Nanotechnology Research Framework," which sets forth how EPA intends strategically to focus on its research program to provide "key information" on potential human health and environmental implications of nanomaterials in a way that complements other federal, academic, and private-sector research initiatives.

3. TSCA PMN Decision Logic

EPA's OPPT has developed a decision logic that OPPT staff apply in assessing engineered nanoscale materials that are chemical substances that are the subject of applications submitted to EPA for premarket approval under TSCA, or for approval of exemption from those requirements. Application of the logic is resulting in EPA's identification of specific areas of inquiry unique to engineered nanoscale materials that are chemical substances. Primary among these areas include potential routes of exposure to workers to engineered nanoparticles and potential environmental releases of these materials. EPA is assessing the adequacy of personal protection equipment (PPE) to prevent potential exposures to engineered nanoscale materials during the manufacturing, processing, and/or distribution and use of these materials. EPA's decision logic is believed to distinguish between "true" engineered nanoscale materials, meaning those 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-dependant properties. According to published sources, EPA has, as of August 2006, reviewed 15 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 Low Release and Low Exposure (LoREX) PMN exemption application in 2005.

More recently, on August 14, 2006, EPA issued a notice acknowledging receipt of a notice of commencement of manufacture or import of siloxane coated alumina nanoparticles pursuant to TSCA Section 5.[12] According to EPA sources, the siloxane coated alumina nanoparticles will have nondispersive uses as an additive to other chemical substances. Apparently, the manufacturer requested EPA approval to make the chemical in 2005.[13]

EPA also is expected to issue and request comment on guidance on its interpretation of certain TSCA regulatory provisions and their application to existing and new engineered nanoscale materials. As interested stakeholders will be invited to comment on the guidance, such guidance will provide stakeholders with an important opportunity to influence the development of domestic regulatory policy on engineered nanoscale materials.

As noted, TSCA is the federal statute presently receiving the most attention by EPA as it considers how best to regulate engineered nanoscale materials. Outlined below is an overview of TSCA, both the law and EPA's implementation of it, followed by a discussion of key issues that have arisen regarding the application of TSCA to engineered nanoscale materials.

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[11] Notice of Expert Peer Review Meeting on the Nanotechnology White Paper External Review Draft. 71 Fed. Reg. 14,205 (Mar. 21, 2006).

[12] Certain New Chemicals; Receipt and Status Information, 71 Fed. Reg. 46,475, 46,480 (Aug. 14, 2006); *see also* Pat Phibbs-Rizzuto, *EPA Reviews 15 New Nanoscale Chemicals, But Finds Only One With Unique Properties*, 158 BNA DAILY ENV'T REP., Aug. 16, 2006, at A-7.

[13] Certain New Chemicals; Receipt and Status Information, 70 Fed. Reg. 46,513, 46,517 (Aug. 10, 2005).

IV. TSCA OVERVIEW

1. Statutory and Regulatory Background

Enacted by Congress in 1976 to protect human health and the environment from the effects of exposure to potentially harmful chemical substances and mixtures, TSCA[14] is the federal statute that authorizes EPA to regulate engineered nanoscale materials that are chemical substances. TSCA is interpreted broadly and is specifically directed toward regulating "chemical substances"[15] through their manufacture, use, and disposal. The term "chemical substance" means "any organic or inorganic substance of a particular molecular identity, including—any combination of such substances occurring in whole or in part as a result of a chemical reaction or occurring in nature, and any element or uncombined radical."[16]

It is acknowledged that an understanding of EPA's definition of terms, such as "chemical substance" as given above, and an understanding of the numerous regulations that EPA has developed in implementing TSCA, requires a basic understanding of chemistry and particular chemical terms. Although it is far beyond the scope of this article to address this in detail, it may be useful to explain briefly certain terms used herein. These include chemical and molecular identity, atoms and molecules, and physical structure, among others.

All matter consists of chemicals in some form based on elements as represented in the Periodic Table of Elements. Elements may exist in pure form or they may be combined with other elements to form compounds, the basic form of which is called a molecule. The element carbon exists in the elemental state in physical forms such as diamond and graphite, which have dramatically different properties, but their chemical identities are simply carbon represented by the letter "C." Compounds of carbon have different chemical identities based on atoms of carbon along with atoms of other elements: for example, methane combines carbon with the element hydrogen with the designation CH_4, which means that a single carbon atom is combined with four atoms of hydrogen; as another common example, carbon combined with hydrogen and oxygen is in one form ethanol, C_2H_5OH. Water, of course, is not a compound of carbon, but rather one of hydrogen and oxygen, specifically H_2O. Water can exist in several physical forms, namely as a solid, liquid, or gas, although the latter is more a function of temperature with the basic chemical structure remaining the same. Thus, it is readily apparent that the identification of a substance by chemical identity alone without reference to its physical form may not in all cases adequately describe the substance's properties. The crux of the debate regarding EPA's authority under TSCA is whether nanoparticles should be considered "new" in the TSCA sense simply because they are in a different physical form.

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[14] Toxic Substances Control Act, 15 U.S.C. §§ 2601-2692 (2006).

[15] *See* Toxic Substances Control Act § 2(b), 15 U.S.C. § 2601(b)(2) (2006).

[16] Toxic Substances Control Act § 3(2)(A), 15 U.S.C. § 2602(2)(A) (2007); *See also* 40 C.F.R. §§ 710.3(d), 720.3(e) (2007). TSCA Section 3(2)(B) excludes from the definition of "chemical substance" mixtures, pesticides, tobacco and tobacco products, certain nuclear materials, firearms and ammunition, and foods, food additives, drugs, cosmetics, and devices. 15 U.S.C. § 2602(2)(B) (2007); *see also* 40 C.F.R. §§ 710.3(d), 720.3(e) (2007). All of these categories, with the exception of mixtures, are regulated under other federal laws. TSCA defines a "mixture" as "any combination of two or more chemical substances if the combination does not occur in nature and is not, in whole or in part, the result of a chemical reaction." Also included within the definition is any chemical substance that is the result of a chemical reaction, but that could have been manufactured for commercial purposes without a reaction. Toxic Substances Control Act § 3(8), 15 U.S.C. § 2602(8) (2007); *see also* 40 C.F.R. §§ 710.3(d), 720.3(u) (2007). In addition to these statutory exclusions, EPA's regulations exclude "articles" and other types of substances (*e.g.*, certain impurities and byproducts) for purposes of various TSCA provisions. *See, e.g.*, 40 C.F.R. §§ 704.5, 710.4(d), 720.30 (2007).

A critically important aspect of TSCA is the TSCA Inventory, which is a continually-updated listing of chemicals in commerce. TSCA Section 8(b)(1) directs EPA to "compile, keep current, and publish a list of each chemical substance . . . manufactured or processed in the United States."[17] The vast majority of the chemicals included on the TSCA Inventory are substances that were in commerce prior to December 1979, and are so listed because entities included them on the Inventory when it was first published on June 1, 1979.[18] No EPA review of these chemical substances occurred at the time or, for the most part, since their original Inventory listing.

Under TSCA, these substances are considered "existing" chemical substances by virtue of their listing on the Inventory.[19] The Inventory is updated with chemical substances that have been added since the original Inventory was issued in 1979, including those chemicals EPA has more recently reviewed and approved as "new" chemicals subject to the PMN provisions under TSCA Section 5. Under TSCA, therefore, a chemical substance is considered either an "existing" chemical substance (because it is included on the Inventory) for TSCA purposes, or a "new" chemical substance (because it is not and must be approved by EPA prior to manufacture). For engineered nanoscale materials, and as discussed further below, the distinction is of some significance.

TSCA applies broadly to 'any person' who manufactures, processes, distributes in commerce, uses, or disposes of a chemical substance.[20] The nature of the activities involved—*i.e.*, manufacture, importation, processing—determines which sets of requirements apply. TSCA's requirements fall most heavily on chemical manufacturers. For TSCA purposes, "manufacture" includes importation.[21] This definition brings importers of chemical substances within TSCA's jurisdictional reach even though actual chemical manufacturing activities occur outside of the United States.

TSCA governs the manufacture of both new chemical substances and regulates uses of existing chemical substances that EPA has determined to be "significant new" uses.[22] As noted, chemical substances that are not listed on the TSCA Inventory, and that are not otherwise exempt from TSCA premarket approval requirements, are considered new chemical substances and thus subject to PMN

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[17] Toxic Substances Control Act § 8(b)(1), 15 U.S.C. § 2607(B)(b)(1) (2006).

[18] *See* Availability of TSCA Initial Inventory; Beginning of 210-Day Reporting Period for Revised Inventory, 44 Fed. Reg. 28,558 (May 15, 1979). The Inventory is continually updated by adding "new chemical substances" for which a premanufacture notice (PMN) and subsequent notice of commencement (NOC) have been submitted pursuant to TSCA Section 5. As of early 2007, there were approximately 83,000 chemical substances listed on the TSCA Inventory—roughly 66,400 non-confidential chemical substances and roughly 16,600 confidential chemical substances. The TSCA Inventory has two components: (1) a Public Inventory, which includes all existing chemical substances whose identity has not been claimed as confidential business information (CBI); and (2) a Confidential Inventory, which is accessible only by EPA and includes all existing chemical substances whose identity has been claimed as CBI. *See* 40 C.F.R. § 720.25(b)(1) (2007). Chemical substances on the TSCA Public Inventory are listed by a specific chemical name and a Chemical Abstracts Service (CAS) Registry Number—a unique number assigned by the CAS to a specific chemical substance—while chemical substances whose identities are claimed confidential are listed in the TSCA Public Inventory by an EPA-assigned accession number and a generic chemical name. *Id.*

[19] Toxic Substances Control Act § 3(9), 15 U.S.C. § 2602(9) (2007); *see also* 40 C.F.R. §§ 710.3, 720.3(v), 720.25(a) (2007).

[20] *See generally* Toxic Substances Control Act § 2(a)(2), 15 U.S.C. § 2601(a)(1-2) (2006) (congressional finding that "there are [chemical substances and mixtures] whose manufacture, processing, distribution in commerce, use, or disposal may present an unreasonable risk of injury to health or the environment").

[21] Toxic Substances Control Act § 3(7), 15 U.S.C. § 2602(7) (2007). Under the implementing regulations for TSCA Sections 5 and 8, "manufacture" is defined to mean "to manufacture, produce, or import for commercial purposes," which in turn is defined to mean "to manufacture, produce, or import with the purpose of obtaining an immediate or eventual commercial advantage." *See, e.g.*, 40 C.F.R. § 710.3(d) (2007).

[22] Toxic Substances Control Act § 5(a), 15 U.S.C. § 2604(a) (2006).

requirements.[23] Similarly, a "significant new" use of a chemical substance that is already listed on the TSCA Inventory is treated much like a new chemical substance and the new use is subject to EPA review in much the same way EPA reviews a new chemical. This is discussed more below.

2. Determining a Chemical's TSCA Inventory Status

To ensure compliance with TSCA, prior to the commercial manufacture of a chemical substance for a non-exempt purpose, the manufacturer must first determine its TSCA Inventory status. As noted, there are two Inventories: the Public Inventory and the Confidential Inventory. If a search of the Public Inventory (which is included on a publicly available, searchable database)[24] does not yield a listing, the next step is to determine whether the substance is included on the Confidential Inventory. If the identity of a chemical substance has been claimed as a trade secret, or otherwise it is not listed on the Public Inventory, it may be listed on the TSCA Confidential Inventory. To determine if it is listed, a *bona fide* intent (BFI) request must be submitted to EPA so EPA can search the Confidential Inventory.[25]

If a chemical substance is not listed on either portion of the TSCA Inventory, manufacturers must submit a PMN for any chemical substance to be manufactured and that is not eligible for a PMN exemption. The PMN form itself is straightforward and seeks information only on the submitter's identity, the chemical substance's identity, production volume, uses, exposures, and environmental fate.[26] TSCA does not require the PMN submitter to test a new chemical substance before submitting a PMN. Health and safety data relating to a new chemical substance's health or environmental effects that are in a submitter's possession or control, however, must be submitted along with the PMN to the extent it "is known to or reasonably ascertainable by" the submitter.[27] The period for EPA review of a PMN is 90 days, unless extended by EPA for up to an additional 90 days.[28]

3. PMN Exemptions

There are several important exemptions from the PMN requirements, some of which are relevant to the discussion regarding TSCA's ability comprehensively to address potential risks arising from engineered nanoscale materials that are chemical substances. TSCA exemptions fall into one of two categories: self-executing and those that require EPA approval. Exemptions are considered "self-executing" because they do not require prior EPA approval and once a manufacturer determines that one of the self-executing exemptions applies, the new chemical substance may be manufactured in the U.S. without first submitting a PMN. The entity must, however, comply with certain recordkeeping and/or other requirements for the particular exemption to apply. The self-executing exemptions are: the exemption for chemical substances having no separate commercial purpose; the polymer exemption; and the research and development (R&D) exemption.

Other exemptions from PMN requirements require explicit EPA prior approval. In these instances, a manufacturer must submit, and EPA must approve, an exemption application before a company may commence the manufacture of the new chemical substance, subject to compliance with any associated

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[23] The PMN regulations are at 40 C.F.R. pt. 720 (2007), and PMN exemptions are at 40 C.F.R. pt. 723 (2007). Existing chemical substances already listed on the TSCA Inventory may be subject to a Significant New Use Rule (SNUR), which also is authorized under TSCA Section 5 and 40 C.F.R. pt. 721, subpt. E and is discussed below.

[24] *See Toxic Substances Chemical Substances Inventory extract database search*, CORNELL UNIV. DEPT. OF ENV'T HEALTH & SAFETY, http://msds.ehs.cornell.edu/tscasrch.asp (last visited Feb. 5, 2007) (unofficial version).

[25] *See* 40 C.F.R. § 720.25(a)(5) (2007).

[26] *See id.* at pt. 720, subpt. C (2007); EPA, *EPA Form 7710-25*, *available at* http://www.epa.gov/opptintr/newchems/pubs/pmnforms.htm.

[27] *See* 40 C.F.R. §§ 720.40(d), 720.50 (2007). The phrase "known to or reasonably ascertainable by" is defined at 40 C.F.R. § 720.3(p) (2007).

[28] Toxic Substances Control Act § 5(a), (c), 15 U.S.C. § 2604(a), (c) (2006); 40 C.F.R. § 720.75. The review period can be extended repeatedly.

recordkeeping and/or other requirements that may apply. These exemptions are for low volume (LVE); LoREX; and the test marketing exemption (TME).

For present purposes, the self-executing R&D exemption is particularly important to the emerging nanotechnology industry.[29] To qualify as an R&D substance, the chemical substance must be manufactured or imported only in "small quantities" for purposes of scientific experimentation or analysis, or for chemical research on or analysis of such substance or another substance, including such research or analysis for the development of a product.[30] The term "small quantities" is not defined quantitatively, but qualitatively, as those "that are not greater than reasonably necessary" for R&D purposes.[31] Substances that satisfy the criteria for an R&D substance must be used by or under the supervision of a "technology qualified individual" (TQI), who is tasked with ensuring compliance with volume, prescribed uses, labeling, handling and distribution, disposal, and recordkeeping requirements.[32]

Two other exemptions that are particularly relevant to emerging nanotechnology industries—the LVE and LoREX exemptions—are not self-executing and require explicit EPA approval. These exemptions require prior EPA review and approval.[33] The process for obtaining EPA approval can be time consuming and resource intensive. Notice must be submitted at least 30 days before manufacture begins, triggering a 30-day period for EPA review and action.[34]

Eligibility for an LVE is based on the manufacture of a new chemical in quantities of 10,000 kilograms or less per year.[35] Eligibility for a LoREX is based on meeting several regulatory criteria throughout the processes of manufacturing, processing, distribution, use, and disposal of the chemical substance. These include: for consumers and the general population, no dermal or inhalation exposure and no drinking water exposure greater than one milligram per year, and for workers, there can be no dermal or inhalation exposure, there can be no releases to ambient surface water in concentrations above one part per billion, no releases to the ambient air from incineration in excess of one microgram per cubic meter, and no releases to groundwater, land, or a landfill, unless it is demonstrated there is negligible groundwater migration potential.[36]

Even where the LVE or LoREX criteria are satisfied, EPA may deny an application for an exemption for a new chemical based on its finding that the substance, its reasonably anticipated metabolites, environmental transformation products, or byproducts may cause serious acute or chronic health effects, or significant environmental effects.[37] Once EPA notifies the applicant that an exemption

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[29] *See* Toxic Substances Control Act § 5(h)(3), 15 U.S.C. § 2604(h)(3) (2006); *see also* 40 C.F.R. § 720.36 (2007).

[30] 40 C.F.R. § 720.3(cc) (2007).

[31] *Id.; see also* EPA, *New Chemical Information Bulletin: Exemptions for Research and Development and Test Marketing*, at 5 (Nov. 1986), http://www.epa.gov/opptintr/newchems/pubs/tmeranddbulletin.pdf.

[32] 40 C.F.R. § 720.3(ee) (2007). This regulation defines a TQI as a person:

(1) who, because of education, training, or experience, or a combination of these factors, is capable of understanding the health and environmental risks associated with the chemical substance which is used under his or her supervision, (2) who is responsible for enforcing appropriate methods of conducting scientific experimentation, analysis, or chemical research to minimize such risks, and (3) who is responsible for the safety assessments and clearances related to the procurement, storage, use, and disposal of the chemical substance as may be appropriate or required within the scope of conducting a research and development activity.

[33] *Id.* § 723.50(a)(2), (g) (2007). This review period can be suspended to allow EPA a longer review period.

[34] As noted, EPA approved the first LoREX for what is believed to be a single wall carbon nanotube in October 2005. The review and approval period was 13 months. *See e.g., supra* note 13.

[35] *See* 40 C.F.R. § 723.50(a), (c) (2007). One kilogram is equivalent to 2.2 pounds.

[36] *Id.* § 723.50(c)(2).

[37] *Id.* § 723.50(d).

has been granted, or if the review period expires without notice from EPA, manufacture or import of the chemical substance may commence, consistent with the terms of the exemption.[38]

4. EPA's "Significant New Use" Authority

TSCA's authority under Section 5 enables EPA to review and assess potential risks posed by chemical substances that are new chemical substances (not listed on the TSCA Inventory), as well as uses of existing chemical substances deemed to be significant new uses. Some have suggested that the co-location of this broad authority in the same TSCA provision is a clear indication that Congress intended EPA to regulate new uses of existing chemicals and new chemicals similarly, adjusting only the administrative process applicable for obtaining EPA approval.[39]

EPA reviews truly "new" chemicals (those not listed on the TSCA Inventory) under TSCA Section 5(a)(1), which requires that entities submit a PMN form to EPA for review as a condition precedent to the commercial manufacture of the chemical substance unless an exemption applies. EPA applies the same condition on uses of existing chemical substances deemed "significant new" uses under TSCA Section 5(a)(2). The form that must be submitted to EPA is a Significant New Use Notification (SNUN), and the notification that EPA publishes announcing the significant new use is referred to as a SNUR. The TSCA legislative history of this provision emphasized that EPA's authority under Section 5(a)(2) is a counterpart to its authority under Section 5(a)(1):

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.[40]

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[38] *Id.* § 723.50(g)(2). TSCA Section 5(e) grants EPA the authority to issue administrative orders controlling new chemical substances where it finds that there is insufficient information for reasonable evaluation of the risk and either the chemical may present an unreasonable risk to health or the environment (referred to as a "risk-based" finding), or will be produced in substantial quantities that will enter the environment or to which there will be substantial or significant human exposure (referred to as an "exposure-based" finding). Toxic Substances Control Act § 5(e)(1)(C), 15 U.S.C. § 2604(e)(1)(A) (2006). Additionally, EPA may ban or limit the manufacture, processing, distribution, use, or disposal of the chemical. EPA must propose Section 5(e) orders prior to the expiration of the 90-day PMN review period, and a proposed order will become effective upon the expiration of that period unless the manufacturer that submitted the PMN files objections to the order. Toxic Substances Control Act § 5(e)(1)(C), 15 U.S.C. § 2604(e)(1)(C) (2006). As a matter of practice, however, rather than acting unilaterally under Section 5(e), EPA typically enters into a consent order with the manufacturer, under which the manufacturer agrees to restrict the manufacture, processing, distribution, use, or disposal of the new chemical substance as provided in the order. Consent orders permit the manufacturer to distribute the chemical substances, subject to various restrictions, pending the development of data necessary to evaluate potential hazards.

[39] The American Bar Association (ABA) Section of Environment, Energy, and Resources (SEER) completed and released publicly a comprehensive legal review of TSCA and nanotechnology in June 2006. ABA SEER, *Regulation of Nanoscale Materials under the Toxic Substances Control Act*, (June 2006), (ABA SEER Paper), *available at* http://www.abanet.org/environ/nanotech/pdf/TSCA.pdf. The ABA SEER paper notes that TSCA Section 5 gives EPA authority to assess the risks of individual chemical substances and to impose limitations on their manufacture, processing, distribution, and use in appropriate cases, including prohibiting their manufacture altogether. Specifically, "[t]his TSCA section has twin provisions: Section 5(a)(1) for "new" chemical substances, and Section 5(a)(2) for significant new uses of existing chemical substances. While the two provisions have different triggers, once triggered they operate almost identically. Much discussion and papers from various stakeholders have focused on EPA's ability to use Section 5(a)(1) to regulate as "new" chemical substances nanomaterials for which conventional-sized versions are already on the TSCA Chemical Substances Inventory (Inventory). Assuming that such distinctions reasonably can be drawn in individual cases, the arguments for this use of Section 5(a)(1) face obstacles. In contrast, the Section 5(a)(2) SNUR process appears to offer EPA adequate authority to effectively regulate nanoscale versions of materials that are already on the TSCA Inventory." *Id.* at 5.

[40] S. REP. NO. 94-698, at 19 (1976), *as reprinted in* 1976 U.S.C.C.A.N. 4491 (Legislative History of the Toxic Substances Control Act). For example, EPA may issue orders under Sections 5(e) and 5(f) with respect to chemicals notified under either Section 5(a)(1) or Section 5(a)(2), as both provisions refer to "a chemical substance with respect to which notice is required by subsection (a)."

EPA's SNUR authority allows it to address perceived risks associated with the manufacturing, processing, and/or use of an existing chemical in a new way. As discussed below, this authority would appear intuitively and factually to have special relevance to Inventory-listed chemicals manufactured at the nanoscale.

A key distinction between EPA's TSCA Section 5(a)(1) PMN authority and its Section 5(a)(2) SNUR authority is that under Section 5(a)(2), EPA must issue a rule, whereas under Section 5(a)(1), EPA has in place a generic rule requiring submission of a PMN.[41] Once EPA has issued a rule under Section 5(a)(2), however, the two provisions operate in much the same way.[42]

In issuing a SNUR, EPA must explain how it considered "all relevant factors," including the following factors specifically listed in the statute: the projected volume of manufacturing and processing of a chemical substance, the extent to which a use changes the type or form of exposure to human beings or the environment to a chemical substance, the extent to which a use increases the magnitude and duration of exposure of human beings or the environment to a chemical substance, and the reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of a chemical substance. EPA's legal burden under TSCA Section 5(a)(2) is relatively light. EPA need not make a legal "finding," which is a legal determination that requires considerable support, with respect to the potential harm that the chemical substance may pose. Rather, EPA need only "consider" these four statutory factors.[43]

Importantly for present purposes, EPA is authorized to issue SNURs for "categories" of chemical substances. The term "category of chemical substances" means 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 this Act."[44]

There is at least one significant precedent for EPA's use of its SNUR authority for a category of chemicals, namely, chemicals that have in common acrylate functionality. In the early 1980s, EPA began to receive PMNs for acrylate chemicals of various types which were intended for use as components of the new and environmentally friendly radiation curing (UV and EB) technology. There was a concern at that time that all acrylates might be carcinogens, and therefore EPA identified acrylates as the first chemical type designated as a category of concern. EPA chose to regulate new acrylates through TSCA Section 5(e) consent orders, and then followed up with promulgation of SNURs for the individual acrylate substances, which, in essence, replicated the restrictions (protective equipment, hazard communication, recordkeeping, distribution restrictions) present in the submitter's Section 5(e) order. Because regulation of individual acrylate PMN substances was quite onerous, EPA proposed a generic rule for the acrylate category of chemicals on November 22, 1993.[45]

The proposed rule was never issued in final because a voluntary testing program initiated by the SAM Panel of the Chemical Manufacturers Association (now the American Chemistry Council) demonstrated in studies completed in the mid-1990s that it could not be assumed that a new acrylate PMN

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41 *See* 40 C.F.R. § 720.22 (2007).

42 Procedurally, a SNUR rulemaking is conducted under the provisions of the Administrative Procedure Act, under which the public is offered an opportunity to provide comment. 5 U.S.C. § 553 (2007). The process involves publication of a proposed rule in the *Federal Register*, and publication of a final rule after EPA has reviewed and considered public comment. EPA has issued more than 700 SNURs using this procedure, and is quite experienced in these matters. Thus, SNURs are by far the most common subject of rulemaking under TSCA. *See generally id.*

43 *See* Toxic Substances Control Act § 19(c)(1)(B), 15 U.S.C. § 2618(c)(1)(B) (2006).

44 Toxic Substances Control Act § 26(c)(2)(A), 15 U.S.C. § 2625(c)(2)(A) (2006).

45 Significant New Uses of Certain Acrylate Esters, 58 Fed. Reg. 61,649 (Nov. 22, 1993) (to be codified at 40 C.F.R. pt. 721).

substance might be a carcinogen, although individual PMN submissions would still be regulated on a case-by-case basis. Consequently, EPA withdrew the proposed Generic Acrylate SNUR on January 9, 1997,[46] and subsequently revoked individual acrylate substance 5(e) orders and SNURs.[47]

EPA exercised its Section 5(a)(2) authority most recently in March 2006 when it issued a SNUR for perfluoroalkyl sulfonates as a category of chemicals.[48] The criterion for qualifying as a category is broad and merely requires that the members of the category "in some . . . way [be] suitable for classification as such" for TSCA purposes.

5. TSCA Section 6: Regulation of Existing Chemicals

While TSCA Section 5 is often noted in discussions of EPA's regulatory authority in connection with engineered nanoscale materials, TSCA also provides EPA with significant authority to regulate existing chemical substances under Section 6. TSCA Section 6(a) authorizes EPA to regulate the manufacture, processing, commercial distribution, use, and/or disposal of a chemical substance when there is a reasonable basis to conclude that the substance "presents or will present an unreasonable risk of injury to health or the environment."[49] The set of regulatory measures available under Section 6 is broad and includes prohibiting or limiting the manufacture, processing, or distribution in commerce of the chemical; prohibiting or limiting the manufacture, processing, or distribution in commerce of the chemical for a particular use or for a particular use at a particular concentration; or requiring that the chemical, or any article containing the chemical, be labeled or accompanied by warnings and instructions for use, distribution, or disposal, among other provisions.[50] EPA is required, however, to select the least burdensome approach that is adequate to achieve the regulatory objectives.[51] This requirement has caused EPA difficulty under other rulemakings where it has tried to ban a substance.[52]

Under TSCA Section 6(b), EPA may order a chemical manufacturer or processor to provide certain information if there is a reasonable basis to conclude that the manufacture or processing of a chemical may present an unreasonable risk to human health or the environment. For example, EPA may order the chemical manufacturer or processor to submit a description of its quality control procedures that apply to the chemical's manufacture. EPA is authorized to require the manufacturer or processor to modify those procedures to the extent it believes necessary to address any inadequacies. Further, if EPA determines

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[46] Certain Acrylate Esters; Withdrawal of Proposed Significant New Use Rule, 62 Fed. Reg. 1,305 (Jan. 9, 1997) (to be codified at 40 C.F.R. pt. 721).

[47] *See* Charles Auer, Kenneth Moss & James Alwood, *Acrylate regulation under TSCA*, 4 CHEM. HEALTH SAFETY, 38 (1997) (EPA authors details the history of the SAM Panel and Generic Acrylate SNUR).

[48] *See, e.g.*, 40 C.F.R. § 721.9582 (2007) (covering 88 perfluoroalkyl sulfonates); Perfluoroalkyl Sulfonates; Proposed Significant New Use Rule, 71 Fed. Reg. 12,311 (Mar. 10, 2006) (to be codified at 40 C.F.R. pt. 721) (proposed addition of 183 perfluoroalkyl sulfonates). EPA's regulatory action is one in a series involving the voluntary phase-out of perfluoroalkyl sulfonate (PFAS) substances, which began in 2000 when the sole U.S. manufacturer of perfluroroctanyl sulfonate (PFOS) voluntarily withdrew production from the market. EPA thereafter issued a SNUR applicable to 13 PFAS substances. Perfluoroalkyl Sulfonates; Proposed Significant New Use Rule, 67 Fed. Reg. 11,014 (Mar. 11, 2002) (to be codified 40 C.F.R. pt. 721). In December 2002, EPA issued a second SNUR applicable to 75 PFAS substances. Perfluoroalkyl Sulfonates; Significant New Use Rule, 67 Fed. Reg. 72,854 (Dec. 9, 2002) (to be codified at 40 C.F.R. pt. 721). EPA's regulation of these chemicals through the use of SNURs has been identified by some TSCA experts as a success story. *See Oversight Hearing on Implementation of TSCA Before the Comm. on Env't & Public Works*, 152 Cong. (2006) (written testimony of William K. Rawson, Partner & Chair of the Env't, Land & Res. Dept. in Wash. D.C.) *available at* http://epw.senate.gov/109th/Rawson_Testimony.pdf.

[49] Toxic Substances Control Act § 6(a), 15 U.S.C. § 2605(a) (2006).

[50] Toxic Substances Control Act § 6(a)(1)-(7), 15 U.S.C. § 2605(a)(1)-(7) (2006).

[51] Toxic Substances Control Act § 6(a), 15 U.S.C. § 2605(a) (2006).

[52] *See e.g.*, Corrosion Proof Fittings v. EPA, 947 F.2d 1201 (5th Cir. 1991) (rules that EPA neglected, among other things, to consider the least burdensome approach to addressing risk before it banned most uses of asbestos still in commerce, thus requiring the Court to invalidate this component of the rule).

that a chemical that has been distributed in commerce presents an unreasonable risk of injury to health or the environment, it may order the manufacturer or processor to notify customers and the public of the risk involved and to replace or repurchase the chemical, as appropriate, to abate that risk.

EPA has exercised its Section 6 authority to prohibit the manufacture, processing, and distribution in commerce of fully halogenated chlorofluorocarbons (CFCs) for aerosol propellant uses, excepting certain limited uses;[53] to prohibit the mixing of nitrosating agents with certain metalworking fluids;[54] to address exposure to airborne asbestos in school buildings;[55] and to regulate the use of hexavalent chromium chemicals in certain heating, ventilation, air conditioning, and refrigeration systems based on EPA's findings that such chemicals are human carcinogens.[56]

In contrast to EPA's legal burden under Section 5, EPA's burden under Section 6 is considerably heavier. EPA is required under Section 6 to make a finding that a chemical substance "presents" or "will present" an unreasonable risk of injury to health or the environment. EPA must also consider the availability of substitute chemicals and the economic impact of the rule. Finally, EPA's rules are subject to judicial review and a "substantial evidence" standard applies. In contrast, Section 5 SNURs are reviewable under the "arbitrary and capricious" standard, which allows EPA considerably more discretion.

6. EPA's Authority under TSCA Sections 7 and 8

TSCA Section 7 authorizes EPA to initiate a civil action to seize a chemical substance or mixture which is believed to present an imminent and unreasonable risk of serious or widespread injury to health or the environment, or an article containing such substance or mixture.[57] EPA also may seek other appropriate relief, including a requirement that manufacturers or others give notice to purchasers or the public of the risks associated with the substance, mixture, or article, as well as recall, replace, or repurchase the substance, mixture, or article.

EPA has broad information-gathering powers under TSCA Section 8. These powers include the ability to impose, under Section 8(a), recordkeeping and reporting requirements for production, use, and exposure-related information and, under Section 8(d), requirements for submitting "health and safety study" data. Pursuant to regulations issued by EPA under Section 8(c), manufacturers, importers, and processors of an existing chemical substance must create and maintain records of "allegations"—whether written or oral—that the chemical "caused a significant adverse reaction to health or the environment."[58] A company's Section 8(c) records must be made available for inspection by EPA at any time and submitted to EPA upon request.[59] Failure to maintain, submit, or permit access to records or reports under these provisions is punishable by both civil and criminal penalties.

Section 8(e), the self-executing "substantial risk" reporting provision of TSCA, places responsibility on manufacturers, processors, and distributors to report information relating to substantial risks of

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[53] Because CFCs were banned under the Clean Air Act Amendments of 1990, EPA revoked its TSCA regulations for CFCs in 1995. *See* Chemical Substances; Deletion of Certain Chemical Regulations; Technical Amendments to the Code of Federal Regulations, 60 Fed. Reg. 31917 (June 19, 1995) (to be codified at 40 C.F.R. pts. 61, 704, 710, 712, 762, 763, 766, 790, 795, 796, 797, 798, & 799).

[54] *See* 40 C.F.R. pt. 747 (2007).

[55] Asbestos; Friable Asbestos-Containing Materials in Schools; Identification and Notification, 47 Fed. Reg. 23360 (May 27, 1982) (to be codified at 40 C.F.R. pt. 763). When Congress, in 1986, enacted Subchapter II of TSCA to address asbestos hazards, EPA revoked the TSCA regulations and promulgated regulations implementing the new statute.

[56] 40 C.F.R. pt. 749, subpt. D (2007).

[57] Toxic Substances Control Act § 7(a), 15 U.S.C. § 2606(a) (2007).

[58] 40 C.F.R. § 717.3(a) (2007).

[59] *Id.* at § 717.17(a)-(b).

chemical substances. This reporting obligation is important and may have special significance to companies conducting research on engineered nanoscale substances. Under Section 8(e):

> Any person who manufactures, processes, or distributes in commerce a chemical substance or mixture and who obtains information which reasonably supports the conclusion that such substance or mixture presents a substantial risk of injury to health or the environment shall immediately inform the Administrator of such information unless such person has actual knowledge that the Administrator has been adequately informed of such information.[60]

Immediately means "not later than the 30th calendar day after the date the subject person has obtained such information."[61] In the event a company becomes aware of an emergency incident of environmental contamination, such information must be reported "as soon as the person has knowledge of the incident."[62] EPA considers a company to have obtained information "at the time any officer or employee capable of appreciating the significance of such information obtains it."[63] "Known" information includes "that information about which a prudent person of similar training, job function, etc., could be reasonably expected to know."[64]

Historically, penalties for non-compliance with the Section 8(e) substantial risk information reporting obligation have been severe. In fact, the largest civil administrative penalty ever collected by EPA under any of the federal environmental statutes that it administers was in 2005 and was based on allegations arising under TSCA Section 8(e) reporting violations.[65]

V. APPLICABILITY OF TSCA TO ENGINEERED NANOSCALE MATERIALS

With this background in mind, it is now appropriate to frame several of the key TSCA issues that have been raised in connection with the application of TSCA to engineered nanoscale materials. These issues include whether engineered nanoscale materials consisting of TSCA Inventory-listed chemicals should be regulated by EPA under TSCA as "new" chemicals; whether certain exemptions from TSCA premarket approval requirements are well-suited when applied to engineered nanoscale substances; and whether TSCA's reporting provisions are sufficiently robust to address issues arising in connection with engineered nanoscale materials that are chemical substances.

1. Whether Engineered Nanoscale Materials Consisting of TSCA Inventory Listed Chemicals Should Be Regulated as "New" Chemical Substances

Several organizations, including Environmental Defense, Inc. (ED), Natural Resources Defense Council (NRDC), and the Royal Society and the Royal Academy of Engineering, an independent

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60 Toxic Substances Control Act § 8(e), 15 U.S.C. § 2607(e) (2007).

61 TSCA Section 8(e); Notification of Substantial Risk; Policy Clarification and Reporting Guidance, 68 Fed. Reg. 33129, 33138 (June 3, 2003) (guidance document articulating EPA's preferences for how and where TSCA section 8(e) notices should be submitted).

62 *Id.*

63 *Id.* at 33137; *see also* Toxic Substance Control Act, Notification [sic] of Substantial Risk Under Section 8(e), 43 Fed. Reg. 11110, 11111 (Mar. 16, 1978) (states EPA's interpretation of, and enforcement policy concerning, section 8(e) of the TSCA).

64 EPA, *TSCA Section 8(e) Reporting Guide* at 6 (June 1991) *available at* http://www.epa.gov/oppt/tsca8e/pubs/rguide.htm.

65 *See* 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; Joseph E. Plamondon, *The DuPont TSCA Enforcement Action: Implications for the Chemical Industry*, 15 ENV'T QUALITY MGMT. 1 (2006).

scientific academy of the United Kingdom (UK), have questioned whether TSCA is, in all cases, well-suited to manage potential heath and safety risks believed to be posed by engineered nanoscale substances. These organizations have recommended that nanoscale versions of existing (Inventory-listed) chemical substances be considered "new" chemical substances for purposes of TSCA Section 5 review.[66] 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."[67]

In short, the argument is that if nanosized versions of existing macro-scaled chemicals are designed to impart new or novel properties and/or characteristics in addition to and/or different from their macro-sized counterparts, it is reasonable to conclude that nanoscale versions of conventional substances may pose risks not associated with their conventional counterparts such that nanoscale versions should be considered "new" chemicals for TSCA regulatory purposes.

It is undisputed that TSCA applies to engineered nanoscale materials that are chemical substances not listed on the TSCA Inventory. Given the breadth of the definition of "chemical substance" under TSCA, engineered nanomaterials consisting of "organic or inorganic substances of a particular molecular identity" clearly fall within TSCA's scope.

Conceding that engineered nanoscale materials that are chemical substances are subject to TSCA, the issue becomes what TSCA provisions apply. Proponents of the argument that nanoscale versions of existing chemicals should be regulated as new substances claim that this interpretation of TSCA is good public policy and could prevent any unintended adverse human health and environmental consequences that may be associated with engineered nanoscale materials. They point to historic examples of chemical substances that were widely used in commerce before sufficient human health and environmental information was developed to characterize their potential for harm.

Second, proponents of this argument assert that engineered nanoscale materials are of interest and commercial value precisely because they are "new" and special. Since these materials are believed to offer new features and added value, they should be subject to TSCA's new chemical provisions.[68]

A third argument proponents assert is that the TSCA definition of "chemical substances" encompasses more than merely a substance's molecular structure. ED, for example, claims that a chemical's physical properties and structure are both relevant in terms of determining whether a chemical is new or existing. ED points to the fact that the term "molecular structure" appears twice in TSCA, in Section 8(a)(2)(A) and Section 26(c)(2)(A), and that because Congress separately addresses both chemical identity and molecular structure, Congress demonstrated that it did not consider these terms to

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[66] *See* Natural Resources Defense Council et al., *EPA Proposal to Regulate Nanomaterials Through a Voluntary Pilot Program*, EPA, at 11-12 (July 5, 2005), EPA Docket OPPT-2004-0122, Doc. ID EPA-HQ-OPPT-2004-0122-0037 at http://www.regulations.gov; *see* Letter from Richard A. Denison, Ph.D., Senior Scientist & Karen Florini, Senior Attorney, Environmental Defense to The Honorable Susan B. Hazen, Acting Assistant Administrator, EPA at 3 (Sept. 2, 2004) (on file with Env't Defense Fund at http://www.environmentaldefense.org/documents/4457_NanotechLetterToEPA.pdf). The Royal Society and the Royal Academy of Engineering 2004, *Nanoscience and Nanotechnologies: Opportunities and Uncertainties*, THE ROYAL SOCIETY (July 29, 2004), *available at* http://www.nanotec.org.uk/finalReport.htm. *See also* Karen Florini et al., *Nanotechnology: Getting It Right the First Time*, 6 SUSTAINABLE DEV. L. & POL'Y 46, 51 (2006) (ED has urged the EPA to clarify that nanomaterials with existing molecular structures still constitute "new" substances unless their chemical and physical properties are demonstrably identical to those of the conventional substance. This definition is based on the grounds that only substances with the same properties, as well as the same molecular structure, share a "particular molecular identity.")

[67] Letter from Richard A. Denison & Karen Florini A. Klee at 1 (May 22, 2006) (ED Letter) (on file with author).

[68] *See id.*

be synonymous.[69] ED notes that if Congress intended chemical identity to be synonymous with molecular structure, there would be no reason for a separate enumeration of these terms within the statute. Further, ED notes that there is nothing in TSCA that expressly precludes the definition of "chemical substance" from including physical and chemical properties.[70]

ED also argues that EPA's "long standing application of TSCA's definition of 'chemical substance' routinely encompasses more than the substance's molecular structure where molecular structure alone is insufficient to define the substance."[71] ED points, by way of example, to EPA's definition of and listing on the TSCA Inventory of unknown or variable composition, complex reaction products, and biological materials—so-called "UVCB" substances—as demonstrating that EPA can and does consider physical properties in defining a chemical substance. In support of the argument, ED notes that the TSCA Inventory includes many so-called "Class 2" substances. EPA defines a Class 2 substance as "those having chemical compositions not completely definite or known; therefore, [a Class 2 substance] cannot be characterized by definite, complete chemical structure diagrams."[72] According to ED, the group of UVCB substances reflects EPA's explicit consideration and reference to a chemical substance's physical properties, and demonstrates that "EPA can—and routinely does—define chemical substances for TSCA purposes . . . with *explicit* consideration of and reference to their physical properties."[73] ED further notes in this regard that engineered nanomaterials are "perfect examples" of such chemical substances and their enhanced or novel properties are what makes these chemicals special: "Their enhanced or novel properties which, in many cases are a direct function of the means by which they are produced, are what make them new, giving them their own molecular identity and distinguishing them from existing chemical substances possessing the same molecular structure. To ignore such factors would be to ignore the very nano-ness of engineered of nanomaterials."[74]

The American Chemistry Council Nanotechnology Panel, on the other hand, challenges ED's interpretation of TSCA, asserting that "existing" nanoscale versions of Inventory-listed substances are not "new" chemical substances for TSCA purposes and cannot be considered new based on the very definition in TSCA of "chemical substance." TSCA Section 3(2) defines the term "chemical substance" in pertinent part as follows:

> Except as provided in subparagraph (B), the term 'chemical substance' means any organic or inorganic substance of a particular molecular identity, including any combination of such substances occurring in whole or in part as a result of a chemical reaction or occurring in nature, and any element or uncombined radical.[75]

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[69] *Id.* at 3.
[70] *Id.* at 3-4.
[71] *Id.* at 4.
[72] Premanufacture Notification; Revisions of Premanufacture Notification Regulations; Final Rule, 60 Fed. Reg. 16298, 16299 (Mar. 29, 1995) (to be codified at 40 C.F.R. pts. 704, 720 & 721).
[73] ED Letter at 5.
[74] *Id.* at 6.
[75] Toxic Substances Control Act § 3(2)(A), 15 U.S.C. § 2602(2)(A) (2007); *See also* 40 C.F.R. §§ 710.3(d), 720.3(e) (2007). Subparagraph (B) expressly excludes the following from the definition of "chemical substance": mixtures; pesticides; tobacco and tobacco products; certain nuclear materials; firearms and ammunition; and food, food additives, drugs, cosmetics, and devices. Toxic Substances Control Act § 3(2)(B), 15 U.S.C. § 2602(2)(B) (2007); *See also* 40 C.F.R. §§ 710.3(d), 720.3(e) (2007). With the exception of mixtures, all of these categories are regulated under other federal laws. The introductory language in Section 3(2)(A) emanates from the TSCA legislation first proposed by EPA in February 1971, "The Toxic Substances Control Act of 1971," which would have amended the Federal Hazardous Substances Act. That proposed legislation, in turn, grew out of a Council on Environmental Quality (CEQ) report on perceived "problems associated with toxic substances in the environment" that found that existing legal authorities were "inadequate to control the actual and potential dangers of toxic substances comprehensively or systematically."

A "chemical substance" is defined by its "molecular identity," and the definition makes no mention of a substance's physical and chemical properties.[76] EPA's regulatory definition of "new chemical substance" mirrors the statutory definition: a "new chemical substance" is any chemical substance not listed on the TSCA Inventory.[77] In ascertaining whether a particular substance appears on the Inventory, all that appears to matter legally, according to the American Chemistry Council Nanotechnology Panel, is whether, based on the substance's molecular identity, it is or is not listed.[78]

Additionally, the Panel claims EPA's historic course of conduct has been to consider only a chemical substance's molecular identity, not its physical or chemical properties or structure. This argument is addressed in the ABA SEER Paper. According to it, EPA's lack of emphasis on molecular structure is reflected in the PMN review process. The Paper notes that "[t]he 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."[79] 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. Of course, it is not clear if in EPA's decision logic referenced above a different result would occur if the existing chemical is manufactured at the nanoscale.

The ABA SEER Paper acknowledges that arguments can be made 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 concludes that molecular structure is the definitive characteristic in most instances. For example, the definition of "chemical substance" explicitly includes "any combination of such substances occurring in whole or in part as a result of a chemical reaction or occurring in nature."[80] EPA has relied on this definition to include as individual entries on the Inventory UVCB substances. Some of these UVCB Inventory entries explicitly consider factors such as the manufacturing process and physical properties, factors that might be relevant to distinguishing nanoscale versions of macroscale existing chemical substances. The ABA SEER Paper notes:

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[76] In a House Foreign and Interstate Commerce Committee Report on the EPA-proposed TSCA legislation that passed the full House in 1972, and which defined "chemical substance" in a virtually identical manner to TSCA Section 3(2), the Committee observed that "[t]he definition [of 'chemical substance'] is specifically limited to substances of a particular molecular identity, and in using the word 'element' the committee means the customary definition of a chemical element." H.R. REP. NO. 92-1477, at 5 (1972). The reported legislation, S. 1478, defined "chemical substance" to mean "any organic or inorganic substance of a particular molecular identity, or any uncombined chemical radical or element."

[77] *See* 40 C.F.R. §§ 710.3, 720.3(v), 720.25(a) (2007).

[78] *See* TSCA Inventory Nomenclature for Enzymes and Proteins, 69 Fed. Reg. 65565, 65567 (Nov. 15, 2004) (to be codified at 40 C.F.R. pt. 720) (stating "[t]he only way to determine if a substance is new or existing is by consulting the TSCA Inventory"); 42 Fed. Reg. 64572, 64591 (Dec. 23, 1977) (to be codified at 40 C.F.R. pt. 710) (promulgation of the original Inventory reporting regulations, stating that the Inventory "defines what is a 'new chemical substance' for purposes of [the PMN requirements in] section 5(a)(1)(A)."); *See also* Becky Cool, *EPA's New Chemical Program Under Section 5 of TSCA*, presentation before WOODROW WILSON INT'L CTR. FOR SCHOLARS (Oct. 2, 2003) (available at Env't Futures at http://www.environmentalfutures.org/nanotech_2.pdf) (under most circumstances, an "'existing' chemical substance is one that was reported for EPA's initial TSCA Inventory as being already in U.S. commerce"; a "'new' chemical substance is one that does not appear on EPA's TSCA Inventory").

[79] ABA SEER Paper at 8, citing *Chemistry Assistance Manual for Premanufacture Notification Submitters* (EPA 744-R-97-003) at 15-16 (Mar. 1997), *available at* http://www.epa.gov/opptintr/newchems/pubs/chem-pmn/index.htm.

[80] Toxic Substances Control Act § 3(2)(A)(i), 15 U.S.C. § 2602(2)(A)(i) (2007).

> For example, the following TSCA Inventory entries for UVCB materials include factors other than molecular structure:
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> Naphtha (petroleum), light catalytic reformed, CAS No. 64741-63-5: A complex combination of hydrocarbons produced from the distillation of a catalytic reforming process. It consists primarily of hydrocarbons having carbon numbers predominantly in the range of C_5 through C_{11} and boiling in the range of approximately 35°C to 190°C (194°F to 446°F). It contains a relatively large proportion of aromatic and branched chain hydrocarbons. This stream may contain 10 vol. % or more benzene.
>
> Caramel (color), CAS No. 8028-89-5: The substance obtained by controlled heat treatment of food-grade carbohydrates . . . . Consists essentially of colloidal aggregates that are dispersible in water but only partly dispersible in alcohol-water solutions. Depending upon the particular caramelizing agent used, may have a positive or negative colloidal charge in solution.[81]

The ABA SEER Paper notes that it is important to recognize, however, that UVCB substances are "combinations" rather than discrete molecular entities and that EPA developed the UVCB approach for complex reaction products for which there is no definite or known molecular formula or chemical structure information, and considered a range of other information in the absence of a precise chemical description. "EPA added them to the Inventory under the 'combination' aspect of the definition of 'chemical substance,'" and that as such combination authority may not be applicable to most nanomaterials since these materials are typically not combinations and usually have very defined particular molecular identities. "Thus, the UVCB precedent does not appear to support using physical properties to distinguish, for purposes of listing on the TSCA Inventory, between chemical substances with known, definite, and common molecular identities."[82]

The ABA SEER Paper further notes also that there are instances of multiple entries on the Inventory for different physical forms of the same molecular identity. For example carbon (CAS No. 7440-44-0), diamond (CAS No. 7782-40-3), and graphite (CAS No. 7782-42-5) all consist of elemental carbon, but have separate entries on the Inventory. Silica (CAS No. 7631-86-9), quartz (CAS No. 14808-60-7), and cristobalite (CAS No. 14464-46-1) all consist of silicon dioxide, but have separate entries on the Inventory. The ABA SEER Paper specifically notes:[83]

> The silicon dioxide example, however, is instructive because EPA has declined to add different physical forms of silicon dioxide to the Inventory as separate entries. Unlike some other national chemical substance inventories, the TSCA Inventory does not include two other forms of silicon dioxide: silica amorphous, fumed, crystalline-free (CAS No. 112945-52-5), and silica gel, precipitated, crystalline-free (CAS No. 112926-00-8). In explaining why it declined to add those entries to the Inventory, EPA said:
>
> > The Agency is aware that silicon dioxide, commonly referred to as silica, occurs and is distributed for commercial purposes in several different physical forms. Inasmuch as the chemical compositions of the various physical forms are the same, EPA does not consider the different physical forms of silica to be separately reportable under TSCA. For the purposes of TSCA, the various physical forms of

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81 ABA SEER Paper at 9.
82 *Id.* at 9-10.
83 *Id.* at 10-11.

> silica (SiO_2) are all considered to be included under CASRN 7631-86-9, which is on the TSCA Inventory.[84]
>
> Thus, EPA has occasionally been inconsistent in including different physical forms of the same particular molecular identity on the Inventory.[85] Despite these examples, EPA's publicly articulated rule of decision is to have a single Inventory entry covering a particular molecular identity extend to all physical forms of that same molecular identity, even those with their own CAS numbers.[86]

A term commonly used in distinguishing different physical forms of the same chemical substance is allotropy. Allotropy is defined as "the ability of a chemical to exhibit a number of different and physically distinct forms in its pure elemental state. Carbon, for instance, can exist as graphite, diamond and fullerene."[87] The physical forms cited are only three of a seemingly endless array of possibilities, including all forms of nanotubes of various sizes. Wikipedia addresses the variability of carbon as follows: "The system of carbon allotropes spans an astounding range of extremes, considering that they are all merely structural formations of the same element."[88]

One may consider that diamond and graphite represent the outer bounds of the category of allotropes of carbon, and that their properties and internal bonding are so dramatically different that they appear to be different substances. Hence, it may make sense that they warrant different entries on the TSCA Inventory. In between these boundaries, however, are, hypothetically, an endless variety of substances such as carbon nanostructures. The dilemma facing EPA, and the regulated community, is where to draw the line as to when a particular nanomaterial should be considered to be a new chemical substance. At the present time, EPA has chosen to define certain nanoparticles to be of interest if they have "unique properties," but in practice these properties have yet to be fully defined.

Silica and its various forms do not meet the strict definition of "allotropy," because it is not a pure element but rather a compound of silicon (silicon dioxide). Nevertheless, the analogy is a good one in that there are different physical forms of silica having dramatically different properties. Despite this fact, EPA has, as discussed above, allowed some of these different physical forms to be characterized by a single entry on the TSCA Inventory, despite the fact that they have been assigned different Chemical Abstracts Service Registry Number. This difference between the way that allotropes of carbon and physical forms of silica compounds are interpreted for TSCA Inventory purposes represents a significant inconsistency in the way EPA has interpreted these TSCA conventions.

The foregoing discussion illustrates the complexity of the question raised, and the challenging legal and regulatory policy issues EPA is now confronting. As we speak, it is unclear how EPA will resolve these issues. What is clear is that further guidance from EPA is needed, and EPA has promised to issue guidance, perhaps early in 2007.

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[84] Letter from Henry P. Lau, Chief, Chemical Inventory Section, EPA, to Daniel C. Hakes, 3M (Nov. 19, 1993) (IC-4482) (on file with author).

[85] These Inventory entries were accepted mainly or exclusively during the original development of the Inventory, when EPA added tens of thousands of substances at once and circumstances precluded as thorough a consideration of particular entries as the PMN review process does today.

[86] An administrative law judge rejected EPA's motion for summary judgment in a TSCA enforcement matter where EPA asserted that sub-molecular differences between an existing chemical substance and the chemical subject to the enforcement action allowed EPA to treat the latter as "new." *In The Matter Of Concord Trading Corp.*, Docket No. TSCA-94-H-19 (July 24, 1997).

[87] *See* Wikipidia the Free Encyclopedia, Allotropy, http://en.wikipedia.org/wiki/Allotropy (last visited Feb. 8, 2007).

[88] *See* Wikipedia the Free Encyclopedia, Allotropes of carbon, http://en.wikipedia.org/wiki/Allotropes_of_carbon (last visited Feb. 8, 2007).

For example, a nanoparticle of a conventional TSCA-listed chemical may be considered by EPA to be an "existing" chemical if only the chemical's surface area is increased (due to its nanoscale) to enhance its catalytic potential. On the other hand, certain carbon-based nanomaterials could be considered "new" even though carbon is listed on the TSCA Inventory, as evidenced by EPA's recent decision to grant a LoREX for at least one type of carbon nanotube. In so doing, EPA apparently concluded that a carbon nanotube, at least this particular carbon nanotube, is a "new" chemical substance. EPA may have concluded the chemical's structure was decidedly and sufficiently different from the Inventory-listed substance to be considered "new" even though the chemical's molecular formula was the same as the conventional form of the chemical.[89] EPA should define with clarity exactly what differences are sufficiently dissimilar for Inventory-listed substances to be regarded as potentially "new."

Even if EPA were to announce that nanosized versions of Inventory-listed chemicals are existing and not new chemicals for TSCA purposes, EPA nonetheless has broad authority under TSCA to consider any potential risks posed by nanoconfigured substances. The ABA SEER Paper emphasizes that EPA has broad authority under a combination of other provisions of TSCA to address potential risks posed by engineered nanoscale materials beyond EPA's PMN authority, including Section 5(a)(2) (authority to issue SNURs); Section 6 (authority to restrict or ban the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance upon a showing that the substance presents or will present an unreasonable risk); Section 7 (authority to address imminently hazardous chemical substances); and Section 8 (authority for information-gathering and reporting).

For present purposes, key among these provisions is EPA's authority under TSCA Section 5. Sections 5(a)(1)(B) and 5(a)(2) authorize EPA to issue a SNUR for any significant new use of an existing chemical substance. Taken together, these provisions enable EPA to perform the same risk assessments and implement the same risk management controls on existing chemical substances engineered at the nanoscale that apply to "new" chemical substances under TSCA's PMN provision. The form through which a SNUN is submitted to EPA is the same as the PMN form—EPA Form 7710-25[90]—and both notices "undergo the same review process."[91] EPA is also authorized to issue a Section 5(e) or Section 5(f) order for any chemical substance "with respect to which notice is required by subsection (a) of . . . section [5]," and that notice can be either a PMN under Section 5(a)(1)(A) or a SNUN under Section 5(a)(1)(B).[92]

The key distinction between Section 5(a)(1)(A) and Sections 5(a)(1)(B) and 5(a)(2) is characterized by the ABA SEER Paper as one of more process than substance. Pursuant to the latter provisions, EPA must promulgate a rule defining a use as a "significant new" use before the obligation to submit a SNUN is triggered. The requirement to submit a PMN does not necessitate a prior rulemaking by EPA. Once EPA has issued a rule under Section 5(a)(2), however, Sections 5(a)(1)(A) and 5(a)(1)(B) operate in an identical manner.

As noted above, in promulgating a SNUR, EPA must consider "all relevant factors," including the four factors noted above. Of these four statutory factors, three appear to be especially relevant to nanoscale materials: the extent to which a use changes the type or form of exposure of human beings or the environment to a chemical substance; the extent to which a use increases the magnitude and duration

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[89] As noted above, EPA's treatment of the relevance of chemical structure would suggest that EPA could well take into account a chemical's physical structure and conclude that different physical forms or structures of a chemical whose chemical composition is identical are nonetheless "new" for TSCA purposes.

[90] *See* 40 C.F.R. § 721.25(a) (2007), (SNUN); *Id.* at § 720.40(a)(2) (PMN).

[91] EPA, *EPA Authorities Under TSCA* 1 at 12 (July 11, 2005) (EPA TSCA Authorities) *available at* http://www.chemicalspolicy.org/downloads/TSCAAuthorities050615.pdf.

[92] Toxic Substances Control Act § 5(e)(1)(A), 15 U.S.C. § 2604(e)(1)(A) (2007); Toxic Substances Control Act § 5(f)(1), (3)(A)(i), 15 U.S.C. § 2604(f)(1), (3)(A)(i) (2007).

of exposure of human beings or the environment to a chemical substance; and the reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of a chemical substance.[93] EPA is not restricted to these four factors and "EPA construes the statute to allow consideration of any other relevant factors."[94] Factors need only be considered, and EPA is not required to make a risk determination or other specific finding before issuing a SNUR.[95]

The ABA SEER Paper also notes that EPA is not limited to issuing SNURs that address individual nanoscale materials. Given the great diversity that reportedly characterizes these materials, EPA's authority to issue a SNUR that covers a category or categories of existing nanoscale materials is important. Section 26(c)(2)(A) defines the term "category of chemical substances" to mean:

> a group of chemical substances the members of which are similar in molecular structure, in physical, chemical, or biological properties, in use, or in 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], except that such term does not mean a group of chemical substances which are grouped together solely on the basis of their being new chemical substances.[96]

Hence, the criterion for qualifying as a category is broad and may mean no more than merely being "in some . . . way suitable for classification as such for purposes of [TSCA]."[97] This criterion is flexible, and arguably allows EPA to establish through a SNUR rulemaking that could include particular classes of existing nanoscale materials as a "category of chemical substances," based on established and common characteristics, which are unique to nanoscale materials.

It is instructive to review how EPA defines and uses categories of concern with the aforementioned acrylate case as a model. EPA first defines the category, then describes human and environmental health concerns, establishes boundaries for the category, and proposes testing strategies for resolving health concerns. If the tests conducted result in adverse findings, EPA has the authority to impose additional restrictions or even ban the substances.

In the acrylate case, the category was defined as "any molecular structure having one or more of the following reactive groups is considered to be a member of the class . . .," with both acrylate and methacrylate sub-structures then being indicated. Originally, the hazard concerns were both for human health (carcinogenicity) and environmental toxicity, but the former issue was resolved through the work of the SAM Panel mentioned earlier, such that the current category only cites ecotoxicity as a general concern. Boundary conditions established for the Acrylate/Methacrylate category are based on molecular weight (MW) and other physical properties such as solubility. Both in the earlier and the current versions of the category, the MW identified as being of concern was 1000 or less. It should be noted that not every category of concern has had boundaries established. Finally, the current testing strategy for the acrylate category involves a number of physical-chemical and environmental fate properties, because EPA already has adequate ecotoxicity data for the category; prior to the SAM Panel work, the testing strategy also included a two-year cancer study.

EPA has currently identified over 40 categories of concern, including such chemical types as alkoxysilanes, epoxides, and neutral organics, which include certain alcohols, ketones, ethers, and alkyl halides. More relevant to the current discussion, EPA has defined one category largely in terms of

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93 Toxic Substances Control Act § 5(a)(2)(B)-(D), 15 U.S.C. § 2604(a)(2)(B)-(D) (2007).

94 Perfluoroalkyl Sulfonates; Proposed Significant New Use Rule, 71 Fed. Reg. 12311, 12314 (Mar. 10, 2006) (to be codified at 40 C.F.R. pt. 721).

95 EPA TSCA Authorities at 14.

96 Toxic Substances Control Act § 26(c)(2)(A), 15 U.S.C. § 2625(c)(2)(A) (2007).

97 *Id.*

physical properties, namely "Respirable, Poorly Soluble Particulates." The "definition" of the category states that "[t]ypically, they are oxides of various metals or nonmetals." The boundary conditions identified focus on the particle size of the substances and their potential for respirability, with particles with a diameter of less that 10 micrometers (1000 nanometers) being included in the category. EPA has further defined the category by identifying five poorly soluble particulate chemical types, including crystalline silica, titanium dioxide, and carbon black.[98] This category, then, would appear to be a particularly good model for nanosize materials, because it defines the category in terms of physical properties, with a number of chemical types specified that meet the boundaries and health concerns for the category.

If one were to develop a new category of concern of, for example, "Nanoparticles," a definition of the category would be developed along with boundary conditions and potential health concerns, and chemical types (such as carbon nanotubes) of greatest concern. As noted above, there continues to be considerable debate over the definition of nanoparticles in the scientific community. For the purpose of defining the term to establish the "category," however, the definition of nanoparticles could be as simple as those particles having one dimension of 100 nanometers or less. At the same time, the means by which one would establish boundary conditions and specific chemical types of concern is far less clear. Further, the presumption here is that not all nanoparticles are toxic, or to the same extent if they are, the boundaries of the sub-category should encompass only the substances of greatest concern.

Therefore, EPA may envision development of a triaging of substances so that EPA and the regulated community could focus on the high-concern materials. Such properties as solubility, aggregation, diffusion, and crystal structure may be well known for certain types of substances that could then be compared to known health effects for them. For certain chemical types, such as fumed silica, there exists significant data to develop model health-property relationships to use in assessing potential risk from new nanosized substances. There would inevitably be data gaps uncovered in this process for which testing may need to be conducted. The end result of the process would be a set of boundary conditions for nanoparticles to be used as a basis of a new category of concern, a list of suggested tests to resolve issues for the category, and, ultimately, a Generic Nanoparticles SNUR that would apply to all existing applicable substances.

As noted above, EPA is expected to issue guidance on this new versus existing issue later this year. In the interim, chemical manufacturers are urged to consult with EPA, or to submit a BFI intent request to EPA, before manufacturing chemical substances listed on the TSCA Inventory at the nanoscale.

2. Appropriateness of Certain PMN Exemptions as Applied to Engineered Nanoscale Substances

Another topic that has invited debate in connection with engineered nanoscale materials concerns the appropriateness of several of the exemptions from TSCA PMN requirements. ED, for example, has urged EPA "not to apply mass-based, or other exemptions in the PMN program, unless the underlying scientific rationale is appropriate when applied to nanomaterials."[99] A key issue here is the relevance of mass-based and volume-based criteria as applied to engineered nanoscale materials, and whether these criteria could ever apply to nanoscale materials, which are in many cases unlikely to be produced in substantial quantities.

The appropriateness of the LVE exemption, which requires EPA approval and which exempts from PMN requirements "a new chemical substance manufactured in quantities of 10,000 kilograms [22,000

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[98] EPA, *TSCA New Chemicals Program (NCP) Chemical Categories* at 118-121, (Oct. 2002), *available at* http://www.epa.gov/opptintr/newchems/pubs/cat02.pdf.

[99] *See supra* note 67, Karen Florini et al., *Nanotechnology: Getting It Right the First Time.*

pounds] or less per year," has been questioned on the grounds that the threshold level is too high, especially considering that few companies are expected in the near term to be producing engineered nanoscale materials in amounts approaching that level.[100]

At first glance, the suitability of the LVE exemption may seem questionable in this context, but a closer review may suggest otherwise. Because the exemption is not self-executing and requires prior EPA approval, EPA's consideration of any potential risks posed by the engineered nanoscale material at issue can be expected to be comprehensive. As noted above, this regulatory review is by no means cursory and involves considerable EPA scrutiny. In fact, EPA's review of an 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.[101]

As described above, although the LVE exemption allows certain new chemicals, including those falling into the category of engineered nanoscale materials, to avoid the full panoply of PMN review, this does not mean EPA does not consider carefully the health and safety implications of the candidate chemical. Indeed, the level of scrutiny EPA reportedly devoted to the LVE/LoREX exemption application likely exceeded the degree of scrutiny typically reserved for conventional new chemicals reviewed under the PMN program.

3. Appropriateness of Reporting Obligations under TSCA Section 8 Authority to Engineered Nanoscale Materials

Another issue that has been raised is whether certain of TSCA's reporting obligations apply to nanoscale chemicals, particularly TSCA Section 8(e). EPA has made it clear that TSCA Section 8(e) applies to all chemicals, including nanoscale materials that are chemical substances.[102] Under the Section 8(e) provision, anyone manufacturing, importing, processing, or distributing in commerce a chemical substance "who obtains information which reasonably supports the conclusion that such substance . . . presents a substantial risk of injury to health or the environment" must inform EPA of the information immediately.[103] Failure to do so can result in substantial penalties. 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, TSCA Section 8(e) reporting is required.[104]

Similarly, TSCA Section 8(c) reporting obligations apply to persons manufacturing, importing, processing, or distributing in commerce engineered nanoscale materials. Such persons must maintain, and make available to EPA for inspection, records of significant adverse reactions alleged to have been caused by the engineered nanoscale material. Under EPA's Section 8(c) implementing regulations, this means that if anyone, including but not limited to a company's employees, customers, or neighbors, makes a written or oral statement to the effect that the company's nanoscale material caused a significant adverse

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100 ED Letter at 3-4, *supra* note 68; Ahson Wardak, *Nanotechnology & Regulation: A Case Study Using the Toxic Substance [sic] Control Act (TSCA)* at 11, *supra* note 2.

101 Pat Phibbs, *Manufacture of New Carbon Nanotube Approved by EPA Under an Exemption*, BNA DAILY ENV'T REP., Oct. 21, 2005, at A-1.

102 *See* Jim Alwood, EPA. Presentation to AM. CHEMISTRY COUNCIL/SOCMA GLOBAL CHEM. REGULATIONS CONF. (Mar. 22, 2005) (TSCA Section 8(e) reporting applies to nanoscale material).

103 Toxic Substances Control Act § 8(e), 15 U.S.C. § 2607(e) (2007).

104 To date, EPA has received at least one Section 8(e) submission addressing an engineered nanoscale material, although it is not clear from the submission whether the nanoscale material was "existing" or "new." *See* 8EHQ-0403-15319 (Apr. 10, 2003) http://www.epa.gov/oppt/tsca8e/pubs/8ehq/2003/april03/8ehq-0403-15319a.pdf (last visited Dec. 1, 2006). The submission, made by DuPont, reported a lung toxicity rat study on single-walled carbon nanotubes.

effect on human health or the environment, the company must maintain a record of that allegation. Notably, EPA defines "manufacture" for purposes of TSCA Section 8(c) broadly to include manufacture for test marketing and manufacture for research and development.[105] EPA has emphasized repeatedly over the past few years that these provisions clearly apply to engineered nanoscale materials.

VI. CONCLUSION

The debate over TSCA's application to engineered nanoscale materials will continue for some time. The discussion above confirms that this debate is interesting and challenging. The foregoing review demonstrates that EPA has robust authority under TSCA. EPA has broad existing authority to review engineered nanoscale materials considered new under TSCA Section 5(a), to review under TSCA uses of existing chemical substances considered by EPA "new," to review comprehensively exemptions from full PMN requirements, and to collect information on and compel and enforce reporting obligations with respect to engineered nanoscale materials.

EPA's stated commitment to issue guidance on these issues will greatly assist the regulated community in understanding EPA's expectations regarding the submission of PMN and exemption applications for engineered nanoscale materials and thus better prepare industry to undertake consistently its TSCA compliance obligations. 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 engineered nanoscale materials believed to consist of TSCA Inventory-listed substances, either though a pre-submission meeting with EPA or the submission of a BFI to commence manufacture.

[105] *See* 40 C.F.R. § 717.3(e)(1) (2007).