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TOXIC SUBSTANCES CONTROL ACT

NANOTECHNOLOGY

The authors of this article say some of EPA's best tools for obtaining the necessary information and assessing and managing risks before nanomaterials enter commerce are the premanufacture notice and the significant new use rule in the Toxic Substances Control Act. While some nanomaterials will not qualify as new chemical substances and, therefore, will not be subject to premanufacture notice requirements, the authors say EPA can use rulemaking procedures to apply the same notice requirements to existing nanomaterials as appropriate through its significant new use rule authority. EPA has taken a first step toward fuller use of this authority with the recent issuance of significant new use rules for siloxane-modified silica and siloxane-modified alumina nanoparticles.

Using TSCA for 'Existing' Nanomaterials: The Case for Significant New Use Rules

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This article is based in part on Duvall's earlier article, ''Regulating Nanomaterials Under Section 5 of the Toxic Substances Control Act'' (30 CRR 1122, 10/30/06).

The opinions expressed here do not represent those of BNA, which welcomes other points of view.

Nanotechnology and its products (here, ''nanomaterials'') represent a great technological advance and have the potential to revolutionize many aspects of our lives.[1] However, some of the same novel properties that give nanomaterials their exciting utility may also create new and poorly understood risks to human health and the environment. The Environmental Protection Agency is charged with protecting human health and the environment, and therefore has a responsibility to assess and, as appropriate, control nanomaterials effectively. A central component of EPA's authority to regulate nanomaterials is the Toxic Sub-

[1] ''Nanotechnology has been touted as the next Industrial Revolution, ushering in advanced materials and systems. Advances in nanotechnology are expected to lead to groundbreaking benefits throughout industries.'' S. REP. NO. 108-147, 1-2 (2003), *reprinted in* 2003 U.S.C.C.A.N. 1713.

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stances Control Act (TSCA).[2] However, whether this statute provides EPA with sufficient authority to regulate nanomaterials effectively continues to be vigorously debated.[3]

Much of the early discussion of EPA's TSCA authority had focused narrowly on whether EPA could review nanoscale versions of bulk materials under its TSCA Section 5 premanufacture notice (PMN) authority, which applies only to chemicals classified as ''new.'' This question has apparently been resolved: EPA has clarified that nanoscale versions of bulk chemicals that are already on the TSCA Inventory of Existing Chemical Substances (the Inventory), and that are therefore not ''new,'' are not subject to the PMN requirements.

Because some nanomaterials will be deemed existing, EPA's resolution of the classification issue leads to more questions about the review and regulation of existing nanomaterials. Some commenters have assumed or argued that if PMN authority is unavailable for a given nanomaterial, that nanomaterial cannot be effectively regulated under TSCA.[4] These commenters frequently focus on Section 6 of TSCA,[5] which gives EPA authority to regulate existing chemical substances if it finds there is a ''reasonable basis to conclude'' that the chemical ''presents or will present an unreasonable risk of injury to health or environment.'' Section 6 imposes high procedural and evidentiary obligations on EPA[6] and is therefore often viewed as a weak regulatory tool, although some believe that EPA could make more effective use of Section 6 than it has.

However, EPA has another regulatory tool to apply to existing nanomaterials: its Section 5 ''significant new use rule'' (SNUR) authority. Together, PMN authority and SNUR authority help EPA to provide effective regulatory oversight to protect the public and ensure that the promise of nanotechnology is not diminished by a loss of public acceptance. EPA's recent *Federal Register* notice issuing SNURs for two nanomaterials may indicate that EPA is beginning to take steps to use this authority to require risk assessments for more kinds of nanomaterials.

I. Nanomaterials Need Appropriate Regulation

While there is no generally accepted definition of ''nanotechnology,'' most definitions focus on the manipulation of matter at a minuscule size (a nanometer is a billionth of a meter, or approximately 1/8,000th of the diameter of a red blood cell) and on the new properties associated with that size. The U.S. National Nanotechnology Initiative (NNI), in which EPA is a participating agency, defines nanotechnology as ''the understanding and control of matter at dimensions of roughly 1 to 100 nanometers, where unique phenomena enable novel applications.''[7]

International definitions are generally similar. The standards organization ASTM International defines nanotechnology as ''a term referring to a wide range of technologies that measure, manipulate, or incorporate materials and/or features with at least one dimension between approximately 1 and 100 nanometers (nm). Such applications exploit the properties, distinct from bulk/macroscopic systems, of nanoscale components.''[8] Likewise, the International Organization for Standardization (ISO) has also developed definitions for nanotechnology, defining ''nanoscale'' as the ''size range from approximately 1 nm to 100 nm'' and ''nano-object'' as a ''material with one, two or three external dimensions in the nanoscale.''[9] Not all definitions use the 100 nm threshold, however, and there is a continuum over which unique size-related effects are manifested, so that it is somewhat arbitrary to use this as a clear line dividing nanomaterials and bulk materials.

Nanomaterials often exhibit properties different from bulk materials, due to factors such as enormous ratio of surface area to volume, influence of quantum mechanics, and other size effects. These properties, which may include changes in color, magnetism, toxicity, and even explosivity, may not be predictable from the properties of chemically related bulk materials.[10]

Nanotechnology is already a booming business, and it is rapidly expanding. There is an extremely diverse array of nanomaterials already in commercial use, and many more in research and development stages. Nanomaterials have been added to clothes, cleaners, electronics, paints, and many other applications.[11] They are said to have the potential to reduce carbon dioxide emissions from energy production by millions of tons,[12]

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[2] 15 U.S.C. §§ 2601-2692.

[3] *See, e.g.*, Jeffrey Rudd, *Regulating the Impacts of Engineered Nanoparticles under TSCA: Shifting Authority from Industry to Governmen*t, 33 COLUM. J. ENVTL. L. 215 (2008); Albert C. Lin, *Size Matters: Regulating Nanotechnology*, 31 HARV. ENVTL. L. REV. 349, 362-67, 374-91 (2007); J. CLARENCE DAVIES, EPA AND NANOTECHNOLOGY: OVERSIGHT FOR THE 21ST CENTURY (Project on Emerging Nanotechnologies, May, 2007), *available at* http://www.nanotechproject.org/process/assets/files/ 2698/197_ nanoepa_pen9.pdf; Letter from Richard A. Denison & Karen Florini, Environmental Defense, to Ann Klee, EPA General Counsel (May 22, 2006), *available at* www.environmentaldefense.org/documents/5265_ StatusofNMsUnderTSCA.pdf.

[4] *See, e.g.*, DAVIES, *supra* note 4, at 12 (''If nanomaterials are not defined as new chemical substances, they are not, in practical terms, subject to most of the TSCA regulatory authorities.'').

[5] 15 U.S.C. § 2605(a).

[6] *See Corrosion Proof Fittings v. EPA*, 947 F.2d 1201, 1215-23, 33 ERC 1961 (5th Cir. 1991) (discussing evidentiary burdens).

[7] NNI, ''What is Nanotechnology,'' http://www.nano.gov/html/facts/whatIsNano.html (last visited Dec. 1, 2008).

[8] ASTM International, E 2456-06 – Terminology for Nanotechnology (2006).

[9] ISO Technical Specification 27687, Nanotechnologies – Terminology and Definitions for Nano-Objects – Nanoparticle, Nanofibre and Nanoplate (Aug. 15, 2008). *See also* British Standards, Publicly Available Specification 133:2007, Terminology for Nanoscale Measurement and Instrumentation (2007) (using the same definition of nanoscale but using the term ''nanomaterial'' instead of ''nano-object'').

[10] *See, e.g.*, J. CLARENCE DAVIES, MANAGING THE EFFECTS OF NANOTECHNOLOGY 8 (Project on Emerging Nanotechnologies, 2006), *available at* http://www.wilsoncenter.org/events/docs/Effectsnanotechfinal.pdf; European Commission Health and Consumer Protection Directorate-General, Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR), ''modified Opinion on The Appropriateness of Existing Methodologies to Assess the Potential Risks associated with engineered and adventitious products of nanotechnologies'' 6, Adopted during the 10th preliminary meeting (March 10, 2006).

[11] *See generally* Project on Emerging Nanotechnologies, Nanotechnology Consumer Products Inventory, http://www.nanotechproject.org/inventories/consumer/.

[12] *See* Project on Emerging Nanotechnologies, *Nanotechnology: Energizing the Future*, NANOFRONTIERS NEWSLETTER (Fall

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create computers hundreds of times more powerful than those of today,[13] and remove industrial contaminants from ground water and soil.[14] Some nanomaterials are not isolated prior to incorporation into bulk materials; for example, some manufacturers use nanotechnology to make nanoscale latex seed particles (10 to 30 nm in one dimension) which are then used to grow bulk latex particles in an emulsion polymerization process. One researcher estimates that the market for nanotechnology-enabled products will grow to trillions of dollars within the next decade.[15]

Yet the research on nanotechnology's effects on health and the environment has not kept pace with the rapid expansion of nanotechnology. The potential risks posed by some nanomaterials may be as diverse as their applications.[16] EPA has stated that certain products of nanotechnology may cause health impacts when inhaled or otherwise applied to the body or may cause durable negative impacts on the environment,[17] but analysts found that only 1 percent of the federal nanotechnology research budget was spent on research that was highly relevant to nanotechnology's risks.[18] While critics of nanotechnology argue that the resulting shortage of information has the potential to expose the world to risks from nanotechnology, proponents should recognize that it poses risks to nanotechnology as well. Nanotechnology unquestionably offers great promise to improve many aspects of life, but it must maintain public acceptance for that promise to be realized. As noted recently,

> Over the past 50 years, we have had vivid examples of how adverse public opinion can block or slow the development and application of new technologies; examples include nuclear power, genetically modified crops and stem cell research . . . . The public's reactions to new technologies are determined by a variety of factors, many of them not in the realms of science or rationality; however, there is evidence that the perceived adequacy of oversight of the technology is an important consideration in shaping people's views.[19]

Ultimately, nanotechnology's various applications and the lack of knowledge regarding their impacts raise new issues under regulatory frameworks such as TSCA.

II. TSCA Tools for Regulating Nanomaterials

TSCA was enacted in 1976 in order to fill gaps in media-specific environmental statutes such as the Clean Air Act and Clean Water Act.[20] It applies broadly to chemical substances, excluding pesticides, drugs, and other substances regulated primarily by other statutes. TSCA offers a variety of regulatory tools to manage chemical risks. Under Section 8, EPA is required to compile and keep current the TSCA Inventory of Existing Chemical Substances, which lists those chemicals that have been manufactured in or imported into the United States for commercial purposes and reported appropriately to EPA. Under Section 4 EPA may require testing of chemical substances that it finds *may* present an unreasonable risk or will be produced in substantial quantities resulting in significant human or environmental exposure. Under Section 6 it may require labeling or even ban a chemical substance if it has a reasonable basis to conclude that the chemical ''presents or will present an unreasonable risk.'' EPA has additional recordkeeping and reporting authority under Section 8, as well as inspection and enforcement authority under Sections 11 and 15-17.

The provisions most relevant to nanotechnology, and the focus of much of the discussion and analysis, are in Section 5. This is because the Section 5 tools allow EPA to gather information and potentially issue restrictions *before* chemicals are widely released, a precautionary strategy which makes sense for chemicals such as nanomaterials, which embody a new technology. Most of the debate so far has been on the new chemical aspects of Section 5, but Section 5 also applies to uses of existing chemicals which EPA determines by rule to be significant new uses. And because restricting new materials or new uses of materials has less potential for disrupting existing markets and activities, Section 5 containers fewer, and lower, regulatory hurdles for EPA to clear than does Section 6.

TSCA Section 5(a) requires manufacturers (defined in Section 3(7) to include importers) of ''new'' chemical substances (i.e., chemicals that are not on the TSCA Inventory) to submit a notice to EPA ninety days before non-exempt manufacture.[21] Section 5(a) also applies to existing chemicals, however (i.e., those that are listed on the TSCA Inventory). Where EPA has determined by

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2008), *available at* http://www.nanotechproject.org/process/assets/files/7045/nanofrontiers3energy.pdf.

[13] University of Bath, Magnetic fields created using nanotechnology could make computers up to 500 times more powerful if new research is successful (June 22, 2006), *available at* http://www.physorg.com/news70201487.html.

[14] EPA Office of the Science Advisor, EPA-100/B-07/001, Nanotechnology White Paper 13 (2007), *available at* http://www.epa.gov/OSA/pdfs/nanotech/epa-nanotechnology-whitepaper-0207.pdf (''EPA Nanotechnology White Paper'').

[15] Press Release, Lux Research, Overhyped Technology Starts to Reach Potential: Nanotech to Impact $3.1 Trillion in Manufactured Goods in 2015 (July 22, 2008), *available at* http://www.luxresearchinc.com/press/RELEASE_Nano-SMR_7_22_08.pdf.

[16] *See, e.g.*, Lin, *supra* note 4, at 356-61; Jennifer Sass, NRDC Issue Paper, Nanotechnology's Invisible Threat: Small Science, Big Consequences (2007), *available at* http://www.nrdc.org/health/science/nano/nano.pdf.

[17] *See* EPA Nanotechnology White Paper, supra note 15, at 13-14.

[18] *Hearing on the National Nanotechnology Initiative Amendments Act of 2008 before the House Committee on Science and Technology* (April 16, 2008) (statement of Andrew D. Maynard, PhD.), *available at* http://democrats.science.house.gov/Media/File/Commdocs/hearings/2008/Full/16apr/Maynard_Testimony.pdf.

[19] J. Clarence Davies, Nanotechnology Oversight: An Agenda for the New Administration 3-4 (Project on Emerging Nanotechnologies, July 2008), *available at* http://www.nanotechproject.org/process/assets/files/6709/pen13.pdf (citation omitted).

[20] Cynthia A. Lewis & James M. Thunder, Federal Chemical Regulation: TSCA, EPCRA and the Pollution Prevention Act 2 (1997).

[21] For ''low volume'' or ''low release'' and ''low exposure'' chemicals, a mini-PMN may be used instead with a shorter review period, although EPA can extend that period as well or can require submission of a full PMN. 40 C.F.R. § 723.50. Thus, this is not a true exemption, despite the claims of some. *Cf., e.g.,* Lin, *supra* note 4, at 365-66. For polymers with certain chemical structures determined to be of low risk, a near-complete exemption exists. 40 C.F.R. § 723.250.

rule that a use of an existing chemical is a significant new use, Section 5 also requires manufacturers and processors of that existing chemical to submit a notice to EPA prior to manufacture or processing it for that use. The notice for new chemicals is called a premanufacture notice (PMN), while the notice for a chemical with a significant new use is called a significant new use notice (SNUN).

The notice must include detailed information about the chemical, its intended uses, and human and environmental exposures, to the extent such information is available. EPA then has 90 days (subject to extension) to review that information and perform a risk assessment. The risk assessment will consider the information submitted and other information available to EPA. Since detailed hazard information on the chemical itself is often lacking, the risk assessment often includes evaluation of the risks posed by structurally analogous chemicals as a surrogate for the chemical at issue, using structure-activity relationship (SAR) models.

Having conducted a risk assessment, EPA then has risk management options. It can decide to take no action, which happens in most instances. In that case, the notice submitter may begin non-exempt commercial manufacture, or the significant new use, after the review period ends. For new chemical substances, the submitter must submit a Notice of Commencement of Manufacture or Import (NOC), after which the chemical will automatically be added to the TSCA Inventory.

Alternatively, EPA may implement risk management controls on the chemical if justified by the risk assessment. There are two kinds of controls available.

If EPA finds that the new chemical substance or the significant new use ''presents or will present'' an unreasonable risk of injury to health or the environment, EPA has the authority under Section 5(f) to ban or severely restrict the chemical or use. That is the same standard as in Section 6. EPA has rarely or never acted under Section 5(f).[22]

EPA can also regulate under the more lenient standard of Section 5(e), if EPA finds -

(1) that there is a lack of sufficient information to permit a reasoned evaluation, and

(2) either

(a) that the chemical or its use ''may present'' an unreasonable risk, or

(b) that the chemical will be produced in substantial quantities and ''may'' reasonably be expected to enter the environment in substantial quantities, or

(c) there is or ''may be'' significant or substantial human exposure to the chemical.

Some have considered the ''may present an unreasonable risk'' standard to be a Catch-22 in that EPA needs to have information to justify regulation under Section 5(e), but Section 5(e) also requires that the information available to EPA be ''insufficient to make a reasoned evaluation.''[23] That concern is acute in the case of nanomaterials, where information on risk may be especially scarce. This position, however, disregards the judicial affirmation of EPA's interpretation of this language as authorizing action

> where EPA's basis for suspecting the existence of an ''unreasonable risk of injury to health'' is substantial—i.e., when there is a more-than-theoretical basis for suspecting that some amount of exposure takes place and that the substance is sufficiently toxic at that level of exposure to present an ''unreasonable risk of injury to health.''[24]

Thus, to regulate under Section 5(e), EPA must have a ''more-than-theoretical basis'' for doing so; it cannot regulate ''based on little more than scientific curiosity.'' Nevertheless, its burden is ''to demonstrate not fact, but doubt and uncertainty'' as to the existence of an unreasonable risk.[25] This is not a Catch-22 at all, but rather a sound basis for Section 5(e) regulation. Section 5(e) is available as a practical matter for nanomaterials that go through PMN or SNUN review in appropriate cases.

EPA has the authority under Section 5(e) to prohibit or limit ''the manufacture, processing, distribution in commerce, use, or disposal of such substance'' pending the development of additional information. Usually, EPA will negotiate a Section 5(e) consent order with the notice submitter rather than issuing a unilateral order. EPA has issued hundreds of orders under Section 5(e), apparently without ever having been challenged in court. When issued for new chemical substances, these Section 5(e) consent orders only bind the original manufacturer of the chemical substance. As a consequence, once the chemical has begun being manufactured and has been listed in the TSCA Inventory (so that it is no longer ''new''), other persons could manufacture it without the restrictions. However, EPA often issues SNURs for substances subject to Section 5(e) consent orders, effectively applying the same restrictions to subsequent manufacturers.[26]

The PMN and SNUN processes are essentially identical. Notifiers complete the same form for both,[27] and EPA has the same control options for both. The key difference is whether EPA must promulgate a rule to render use of the chemical subject to the Section 5 notice requirement.[28] For new chemicals, EPA has a generic rule in place requiring submission of a notice.[29] For existing chemicals, EPA must issue a rule designating a significant new use before submission of a notice is re-

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[22] The ''presents or will present an unreasonable risk'' standard was construed in *Corrosion Proof Fittings v. EPA*, 947 F.2d 1201, 1215-23, 33 ERC 1961 (5th Cir. 1991), which invalidated EPA's Section 6 ban on most uses of asbestos. Since then, many have considered that standard, along with the ''substantial evidence'' judicial review standard, to be impractically difficult to meet, although many of the court's conclusions related to required findings specific to Section 6.

[23] DAVIES, *supra* note 11, at 11-12.

[24] *Chemical Manufacturers Association v. EPA*, 859 F.2d 977, 985, 28 ERC 1510 (D.C. Cir. 1988).

[25] *Ausimont U.S.A., Inc. v. EPA*, 838 F.2d 93, 97, 27 ERC 2235 (3d Cir. 1988).

[26] 40 C.F.R. § 721.160(a).

[27] *See* 40 C.F.R. §§ 720.40(a)(2)(i), 721.25(a) (referring to EPA Form No. 7710-25). *See also* EPA Form No. 7710-25, p. 1, *available at http://www.epa.gov/oppt/newchems/pubs/pmnforms.htm*. The form distinguishes PMNs and SNURs only by whether the PMN or SNUR box is checked.

[28] Another difference is that SNURs can apply to processors as well as manufacturers, whereas PMN requirements only apply to manufacturers. Chemicals subject to a SNUR are also subject to export notification requirements under Section 12(b). Moreover, every person subject to the SNUR (not just the first manufacturer) has to file the required notice. *See* 40 C.F.R. § 721.5.

[29] 40 C.F.R. § 720.22.

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quired. Thus, the distinction is one of procedure only, not substantive authority.

III. Nanomaterials and PMN Requirements

Much of the public debate about regulation of nanomaterials under TSCA has focused on whether nanoscale versions of macroscale materials already on the Inventory were also considered to be on the Inventory or whether, due to their unique properties, they should be considered to be new. The underlying reason for this debate was the concern that while EPA can review and (as appropriate) regulate ''new'' nanomaterials through the PMN process under Section 5, it could not effectively do so for ''existing'' nanomaterials under other provisions of TSCA. The next section argues that this concern is not well grounded because the SNUR provisions do enable EPA to regulate ''existing'' nanomaterials effectively. This section explains EPA's resolution of the PMN question about nanoscale versions of existing chemicals.

A chemical substance is deemed existing if it is one of the more than 83,000 chemical substances listed on the TSCA Inventory, and new if it is not.[30] On the inventory, particular nomenclature is used to describe the chemical makeup and structure of each listed chemical. Some chemical substances are listed confidentially with only a general description available to the public in order to protect confidential business information. EPA lists chemical substances on the TSCA Inventory if they were manufactured and reported prior to 1979 or if they have subsequently gone through the PMN process and the PMN submitter has submitted an NOC.

A fundamental aspect of most nanomaterials is that they may have properties profoundly different from macroscale materials. These new properties yield the valuable performance which drives nanotechnology research. They may also result in different toxicity and different potential exposure than macroscale materials, even those with the same chemical composition. These new properties prompted some commenters to call on EPA to declare that all nanomaterials are ''new'' for purposes of PMN requirements.[31]

EPA declined to do so. Instead, it kept to its long-time interpretation that a chemical is new or existing based on whether a substance with the same chemical structure is already listed on the Inventory. Section 3(2)(a) defines ''chemical substance'' as ''any organic or inorganic substance of a particular molecular identity.'' ''Particular molecular identity'' is not defined in the statute, but in January 2008 EPA explained that the term refers not to properties, but rather to ''such structural and compositional features as the types and number of atoms in the molecule, the types and number of chemical bonds, the connectivity of the atoms in the molecule, and the spatial arrangement of the atoms within the molecule.''[32] In doing so, EPA rejected a nanomaterials classification scheme for purposes of the TSCA Inventory that relied on properties. Instead, EPA called for a case-by-case analysis of whether a particular nanomaterial is new or existing based on its molecular identity. A critic of TSCA has conceded that ''the agency's interpretation of how TSCA defines a new chemical may be legally correct.''[33]

This approach means that some nanomaterials will likely be considered existing (e.g., nanoscale titanium dioxide), because they have the same structure as macroscale chemicals already listed on the Inventory. It also means that some nanomaterials will be new, and thus subject to the PMN requirements prior to non-exempt manufacture.

One commenter has suggested that ''the majority of nanomaterials'' will be existing chemicals ''because they have the same chemical composition and structure as some larger material (e.g., silver, titanium dioxide, carbon).''[34] This is unlikely to be the case, particularly as nanotechnology advances, as new chemical compositions will be needed to make appropriately functional nanomaterials. In any case, EPA has already taken the position that nanomaterials composed entirely of carbon (an existing chemical) may be new chemicals. In January 2008, EPA suggested that carbon nanotubes (''CNTs'') and fullerenes are examples of new chemicals.[35] In October 2008, EPA reconfirmed that CNTs are new chemicals unless they have gone through the PMN process and an NOC has been filed.[36]

EPA has received numerous PMNs for nanomaterials.[37] Current nanomaterial manufacturers should confirm the status of their nanomaterials immediately. In the CNT clarification, EPA advised that ''[s]ome time after March 1, 2009, EPA anticipates focusing its compliance monitoring efforts to determine if companies are complying with TSCA section 5 requirements for carbon nanotubes.''[38]

Following EPA's issuance of its general approach for TSCA Inventory status of nanomaterials, some com-

[30] EPA is considering a ''reset'' of the TSCA Inventory to remove those no longer in commerce. TSCA Inventory Reset and Inorganic High Production Volume Challenge Programs; Notice of Public Meeting, 73 Fed. Reg. 70,640 (Nov. 21, 2008) (33 CRR 107, 2/2/09).

[31] *See, e.g.*, Letter from Richard A. Denison and Karen Florini, Environmental Defense, to Ann Klee, EPA General Counsel (May 22, 2006), *available at* http://www.environmentaldefense.org/documents/5265_StatusofNMsUnderTSCA.pdf.

[32] EPA, TSCA Inventory Status of Nanoscale Substances – General Approach 3 (Jan. 23, 2008), *available at* http://www.epa.gov/oppt/nano/nmsp-inventorypaper2008.pdf.

[33] Davies, *supra* note 20, at 12.

[34] *Id.*

[35] EPA, *supra* note 33, at 5 (''A nanoscale substance might not have a non-nanoscale counterpart with the same molecular identity (e.g., nanotubes and carbon fullerenes), or a substance might be found in both nanoscale and non-nanoscale forms, but if the substance has not been reported previously to EPA and placed on the Inventory in either form, it is considered a new chemical.'').

[36] *See* Toxic Substances Control Act Inventory Status of Carbon Nanotubes, 73 Fed. Reg. 64,946 (Oct. 31, 2008) (''EPA generally considers CNTs to be chemical substances distinct from graphite or other allotropes of carbon listed on the TSCA Inventory. Many CNTs may therefore be new chemicals under TSCA section 5.'') (32 CRR 1070, 11/10/08).

[37] *See, e.g.*, 74 Fed. Reg. 280, 283 (Jan. 5, 2009) (two multi-walled carbon nanotubes); 73 Fed. Reg. 75,711, 75, 713 (Dec. 12, 2008) (four fullerenes); 73 Fed. Reg. 31,108, 31,110 (May 30, 2008) (a carbon nanomaterial); 73 Fed. Reg. 25,696, 25,698 (May 7, 2008) (single-walled carbon nanotubes); 73 Fed. Reg. 11,632, 11, 634 (Mar. 4, 2008) (multi-walled carbon nanotubes).

[38] Toxic Substances Control Act Inventory Status of Carbon Nanotubes, 73 Fed. Reg. 64,946, 64,947 (Oct. 31, 2008) (33 CRR 169, 2/23/09).

menters have recommended legislation to change the definition of ''chemical substances'' to incorporate more than ''particular molecular identity'' in order to reflect the advances of nanotechnology.[39] It is questionable whether taking such a step would significantly streamline EPA's regulation of nanomaterials, at least in the short term, and it is also unknown how likely any such legislation would be. Yet even where nanomaterials are deemed existing under the present framework, EPA can still require submission of a notice for its review prior to manufacture via its SNUR authority.

IV. Nanomaterials and SNUR Authority

A. SNUR Background and Procedures

TSCA's PMN and SNUR provisions are parallel aspects of EPA's authority to require submission of a notice for its review prior to manufacture of a chemical substance. Persons subject to a SNUR must comply with the same notice requirements and EPA regulatory procedures as PMN submitters.[40] TSCA provides the same risk management tools for dealing with chemicals of concern reviewed under either authority, including orders under Sections 5(e) or 5(f). The main difference is one of procedure: whereas PMNs are automatically required for any chemical that is new without EPA action, EPA must issue SNURs through rulemaking in order to require submission of notices by manufacturers of existing chemical substances. This procedural hurdle is not inconsequential, but it should not be overestimated.[41]

After EPA has made the determination that a ''use'' is ''new'' and ''significant,'' as described below, EPA has authority to publish a SNUR for a chemical substance or for a category of chemical substances. TSCA provides no special requirements for SNUR rulemaking, so it is governed by the Administrative Procedure Act (''APA''), which requires notice (i.e., a proposed rule published in the Federal Register) and opportunity to comment, followed by a final rule together with ''a concise general statement of basis and purpose'' of the SNUR.[42]

EPA has used this procedure to issue hundreds of SNURs. A large fraction of these have followed Section 5(e) consent orders for chemical substances that had gone through the PMN process, and have been expedited under EPA regulations to apply the order's restrictions to all manufacturers.[43] EPA also has procedures to expedite SNURs for chemicals that went through PMN review without Section 5(e) orders but about which EPA has concerns.[44] Thus, once chemical substances are added to the TSCA Inventory, EPA can issue SNURs for them fairly quickly when appropriate.

For chemicals which were added initially to the TSCA Inventory without PMN review, SNURs are less common and take a longer time. In recent years EPA has promulgated few SNURs for non-PMN chemicals, and most have required extended periods to complete the rulemaking process.[45] It may be, however, that EPA has unduly limited itself in promulgating SNURs, for example by limiting its use of categories, as discussed below.

Once EPA has promulgated a SNUR, any person intending to manufacture or process the identified chemical substance or substances must file a SNUN. As with PMNs, Section 5(a) does not require the new development of any particular data before submission of a SNUN; information only must be submitted as it is available. Nevertheless, EPA may suggest relevant data for SNUN submitters to provide[46] or encourage prenotice consultation on what data would be helpful to submit.[47]

B. What Is a 'Significant New Use'?

EPA has a large amount of leeway in determining what constitutes a ''use'' to be analyzed under the SNUR standards. As interpreted by EPA, ''use'' can include any manner of manufacturing and related safeguards, new exposure levels or routes, changes in site, any exceedance of or failure to follow the standards and restrictions in a PMN or Section 5(e) order, or a number of other actions or changes.

Unlike rulemaking under TSCA Section 6, SNUR rulemaking has no requirement for EPA to establish that a new use ''presents or will present an unreasonable risk of injury to health or the environment.''[48] Nor is EPA required to find that a chemical substance ''may present'' an unreasonable risk, as it is for Section 5(e)

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[39] *E.g.*, DAVIES, *supra* note 20, at 12-13; *see also* Rudd, *supra* note 4, at 259-282 (recommending wide-ranging amendments to TSCA regarding engineered nanoparticles).

[40] 40 C.F.R. § 721.1(c).

[41] There are other differences between PMN and SNUR authority. For example, ''exemptions'' for low volume or for low release and low exposure, *supra* note 22, only apply to PMN authority. *See* 40 C.F.R. § 723.50. Thus, there is no option for a mini-version of a SNUN.

[42] 5 U.S.C. § 553.

[43] *See* 40 C.F.R. § 721.160.

[44] 40 C.F.R. § 721.170. Essentially, the concern criteria call for a SNUR if the uses would have called for a Section 5(e) order had the original PMN identified them.

[45] *See, e.g.*, Mercury Switches in Motor Vehicles; Significant New Use Rule, 72 Fed. Reg. 56,903 (Oct. 5, 2007) (14 months from proposed rule to final rule); Certain Polybrominated Diphenylethers; Significant New Use Rule, 71 Fed. Reg. 34,015 (June 13, 2006) (18 months); 2-ethoxyethanol, 2-ethoxyethanol acetate, 2-methoxyethanol, 2-methoxyethanol acetate; Significant New Use Rule, 70 Fed. Reg. 71,401 (Nov. 29, 2005) (9 months); Burkholderia Capacia Complex; Significant New Use Rule, 68 Fed. Reg. 35,315 (June 13, 2003) (17 months); Perfluoroalkyl Sulfonates; Significant New Use Rule, 67 Fed. Reg. 72,854 (Dec. 9, 2002) (10 months); Perfluoroalkyl Sulfonates; Significant New Use Rule, 67 Fed. Reg. 11,008 (Mar. 11, 2002) (15 months).

[46] *See, e.g.*, Significant New Use Rules on Certain Chemical Substances, 73 Fed. Reg. 65,743, 65,751-52 (Nov. 5, 2008) (recommending that SNUN submissions for two nanoparticles include ''a 90-day inhalation toxicity test (OPPTS 870.3465 test guideline)'').

[47] *See, e.g.*, Burkholderia Cepacia Complex; Significant New Use Rule, 68 Fed. Reg. 35,315, 35,318 (June 13, 2003); EPA, *supra* note 33, at 7.

[48] TSCA § 6(a), 15 U.S.C. § 2605(a). It was the difficulty of meeting that standard and other Section 6 requirements that led to invalidation of the Section 6 asbestos ban in *Corrosion Proof Fittings v. EPA*, 947 F.2d 1201, 33 ERC 1961 (5th Cir. 1991), which is often cited as evidence that TSCA is ineffective in regulating existing chemicals. EPA's decisions regarding Section 5 ''significant new uses'' are also subject to the deferential APA ''arbitrary and capricious'' test, whereas EPA's decisions under Section 6 are subject to a more probing ''substantial evidence'' test. TSCA § 19(c)(1)(B), 15 U.S.C. § 2618(c)(1)(B).

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orders.[49] Rather, after consideration of relevant factors, EPA need only conclude that a use is both ''new'' and ''significant.'' The basic standard is described by Section 5(a)(2):

> A determination by the Administrator that a use of a chemical substance is a significant new use with respect to which notification is required under paragraph (1) shall be made by a rule promulgated after a consideration of all relevant factors, including—
>
> (A) the projected volume of manufacturing and processing of a chemical substance,
>
> (B) the extent to which a use changes the type or form of exposure of human beings or the environment to a chemical substance,
>
> (C) the extent to which a use increases the magnitude and duration of exposure of human beings or the environment to a chemical substance, and
>
> (D) the reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of a chemical substance.[50]

TSCA allows consideration of ''all relevant factors,'' not just those enumerated in Section 5(a)(2).[51] For example, EPA may consider the toxicity and environmental effects of a chemical as well as the four listed factors.[52]

In order to conclude that a use is new, ''EPA must determine that the use is not ongoing.''[53] EPA typically designates a use as a significant new use as of the proposal date of the SNUR, to keep anyone from defeating the SNUR by initiating the proposed significant new use before the proposed SNUR becomes final, and then arguing that the use is ''ongoing.''[54] In several instances, EPA has designated a use as ''new'' after it has ceased (e.g., due to the sole manufacturer's decision to stop manufacture),[55] because it is no longer ''ongoing.'' Waiting for complete cessation of manufacture has limited EPA's issuance of SNURs for chemicals which did not undergo PMN review. Moreover, while the phrase ''not ongoing'' would seem to suggest that *any* ongoing activity or exposure potential could make a use not new, TSCA's legislative history indicates that *increases* in the level of ongoing activity or exposure potential can constitute a new use.[56] It is certainly the case that a use is not ''ongoing'' simply because the chemical is listed on the Inventory as an existing chemical, as some have suggested.[57]

EPA cannot issue a SNUR for chemical substances simply because they are new, however.[58] Rather, it must determine that the new use is ''significant.'' TSCA's legislative history indicates that significance is not a matter of commercial importance, but rather a function of potential threats to health or the environment:

> By limiting the notification requirement for existing chemical substances to ones to be manufactured or processed for significant new uses, the Committee intends to indicate that only when a new use of a substance may reasonably be expected to have health or environmental importance should it be subjected to the notification requirement.[59]
>
> Thus, the conferees intend that any potential threats to health or the environment from the manufacture, processing, distribution in commerce, or disposal of a substance associated with a new use be considered by the Administrator when determining the significance of a new use.[60]

While nanomaterials do raise new issues under this SNUR framework, EPA's SNUR authority allows it to regulate nanomaterials effectively and to gather information and impose restrictions if necessary prior to commercial manufacture.

C. Designating Significant New Uses of Nanomaterials

Nanomaterials that are nano-sized versions of chemical substances on the TSCA Inventory or nanomaterials that have gone through the PMN process are potential candidates for SNURs. The novel sizes, shapes and applications of nanomaterials would likely qualify as ''uses.'' EPA could find that various uses of nanomaterials are ''new'' as their incidence increases, and ''significant'' in terms of any number of risk or impact parameters. After issuing proposed or final SNURs, EPA

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[49] *See Chemical Manufacturers Association v. EPA*, 859 F. 2d. 977, 28 ERC 1510 (D.C. Cir. 1988) (discussing the ''may present'' criterion under Section 4, similar to that under Section 5(e)); *see also Ausimont U.S.A., Inc. v. EPA*, 838 F. 2d. 93, 27 ERC 2235 (3d. Cir. 1988).

[50] Section 5(a)(2).

[51] EPA has noted this in SNUR rulemaking. *See, e.g.*, Mercury Switches in Motor Vehicles; Significant New Use Rule, 72 Fed. Reg. 56,903, 56,904 (Oct. 5, 2007).

[52] *See, e.g.*, Perfluoroalkyl Sulfonates; Significant New Use Rule, 72 Fed. Reg. 57,222, 57, 225 (Oct. 9, 2007).

[53] *See, e.g.*, Significant New Use Rules on Certain Chemical Substances, 73 Fed. Reg. 65,743, 65,756 (Nov. 5, 2008).

[54] *See, e.g.*, Certain Polybrominated Diphenylethers; Significant New Use Rule, 71 Fed. Reg. 34,015, 34,017 (June 13, 2006).

[55] *See, e.g.*, Mercury Switches in Motor Vehicles; Significant New Use Rule, 72 Fed. Reg. 56,903, 56,905 (Oct. 5, 2007); Certain Polybrominated Diphenylethers; Significant New Use Rule, 71 Fed. Reg. 34,015, 34,017 (June 13, 2006); Perfluoroalkyl Sulfonates; Proposed Significant New Use Rule, 71 Fed. Reg. 12,311, 12,314 (Mar. 10, 2006).

[56] *E.g.*, H.R. REP. NO. 94-1679, at 66 (1976) (Conf. Rep.), *reprinted in* H.R. Comm. on Interstate and Foreign Commerce, 94th Cong., LEGISLATIVE HISTORY OF THE TOXIC SUBSTANCES CONTROL ACT (TSCA LEGISLATIVE HISTORY) at 679 (1976) (''[A] significant increase in the projected volume of manufacture or processing for a substance, a significant change in the type or form of human or environmental exposure, or a significant increase in the magnitude or duration of human or environmental exposure could be the basis for determining that a use is a significant new use.''), *quoted in* Chemicals; Toxic Chemical Release Reporting; Community Right-to-Know; Significant New Use Rule, 58 Fed. Reg. 63,500, 63,505 (Dec. 1, 1993) (promulgating 18 SNURs where the new use for each was manufacture of 10,000 lbs. or more per facility per year for any use).

[57] *See* Rudd, *supra* note 4, at 241.

[58] ''It has been suggested to the Committee that the Administrator could determine that any new use of a particular substance could be considered significant. The Committee does not intend that a new use be considered a significant new use solely on the basis that it is new.'' H.R. REP. NO. 94-1341, at 24 (1976), *reprinted in* TSCA LEGISLATIVE HISTORY at 431.

[59] H.R. REP. NO. 94-1341, at 24 (1976), *reprinted in* TSCA LEGISLATIVE HISTORY at 431.

[60] H.R. REP. NO. 94-1679, at 66 (1976) (Conf. Rep.), *reprinted in* TSCA LEGISLATIVE HISTORY at 679, *quoted in* Chemicals; Toxic Chemical Release Reporting; Community Right-to-Know; Significant New Use Rule, 58 Fed. Reg. 63,500, 63,505 (Dec. 1, 1993).

would be able to collect information through rulemaking comments and SNUNs, and could also take actions under Sections 5(e) or 5(f) as appropriate to restrict nanomaterials and to obtain more data. In some instances, new guidance or regulatory definitions could help streamline the process, provide better notice to producers and users of nanomaterials, and reassure stakeholders. For the most part, however, EPA simply needs to use its existing SNUR tools.

1. Information Gathering

In order to designate and describe ''significant new uses'' and for other aspects of nanomaterial SNURs, EPA would require information. Its existing knowledge base regarding nanomaterials, particularly their health and environmental effects, is inadequate. According to EPA, ''we have a very limited understanding of nanoparticles' physicochemical properties'', and EPA has described its large research needs.[61] For example, there is conflicting evidence regarding the degree, if any, to which nanomaterials would penetrate the skin and upon doing so have any toxicological impact.[62] Pulmonary exposures via inhalation are also the subject of contradictory reports.[63] In assessing the likelihood of pulmonary or other exposure from nanomaterials, factors in addition to particle size may be important (e.g., surface treatments, tendency to aggregate/disaggregate, particle shape, surface charges, and surface coatings). The hazards of novel structures will be even less predictable than those of fine particles of bulk materials.[64]

Nevertheless, where appropriate, EPA could promulgate SNURs for nanomaterials even in the absence of complete information.[65] In doing so, it is important for EPA and regulated entities to keep in mind the nature of a SNUR. Its only effect is to require submission of a notice containing available information to EPA prior to manufacture or processing for a significant new use.[66] It does not require the development of additional information, and it does not otherwise regulate existing chemicals. The possibility exists that, after reviewing the information, EPA may take action under Section 5(e) or Section 5(f). This possibility may motivate at least some amount of data creation by SNUN submitters. Before it could take action under either section, however, EPA would have to make prescribed statutory findings beyond the those necessary for promulgation of a SNUR. EPA orders under Sections 5(e) or 5(f) would be subject to judicial review.[67]

2. Categorical Nanomaterial SNURs

One way to expedite the issuance of nanomaterial SNURs would be to issue them for broad categories of nanomaterials. EPA may take for a category any action it could take for an individual chemical.[68] EPA has broad discretion to define a category of nanomaterials:

> The term ''category of chemical substance'' 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 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 . . . .[69]

Thus, categories only need to be in some way ''suitable for classification as such.'' The legislative history encouraged the use of categories.[70] EPA has issued several categorical SNURs.[71]

EPA can be creative in defining categories. For example, if EPA has a concern about nanomaterials which may penetrate the skin due to their small size, it could propose a SNUR for the category of nanomaterials whose use is likely to result in skin contact and which are likely to penetrate the skin. TSCA would not require EPA to make specific findings for each member of the category.[72]

EPA would not even have to identify each member of the SNUR category individually. For example, EPA pro-

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[61] EPA NANOTECHNOLOGY WHITE PAPER, *supra* note 15, Chap. 5.

[62] *See id.* at 47.

[63] *See id.* at 46.

[64] *See, e.g.*, J.S. Tsuji et al., *Research Strategies for Safety Assessment of Nanomaterials, Part IV: Risk Assessment of Nanoparticles*, 89 TOX. SCI. 42-50 (2006), *available at http://toxsci.oxfordjournals.org/cgi/content/abstract/89/1/42*.

[65] In the context of Section 4 rulemaking, one court has stated that ''[a]lthough mere scientific curiosity does not form an adequate basis for a rule . . . , [t]hese questions broaching the frontiers of scientific knowledge highlight the need for testing.'' *Ausimont U.S.A., Inc. v. EPA*, 838 F. 2d. 93, 96, 27 ERC 2235 (3d. Cir. 1988). A SNUR requires even less information than a Section 4 test rule to compel the submission of a notice for EPA review.

[66] It also triggers export notification requirements under TSCA Section 12(b)(2). EPA has reduced the impact of those requirements, however. *See* Export Notification; Change to Reporting Requirements, 71 Fed. Reg. 68,750 (Nov. 28, 2006) (amending 40 CFR part 707, subpart D).

[67] Judicial review of Section 5(e) and 5(f) orders would be pursuant to the APA, 5 U.S.C. § 706. Under Section 26(f) of TSCA, a Section 5(e) order would have to be accompanied by a statement of its basis and purpose, but the statement is not subject to judicial review. The findings necessary for an order under Section 5(e) are similar to those required for a test rule under Section 4(a). See the discussions of the Section 4(a) findings in *Chemical Manufacturers Association v. EPA*, 899 F. 2d. 344, 31 ERC 1321 (5th Cir. 1990); *Chemical Manufacturers Association v. EPA*, 859 F. 2d. 977, 28 ERC 1510 (D.C. Cir. 1988); *Ausimont U.S.A. Inc. v. EPA*, 838 F. 2d. 93, 27 ERC 2235 (3d. Cir. 1988); *Shell Chemical Co. v. EPA*, 826 F. 2d. 295, 26 ERC 1528 (5th Cir. 1987).

[68] TSCA § 26(c)(1), 15 U.S.C. § 2625(c)(1).

[69] TSCA § 26(c)(2)(A), 15 U.S.C. § 2625(c)(2)(A).

[70] ''The conferees expect that the Administrator will find the authority to categorize especially helpful in promulgating rules under section 5 (a) (2) concerning what constitutes significant new use of chemical substances.'' H.R. REP. NO. 94-1679, at 102 (1976) (Conf. Rep.), *reprinted in* TSCA LEGISLATIVE HISTORY at 715. During consideration of the conference report, Senator Magnuson remarked that ''[t]he Administrator is expected to promulgate rules concerning significant new uses by categories in order to avoid a multiplicity of rulemakings.'' 122 CONG. REC. 32,852 (1976), *reprinted in* TSCA LEGISLATIVE HISTORY at 723.

[71] Perfluoroalkyl Sulfonates; Significant New Use Rule, 72 Fed. Reg. 57,222 (Oct. 9, 2007) (183 chemicals); Certain Polybrominated Diphenylethers; Significant New Use Rule, 71 Fed. Reg. 34,015 (6 chemicals); Perfluoroalkyl Sulfonates; Significant New Use Rule, 67 Fed. Reg. 72,854 (Dec. 9, 2002) (75 chemicals); Perfluoroalkyl Sulfonates; Significant New Use Rule, 67 Fed. Reg. 11,008 (Mar. 11, 2002) (13 chemicals).

[72] ''It should be noted that in taking action under any provision of the bill respecting a category of chemical substances, the Administrator will not have to make the requisite finding for such action with respect to every chemical within the category.'' H.R. REP. NO. 94-1341, at 61 (1976), *reprinted in* TSCA LEGISLATIVE HISTORY at 468.

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posed a SNUR for certain acrylate esters, not naming them individually but providing a general chemical structure.[73] EPA has also issued rules under other statutes making categories of chemicals subject to regulation without naming all the individual members of the categories.[74] The minimum requirement, based on the Due Process Clause of the Fifth Amendment of the U.S. Constitution, is that regulated entities have sufficient notice that their chemicals are covered by the category from the category description.

D. SNURs for Siloxane-Modified Nanoparticles

The preceding discussion regarding designation of nanomaterials as significant new uses is not simply theoretical. EPA published a *Federal Register* notice promulgating direct final SNURs for two siloxane-modified silica and siloxane-modified alumina nanoparticles, to take effect in January, 2009.[75] These are the first SNURs known to have been issued on nanomaterials.

The two nanoparticles were the subject of PMNs filed in October, 2005 (P-05-673 and P-05-687) for ''additive, open, non-dispersive use[76] and are listed on the confidential TSCA Inventory. EPA designated (a) use without impervious gloves or a respirator, (b) manufacture or use as a powder, or (c) any uses ''different'' from those described in the original PMNs as significant new uses. Any person wishing to use either of these nanoparticles for a significant new use must submit a SNUN for EPA's evaluation. Issuance of these SNURs likely indicates that EPA is contemplating greater use of its SNUR authority to regulate nanomaterials.[77]

EPA also encourages any SNUN submitter under these SNURs to include the results of inhalation toxicity testing. EPA has used its recommendations for testing in many non-nanomaterials cases to obtain information. SNUN submitters have an incentive to create the data in hopes of avoiding a restrictive Section 5(e) order. Data recommendations such as the one in these initial nanoparticle SNURs can be particularly important for submitters of nanomaterial PMNs and SNUNs, because these manufacturers and processors may have little idea of what testing EPA would consider to be most helpful in a Section 5 risk assessment.

By issuing the nanoparticle SNURs, EPA is complementing its program to encourage voluntary measures by industry to submit data and manage risk. EPA must manage the relationship between its voluntary and regulatory tools carefully in order to maintain maximum efficacy. Describing EPA's voluntary Nanoscale Materials Stewardship Program,[78] one commenter argued that ''[t]here should be an interplay between modifying the regulations (such as promulgating a significant new use rule for nano) and the voluntary effort. A sequential approach will leave nano unregulated for far too long and will also be less productive than if the two efforts proceed in tandem.''[79] This observation remains salient. While the voluntary program should remain robust, a new focus on SNURs can bolster EPA's information-gathering and risk managing capabilities substantially.

The step taken by EPA is a conservative one, mainly because EPA chose not to issue a categorical SNUR. EPA has received PMNs for other nanomaterials having the same generic description as the two for which it promulgated SNURs,[80] but did not issue a SNUR encompassing any broader category, let alone all nanomaterials as has been supported by some commenters.[81] As discussed above, as the number of nanomaterials entering the market grows ever larger, EPA could still expand and expedite SNUR promulgation for nanomaterials by using its authority to designate categories in the future. Nevertheless, the issuance of two narrow SNURs may operate as a test case for greater use of the SNUR process in the nanomaterials arena. The degree to which EPA plans to expand its use of SNURs to assess and manage nanomaterial risks, particularly for nanomaterials that were not the subject of PMNs, remains uncertain. However, EPA recently confirmed that it plans to ''continue to review new chemical nanoscale materials . . . and apply, as appropriate, testing requirements and exposure controls under section 5(e) and Significant New Use Rules (SNURs) under section 5(a)(2).''[82]

CONCLUSION

Nanotechnology presents both opportunities and challenges to EPA. Among the many benefits promised by nanotechnology are improvement of human health and environmental quality, EPA's core goals. Yet this promise will not be realized if nanomaterials are not perceived to be effectively regulated, because recent history has shown that a loss of public confidence in products created through new technology, spurred by ineffective regulation and risk management, can hinder that technology's development and dissemination for decades. EPA also must protect people and the environment from the mostly unknown risks of nanotechnol-

[73] Significant New Uses of Certain Acrylate Esters, 58 Fed. Reg. 61,649 (Nov. 22, 1993) (proposed rule). EPA withdrew the proposed rule on the basis that new information resulted in a lowering of EPA's hazard concerns. Certain Acrylate Esters; Withdrawal of Proposed Significant New Use Rule, 62 Fed. Reg. 1305 (Jan. 9, 1997).

[74] *See, e.g.*, 40 C.F.R. § 302.4(b) (designating as hazardous substances subject to CERCLA release reporting requirements all hazardous wastes that meet any of the RCRA characteristics); 40 C.F.R. § 372.65(c) (identifying categories of chemicals subject to EPCRA § 313 reporting requirements).

[75] Significant New Use Rules on Certain Chemical Substances, 73 Fed. Reg. 65,743, 65,751-52 (Nov. 5, 2008).

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

[77] *Compare* DAVIES, *supra* note 4, at 23 (''To date, EPA has shown no inclination to use the significant new use provisions to deal with nano.'').

[78] EPA, Nanoscale Materials Stewardship Program, http://www.epa.gov/oppt/nano/stewardship.htm (last visited Dec. 3, 2008).

[79] DAVIES, *supra* note 4, at 25.

[80] For example, PMNs were submitted on May 30, 2007 by Byk-Chemie USA, Inc. for siloxanes coated alumina and silica nanoparticles, P-07-0465 and P-07-466 respectively, for use as an ''additive in coatings.'' Certain New Chemicals; Receipt and Status Information, 72 Fed. Reg. 47,026, 47,029 (Aug. 22, 2007).

[81] *E.g.*, DAVIES, *supra* note 4, at 63.

[82] EPA OFFICE OF POLLUTION PREVENTION AND TOXICS, NANOSCALE MATERIALS STEWARDSHIP PROGRAM INTERIM REPORT 3 (Jan. 14, 2009), *available at* http://www.epa.gov/oppt/nano/nmsp-interim-report-final.pdf (reporting that because data gaps remained after institution of a voluntary reporting program, EPA would consider greater use of TSCA for information gathering) (33 CRR 46, 1/19/09).

ogy, even as the applications of nanotechnology are becoming more ubiquitous.

Some of EPA's best tools for obtaining the necessary information and assessing and managing risks before nanomaterials enter commerce are the PMN and SNUR tools in TSCA. While some nanomaterials will not qualify as new chemical substances and will therefore not be subject to PMN requirements, EPA can use rulemaking procedures to apply the same notice requirements to existing nanomaterials as appropriate through its SNUR authority. EPA has taken a first step toward fuller use of this authority with the recent issuance of SNURs for two nanomaterials. All affected parties should closely monitor EPA's next steps.

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