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Regulation of Nanoscale Materials under the Toxic Substances Control Act

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EXECUTIVE SUMMARY

Nanotechnology, loosely described as creating or using materials or processes at a scale of approximately one to one hundred nanometers (a nanometer is one billionth of a meter, or 10^{-9} m) in at least one dimension, is a rapidly-growing technology being used in virtually all major industrial sectors, including electronics, medicine, coatings, consumer products, aerospace, and specialty materials. Nanotechnology holds promise for environmental protection as well, offering the possibility of increased energy efficiency, improved pollution controls, and more effective cleanup technologies. With these promises come concerns: the possibility that applications of nanotechnology may pose new or unusual risks to human health or the environment.[2]

This paper addresses how the risks that may be associated with nanotechnology can be addressed by the Toxic Substances Control Act (TSCA). Unlike most other environmental statutes that focus on controlling the end products of economic activity (*e.g.*, emissions, discharges, and wastes), TSCA is largely a "front-loaded" statute that provides EPA with the authority and obligation to regulate chemicals before and during their use. In that sense, TSCA is essential to the concept of "cradle-to-grave" regulation of commercial activity. TSCA complements several other statutes available to EPA to regulate the nanotechnology (*e.g.*, Clean Air Act, Clean Water Act, Resource Conservation and Recovery Act, Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)). Other U.S. agencies also have the authority to regulate nanotechnology (*e.g.*, Food and Drug Administration (FDA), Consumer Product Safety Commission, and Occupational Safety and Health Administration (OSHA)).

This paper comes to the following conclusions regarding the ability of TSCA to regulate nanoscale materials:

- Nanomaterials include chemical substances and mixtures that EPA can regulate pursuant to TSCA.

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[1] This report was prepared by Christopher L. Bell, Sidley Austin, TSCA Team Leader; Mark N. Duvall, The Dow Chemical Company; James C. Chen, Crowell & Moring; James Votaw, WilmerHale; and with contributions from the TSCA Nano Team of the Section of Environment, Energy, and Resources, which the authors gratefully acknowledge.

[2] An overview of the nature, promises, and possible risks associated with nanotechnology can be found in U.S. Environmental Protection Agency (EPA), External Review Draft: Nanotechnology White Paper (Dec. 2, 2005), available at http://www.epa.gov/osa/pdfs/EPA_nanotechnology_white_paper_external_review_draft_12-02-2005.pdf.

- TSCA, and the risk evaluation provisions of Section 5 in particular, was intended to address new health or environmental risks and the chemical products of new technologies. If a "new" chemical substance is manufactured at the nanoscale, it is subject to the same premanufacture notification (PMN) review requirements under TSCA Section 5(a)(1) that are applicable to any new chemical. Reasonable minds may differ as to whether EPA may properly consider nanoscale versions of existing chemical substances to be "new" and therefore subject to TSCA's PMN review requirements, however. This paper reviews the major arguments for and against EPA's legal authority to conclude that chemicals of identical or indistinguishable chemical structure, but differing in particle size or morphology (*i.e.*, form and structure), are "new" for purposes of TSCA regulation.

- As an alternative to its Section 5(a)(1) PMN authority over "new" chemical substances, EPA may regulate nanomaterials as existing chemical substances under its Section 5(a)(2) authority to promulgate significant new use rules (SNURs). Promulgation of SNURs for individual nanomaterials or categories of nanomaterials would be feasible for EPA, as shown by its promulgation of more than 700 SNURs. Once such a SNUR is issued, EPA can then regulate individual nanomaterials in a manner identical to how it would regulate them under the Section 5(a)(1) PMN process as "new" chemical substances.

- In addition, EPA has other authorities under TSCA to regulate nanomaterials, including the authority to require health and environmental testing; collect production, health, and environmental information about nanomaterials; and promulgate rules regulating, and even prohibiting, the manufacture, processing, distribution, and use of nanomaterials.

I. EPA HAS THE AUTHORITY TO REGULATE NANOMATERIALS UNDER TSCA

A threshold question is whether EPA has the authority under TSCA to regulate nanomaterials. TSCA provides EPA the authority to establish a regulatory framework governing "chemical substances." A "chemical substance" is "any organic or inorganic substance of a particular molecular identity, including – (i) any combination of such substances occurring in whole or in part as a result of a chemical reaction or occurring in nature and (ii) any element or

uncombined radical." [3] Nanomaterials that fall within the broad sweep of "organic or inorganic" substances are "chemical substances" that EPA has the authority to regulate under TSCA.[4]

Having established that nanomaterials can be "chemical substances" that can be regulated under TSCA, the next issue is determining the nature of EPA's TSCA authority. The most flexible authority provided under TSCA is that of Section 5. In considering action under Section 5, the first step is determining whether EPA can use its authority to regulate nanomaterials as "new" chemicals. To the extent that EPA's "new" chemical TSCA authority does not *per se* apply to nanoscale versions of existing chemicals, this does not preclude EPA's authority to regulate nanomaterials as "existing" chemicals under Section 5(a)(2) or other provisions of TSCA.

II. REGULATING NANOMATERIALS UNDER TSCA SECTION 5

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. This 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 has 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.

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[3] TSCA § 3(2)(A), 15 U.S.C. § 2602(2)(A). There are a number of statutory exclusions from the definition of "chemical substance" that are regulated under TSCA, including pesticides that are regulated by EPA under FIFRA, foods and drugs regulated by the FDA, and tobacco.

[4] The fact that nanomaterials may present novel or unusual challenges does not vitiate EPA's TSCA jurisdiction. For example, EPA has under TSCA successfully regulated biotechnology, including microorganisms, which EPA has recognized are not traditional chemical substances. *See* 59 Fed. Reg. 45526, 45527 (Sept. 1, 1994) ("While the term 'chemical substance' has been interpreted to include microorganisms, EPA acknowledges that microorganisms are not generally referred to as chemicals."). EPA reasoned that a microorganism is "[a] living organism [which] is [a] 'combination of such substances occurring in whole or in part as a result of a chemical reaction or occurring in nature . . . ." 49 Fed. Reg. 50880, 50886 (Dec. 31, 1984). With regard to DNA, EPA concluded that DNA "however created, is 'an organic substance of a particular molecular identity.'" *Id.*

A. Technical Challenges in Distinguishing Between "Nanoscale" and Conventionally-Sized Chemical Substances

As a preliminary matter, EPA must address the difficult task of defining key terms such as "nanotechnology," "nanomaterials," and "nanoparticles." As noted above, nano-size particles have generally been understood to involve those particles that are one billionth of a meter in size or smaller. Size has not been the sole factor in defining "nanomaterials," however. For example, the U.S. National Nanotechnology Initiative (NNI) takes into account the properties of nanoscale particles in its definition of nanotechnology, while other definitions include the methods by which nanoscale materials are made. The International Organization for Standardization (ISO) has launched an initiative to develop, among other things, international consensus standards on terms, definitions, and nomenclature related to nanotechnology. (ASTM International has already developed a draft set of such definitions.) The U.S. is participating in the ISO effort (several U.S. government entities, including NNI, EPA, OSHA, the National Institute of Standards and Technology, and the Department of Defense are on the U.S. ISO delegation).[5]

The public discussion of EPA's authority to regulate nanomaterials typically presumes that "nanoscale" materials are clearly distinguishable from conventional-sized forms of materials with the same chemical structure. Neither particle size nor the form and structure of a chemical substance necessarily allows for easy distinctions between nanomaterials and conventional-sized materials, however.

Most chemical substances are comprised of or formed from nanoscale primary particles. These particles naturally aggregate and agglomerate to varying degrees (depending on the material and the process) into larger-scale particles. These aggregated or agglomerated nanoscale particles for the most part exist as micronscale or larger particles as commercially produced (so-called "conventional" or "bulk" materials). This is also true of so-called "engineered" (*i.e.*, intentionally manufactured) nanoscale materials. Carbon nanotubes, for example, may be synthesized as nanoscale primary particles, but, in the real world, natural physical forces that operate on any particle of that scale cause them to form aggregates and agglomerates in size ranges overlapping conventional particle sizes. As with conventional materials, the extent of aggregation and particle size are driven by process parameters, not molecular qualities. It is uncertain how one can articulate a non-arbitrary rationale distinguishing between "nanoscale" and "macroscale" substances based on either initial or final particle size.

Distinguishing between chemically similar materials on the basis of morphology (*i.e.*, form or structure) presents similar challenges. EPA would have to define the morphology intended to be represented by the "existing" Inventory entry, determine which variations in form or structure should be deemed "new," and articulate a rationale for the criteria selected. It is

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[5] The National Technology Transfer Act of 1994 obligates U.S. government agencies to participate in relevant consensus standards writing activities, and to use such standards in rulemakings where applicable (unless an agency explains why potentially applicable standards should not be used).

difficult to see how this can be accomplished other than on a case-by-case basis. It may also be difficult to apply such principles consistently without casting doubt on the Inventory status of a great many existing chemical substances (*e.g.*, carbon blacks) that reflect a multitude of engineered particle morphology variations designed to achieve particular particle properties (*e.g.*, smaller aggregate size or greater conductivity).

This very brief summary suggests that the discussion of EPA's legal authority under TSCA to regulate nanomaterials, whether as "new" or "existing" chemical substances, should be conducted with an understanding of the technical difficulties in distinguishing between nanoscale and conventional-sized materials of the same molecular identity. In addition, while this paper uses terms such as "nanomaterials" or "nanotechnology," it must be understood that these terms encompass a very diverse range of materials, uses, and risk profiles that may be very difficult to regulate as a single class of chemical substances.

B. Whether Nanomaterials Qualify As "New" Chemical Substances Subject to Regulation under Section 5(a)(1)

TSCA Section 8(b)(1) requires EPA to "compile, keep current, and publish a list of each chemical substance which is manufactured or processed in the United States," a list known as the TSCA Inventory.[6] A "new chemical substance" is any chemical substance that is not on the Inventory.[7]

With limited exceptions, "new" chemical substances cannot be manufactured unless the manufacturer first complies with the PMN provisions of TSCA Section 5(a)(1).[8] A person who intends to manufacture a "new" chemical substance must submit to EPA certain information for EPA's review at least 90 days before manufacturing the chemical. The outcomes of the PMN process can include placing the chemical substance on the Inventory and allowing it to be manufactured, processed, and used without limitation; subjecting the chemical substance to certain use restrictions; seeking more data about the substance before a decision is made; or a complete prohibition on manufacture (*e.g.*, through a TSCA Section 5(e) order).

Nanomaterials that are also "new" chemical substances are subject to the PMN requirements of TSCA Section 5(a)(1) like any other new chemical. For combinations of materials not presently reflected on the Inventory (EPA has given the example of a carbon-gold compound), the chemical substance is "new" and the requirement to submit a PMN clearly applies. The challenge in this context is determining when nanomaterials are "new." Many

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6 TSCA § 8(b)(1), 15 U.S.C. § 2607(b)(1).

7 TSCA § 3(9), 15 U.S.C. § 2602(9). EPA's regulatory definition of a "new chemical substance" tracks the statutory definition. *See* 40 C.F.R. §§ 710.3, 720.3(v), 720.25(a).

8 There are a variety of limitations on or exceptions to the PMN requirements, including chemicals used for research and development and chemicals manufactured in low volumes or for purposes of test marketing.

engineered nanomaterials share an identical or indistinguishable chemical structure with materials on the Inventory, such as silver or titanium, but may differ in primary particle morphology and typical particle size, depending on the material and when measured. These differences may result in very different physical characteristics and properties than those generally associated with the conventional form of the chemical, and that may cause the nanomaterials also to have different risk profiles than their chemically identical brethren. The question then arises whether EPA has the authority to require PMN review of such nanomaterials as "new" chemical substances, or whether such materials are subject only to EPA's other TSCA authorities applicable to "existing" chemical substances.

TSCA defines a "chemical substance" in terms of its "particular molecular identity."[9] A "new" chemical is considered a chemical that does not have the same particular molecular identity as any chemical on the Inventory. Applying contemporary TSCA nomenclature practices and conventions, the nanoscale versions of "existing" chemical substances are described identically, and their molecule identities are depicted identically to the conventional-sized version of the same chemical such that they can be said to have the same "particular molecular identity" as the existing chemical. Therefore, one would initially come to the conclusion that a nanoscale "existing" chemical is not a "new" chemical and therefore is not subject to the TSCA Section 5(a)(1) process.

EPA's historical practice generally has been to look to a chemical substance's molecular identity and not at other factors, such as physical or chemical properties, to determine whether a chemical substance is "new." EPA's emphasis on molecular structure is reflected in the PMN review process. The initial steps of the PMN review process involve EPA establishing a complete and accurate chemical name for the substance and determining whether the chemical is already on the Inventory.[10] 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.[11] EPA will consider the reactants and chemical reactions involved in manufacturing the chemical, but those are generally reviewed to verify the composition of the chemical substance under review, not to establish the physical or chemical properties of the chemical. To provide another example, a potential manufacturer making a *bona fide* intent request to EPA under 40 C.F.R. Section 720.25(b) to determine whether a chemical is on the Confidential Inventory does not have to provide EPA

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9 TSCA § 3(2)(A), 15 U.S.C. § 2602(2)(A).

10 *Chemistry Assistance Manual for PMN Submitters* (EPA 744-R-97-003) (Mar. 1997) at 15-16.

11 While data about the chemical's physical and chemical properties must be submitted with the PMN, EPA uses that information to assess the health and environmental risks posed by the chemical, and not for purposes of determining whether the chemical is on the Inventory. The risk assessment component of the PMN review is triggered only after EPA determines that the chemical is, in fact, not on the Inventory.

with information on the size or any other physical and chemical properties of the chemical; EPA makes the determination of whether a chemical is on the Confidential Inventory based solely on the chemical identity of the substance.[12]

Nevertheless, 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, while recognizing that molecular structure is the definitive characteristic in most instances.

For one thing, 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."[13] Relying on that definition, EPA has included as individual entries on the Inventory many substances of unknown or variable composition, complex reaction products, and biological materials (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. For example, the following TSCA Inventory entries for UVCB materials include factors other than molecular structure:

> 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.

It is important to recognize, however, that UVCB substances are "combinations" rather than discrete molecular entities. 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

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[12] A portion of the TSCA Inventory where the chemical identity of the substances is maintained as confidential business information is maintained as confidential by EPA and can only be accessed through so-called *bona fide* requests to EPA.

[13] TSCA § 3(2)(A)(i), 15 U.S.C. § 2602(2)(A)(i).

definition of "chemical substance." That "combination" authority may not be applicable to most nanomaterials, however, since they are typically not combinations and usually have 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.

There are also scattered 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 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 silica (SiO_2) are all considered to be included under CASRN 7631-86-9, which is on the TSCA Inventory.[14]

Thus, EPA has occasionally been inconsistent in including different physical forms of the same particular molecular identity on the Inventory.[15] Despite these examples, EPA's publicly articulated rule of decision is to have a single Inventory entry covering a particular molecular

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

[15] 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.

identity extend to all physical forms of that same molecular identity, even those with their own CAS numbers.[16]

While that has been EPA's articulated principle, the question for EPA today is whether it is statutorily limited to that principle. In this regard, it should be noted that Congress did intend to define "chemical substance" somewhat broadly:

> The Committee recognizes that basically everything in our environment is composed of chemical substances and therefore the definition of "chemical substances" is necessarily somewhat broad. However, because of the breadth of the definition, the Committee has carefully defined the authorities of the Administrator respecting such substances.[17]

That broad statement might suggest that EPA has the statutory authority to interpret the definition of "chemical substance" sufficiently flexibly as to regulate a new chemical substance nanomaterial with the same molecular identity as macro-sized materials already on the Inventory. Alternatively, it might also be read to support the general conclusion that, although nanoscale materials were not specifically contemplated by Congress in 1976, they are nevertheless chemical substances subject to TSCA, and to support a view of that EPA's discretion to implement its various TSCA authorities was "carefully defined" by Congress. Congressional statements about the applicability of TSCA to "chemical substances" broadly defined do not automatically lead to conclusions about Congressional intent with respect to the distinction between "new" and "existing" chemical substances.

TSCA Section 5(e) does give EPA broad risk management authority, *i.e.*, authority to restrict or prohibit the manufacture of a new chemical substance if there is inadequate data to permit a reasoned evaluation of the health or environmental effects of the new chemical substance and, in the absence of such information, activities involving the new chemical substance may present an unreasonable risk or there may be significant or substantial human exposure to the new chemical substance. In this situation, the general lack of data on the health or environmental effects of individual nanomaterials gives rise to the question of whether these risks can or should be addressed through EPA's new chemical PMN authority.[18] EPA's

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16 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).

17 H.R. Rep. No. 1341, 94th Cong., 2nd Sess. 10 (1976), *reprinted in* H. Comm. On Interstate and Foreign Commerce, Legislative History of the Toxic Substances Control Act (1976) (Legislative History) at 418.

18 For the reasons discussed at the beginning of this paper, it may be difficult to assess the risks for nanomaterials as a class given the diversity of materials that arguably might fit

PMN authority over "new" chemical substances, however, is not its only source of legal authority to assess and manage such risks.

As discussed below, Congress gave EPA a companion authority to its PMN authority that allows EPA to perform the same risk assessments and take the same risk management actions for existing chemical substances used for a significant new use as it can perform or take for new chemical substances. In particular, the risk management provisions of Section 5(e) apply to chemical substances "with respect to which notice is required by subsection (a)"; that notice can be a PMN or a significant new use notice (SNUN). Significantly, EPA uses the same form for both PMNs and SNUNs. Thus, the public policy interest in having EPA conduct risk assessments of individual nanomaterials, and impose appropriate risk management requirements, does not necessarily lead to the conclusion that nanomaterials must necessarily be "new" rather than "existing," since those goals can be met through either the PMN or SNUR authorities.

If EPA should decide to interpret the term "chemical substance" to authorize it to require PMNs for nanoscale versions of conventionally-sized chemical substances already on the Inventory, it should carefully consider the following points:

- Based on the statute and prior EPA pronouncements (*e.g.*, EPA's statements regarding silicon dioxide) and actions, most nanomaterial manufacturers today reasonably do not consider their nanomaterials to be new chemical substances. Accordingly, EPA would need to announce a new interpretation or rule publicly.[19] This would place manufacturers on notice of their obligation to submit PMNs under Section 5(a)(1). To the extent EPA changes its legal position, manufacturers should be given a reasonable time to come into compliance.

- EPA would need to consider the status of currently manufactured nanomaterials for which PMNs have not been submitted. The resolution of this issue will depend, among other things, on how EPA implements a change in policy (*e.g.*, whether by interpretive rule or substantive rulemaking) and any prior action EPA might have taken with respect to a particular chemical substance (*e.g.*, a determination by EPA in response to a *bona fide* request that a specific nanomaterial was already on the Inventory and did not have to go through the PMN process). Attempting to reverse prior EPA determinations regarding individual nanomaterials

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in that category. The ISO initiative on nanotechnologies includes standards on the environmental, health, and safety issues associated with nanotechnologies. The U.S. is leading the ISO working group developing these EHS standards.

[19] EPA is well aware that significant changes in existing policies (*e.g.*, through interpretative rulemakings) generally require that the public be provided with prior notice and an opportunity for comment, as do substantive rulemakings.

would pose particularly challenging procedural issues. Further, any decision to change the TSCA status of nanomaterials would have to take into account not only the legal obligations of manufacturers, but also the practical and legal impacts on the distributors, processors, and users of such materials.

- EPA would need to address the considerable technical challenges facing any effort aimed specifically at nanomaterials. As discussed above, defining nanomaterials in a manner so that they can be meaningfully and practically distinguished for regulatory purposes from conventionally-sized materials of the same molecular structure (whether by particle size or morphology) is not easily done.

- EPA would need to develop procedures and criteria for reviewing nanomaterial PMNs so that its review would not shut down this promising technology.

- EPA should consider how any change in policy with respect to nanomaterials may affect the regulation of conventional-sized materials. In particular, establishing the principle that materials of identical chemical structure are distinguishable for TSCA Inventory purposes based solely on differences in particle size or form and structure could result in significant changes to the implementation of TSCA for all chemical substances.

C. Whether Nanomaterials Qualify As "Significant New Uses" of Existing Chemical Substances Subject to Regulation under Section 5(a)(2)

In light of the uncertain legal authority to regulate nanomaterials under Section 5(a)(1) through the PMN process where conventional-sized versions appear on the Inventory, EPA should consider that it does have all the risk assessment authority of Section 5(a)(1) available to it under its significant new use authority of Section 5(a)(2) if nanomaterials are considered to be existing chemical substances. That authority requires EPA first to promulgate a SNUR through rulemaking, but otherwise all of its PMN authority remains available. This SNUR authority offers EPA considerable flexibility to regulate nanomaterials.

The TSCA legislative history 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.[20]

[20] S. Rep. No. 698, 94th Cong., 2nd Sess. 19 (1976), *reprinted in* Legislative History at 175.

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)."

Congress regarded both the PMN and the SNUR authority as suitable for addressing risks presented by new technology:

> The provisions of the section [Section 5, not simply Section 5(a)(1)] reflect the conferees[']recognition that the most desirable time to determine the health and environmental effects of a substance, and to take action to protect against any potential adverse effects, occurs before commercial production begins. Not only is human and environmental harm avoided or alleviated, but the cost of any regulatory action in terms of loss of jobs and capital investment is minimized. For these reasons the conferees have given the Administrator broad authority to act during the notification period.[21]

This determination of health and environmental effects must be made before a new chemical is manufactured, and can be made before a new use of an existing chemical is undertaken. A key distinction between Section 5(a)(1) PMNs and Section 5(a)(2) SNURs is that under Section 5(a)(2), EPA must promulgate a rule subject to public notice and comment, whereas under Section 5(a)(1), EPA already has in place a generic rule requiring submission of a notice.[22] Once EPA has issued a rule under Section 5(a)(2), however, the two provisions operate in a very similar manner.

SNUR rulemakings proceed under the provisions of the Administrative Procedure Act.[23] This involves publication of a proposed rule, opportunity for public comment, and publication of a final rule together with a "concise general statement" of the SNUR's basis and purpose. EPA has already promulgated more than 700 SNURs using this procedure. Thus, SNURs are by far the most common subject of rulemaking under TSCA. This history of successful SNUR promulgation is strong evidence that EPA can practicably exercise its SNUR authority over nanoscale versions of existing chemicals.

In promulgating a SNUR, EPA must explain how the SNUR reflects EPA's consideration of the following statutory factors:

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21 H.R. Conf. Rep. No 1679, 94th Cong., 2nd Sess. (1976) 65, 66, *reprinted in* Legislative History at 678, 679 (emphasis added).

22 *See* 40 C.F.R. § 720.22.

23 5 U.S.C. § 553.

(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 to 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.

Nanomaterials may raise concerns under any of these factors, but (B), (C), and (D) seem particularly relevant to the unique characteristics of nanomaterials. Specifically, EPA's SNUR authority allows it to address new risks associated with manufacturing, processing, or using an existing chemical in a new way. Thus, the statutory factors that EPA must consider in issuing a SNUR are some of the very factors that would cause EPA to want to issue a SNUR for a nanomaterial or category of nanomaterials.

These statutory factors must simply be considered; specific findings are not required. These factors are considerably less burdensome for EPA in rulemaking than the requirements for issuing a rule under Section 6, which include both a finding that a chemical substance "presents, or will present an unreasonable risk of injury to health or the environment," and consideration of factors such as the chemical substance's effects, benefits, and substitutes, and the economic impact of the rule. Whereas Section 6 rules are judicially reviewable under the "substantial evidence" test, SNURs are reviewable under the more deferential "arbitrary and capricious" test.[24]

EPA is not limited to issuing SNURs on individual nanomaterials, but may instead issue SNURs for categories of nanomaterials. The language of Section 5(a)(2) is not expressly limited to substance-by-substance rulemaking. EPA has already used Section 5(a)(2) to address chemical categories.[25] While such rulemaking has ultimately listed individual chemical substances within the categories, the rulemaking has been based on category characteristics. EPA's 1989 new chemical follow-up SNUR amendments addressed the category of PMN chemicals for which it had previously issued an order under Section 5(e)[26] and the category of non-Section 5(e) PMN chemicals for which EPA had concerns about actions by other

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[24] TSCA § 19(c)(1)(B), 15 U.S.C. § 2618(c)(1)(B).

[25] *See, e.g.*, 40 C.F.R. § 721.9582, covering 88 perfluoroalkyl sulfonates; 71 Fed. Reg. 12311 (Mar. 10, 2006) (proposed addition of 183 perfluoroalkyl sulfonates).

[26] 40 C.F.R. § 721.160.

manufacturers.[27] EPA issued rules setting up an expedited process for promulgating SNURs covering members of these broad categories. EPA's experience with categorical SNURs to date suggests that EPA can successfully promulgate categorical SNURs for nanomaterials.

In issuing the new chemical follow-up amendments, EPA cited Section 26(c) of TSCA as supporting a categorical approach.[28] TSCA Section 26(c), "Action with respect to categories," provides in part:

> (1) Any action authorized or required to be taken by the Administrator under any provision of this [Act] with respect to a chemical substance or mixture may be taken by the Administrator in accordance with that provision with respect to a category of chemical substances . . . .
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> (2) For purposes of paragraph (1):
>
> (A) 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 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], 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.[29]

Thus, the bottom-line criterion for qualifying as a category is being "in some . . . way suitable for classification as such" for purposes of TSCA, an extremely flexible test. EPA may be able to establish through rulemaking that particular classes of nanomaterials meet the definition of a "category of chemical substances" on the basis of their common characteristics, unique to nanomaterials. EPA could then conduct its risk assessments, and impose risk management controls, on individual nanomaterials in the same manner as it does through the PMN process.

One aspect of Section 5(a)(2) that may present a challenge to EPA in promulgating SNURs for some nanomaterials is the required determination that the particular use of the chemical substance for which a SNUR is promulgated be, in fact, a "new" use. EPA has consistently taken the position that if a substance is being used in a particular manner at the time

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[27] 40 C.F.R. § 721.170.

[28] 52 Fed. Reg. 15594, 15597 (Apr. 29, 1987) (proposed rule); 54 Fed. Reg. 31298 (July 27, 1999) (final rule).

[29] 15 U.S.C. § 2625(c).

that a SNUR is proposed, that specific use is not "new" and cannot be the subject of a SNUR.[30] Thus, to the extent that nanoscale versions of some chemical substances are already being distributed in commerce for certain uses, it may be difficult for EPA to make the requisite determination that those uses are "new." Therefore, in order to preserve the effectiveness of the SNUR as a risk management tool, EPA must proceed apace in identifying projected new uses of nanomaterials that meet the statutory factors. If EPA delays unnecessarily, it may find that its ability to promulgate SNURs for certain nanomaterials is constrained -- as more and more uses of nanoscale materials become "existing" uses.

One additional difference between Section 5(a)(1) PMNs and Section 5(a)(2) SNURs is that SNUR rulemakings under Section 5(a)(2) trigger Section 12(b) export notification requirements.[31] EPA recently proposed to amend its Section 12(b) regulations to limit export notifications for exports of SNUR chemicals to a one-time occurrence (per chemical per country, not per calendar year), as has been the case for Section 4 chemicals for several years.[32] If adopted, this provision would minimize the impact of the export notification requirement for nanomaterials covered by SNURs.

III. REGULATING NANOMATERIALS UNDER OTHER PROVISIONS OF TSCA

A. TSCA Section 4 Test Rules

TSCA Section 4 authorizes EPA to require manufacturers and processors of existing chemicals to conduct tests "to develop data with respect to the health and environmental effects" of the chemical.[33] EPA may require such testing by rule if it determines that a chemical substance may present an unreasonable risk to human health or the environment. EPA also may promulgate a test rule without a risk-based finding if it determines that chemical is produced in substantial quantities and there may be substantial human or environmental exposure to the chemical, that there are insufficient data available to determine the environmental or health effects of the chemical, and that testing is necessary to provide such data. EPA also can obtain test data without going through the rulemaking process, issuing consent decrees requiring testing where a consensus exists among EPA and interested parties and the public about the adequacy of a proposed testing program. Further, the statute contemplates that EPA will use its TSCA

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30 *See, e.g.*, 68 Fed Reg. 35315 (June 13, 2003) (SNUR for *Burkholderia cepacia* complex), where EPA explains that existing uses of *Burkholderia* are not appropriate for inclusion in the SNUR for the microorganism. *See*, *more generally*, 55 Fed. Reg. 17376 (Apr. 24, 1990), where EPA explains that: "To establish a significant new use, EPA must determine that the use is not ongoing."

31 Export notification requirements would also be triggered for nanomaterials subject to rulemakings or proceedings under TSCA Section 4, 6, or 7.

32 Proposed 40 C.F.R. § 707.65(a)(2)(ii), 71 Fed. Reg. 6733, 6743 (Feb. 9, 2006).

33 TSCA § 4(a), 15 U.S.C. § 2603(a).

Section 4 authority in order to address not only EPA's own need for health and safety data, but also the health and safety data needs of sister agencies, such as the National Institute of Occupational Safety and Health, the Department of Labor, and the National Cancer Institute.[34]

EPA has also successfully used the threat of invoking its TSCA Section 4 authority to encourage manufacturers and processors to enter into voluntary agreements to test existing chemicals, most notably the "high production volume" testing program that includes over 2,200 chemicals (each with an annual production rate of over one million pounds).

Accordingly, neither the statute nor EPA's existing Section 4 rules prohibit EPA from exercising its authority under TSCA Section 4 to require manufacturers or processors of nanoscale versions of chemical substances to test those chemicals to better evaluate the potential environmental or health risks posed by those materials. Unless voluntary testing agreements are entered, however, EPA would need to demonstrate, through notice and comment rulemaking, that it can support either a risk- or exposure-based finding for a nanoscale substance that is subject to the test rule. EPA can base such a decision on risk, or on a determination that the nanomaterial is produced in substantial quantities and there may be substantial human or environmental exposure, and that testing is necessary to fill data gaps. Further, consistent with EPA's successful HPV testing initiative, EPA may consider whether a voluntary approach to testing might be appropriate for certain classes of nanomaterials.

Whether through voluntary efforts, negotiated testing agreements, or rulemaking, the authority to require the generation of health and safety data is an extremely valuable tool that is available to EPA under TSCA Section 4. The importance of this tool with respect to nanomaterials is underscored by EPA's *Nanotechnology White Paper*, which identifies a considerable body of data that EPA and its sister agencies believe are important to understanding the health and safety implications of nanomaterials.

B. TSCA Section 6 Rules

TSCA Section 6(a) authorizes EPA to regulate the manufacture, processing, commercial distribution, use, and/or disposal of an existing chemical 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."[35] EPA has the authority under TSCA Section 6 to promulgate regulations:

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34 *See* TSCA § 4(e), 15 U.S.C. § 2603(e), establishing an Interagency Testing Committee to recommend substances for testing under Section 4. A recent example of a test rule that was promulgated to address another agency's data needs is the 2004 *In Vitro* Dermal Absorption Rate test rule, which was promulgated under Section 4 to generate data of interest to OSHA. *See* 69 Fed. Reg. 22402 (Apr. 26, 2004).

35 TSCA § 6(a), 15 U.S.C. § 2605(a).

- prohibiting or limiting the manufacture, processing, or distribution in commerce of the chemical generally or for a particular use, as well as prohibiting or regulating the commercial use of a chemical;

- requiring that the chemical, or any article containing the chemical, be labeled or accompanied by warnings and instructions for use, distribution, or disposal;

- requiring creation and maintenance of records of manufacturing/processing methods and reasonable monitoring or testing necessary to assure regulatory compliance;

- regulating disposal of the chemical, or any article containing the chemical; or

- requiring notification to distributors, other persons in possession of the chemical, and the general public of the unreasonable risk of injury.[36]

Unlike the Section 5 SNUR authority, Section 6 provides EPA with the capacity to prohibit or limit outright certain activities, but the exercise of that authority must be established through on the record rulemaking based upon a finding of unreasonable risk and a requirement that EPA impose the least economically burdensome controls to manage that risk.[37]

C. TSCA Section 7: EPA's Imminent Hazard Authority

TSCA Section 7 authorizes EPA to initiate a civil action to seize an imminently hazardous substance, mixture, or article containing them, and seek such other relief against any person who manufactures, processes, distributes, uses, or disposes of an imminently hazardous substance, mixture, or article containing them. EPA's authority under TSCA Section 7 is broad, and authorizes EPA to seek a court order requiring recalls, replacements/repurchases, public notices of risk, or a combination of any of these requirements.

D. EPA's Information-Gathering Authorities

EPA has broad information-gathering powers regarding existing chemicals (*i.e.*, in addition to the information it may gather through the review of "new" chemicals) under TSCA Sections 5, 6, and 8, some of which are self-implementing and do not require any new action by EPA to be applicable to nanomaterials. These include:

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[36] TSCA § 6(a)(1)-(7), 15 U.S.C. § 2605(a)(1)-(7).

[37] EPA may take immediate action under TSCA Section 5(f) if it determines that a chemical that is the subject of a PMN or SNUN presents or will present an unreasonable risk before it is able to issue a TSCA Section 6 rule.

- TSCA Section 5 -- As part of the PMN and SNUR processes, EPA can issue TSCA Section 5(e) orders seeking additional information about chemicals for which PMNs or SNUNs have been submitted, but where EPA determines that it does not have sufficient information to evaluate the PMN or SNUN.

- TSCA Section 6(b) -- Authorizes EPA to order a manufacturer or processor to provide certain information to EPA if EPA has a reasonable basis to conclude that the manufacture or processing of an existing chemical substance may present an unreasonable risk to human health or the environment. EPA may, for example, order the manufacturer or processor to submit a description of the chemical substance's quality control procedures. EPA can require the manufacturer or processor to modify those procedures to the extent EPA believes necessary to address any inadequacies. Further, if EPA determines that a chemical that has been distributed presents an unreasonable risk, EPA is authorized to order the manufacturer or processor to notify its customers and the public of the risk and to replace or repurchase the chemical, as appropriate, to abate the risk.

- TSCA Section 8(a) -- EPA has promulgated a number of information-gathering rules under this provision, including rules to gather detailed information on specific chemicals and more generic rules such as the Inventory Update Rule that collects basic production information on chemicals on the Inventory every four years.

- TSCA Section 8(c) -- Manufacturers and processors of chemicals must create and maintain records of "allegations" -- whether written or oral -- that the chemical "caused a significant adverse reaction to health or the environment."[38] These records must be made available to EPA upon request. This is a very broad information-gathering tool because it encompasses allegations that can come from any source and that can be made without formal proof or regard for evidence. Thus EPA could, for example, request TSCA Section 8(c) records from certain sectors where nanomaterials are prevalent to determine if there are significant numbers of allegations regarding adverse reactions associated with nanomaterials or products containing nanomaterials.

- TSCA Section 8(d) -- EPA can, by rule, designate chemicals for which manufacturers and processors must submit to EPA any health and safety studies conducted regarding the listed chemicals. Such rules are retrospective as well as prospective; qualifying studies must be submitted

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[38] 40 C.F.R. § 717.3(a).

that were conducted in the ten years prior to the listing and for the next ten years after the listing.

- TSCA Section 8(e) -- Manufacturers, processors, or distributors of chemicals must "immediately inform EPA if they obtain information that reasonably supports the conclusion that the chemical substance . . . presents a substantial risk of injury to health or the environment." This has been an important information-gathering tool for EPA, and has also been the subject of recent enforcement actions. As nanomaterials are more broadly introduced into the economy, Section 8(e) will be a key mechanism for EPA to track the occurrence of adverse effects on human health or the environment.

Nanoscale materials are not excluded from these various information-gathering authorities and may allow EPA to collect a broad range of production, health, and environmental risk information regarding nanomaterials. In particular, the "allegations of adverse effects" recordkeeping and the "substantial risk" reporting requirements together might form the basis of an "early warning" system for potential risks associated with the products of nanotechnology. EPA could then use this new information in assessing the risks and benefits of particular nanomaterials.

E. TSCA Section 21 Citizen Petitions

In addition to EPA's authorities, TSCA Section 21 allows citizens to petition EPA to initiate a proceeding for the issuance, amendment, or repeal of a rule under TSCA Section 4, 6, or 8 or an order under Section 5(e) or 6(b)(2) regarding chemical substances. A TSCA Section 21 petition must set forth facts that the petitioner believes establish the need for the action requested. Nanomaterials are not excluded from the scope of Section 21 petitions.

EPA is required to grant or deny the petition within 90 days of its filing. If EPA grants the petition, it must promptly commence an appropriate proceeding. If EPA denies the petition, it must publish its reasons for the denial in the *Federal Register*. Within 60 days of denial, or the expiration of the 90-day period, if no action is taken, the petitioner may commence a civil action in a U.S. district court to compel initiation of the requested rulemaking proceeding.

CONCLUSION

The following conclusions can be made regarding the ability of TSCA to regulate nanotechnology: (1) nanomaterials include chemical substances and mixtures that EPA can regulate pursuant to TSCA; (2) if a "new" chemical substance is manufactured at the nanoscale, it is subject to the same PMN review requirements under TSCA Section 5(a)(1) that are applicable to any new chemical; and (3) as an alternative to its Section 5(a)(1) PMN authority over "new" chemical substances, EPA may regulate nanomaterials as existing chemical substances under its Section 5(a)(2) authority to promulgate SNURs. In addition, EPA has other authorities under TSCA to regulate nanomaterials, including the authority to require health and environmental testing; collect production, health, and environmental information about

nanomaterials; and promulgate rules regulating, and even prohibiting, the manufacture, processing, distribution, and use of nanomaterials.