CHAPTER 2

TSCA and Nanomaterials

Executive Summary

Nanotechnology, loosely described as the creation or use of materials or processes at a scale of approximately 1 to 100 nanometers in at least one dimension, is a rapidly growing technology being utilized in virtually all major industrial sectors, including electronics, medicine, coatings, consumer products, aerospace, and specialty materials.[1] 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 benefits, though, come concerns: the possibility that applications of nanotechnology may pose new or unusual risks to human health or the environment.[2]

This chapter addresses how the risks that may be associated with nanotechnology can be addressed under the Toxic Substances Control Act (TSCA). Unlike most other environmental statutes, which 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 nanotechnology (e.g., the Clean Air Act, Clean Water Act, Resource Conservation and Recovery Act, and Federal Insecticide, Fungicide, and Rodenticide Act, or FIFRA).

This chapter expands upon the Section of Environment, Energy, and Resources' June 2006 paper entitled *Regulation of Nanoscale Materials under the Toxic Substances Control Act*. The Team Leader on that paper was Christopher L. Bell, Sidley Austin. Revisions are by Lynn L. Bergeson, Bergeson & Campbell, P.C.

Other federal agencies also have the authority to regulate nanotechnology, including but not limited to the Food and Drug Administration (FDA), the Consumer Product Safety Commission, and the Occupational Safety and Health Administration (OSHA).

This chapter comes to the following conclusions regarding the ability of EPA to regulate nanoscale materials under TSCA:

- Nanomaterials include chemical substances and mixtures that EPA can regulate pursuant to TSCA.
- 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)(A) that are applicable to any new chemical.
- In addition to its Section 5(a)(1) PMN authority over "new chemical substances," EPA can regulate nanoscale versions of chemical substances already listed on the TSCA Chemical Substances Inventory (Inventory) as existing chemical substances under its Section 5(a)(2) authority to promulgate significant new use rules (SNUR). Promulgation of SNURs for individual nanomaterials or categories of nanomaterials would be feasible for EPA, as shown by its promulgation of approximately 40 existing chemical 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."
- EPA also 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.

Does EPA Have the Authority to Regulate Nanomaterials under TSCA?

A threshold question is whether EPA has the authority under TSCA to regulate nanomaterials. TSCA provides EPA with 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 unquestionably are "chemical substances" that EPA has the authority to regulate under TSCA.[4]

Having established that nanomaterials can be "chemical substances" subject to regulation 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 apply per se to nanoscale versions of existing chemicals, this does not preclude EPA's authority to regulate such nanomaterials as "existing" chemicals under Section 5(a)(2) or other provisions of TSCA.

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)(A) for "new chemical substances," and Section 5(a)(2) for significant new uses of both new and existing chemical substances. While the two provisions have different triggers, once triggered they operate almost identically. Much discussion and many papers from various stakeholders have focused on EPA's ability to use Section 5(a)(1)(A) to regulate as "new chemical substances" nanomaterials for which conventional-sized versions are already on the Inventory. Assuming that such distinctions reasonably can be drawn in individual cases, the arguments for this use of Section 5(a)(1)(A) were fraught with obstacles, and in any event EPA settled the debate on January 23, 2008, when it issued as part of the voluntary Nanoscale Materials Stewardship Program (NMSP) its so-called TSCA Inventory Paper.[5] 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.

Technical Challenges in Distinguishing between "Nanoscale" and Conventional-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 earlier, 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 under way an initiative to develop, among other things, international consensus standards on terms, definitions, and nomenclature related to nanotechnology.[6] (In December 2006, ASTM International issued its own standard on such definitions.)[7] The United States is participating in the ISO effort, and 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.[8]

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.

Many 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 micron-sized or larger particles as commercially produced (so-called conventional or bulk materials). This is also true of "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 nonarbitrary rationale distinguishing between "nanoscale"

and "bulk" or "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 difficult to see how this can be accomplished other than on a case-by-case basis. It also may 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 carried out with an understanding of the technical difficulties in distinguishing between nanoscale and conventional-sized materials of the same molecular identity. In addition, while this chapter uses terms such as "nanomaterials" or "nanotechnology," it must be understood that these terms encompass a widely diverse range of materials, uses, and risk profiles that may be very difficult to regulate as a single class of chemical substances.

Whether Nanomaterials Qualify as "New Chemical Substances" Subject to Regulation under Section 5(a)(1)(A)

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.[9] A "new chemical substance" is any chemical substance that is not on the Inventory.[10]

With limited exceptions, "new chemical substances" cannot be manufactured unless the manufacturer first complies with the PMN provisions of TSCA Section 5(a)(1)(A).[11] A person who intends to manufacture or import a "new chemical substance" must submit to EPA certain information for EPA's review at least 90 days before manufacturing or importing 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; placing it on the Inventory but 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 also are "new chemical substances" are subject to the PMN requirements of TSCA Section 5(a)(1) like any other new chemical.[12] For combinations of materials not presently reflected on the Inventory (e.g., 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 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 it is measured. These differences may result in very different physical characteristics and properties than those generally associated with the conventional form of the chemical, and this may cause the nanomaterials to have different risk profiles than their chemically identical brethren have. 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."[13] A "new" chemical is considered a chemical that does not have the same particular molecular identity as any chemical on the Inventory.[14] 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 the nanoscale version of an "existing" chemical is not a "new" chemical and therefore is not subject to the TSCA Section 5(a)(1)(A) process.

EPA has now agreed with this conclusion. In the TSCA Inventory Paper, EPA explains that "[a]lthough a nanoscale substance that has the same molecular identity as a non-nanoscale substance listed on the Inventory differs in particle size and may differ in certain physical and/or chemical properties resulting from the difference in particle size, EPA considers the two forms to be the same chemical substance because they have the same molecular identity."[15] EPA continues, "[t]he Inventory listing in this case is considered to represent both the nanoscale and non-nanoscale forms of the substance and, as such, does not distinguish between two forms having the same molecular identity that differ only in particle size and/or physical/chemical properties resulting from the

difference in particle size."[16] A nanoscale substance whose particular molecular identity is not identical to any substance on the Inventory, EPA explains, constitutes a "new chemical substance."[17]

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 identity, at least to a limited degree, while recognizing that molecular identity is the definitive characteristic in most instances.

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."[18] 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 definition of "chemical substance." That "combination" authority may not be applicable to most nanomaterials, however, since they typically are 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.

TSCA Section 5(e) provides 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.[19]

According to an article that appeared in the Bureau of National Affairs' *Daily Environment Report*,[20] EPA exercised its TSCA Section 5(e) authority in October 2008 when it issued a TSCA Section 5(e) Consent Order regarding the manufacture of multi-walled carbon nanotubes.[21] The order requires the company to conduct an inhalation study on rats, prescribes the use of personal protective equipment for workers exposed to the nanotubes, and sets out other conditions as well. The order does not name the company, but the U.K.-based Thomas Swan & Co. Ltd. issued a press statement that a subsidiary in New Jersey had obtained a Consent Order to begin manufacturing a multi-walled carbon nanotube product. The order is most likely for the subsidiary, Swan Chemical Inc. of Lyndhurst. The Consent Order was issued in response to a PMN submitted by the company and the order states that nanotubes will be used as a property modifier in electronic applications and in polymer composites. According to the order, EPA approved the PMN even though the firm did not provide any data about the multi-walled carbon nanotubes in its submission. Under the Consent Order, the manufacturer must:

- conduct a 90-day inhalation toxicity study in rats;
- submit certain physical and chemical information about the multi-walled carbon nanotubes;
- deliver to EPA a 1-gram sample of the multi-walled carbon nanotubes along with a copy of the material safety data sheet that will accompany them;

- require workers to wear protective gloves, clothing, and a full-face respirator approved by the National Institute for Occupational Safety and Health;
- use the multi-walled carbon nanotubes only for one or more specific applications named in the Consent Order, but kept confidential;
- distribute the carbon nanotubes only to companies that agree to follow the same restrictions, with the exception of the testing requirements; and
- maintain for five years records of information including the volume made, customers that purchased them, and proof that a program to help workers use required equipment was established.

Previously, on May 7, 2008, EPA issued a *Federal Register* notice stating that Swan Chemical had submitted a PMN to make single-walled carbon nanotubes as property modifiers in electronics and polymer composites.[22] Similarly, on January 5, 2009, EPA announced receipt of several PMNs concerning multi-walled carbon nanotubes.[23]

EPA's PMN authority over "new chemical substances," however, is not its only source of legal authority to assess and manage such risks. As discussed in the next section, Congress gave EPA 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 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.

Whether Nanomaterial Uses Qualify as "Significant New Uses" of Existing Chemical Substances Subject to Regulation under Section 5(a)(2)

In light of the earlier discussion on Section 5(a)(1), it is important to note that EPA has risk assessment authority under its significant new use authority of Section 5(a)(2). This section of TSCA 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.[24]

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.[25]

This determination of health and environmental effects must be made before a new chemical is manufactured, and it 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.[26] 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.[27] 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 approximately 40 existing chemical SNURs using

this procedure. 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:

> (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.[28]

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.[29]

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.[30] 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)[31] and the category of non-Section 5(e) PMN chemicals for which EPA had concerns about actions by other manufacturers.[32] 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.[33] 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 . . . .
>
> (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.[34]

Thus, the bottom-line criterion for qualifying as a category is being "in some . . . way suitable for classification as such" for purposes of TSCA, which is 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, which are 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 that a SNUR is proposed, that specific use is not "new" and cannot

be the subject of a SNUR.[35] 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."

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.[36] EPA has now amended 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.[37] This provision should minimize the impact of the export notification requirement for any nanomaterials covered by SNURs.

EPA issued SNURs for four nanoscale substances most recently on June 24, 2009.[38] According to EPA, four of these chemical substances, including multi-walled carbon nanotubes (generic) and single-walled carbon nanotubes, are subject to TSCA Section 5(e) consent orders issued by EPA. Under the SNURs, persons who intend to manufacture, import, or process any of these substances for an activity that is designated as a significant new use must notify EPA at least 90 days before commencing that activity. Once notified, EPA will evaluate the intended use and, if necessary, prohibit or limit that activity before it occurs. EPA states that, for the four PMN substances subject to consent orders, including multi-walled carbon nanotubes and single-walled carbon nanotubes, EPA determined that activities associated with the PMN substances "may present unreasonable risk to human health or the environment." The consent orders require protective measures intended to limit exposures or otherwise mitigate the potential unreasonable risk. The 5(e) SNURs designate as a "significant new use" the absence of the protective measures required in the corresponding consent orders.

Regulating Nanomaterials under Other Provisions of TSCA

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.[39] 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 a chemical is produced in substantial quantities and there may be

substantial human or environmental exposure to the chemical, that insufficient data are 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, by 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 Section 4 authority to address EPA's own need for health and safety data as well as the health and safety data needs of other federal agencies such as the National Institute of Occupational Safety and Health, the Department of Labor, and the National Cancer Institute.[40]

EPA also has 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. The most notable instance of this is the High Production Volume (HPV) Challenge Program, which included over 2,200 chemicals with an annual production volume of over 1 million pounds.

Accordingly, neither the statute nor EPA's existing Section 4 regulations preclude EPA from exercising its authority under TSCA Section 4 to require manufacturers or processors of nanoscale versions of existing chemical substances to test those chemicals in an effort to better evaluate the potential environmental or health risks posed by them. Unless voluntary testing agreements are reached, 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 HPV initiative, EPA may consider whether a voluntary approach to testing might be appropriate for certain classes of nanomaterials.[41]

Whether through voluntary efforts, negotiated testing agreements, or rulemaking, the authority to require the generation of health and safety data 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.

Importantly, EPA reported in early 2009 that it is preparing a draft TSCA Section 4 test rule for multi-walled carbon nanotubes. According

to a notice in EPA's May 11, 2009, Regulatory Agenda, a TSCA Section 4(a) test rule "may be needed to determine the health effects" of multi-walled carbon nanotubes. EPA states that the results of the tests that could be required under the rule could assist in understanding the health effects of the substance to manage/minimize any potential risk and exposure. Results could also help with establishing a correlation between the chemical/physical properties and health effects needed to protect the health of workers handling the substance. EPA has not determined when it will publish a notice of proposed rulemaking (NPRM).

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."[42] EPA has the authority under TSCA Section 6 to promulgate regulations:

- 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.[43]

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.[44] In addition, EPA is required to impose the least economically burdensome controls to manage that risk.

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 to 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.

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 the following:

- 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, which collects basic

production information on chemicals on the Inventory every five years. EPA reportedly is preparing to issue a TSCA Section 8(a) rule on certain nanoscale materials in 2009.

- 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."[45] 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 that were conducted in the ten years prior to the listing and for the next ten years after the listing must be submitted.
- 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.[46]

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.

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

On January 28, 2008, EPA launched the NMSP "to complement and support its new and existing chemical efforts on nanoscale materials under [TSCA]."[47] EPA has emphasized that data from the NMSP "will provide important baseline information on health and environmental effects, exposures, risks, management practices, and data needs that will assist EPA and others in properly assessing and managing risks related to nanoscale materials."[48] EPA has further stated that "[d]ata submitted during the first 6 months of the [Basic] program will be a factor when [EPA] considers whether to use regulatory information gathering authority under TSCA,"[49] and that approximately two years after the NMSP's launch date, EPA will issue a detailed evaluation report on the NMSP that will "include consideration of [the] use of regulatory authorities under TSCA."[50]

On January 12, 2009, EPA released its interim report on the NMSP.[51] EPA states that, based on the current interim results, "the NMSP can be considered successful." EPA notes that a number of the environmental health and safety data gaps still exist, however, and "EPA is considering how to best use testing and information gathering authorities under the Toxic Substances Control Act to help address those gaps." According to EPA, it will continue to review new chemical nanoscale materials submitted under TSCA Sections 5(a) and 5(h)(4) and apply, as appropriate, testing requirements and exposure controls under Section 5(e) and SNURs

under Section 5(a)(2). EPA continues to welcome new participants and information submissions for the NMSP, which will continue until January 2010. According to a notice in EPA's November 24, 2008, Regulatory Agenda, EPA intends to publish a final evaluation of the NMSP, including next steps, in April 2010.

With respect to its regulatory authorities under TSCA, the following conclusions can be made regarding EPA's ability 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.

Notes

1. A nanometer is one-billionth of a meter, or 10^{-9} m. *See* National Nanotechnology Initiative (NNI), "Frequently Asked Questions," http://www.nano.gov/html/facts/faqs.html.
2. An overview of the nature, benefits, and possible risks associated with nanotechnology can be found in U.S. Environmental Protection Agency (EPA), *Nanotechnology White Paper* (Feb. 2007), *available at* http://www.epa.gov/osa/pdfs/nanotech/epa-nanotechnology-whitepaper-0207.pdf.
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," including for pesticides that are regulated by EPA under FIFRA, foods and drugs regulated by the FDA, and tobacco.
4. *See, e.g.*, 72 Fed. Reg. 38083, 38084 (July 12, 2007) (stating that "[n]anoscale materials that meet the TSCA section 3(2)(A) definition of 'chemical substance' are subject to TSCA"). 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, that 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.*

5. *See* EPA, "TSCA Inventory Status of Nanoscale Substances—General Approach" (Jan. 23, 2008) (TSCA Inventory Paper), *available at* http://www.epa.gov/opptintr/nano/nmsp-inventorypaper2008.pdf.
6. *See* ISO, "TC 229—Nanotechnologies," *available at* http://www.iso.org/iso/standards_development/technical_committees/list_of_iso_technical_committees/iso_technical_committee.htm?commid=381983. In fact, on September 25, 2008, ISO's Technical Committee (TC) 229 announced the issuance of ISO/TS 27687:2008, a standard that provides definitions for various nanotechnology terms, including "nano-object," "nanoparticle," "nanofiber," and "nanoplate." *See* ISO, "New ISO/TS 27687 Will Help Defining Nanotechnologies" (Sept. 25, 2008), *available at* http://www.iso.org/iso/pressrelease.htm?refid=Ref1161.
7. *See* ASTM International, "Terminology for Nanotechnology Standard Now Available from ASTM International" (Dec. 2006), *available at* http://www.astmnewsroom.org/default.aspx?pageid=1192.
8. 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).
9. TSCA § 8(b)(1), 15 U.S.C. § 2607(b)(1).
10. 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).
11. There are a variety of limitations on or exemptions from the PMN requirements, including those regarding chemicals used for research and development and chemicals manufactured in low volumes or for purposes of test marketing.
12. At least two engineered nanomaterials are known to be listed on the Inventory after having undergone PMN review. *See* 71 Fed. Reg. 46475, 46480 (Aug. 14, 2006) (P-05-0687, "siloxane coated alumina nanoparticles"); 71 Fed. Reg. 33449, 33454 (June 9, 2006) (P-05-0673, "siloxane coated silica nanoparticles").
13. TSCA § 3(2)(A), 15 U.S.C. § 2602(2)(A).
14. *See* TSCA Inventory Paper at 2–3.
15. *Id.* at 6.
16. *Id.*

17. *Id.* at 5. EPA cites "nanotubes and carbon fullerenes" as examples of new chemical substances. On October 31, 2008, EPA issued a *Federal Register* notice stating again its view that many carbon nanotubes will be considered new chemicals and thus subject to EPA premanufacture review. 73 Fed. Reg. 64946 (Oct. 31, 2008).
18. TSCA § 3(2)(A)(i), 15 U.S.C. § 2602(2)(A)(i).
19. For the reasons discussed at the beginning of this chapter, it may be difficult to assess the risks for nanomaterials as a class given the diversity of materials that arguably might fit in that category. The ISO initiative on nanotechnologies includes standards on the environmental, health, and safety (EHS) issues associated with nanotechnologies. The United States is leading the ISO TC 229 working group developing these EHS standards.
20. P. Rizzuto, *EPA Consent Order Allows Company to Produce Multi-Walled Carbon Nanotubes*, Env't Rep. (BNA) A-5 (Oct. 14, 2008).
21. A redacted copy of the Consent Order is reproduced in the appendix to this chapter.
22. 73 Fed. Reg. 25696 (May 7, 2008).
23. 74 Fed. Reg. 280 (Jan. 5, 2009).
24. S. Rep. No. 698, 94th Cong., 2nd Sess. 19 (1976), *reprinted in* Legislative History at 175.
25. H.R. Conf. Rep. No 1679, 94th Cong., 2nd Sess. (1976) 65, 66, *reprinted in* Legislative History at 678, 679 (emphasis added).
26. *See* 40 C.F.R. § 720.22.
27. 5 U.S.C. § 553.
28. TSCA § 5(a)(2)(A)–(D), 15 U.S.C. § 2604(a)(2)(A)–(D).
29. TSCA § 19(c)(1)(B), 15 U.S.C. § 2618(c)(1)(B).
30. *See, e.g.*, 40 C.F.R. § 721.9582, covering 88 perfluoroalkyl sulfonates; 72 Fed. Reg. 57222 (Oct. 9, 2007) (addition of 183 perfluoroalkyl sulfonates).
31. 40 C.F.R. § 721.160.
32. 40 C.F.R. § 721.170.
33. 52 Fed. Reg. 15594, 15597 (Apr. 29, 1987) (proposed rule); 54 Fed. Reg. 31298 (July 27, 1999) (final rule).
34. TSCA § 26(c), 15 U.S.C. § 2625(c).
35. *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 also* 55 Fed. Reg. 17376 (Apr. 24, 1990) (explaining that "[t]o establish a significant new use, EPA must determine that the use is not ongoing").
36. Export notification requirements would also be triggered for nanomaterials subject to rulemakings or proceedings under TSCA Section 4, 6, or 7.
37. 40 C.F.R. § 707.65(a)(2)(ii), 71 Fed. Reg. 66234, 66244 (Nov. 14, 2006).
38. 74 Fed. Reg. 29982 (June 24, 2009).

39. TSCA § 4(a), 15 U.S.C. § 2603(a).
40. *See* TSCA § 4(e), 15 U.S.C. § 2603(e), establishing an Interagency Testing Committee to recommend substances for testing under Section 4. An 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).
41. One component of EPA's voluntary NMSP is the In-Depth Program, under which participants would "develop a plan and submit [testing and other] data over a longer period of time to be determined in the plan." 73 Fed. Reg. 4861, 4863 (Jan. 28, 2008).
42. TSCA § 6(a), 15 U.S.C. § 2605(a).
43. TSCA § 6(a)(1)–(7), 15 U.S.C. § 2605(a)(1)–(7).
44. 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.
45. 40 C.F.R. § 717.3(a).
46. EPA's position has always been that Section 8(e) applies to nanoscale chemicals just as it does to bulk chemicals; *see, e.g.*, EPA, "Concept Paper for the Nanoscale Materials Stewardship Program Under TSCA," at 18 (undated) (including discussion of Section 8(e)), *available at* http://www.epa.gov/oppt/nano/nmsp-conceptpaper.pdf, and several companies have made Section 8(e) submissions for nanoscale substances. *See, e.g.*, 8EHQ-1208-17079D (Dec. 4, 2008) (Sepiolite nanoclay), *available at* http://www.epa.gov/opptintr/tsca8e/pubs/8ehq/2008/dec08/8ehq_1208_17079d.pdf; 8EHQ-0708-17208B (Sept. 9, 2008) (carbon nano tube), *available at* http://www.epa.gov/opptintr/tsca8e/pubs/8ehq/2008/sep08/8ehq_0908_17208b.pdf; FYI-0708-01611A (July 9, 2008) (multi-walled carbon nanotubes), *available at* http://www.epa.gov/opptintr/tsca8e/pubs/8ehq/2008/jul08/fyi_0708_01611a.pdf; 8EHQ-0408-17079B (Mar. 31, 2008) (Sepiolite nanoclay), *available at* http://www.epa.gov/opptintr/tsca8e/pubs/8ehq/2008/apr08/8ehq_0408_17079b.pdf; 8EHQ-0308-17109A (Mar. 24, 2008) (multi-walled carbon nanotubes), *available at* http://www.epa.gov/opptintr/tsca8e/pubs/8ehq/2008/mar08/8ehq_0308_17109a.pdf; 8EHQ-0308-17088A (Feb. 27, 2008) (submission by DuPont AirProducts NanoMaterials L.L.C.), *available at* http://www.epa.gov/opptintr/tsca8e/pubs/8ehq/2008/mar08/8ehq_0308_17088a.pdf; 8EHQ-0308-16999B (Feb. 27, 2008) (submission by DA NanoMaterials L.L.C.), *available at* http://www.epa.gov/opptintr/tsca8e/pubs/8ehq/2008/mar08/8ehq_0308_16999b.pdf; 8EHQ-0707-16911A (July 19, 2007) (surface-modified nanoparticle), *available at* http://www.epa.gov/oppt/tsca8e/pubs/8ehq/2007/jul07/8ehq_0707_16911a_8807000000329.pdf; 8EHQ-0403-15319 (Apr. 10, 2003) (single-walled

carbon nanotubes); *see also* FYI-0708-01611A (July 9, 2008) (multi-walled carbon nanotubes), http://www.epa.gov/opptintr/tsca8e/pubs/8ehq/2008/jul08/fyi_0708_01611a.pdf.

47. 73 Fed. Reg. at 4861.
48. EPA, "Supporting Statement for an Information Collection Request (ICR)" (undated) at 2, *available at* http://www.epa.gov/oppt/nano/nmsp-icr-supportingstatement.pdf.
49. 73 Fed. Reg. at 4863.
50. EPA, "Nanoscale Materials Stewardship Program," *available at* http://www.epa.gov/oppt/nano/stewardship.htm.
51. EPA, Nanoscale Materials Stewardship Program Interim Report (Jan. 2009), *available at* http://www.epa.gov/oppt/nano/nmsp-interim-report-final.pdf.

APPENDIX

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

OFFICE OF POLLUTION PREVENTION AND TOXICS

REGULATION OF A NEW CHEMICAL SUBSTANCE

PENDING DEVELOPMENT OF INFORMATION

In the matter of:	)	Premanufacture Notice Number:
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[ ]	)	P-08-0177
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Consent Order and Determinations Supporting Consent Order

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PREAMBLE

I INTRODUCTION

Under the authority of § 5(e) of the Toxic Substances Control Act ("TSCA") (15 U.S.C. 2604(e)), the Environmental Protection Agency ("EPA" or "the Agency") issues the attached Order, regarding premanufacture notice ("PMN") P-08-0177 for the chemical substance multiwalled carbon nano tubes, ("MWCNT" or the "PMN substance") submitted by [ ], ("the Company"), to take effect upon expiration of the PMN review period. The Company submitted the PMN to EPA pursuant to section 5(a)(1) of TSCA and 40 CFR Part 720.

Under § 15 of TSCA, it is unlawful for any person to fail or refuse to comply with any provision of § 5 or any order issued under § 5. Violators may be subject to various penalties and to both criminal and civil liability pursuant to § 16, and to specific enforcement and seizure pursuant to § 17. In addition, chemical substances subject to an Order issued under § 5 of TSCA, such as this one, are subject to the § 12(b) export notice requirement.

II. SUMMARY OF TERMS OF THE ORDER

The Consent Order for this PMN substance requires the Company to:

(1) Deliver to EPA a 1 gram sample of the PMN substance along with a copy of MSDS;

(2) Submit to EPA the results of a 90-day inhalation toxicity study in rats with a post exposure observation period of up to 3 months, including bronchoalveolar lavage fluid ("BALF") analysis (OPPTS 870.3465 or OECD 413) at least 14 weeks before either (a) manufacturing or importing a total of [ ] kg of the PMN substance, or (b) [ ] years [ ] months

after commencing non-exempt commercial manufacture of the PMN substance, whichever comes first. The production/time limit shall be calculated from a date 2 years after signing this Consent Order by the Company,

(3) Within 6 months of commencing non-exempt commercial manufacture of the PMN substance, submit certain material characterization data;

(4) Use gloves impervious to nanoscale particles and chemical protective clothing;

(5) Use a NIOSH–approved full-face respirator with an N -100 cartridge while exposed by inhalation in the work area;

(6) Use the PMN substance only as a [ ];

(7) distribute the PMN substance only to a person who agrees to follow the same restrictions (except the testing requirements); and

(8) maintain certain records.

III. CONTENTS OF PMN

Confidential Business Information Claims (Bracketed in the Preamble and Order):

name of the technical contact, the name of the company, production volume, uses

Chemical Identity: multi-walled carbon nanotubes

Use:

Specific : [ ]

Generic: property modifier in electronic applications, contained use, property modifier in polymer composites, contained use.

Maximum 12-Month Production Volume: [ ] kg

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Test Data Submitted with PMN: none

IV. EPA'S ASSESSMENT OF RISK

The following are EPA's predictions regarding the probable toxicity, human exposure and environmental release of the PMN substance, based on the information currently available to the Agency.

Human Health Effects Summary:

Absorption: Absorption of the PMN chemical is expected to be poor via all routes of exposure.

Toxicological Endpoints: There is a concern for health effects based on analogy to respirable, poorly soluble particulates and other carbon nanotubes and for lung irritation based on particle size.

Basis: chemical category, see www.epa.gov/oppt/newchems/chemcat.htm

Environmental Effects Summary: No significant effects expected.

Exposure and Environmental Release Summary:

Scenario	No. of Sites	No. of Workers	Inhal (mg/d)	Dermal (mg/d)	Release to water (kg/y)
Use 1	[ ]	[ ] [ ]	0.02	1600 3100	13
Use 2	[ ]	[ ] [ ]	0.02	1600 3100	13

During Use 1 and Use 2, [ ] workers are expected to be exposed by both inhalation and dermal

routes, and [ ] workers are expected to be exposed via the dermal route only.

Risk to Workers: health risk to workers exposed to the PMN chemical via the inhalation route and via the dermal route.

Risk to General Public: potential risk to the general population from water, landfill and/or incineration releases.

V. EPA'S CONCLUSIONS OF LAW

The following findings constitute the basis of the Consent Order:

(A) EPA is unable to determine the potential for human health effects from exposure to the PMN substance. EPA therefore concludes, pursuant to § 5(e)(1)(A)(i) of TSCA, that the information available to the Agency is insufficient to permit a reasoned evaluation of the human health effects of the PMN substance.

(B) In light of the potential risk to human health posed by the uncontrolled manufacture, import, processing, distribution in commerce, use, and disposal of the PMN substance, EPA has concluded, pursuant to § 5(e)(1)(A)(ii)(I) of TSCA, that uncontrolled manufacture, import, processing, distribution in commerce, use, and disposal of the PMN substance may present an unreasonable risk of injury to human health.

VI. INFORMATION REQUIRED TO EVALUATE HEALTH EFFECTS

Triggered Testing. The Order prohibits the Company from exceeding a specified

production time period or production volume unless the Company submits the information described in the Testing section of this Order in accordance with the conditions specified in the Testing section. The Order requires submission of the following triggered testing:

Information	Effects	Guidelines
90-day inhalation toxicity study on rats with a post-exposure observation period of up to 3 months, including bronchoalveolar lavage fluid ("BALF") analysis.	lung	OPPTS 870.3465 or OECD 413

The Order's restrictions on manufacture, import, processing, distribution in commerce, use, and disposal of the PMN substance will remain in effect until the Order is modified or revoked by EPA based on submission of that or other relevant information.

EPA encourages the Company to develop additional health effects testing in coordination with other multi-walled carbon nanotube (MWCNT) manufacturers. This can be done under the in-depth portion of EPA's Nanoscale Materials Stewardship Program or through independent testing. If, for example, a consortium of companies commit to testing a representative set of MWCNT for subchronic mammalian toxicity, EPA may consider waiving the triggered testing requirement. EPA would be willing to facilitate the process in coordination with other ongoing health effects testing for MWCNT nationally and internationally. EPA would consider accepting the results of such testing in lieu of triggered testing in this order.

CONSENT ORDER

I. SCOPE OF APPLICABILITY AND EXEMPTIONS

(a) Scope. The requirements of this Order apply to all commercial manufacturing, processing, distribution in commerce, use and disposal of the chemical substance, multi-walled carbon nanotubes (MWCNT), P-08-0177 ("the PMN substance"), in the United States by [ ] ("the Company"), except to the extent that those activities are exempted by paragraph (b).

(b) Exemptions. Manufacturing, processing, distribution in commerce, use and disposal of the PMN substance is exempt from the requirements of this Order (except the requirements in the Recordkeeping and Successor Liability Upon Transfer Of Consent Order sections) only to the extent that (1) these activities are conducted in full compliance with all applicable requirements of the following exemptions, and (2) such compliance is documented by appropriate recordkeeping as required in the Recordkeeping section of this Order.

(1) Completely Reacted (Cured). The requirements of this Order do not apply to quantities of the PMN substance that have been completely reacted (cured).

(2) Export. Until the Company begins commercial manufacture of the PMN substance for use in the United States, the requirements of this Order do not apply to manufacture, processing or distribution in commerce of the PMN substance solely for export in accordance

with TSCA §12(a) and (b), 40 CFR 720.3(s) and 40 CFR Part 707. However, once the Company begins to manufacture the PMN substance for use in the United States, no further activity by the Company involving the PMN substance is exempt as "solely for export" even if some amount of the PMN substance is later exported. At that point, the requirements of this Order apply to all activities associated with the PMN substance while in the territory of the United States. Prior to leaving U.S. territory, even those quantities or batches of the PMN substance that are destined for export are subject to terms of the Order, and count towards any production volume test triggers in the Testing section of this Order.

(3) Research & Development ("R&D"). The requirements of this Order do not apply to manufacturing, processing, distribution in commerce, use and disposal of the PMN substance in small quantities solely for research and development in accordance with TSCA §5(h)(3), 40 CFR 720.3(cc), and 40 CFR 720.36.

(4) Byproducts. The requirements of this Order do not apply to the PMN substance when it is produced, without separate commercial intent, only as a "byproduct" as defined at 40 CFR 720.3(d) and in compliance with 40 CFR 720.30(g).

(5) No Separate Commercial Purpose. The requirements of this Order do not apply to the PMN substance when it is manufactured, pursuant to any of the exemptions in 40 CFR 720.30(h), with no commercial purpose separate from the substance, mixture, or article of which it is a part.

(c) Automatic Sunset. If the Company has obtained for the PMN substance a Test Market Exemption ("TME") under TSCA §5(h)(1) and 40 CFR 720.38 or a Low Volume Exemption

(LVE) or Low Release and Exposure Exemption ("LoREx") under TSCA §5(h)(4) and 40 CFR 723.50(c)(1) and (2) respectively, any such exemption is automatically rendered null and void as of the effective date of this Consent Order.

II. TERMS OF MANUFACTURE, IMPORT, PROCESSING, DISTRIBUTION IN COMMERCE, USE, AND DISPOSAL PENDING SUBMISSION AND EVALUATION OF INFORMATION

PROHIBITION

The Company is prohibited from manufacturing, importing, processing, distributing in commerce, using, or disposing of the PMN substance in the United States, for any nonexempt commercial purpose, pending the development of information necessary for a reasoned evaluation of the human health and environmental effects of the substance, and the completion of EPA's review of, and regulatory action based on, that information, except in accordance with the conditions described in this Order.

TESTING

(a) Section 8(e) Reporting. Any information on the PMN substance which reasonably supports the conclusion that the PMN substance presents a substantial risk of injury to health or the environment required to be reported under EPA's section 8(e) policy statement at 43 Federal Register 11110 (March 16, 1978) as amended at 52 Federal Register 20083 (May 29, 1987), shall reference the appropriate PMN identification number for this substance and shall contain a statement that the substance is subject to this Consent Order. Additional information regarding section 8(e) reporting requirements can be found in the reporting guide referenced at 56 Federal

Register 28458 (June 20, 1991).

(b) Notice of Study Scheduling. The Company shall notify, in writing, the EPA Laboratory Data Integrity Branch (2225A), Office of Enforcement and Compliance Assurance, U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, N.W., Washington, D.C. 20460, of the following information within 10 days of scheduling any study required to be performed pursuant to this Order, or within 15 days after the effective date of this Order, whichever is later:

(1) The date when the study is scheduled to commence;

(2) The name and address of the laboratory which will conduct the study;

(3) The name and telephone number of a person at the Company or the laboratory whom EPA may contact regarding the study; and

(4) The appropriate PMN identification number for the substance and a statement that the substance is subject to this Consent Order.

(c) Good Laboratory Practice Standards and Test Protocols. Each study required to be performed pursuant to this Order must be conducted according to TSCA Good Laboratory Practice Standards at 40 CFR Part 792 and using methodologies generally accepted in the relevant scientific community at the time the study is initiated. Before starting to conduct any such study, the Company must obtain approval of test protocols from EPA by submitting written protocols. EPA will respond to the Company within 4 weeks of receiving the written protocols. Published test guidelines specified in paragraph (d) provide general guidance for development of test protocols, but are not themselves acceptable protocols. Approval of the test protocol does not mean pre-acceptance of test results.

(d) Triggered Testing Requirements.

(1) 90-day inhalation toxicity study. The Company is prohibited from manufacturing or importing the PMN substance beyond the following aggregate manufacture and import volumes ("the production limits"), unless the Company conducts the following studies on the PMN substance and submits all final reports and underlying data in accordance with the conditions specified in this Testing section. The production/time limit shall be calculated from the date 2 years after signing this Consent Order by the Company.

Production/Time Limit	Study	Guideline
[ ] years [ ] months, or [ ] kg whichever comes first	90-day inhalation toxicity study on rats with a post-exposure observation period of up to 3 months, including bronchoalveolar lavage fluid (BALF) analysis	OPPTS 870.3465 or OECD 413

If an appropriate adaptation of the 90-day inhalation study for the evaluation of MWCNT is not developed within two years of the date the Company signs this Consent Order or if the Company commits to an appropriate program to test representative MWCNTs, e.g., under the in-depth portion of the Nanoscale Materials Stewardship program, the Company may petition EPA, pursuant to Section IV of this Consent Order, to modify the above testing requirement. If a consortium of companies commit to test a representative set of MWCNT for subchronic mammalian toxicity, EPA will consider waiving the above requirement.

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(2) Material Characterization. Within 6 months of commencing non-exempt commercial manufacture of the PMN substance, the Company must submit the following material characterization data (including data summaries and procedures) obtained from *(1)* microscopy analysis (scanning electron microscopy, SEM, or transmission electron microscopy, TEM), and (2) X-Ray analysis (X-ray diffraction, XRD, X-ray fluorescence, XRF, or X-ray spectroscopy, EDX):

A. type of multi-walled carbon nanotube
   - concentric cylinders or scrolled tubes
   - number of walls/tubes

B. configuration of nanotube ends (e.g., open, capped)

C. description of any branching

D. width/diameter of inner most wall/tube (average and range)

E. carbon unit cell ring size and connectivity (e.g., typically 6 membered rings but can include other ring sizes)

F. alignment of nanotube along long axis (e.g., straight, bent, buckled)

G. hexagonal array orientation when rolled up (e.g., armchair, chiral, zig-zag)
   - chiral or twist angle (the angle between the axis of the hexagonal pattern and the long axis of the nanotube)

H. particle size of catalyst used in the manufacture of the nanotube

I. molecular weight (average and range)

J. Particle properties: shape, size (average and distribution), weight (average and distribution), count, surface area (average and distribution), surface to volume ratio, aggregation/agglomeration.

(e) Test Reports. The Company shall: (1) conduct each study in good faith, with due care, and in a scientifically valid manner; (2) promptly furnish to EPA the results of any interim phase of each study; and (3) submit, in triplicate (with an additional sanitized copy, if confidential business information is involved), the final report of each study and all underlying data ("the report and data") to EPA no later than 14 weeks prior to exceeding the applicable production limit. The final report shall contain the contents specified in 40 CFR 792.185. Underlying data shall be submitted to EPA in accordance with the applicable "Reporting", "Data and Reporting", and "Test Report" subparagraphs in the applicable test guidelines. However, for purposes of this Consent Order, the word "should" in those subparagraphs shall be interpreted to mean "shall" to make clear that the submission of such information is mandatory. EPA will not require the submission of raw data such as slides and laboratory notebooks unless if EPA finds, on the basis of professional judgment, that an adequate evaluation of the study cannot take place in the absence of these items.

(f) Testing Waivers. The Company is not required to conduct a study specified in paragraph (d) of this Testing section if notified in writing by EPA that it is unnecessary to conduct that study.

(g) Equivocal Data. If EPA finds that the data generated by a study are scientifically equivocal, the Company may continue to manufacture and import the PMN substance beyond the applicable

production limit. To seek relief from any other restrictions of this Order, the Company may make a second attempt to obtain unequivocal data by reconducting the study under the conditions specified in paragraphs (b), (c), and (e)(1) and (2). The testing requirements may be modified, as necessary to permit a reasoned evaluation of the risks presented by the PMN substance, only by mutual consent of EPA and the Company.

(h) EPA Determination of Invalid Data.

(1) Except as described in subparagraph (h)(2), if, within 6 weeks of EPA's receipt of a test report and data, the Company receives written notice that EPA finds that the data generated by a study are scientifically invalid, the Company is prohibited from further manufacture and import of the PMN substance beyond the applicable production limit.

(2) The Company may continue to manufacture and import the PMN substance beyond the applicable production limit only if so notified, in writing, by EPA in response to the Company's compliance with either of the following subparagraphs (h)(2)(i) or (h)(2)(ii).

(i) The Company may reconduct the study in compliance with paragraphs (b), (c), and (e)(1) and (2). If there is sufficient time to reconduct the study and submit the report and data to EPA at least 14 weeks before exceeding the production limit as required by subparagraph (e)(3), the Company shall comply with subparagraph (e)(3). If there is insufficient time for the Company to comply with subparagraph (f)(3), the Company may exceed the production limit and shall submit the report and data in triplicate to EPA within a reasonable period of time, all as specified by EPA in the notice described in subparagraph (h)(1). EPA will respond to the Company, in writing, within 6 weeks of receiving the Company's report and data.

(ii) The Company may, within 4 weeks of receiving from EPA the notice

described in subparagraph (h)(1), submit to EPA a written report refuting EPA's finding. EPA will respond to the Company, in writing, within 4 weeks of receiving the Company's report.

(i) Company Determination of Invalid Data.

(1)Except as described in subparagraph (i)(2), if the Company becomes aware that circumstances clearly beyond the control of the Company or laboratory will prevent, or have prevented, development of scientifically valid data under the conditions specified in paragraphs (c) and (e), the Company remains prohibited from further manufacture and import of the PMN substance beyond the applicable production limit.

(2) The Company may submit to EPA, within 2 weeks of first becoming aware of such circumstances, a written statement explaining why circumstances clearly beyond the control of the Company or laboratory will cause or have caused development of scientifically invalid data. EPA will notify the Company of its response, in writing, within 4 weeks of receiving the Company's report. EPA's written response may either:

(i) allow the Company to continue to manufacture and import the PMN substance beyond the applicable production limit, or

(ii) require the Company to continue to conduct, or to reconduct, the study in compliance with paragraphs (b), (c), and (e)(1) and (2). If there is sufficient time to conduct or reconduct the study and submit the report and data to EPA at least 14 weeks before exceeding the production limit as required by subparagraph (e)(3), the Company shall comply with subparagraph (e)(3). If there is insufficient time for the Company to comply with subparagraph (e)(3), the Company may exceed the production limit and shall submit the report and data in triplicate to EPA within a reasonable period of time, all as specified by EPA in the notice

described in subparagraph (i)(2). EPA will respond to the Company, in writing, within 6 weeks of receiving the Company's report and data, as to whether the Company may continue to manufacture and import beyond the applicable production limit.

(j) Unreasonable Risk.

(1) EPA may notify the Company in writing that EPA finds that the data generated by a study are scientifically valid and unequivocal and indicate that, despite the terms of this Order, the PMN substance will or may present an unreasonable risk of injury to human health or the environment. EPA's notice may specify that the Company undertake certain actions concerning further testing, manufacture, import, processing, distribution, use and/or disposal of the PMN substance to mitigate exposures to or to better characterize the risks presented by the PMN substance. Within 2 weeks from receipt of such a notice, the Company must cease all manufacture, import, processing, distribution, use and disposal of the PMN substance, unless either:

(2) within 2 weeks from receipt of the notice described in subparagraph (j)(1), the Company complies with such requirements as EPA's notice specifies; or

(3) within 4 weeks from receipt of the notice described in subparagraph (j)(1), the Company submits to EPA a written report refuting EPA's finding and/or the appropriateness of any additional requirements imposed by EPA. The Company may continue to manufacture, import, process, distribute, use and dispose of the PMN substance in accordance with the terms of this Order pending EPA's response to the Company's written report. EPA will respond to the Company, in writing, within 4 weeks of receiving the Company's report. Within 2 weeks of receipt of EPA's written response, the Company shall comply with any requirements imposed by

EPA's response or cease all manufacture, import, processing, distribution, use and disposal of the PMN substance.

(k) Other Requirements. Regardless of the satisfaction of any other conditions in this Testing section, the Company must continue to obey all the terms of this Consent Order until otherwise notified in writing by EPA. The Company may, based upon submitted test data or other relevant information, petition EPA to modify or revoke provisions of this Consent Order pursuant to Part VI of this Consent Order.

PROTECTION IN THE WORKPLACE

(a) Establishment of Program. During manufacturing, processing, and use of the PMN substance at any site controlled by the Company (including any associated packaging and storage and during any cleaning or maintenance of equipment associated with the PMN substance), the Company must establish a program whereby:

(1) General Dermal Protection. Each person who is reasonably likely to be dermally exposed in the work area to the PMN substance through direct handling of the substance or through contact with equipment on which the substance may exist, or because the substance becomes airborne in a form listed in subparagraph (a)(5) of this section, is provided with, and is required to wear, personal protective equipment that provides a barrier to prevent dermal exposure to the substance in the specific work area where it is selected for use. Each such item of personal protective equipment must be selected and used in accordance with OSHA dermal protection requirements at 29 CFR 1910.132, 1910.133, and 1910.138.

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(2) Specific Dermal P rotective Equipment. The dermal personal protective equipment required by subparagraph (a)(1) of this section must include, but is not limited to, the following items:

(i) Gloves impervious to the PMN substance

(ii) full body clothing impervious to the PMN substance

(3) Demonstration of Imperviousness. The Company is able to demonstrate that each item of chemical protective clothing selected, including gloves, provides an impervious barrier to prevent dermal exposure during normal and expected duration and conditions of exposure within the work area by any one or a combination of the following:

(i) Permeation Testing. Testing the material used to make the chemical protective clothing and the construction of the clothing to establish that the protective clothing will be impervious for the expected duration and conditions of exposure. The testing must subject the chemical protective clothing to the expected conditions of exposure, including the likely combinations of chemical substances to which the clothing may be exposed in the work area. Permeation testing shall be conducted according to the American Society for Testing and Materials (ASTM) F739 "Standard Test Method for Resistance of Protective Clothing materials to Permeation by Liquids or Gases." Results shall be recorded as a cumulative permeation rate as a function of time, and shall be documented in accordance with ASTM F739 using the format specified in ASTM F1194-89 "Guide for Documenting the Results of Chemical Permeation Testing on Protective Clothing Materials." Gloves may not be used for a time period longer than they are actually tested and must be replaced at the end of each work shift during which they are exposed to the PMN substance.

(ii) Manufacturer's Specifications. Evaluating the specifications from the

manufacturer or supplier of the chemical protective clothing, or of the material used in construction of the clothing, to establish that the chemical protective clothing will be impervious to the PMN substance alone and in likely combination with other chemical substances in the work area.

(4) Respiratory Protection. Each person who is reasonably likely to be exposed by inhalation in the work area to the PMN substance in the form listed in subparagraph (a)(5) of this section, is provided with, and is required to wear, at a minimum, a NIOSH-certified respirator with an APF of 50, from the respirators listed in subparagraph (a)(6) of this section, and the respirator is used in accordance with OSHA and NIOSH respiratory protection requirements at 29 CFR 1910.134 and 42 CFR Part 84. All respirators must be issued, used, and maintained according to an appropriate respiratory protection program under the Occupational Safety and Health Administration (OSHA) requirements in 29 CFR 1910.134.

(5) Physical States. The following physical states of airborne chemical substances are listed for subparagraphs (a)(1) and (4) of this section:

(i) Particulate (including solids or liquid droplets).

(6) Authorized Respirators. The following NIOSH-certified respirators meet the minimum requirements for subparagraph (a)(4) of this section: Particulate/Aerosol/Mist Exposures, NIOSH-certified air-purifying, tight-fitting full-face respirator equipped with N100 filters.

MANUFACTURING

(a)(1) Prohibition. The Company shall not cause, encourage, or suggest the manufacture or import of the PMN substance by any other person.

(2) Sunset Following SNUR. Subparagraph (a)(1) shall expire 75 days after promulgation of a final significant new use rule ("SNUR") governing the PMN substance under section 5(a)(2) of TSCA unless the Company is notified on or before that day of an action in a Federal Court seeking judicial review of the SNUR. If the Company is so notified, subparagraph (a)(1) shall not expire until EPA notifies the Company in writing that all Federal Court actions involving the SNUR have been resolved and the validity of the SNUR affirmed.

(3) Notice of SNUR. When EPA promulgates a final SNUR for the PMN substance and subparagraph (a)(1) expires in accordance with subparagraph (a)(2), the Company shall notify each person whom it causes, encourages or suggests to manufacture or import the PMN substance of the existence of the SNUR.

(b) The Company shall not manufacture the PMN substance other than as [ ].

(c) The Company shall provide to EPA a 1 gram sample of the PMN substance as specified by EPA in a future written request along with a copy of MSDS for the substance.

PROCESSIN G AND USE

The Company shall not process or use the PMN substance other than as [ ].

DISTRIBUTION

(a) Distribution Requirements. Except after the PMN has been completely reacted , the Company shall distribute the PMN substance outside the Company, other than for disposal, only to a person who has agreed in writing prior to the date of distribution, to:

(1) Not further distribute the PMN substance to any other person, other than for disposal, until after the PMN substance has been completely reacted.

(2) Comply with the same requirements and restrictions, if any, required of the Company in the Protection in the Workplace.

(3) Not process and use the PMN substance other than as [ ].

(b) Temporary Transport and Storage. Notwithstanding paragraph (a), the Company may distribute the PMN substance outside the Company for temporary transport and storage in sealed containers (labeled in accordance with paragraph (b)(2) of the Hazard Communication Program section of this Order) provided the following two conditions are met:

(1) Subsequent to any such exempt temporary transport or storage of sealed containers, the PMN substance may be distributed only to the Company or a person who has given the Company the written agreement required by paragraph (a).

(2) Any human exposure or environmental release resulting from opening the sealed containers and removing or washing out the PMN substance may occur only while the PMN substance is in the possession and control of the Company or a person who has given the Company the written agreement required by paragraph (a).

(c) Recipient Non-Compliance. If, at any time after commencing distribution in commerce of the PMN substance, the Company obtains knowledge that a recipient of the substance has failed to comply with any of the conditions specified in paragraph (a) of this Distribution section or, after paragraph (a)(1) expires in accordance with subparagraph (d)(1), has engaged in a significant new use of the PMN substance (as defined in 40 CFR Part 721, Subpart E) without submitting a

significant new use notice to EPA, the Company shall cease supplying the substance to that recipient, unless the Company is able to document each of the following:

(1) That the Company has, within 5 working days, notified the recipient in writing that the recipient has failed to comply with any of the conditions specified in paragraph (a) of this Distribution section, or has engaged in a significant new use of the PMN substance without submitting a significant new use notice to EPA.

(2) That, within 15 working days of notifying the recipient of the noncompliance, the Company received from the recipient, in writing, a statement of assurance that the recipient is aware of the terms of paragraph (a) of this Distribution section and will comply with those terms, or is aware of the terms of the significant new use rule for the PMN substance and will not engage in a significant new use without submitting a significant new use notice to EPA.

(3) If, after receiving a statement of assurance from a recipient under subparagraph (c)(2) of this Distribution section, the Company obtains knowledge that the recipient has failed to comply with any of the conditions specified in paragraph (a) of this Distribution section, or has engaged in a significant new use of the PMN substance without submitting a significant new use notice to EPA, the Company shall cease supplying the PMN substance to that recipient, shall notify EPA of the failure to comply, and shall resume supplying the PMN substance to that recipient only upon written notification from the Agency.

(d) Sunset Following SNUR. (1) Paragraph (a)(1) of this Distribution section shall expire 75 days after promulgation of a final SNUR for the PMN substance under section 5(a)(2) of TSCA, unless the Company is notified on or before that day of an action in a Federal Court seeking judicial review of the SNUR. If the Company is so notified, paragraph (a)(1) of this Distribution

section shall not expire until EPA notifies the Company in writing that all Federal Court actions involving the SNUR have been resolved and the validity of the SNUR affirmed.

(2) When EPA promulgates a final SNUR for the PMN substance and paragraph (a)(1) of this Distribution section expires in accordance with subparagraph (d)(1), the Company shall notify each person to whom it distributes the PMN substance of the existence of the SNUR. Such notification must be in writing and must specifically include all limitations contained in the SNUR which are defined as significant new uses, and which would invoke significant new use notification to EPA for the PMN substance. Such notice must also reference the publication of the SNUR for this PMN substance in either the Federal Register or the Code of Federal Regulations. After promulgation of a SNUR and expiration of subparagraph (a)(1), such notice may substitute for the written agreement required in the introductory clause of paragraph (a); so that, if the Company provides such notice to the persons to whom it distributes the PMN substance, then the Company is not required to obtain from such persons the written agreement specified in paragraph (a).

III. RECORDKEEPING

(a) Records. The Company shall maintain the following records until 5 years after the date they are created and shall make them available for inspection and copying by EPA in accordance with section 11 of TSCA:

(1) Exemptions. Records documenting that the PMN substance did in fact qualify for any one or more of the exemptions described in Section I, Paragraph (b) of this Order. Such records must satisfy all the statutory and regulatory recordkeeping requirements applicable to the exemption being claimed by the Company. Any amounts or batches of the PMN substance

eligible for the Export exemption in Section I, Paragraph (b)(3) of this Order, are exempt from all the requirements in this Recordkeeping section, if the Company maintains, for 5 years from the date of their creation, copies of the export label and export notice to EPA, required by TSCA sections 12(a)(1)(B) and 12(b), respectively. Any amounts or batches of the PMN substance eligible for the Research and Development exemption in Section I, Paragraph (b)(4) of this Order, are exempt from all the requirements in this Recordkeeping section, if the Company maintains, for 5 years from the date of their creation, the records required by 40 CFR 720.78(b). For any amounts or batches of the PMN substance claimed to be eligible for any other exemption described in Section I, Paragraph (b) of this Order, the Company shall keep records demonstrating qualification for that exemption as well as the records specified in paragraphs (2) and (3) below, but is exempt from the other recordkeeping requirements in this Recordkeeping section;

(2) Records documenting the manufacture and importation volume of the PMN substance and the corresponding dates of manufacture and import;

(3) Records documenting the names and addresses (including shipment destination address, if different) of all persons outside the site of manufacture or import to whom the Company directly sells or transfers the PMN substance, the date of each sale or transfer, and the quantity of the substance sold or transferred on such date;

(4) Records documenting the addresses of all sites of manufacture, import, processing, and use;

(5) Records documenting establishment and implementation of a program for the use of any applicable personal protective equipment required pursuant to the Protection in the Workplace section of this Order;

(6) Records documenting the determinations required by the Protection in the Workplace

section of this Order that chemical protective clothing is impervious to the PMN substance;

(7) Records documenting compliance with any applicable manufacturing, processing, use, and distribution restrictions in the Manufacturing, Processing, Use, and Distribution sections of this Order, including distributees' written agreement to comply with the Distribution section of this Order;

(8) Copies of any Transfer Documents and notices required by the Successor Liability section of this Order, if applicable; and

(9) The Company shall keep a copy of this Order at each of its sites where the PMN substance is manufactured of imported.

(a) Applicability. The provisions of this Recordkeeping Section are applicable only to activities of the Company and its Contract Manufacturer, if applicable, and not to activities of the Company's customers.

(b) OMB Control Number. Under the Paperwork Reduction Act and its regulations at 5 CFR Part 1320, particularly 5 CFR 1320.5(b), the Company is not required to respond to this "collection of information" unless this Order displays a currently valid control number from the Office of Management and Budget ("OMB"), and EPA so informs the Company. The "collection of information" required in this TSCA §5(e) Consent Orders has been approved under currently valid **OMB Control Number 2070-0012.**

IV. REQUESTS FOR PRE-INSPECTION INFORMATION

(a) EPA's Request for Information. Pursuant to section 11 of TSCA and 40 CFR 720.122, EPA

may occasionally conduct on-site compliance inspections of Company facilities and conveyances associated with the PMN substance. To facilitate such inspections, EPA personnel may contact the Company in advance to request information pertinent to the scheduling and conduct of such inspections. Such requests may be written or oral. The types of information that EPA may request may include, but are not limited to, the following:

(i) Expected dates and times when the PMN substance will be in production within the subsequent 12 months;

(ii) Current workshift schedules for workers who are involved in activities associated with the PMN substance and may reasonably be exposed to the PMN substance;

(iii) Current job titles or categories for workers who are involved in activities associated with the PMN substance and may reasonably be exposed to the PMN substance;

(iv) Existing exposure monitoring data for workers who are involved in activities associated with the PMN substance and may reasonably be exposed to the PMN substance;

(v) Records required by the Recordkeeping section of this Order; and/or

(vi) Any other information reasonably related to determining compliance with this Order or conducting an inspection for that purpose.

(b) Company's Response. The Company shall respond to such requests within a reasonable period of time, but in no event later than 30 days after receiving EPA's request. When requested in writing by EPA, the Company's response shall be in writing. To the extent the information is known to or reasonably ascertainable to the Company at the time of the request, the Company's response shall demonstrate a good faith effort to provide reasonably accurate and detailed answers to all of EPA's requests.

(c) Confidential Business Information. Any Confidential Business Information ("CBI") that the Company submits to EPA pursuant to paragraph (b) shall be protected in accordance with §14 of TSCA and 40 CFR Part 2.

V. SUCCESSOR LIABILITY UPON TRANSFER OF CONSENT ORDER

(a) Scope. This section sets forth the procedures by which the Company's rights and obligations under this Order may be transferred when the Company transfers its interests in the PMN substance, including the right to manufacture the PMN substance, to another person outside the Company (the "Successor in Interest").

(b) Relation of Transfer Date to Notice of Commencement ("NOC").

(1) Before NOC. If the transfer from the Company to the Successor in Interest is effective before EPA receives a notice of commencement of manufacture or import ("NOC") for the PMN substance from the Company pursuant to 40 CFR 720.102, the Successor in Interest must submit a new PMN to EPA and comply fully with Section 5(a)(1) of TSCA and 40 CFR part 720 before commencing manufacture or import of the PMN substance.

(2) After NOC. If the transfer from the Company to the Successor in Interest is effective after EPA receives a NOC, the Successor in Interest shall comply with the terms of this Order and shall not be required to submit a new PMN to EPA.

(c) Definitions. The following definitions apply to this Successor Liability section of the Order:

(1) "Successor in Interest" means a person outside the Company who has acquired the

Company's full interest in the rights to manufacture the PMN substance, including all ownership rights and legal liabilities, through a transfer document signed by the Company, as transferor, and the Successor in Interest, as transferee. The term excludes persons who acquire less than the full interest of the Company in the PMN substance, such as a licensee who has acquired a limited license to the patent or manufacturing rights associated with the PMN substance. A Successor in Interest must be incorporated, licensed, or doing business in the United States in accordance with 40 CFR 720.22(a)(3).

(2) "Transfer Document" means the legal instrument(s) used to convey the interests in the PMN substance, including the right to manufacture the PMN substance, from the Company to the Successor in Interest.

(d) Notices.

(1) Notice to Successor in Interest. On or before the effective date of the transfer, the Company shall provide to the Successor in Interest, by registered mail, a copy of the Consent Order and the "Notice of Transfer" document which is incorporated by reference as Attachment C to this Order.

(2) Notice to EPA. Within 10 business days of the effective date of the transfer, the Company shall, by registered mail, submit the fully executed Notice of Transfer document to: U.S. Environmental Protection Agency, New Chemicals Branch (7405), 1200 Pennsylvania Avenue, N.W., Washington, D.C. 20460.

(3) Transfer Document. Copies of the Transfer Document must be maintained by the Successor in Interest at its principal place of business, and at all sites where the PMN substance is manufactured or imported. Copies of the Transfer Document must also be made available for

inspection pursuant to Section 11 of TSCA, must state the effective date of transfer, and must contain provisions which expressly transfer liability for the PMN substance under the terms of this Order from the Company to the Successor in Interest.

(e) Liability.

(1) The Company shall be liable for compliance with the requirements of this Order until the effective date of the transfer described above.

(2) The Successor in Interest shall be liable for compliance with the requirements of this Order effective as of the date of transfer.

(3) Nothing in this section shall be construed to prohibit the Agency from taking enforcement action against the Company after the effective date of the transfer for actions taken, or omissions made, during the time in which the Company manufactured, processed, used, distributed in commerce, or disposed of the PMN substance pursuant to the terms of this Consent Order.

(f) Obligations to Submit Test Data under Consent Order. If paragraph (d) of the Testing section of this Consent Order requires the Company to submit test data to EPA at a specified production volume ("test trigger"), the aggregate volume of the PMN substance manufactured and imported by the Company up to the date of transfer shall count towards the test trigger applicable to the Successor in Interest.

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VI. MODIFICATION AND REVOCATION OF CONSENT ORDER

The Company may petition EPA at any time, based upon new information on the health effects of, or human exposure to, the PMN substance, to modify or revoke substantive provisions of this Order. The exposures and risks identified by EPA during its review of the PMN substance and the information EPA determined to be necessary to evaluate those exposures and risks are described in the preamble to this Order. However, in determining whether to amend or revoke this Order, EPA will consider all relevant information available at the time the Agency makes that determination, including, where appropriate, any reassessment of the test data or other information that supports the findings in this Order, an examination of new test data or other information or analysis, and any other relevant information.

EPA will issue a modification or revocation if EPA determines that the activities proposed therein will not present an unreasonable risk of injury to health or the environment and will not result in significant or substantial human exposure or substantial environmental release in the absence of data sufficient to permit a reasoned evaluation of the health or environmental effects of the PMN substance.

In addition, the Company may petition EPA at any time to make other modifications to the language of this Order. EPA will issue such a modification if EPA determines that the modification is useful, appropriate, and consistent with the structure and intent of this Order as issued.

VII. EFFECT OF CONSENT ORDER

By consenting to the entry of this Order, the Company waives its rights to file objections to this Order pursuant to section 5(e)(1)(C) of TSCA, to receive service of this Order no later than 45 days before the end of the review period pursuant to section 5(e)(1)(B) of TSCA, and to challenge the validity of this Order in any subsequent action. Consenting to the entry of this Order, and agreeing to be bound by its terms, do not constitute an admission by the Company as to, the facts or conclusions underlying the Agency's determinations in this proceeding. This waiver does not affect any other rights that the Company may have under TSCA.

_____ _____

Date

Jim Willis, Director
Chemical Control Division
Office of Pollution Prevention and Toxics

_____ _____

Date

Name:
Title:
Company: [ ]

ATTACHMENT A

DEFINITIONS

[Note: The attached Order may not contain some of the terms defined below.]

"Chemical name" means the scientific designation of a chemical substance in accordance with the nomenclature system developed by the International Union of Pure and Applied Chemistry or the Chemical Abstracts Service's rules of nomenclature, or a name which will clearly identify a chemical substance for the purpose of conducting a hazard evaluation.

"Chemical protective clothing" means items of clothing that provide a protective barrier to prevent dermal contact with chemical substances of concern. Examples can include, but are not limited to: full body protective clothing, boots, coveralls, gloves, jackets, and pants.

"Company" means the person or persons subject to this Order.

"Commercial use" means the use of a chemical substance or any mixture containing the chemical substance in a commercial enterprise providing saleable goods or a service to consumers (e.g., a commercial dry cleaning establishment or painting contractor).

"Common name" means any designation or identification such as code name, code number, trade name, brand name, or generic chemical name used to identify a chemical substance other than by its chemical name.

"Consumer" means a private individual who uses a chemical substance or any product containing the chemical substance in or around a permanent or temporary household or residence, during recreation, or for any personal use or enjoyment.

"Consumer product" means a chemical substance that is directly, or as part of a mixture, sold or made available to consumers for their use in or around a permanent or temporary household or residence, in or around a school, or in recreation.

"Container" means any bag, barrel, bottle, box, can, cylinder, drum, reaction vessel, storage tank, or the like that contains a hazardous chemical. For purposes of this section, pipes or piping systems, and engines, fuel tanks, or other operating systems in a vehicle, are not considered to be containers.

"Contract Manufacturer" means a person, outside the Company, who is authorized to manufacture and import the PMN substance under the conditions specified in Part II. of this Consent Order and in the Consent Order for Contract Manufacturer.

"Identity" means any chemical or common name used to identify a chemical substance or a mixture containing that substance.

"Immediate use." A chemical substance is for the "immediate use" of a person if it is under

the control of, and used only by, the person who transferred it from a labeled container and will only be used by that person within the work shift in which it is transferred from the labelled container.

"Impervious." Chemical protective clothing is "impervious" to a chemical substance if the substance causes no chemical or mechanical degradation, permeation, or penetration of the chemical protective clothing under the conditions of, and the duration of, exposure.

"Manufacturing stream" means all reasonably anticipated transfer, flow, or disposal of a chemical substance, regardless of physical state or concentration, through all intended operations of manufacture, including the cleaning of equipment.

"MSDS" means material safety data sheet, the written listing of data for the chemical substance.

"NIOSH" means the National Institute for Occupational Safety and Health of the U.S. Department of Health and Human Services.

"Non-enclosed process" means any equipment system (such as an open-top reactor, storage tank, or mixing vessel) in which a chemical substance is manufactured, processed, or otherwise used where significant direct contact of the bulk chemical substance and the workplace air may occur.

"Non-industrial use" means use other than at a facility where chemical substances or mixtures are manufactured, imported, or processed.

"PMN substance" means the chemical substance described in the Premanufacture notice submitted by the Company relevant to this Order.

"Personal protective equipment" means any chemical protective clothing or device placed on the body to prevent contact with, and exposure to, an identified chemical substance or substances in the work area. Examples include, but are not limited to, chemical protective clothing, aprons, hoods, chemical goggles, face splash shields, or equivalent eye protection, and various types of respirators. Barrier creams are not included in this definition.

"Process stream" means all reasonably anticipated transfer, flow, or disposal of a chemical substance, regardless of physical state or concentration, through all intended operations of processing, including the cleaning of equipment.

"Scientifically invalid" means any significant departure from the EPA-approved protocol or the Good Laboratory Practice Standards at 40 CFR Part 792 without prior or subsequent Agency approval that prevents a reasoned evaluation of the health or environmental effects of the PMN substance.

"Scientifically equivocal data" means data which, although developed in apparent

conformity with the Good Laboratory Practice Standards and EPA-approved protocols, are inconclusive, internally inconsistent, or otherwise insufficient to permit a reasoned evaluation of the potential risk of injury to human health or the environment of the PMN substance.

"Sealed container" means a closed container that is physically and chemically suitable for long-term containment of the PMN substance, and from which there will be no human exposure to, nor environmental release of, the PMN substance during transport and storage.

"Use stream" means all reasonably anticipated transfer, flow, or disposal of a chemical substance, regardless of physical state or concentration, through all intended operations of industrial, commercial, or consumer use.

"Waters of the United States" has the meaning set forth in 40 CFR 122.2.

"Work area" means a room or defined space in a workplace where the PMN substance is manufactured, processed, or used and where employees are present.

"Workplace" means an establishment at one geographic location containing one or more work areas.

ATTACHMENT B
NOTICE OF TRANSFER OF
TOXIC SUBSTANCES CONTROL ACT
SECTION 5(e) CONSENT ORDER

_____ _____
Company (Transferor) PMN Number

1. Transfer of Manufacture Rights. Effective on _____, the Company did sell or otherwise transfer to _____, ("Successor in Interest") the rights and liabilities associated with manufacture of the above-referenced chemical substance, which was the subject of a premanufacture notice (PMN) and is governed by a Consent Order issued by the U.S. Environmental Protection Agency (EPA) under the authority of §5(e) of the Toxic Substances Control Act (TSCA, 15 U.S.C. §2604(e)).

2. Assumption of Liability. The Successor in Interest hereby certifies that, as of the effective date of transfer, all actions or omissions governed by the applicable Consent Order limiting manufacture, processing, use, distribution in commerce and disposal of the PMN substance, shall be the responsibility of the Successor in Interest. Successor in Interest also certifies that it is incorporated, licensed, or doing business in the United States in accordance with 40 CFR 720.22(a)(3).

3. Confidential Business Information. The Successor in Interest hereby:
___ reasserts,
___ relinquishes, or
___ modifies
all Confidential Business Information (CBI) claims made by the Company, pursuant to Section 14 of TSCA and 40 CFR part 2, for the PMN substance(s). Where "reasserts" or "relinquishes" is indicated, that designation shall be deemed to apply to all such claims. Where "modifies" is indicated, such modification shall be explained in detail in an attachment to this Notice of Transfer. Information which has been previously disclosed to the public (e.g., a chemical identity that was not claimed as CBI by the original submitter) would not subsequently be eligible for confidential treatment under this Notice of Transfer.

_____ _____
Company (Transferor) PMN Number

_____ _____
Signature of Authorized Official Date

_____

2

Printed Name of Authorized Official

Title of Authorized Official

Successor in Interest

Signature of Authorized Official Date

Printed Name of Authorized Official

Title of Authorized Official

Address

City, State, Zip Code

Successor's Technical Contact

Address

City, State, Zip Code

Phone