Good Governance: Evolution of the Nanoscale Materials Stewardship Program

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ABSTRACT

Governance issues are seldom the subject of wide consensus, and the question of how best the U.S. Environmental Protection Agency ("EPA") should obtain needed information and data on the human health and environmental implications of nanoscale materials is no exception. EPA has considered the issue carefully and believes, with good reason, that a voluntary approach makes the most sense at this time. Not everyone agrees, however, and some urge EPA to exercise its statutory authority under the Toxic Substances Control Act to mandate the submission of information and data, and to do so quickly. This article discusses the origins and current status of EPA's voluntary Nanoscale Materials Stewardship Program ("NMSP"), outlines the key issues EPA confronted in developing the Program, and discusses the reasons why it is critically important for nanotechnology stakeholders to participate in the Program early and robustly. While stakeholders may not agree on what is the best way for EPA to obtain information on nanoscale materials, there is broad consensus that NMSP participation is critically important to maintain the public trust and confidence in this emerging technology, to provide EPA with needed information and data, and to demonstrate that potentially more burdensome rulemaking initiatives are not needed to achieve these goals.

I. INTRODUCTION

The U.S. Environmental Protection Agency ("EPA"), along with regulators globally, is considering a range of governance mechanisms to hasten the development and review of data and other information to assess the human health and safety and environmental implications of nanotechnology. One governance mechanism implemented or under consideration in a variety of countries is a voluntary reporting program designed to obtain data and information. On July 12, 2007, EPA released its draft *Concept Paper for the Nanoscale Materials Stewardship Program Under TSCA* ("Concept Paper"), which outlines EPA's initial thinking on the design and development of a voluntary Nanoscale Materials Stewardship Program ("NMSP").[1] EPA also released its draft *TSCA Inventory Status of Nanoscale Substances—General Approach* ("TSCA Inventory Paper"), which sets forth EPA's "general approach" to defining nanoscale materials as new or existing under the Toxic Substances Control Act ("TSCA").[2]

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1 72 Fed. Reg. 38081 (July 12, 2007).

2 *Id.* at 38083.

Both documents are significant for different reasons, and understanding each offers important insights into a myriad of policy, legal, and regulatory issues that EPA and interested stakeholders are facing, both in designing and implementing a voluntary program along the lines contemplated by the NMSP, and more broadly in demonstrating stakeholders' commitment to participating in a voluntary program that provides robust and meaningful information to enable EPA to assess potential risks posed by nanoscale materials. This article reviews the evolution of the NMSP, describes the Concept Paper and TSCA Inventory Paper, and discusses key issues associated with both papers.

II. THE NMSP'S NPPTAC ORIGINS

EPA is well aware of the potential nanotechnology offers and is equally cognizant of potential risks to human health and the environment that may arise from exposure to certain nanoscale materials. The EPA program office most engaged in the regulatory implications of nanoscale materials is EPA's Office of Pollution Prevention and Toxics ("OPPT"). OPPT is tasked with implementing TSCA, which authorizes EPA to regulate existing and new chemical substances, including nanoscale chemical substances, particles, and structures.

EPA has been exploring its TSCA regulatory and governance options with regard to nanoscale materials for several years. EPA publicly shared its initial thinking on May 10, 2005, when OPPT issued a *Federal Register* notice announcing its decision to convene a public meeting on June 23, 2005, to seek the public's views on the feasibility and wisdom of establishing a voluntary program to obtain information on existing nanoscale materials consisting of chemical substances.[3] The decision to convene such a meeting and to develop a voluntary reporting program was prompted, among other considerations, by growing recognition that nanoscale materials appear to be finding their way into an increasing number of commercial applications, including coatings, clothing, computers, cosmetics, and medical devices, that some nanoscale materials have entered one or more of EPA's various regulatory review processes, and that EPA needs a comprehensive and cogent risk assessment process that is able to identify, characterize, and manage risks that may be associated with nanoscale materials to protect human health and the environment.

EPA also noted the growing prominence of unresolved legal and regulatory policy issues arising under TSCA that demand resolution swiftly. For example, much of the appeal of nanoscale materials is their ability to impart novel physical/chemical properties to enhance certain product functionalities. A core issue OPPT identified in 2005 is determining under TSCA when an existing chemical's molecular identity is sufficiently altered to become a "new" chemical substance such that EPA's authority under TSCA Section 5 to obtain pre-market approval is triggered. EPA properly recognized that resolution of this issue is important to ensure the protection of human health and the environment and to preserve the integrity of the TSCA new chemicals program.

In the May 10, 2005 *Federal Register* notice, EPA acknowledged that nanoscale materials consisting of new chemical substances are subject to the notification requirements under TSCA Section 5, and the manufacturer of a new chemical substance must submit a premanufacture notice ("PMN"), including available toxicity and other data, to EPA at least 90 days before production of the chemical can begin. New chemicals generally are those not listed on the TSCA Inventory maintained under TSCA Section 8(b). EPA also acknowledged, however, that nanoscale materials consisting of existing chemical substances "may enter commerce without notification to EPA."[4] EPA's notice sought comment on the scope and purpose of a voluntary pilot program for nanoscale materials that are existing chemical substances; the kinds of information that are relevant to the evaluation of potential risks from exposure to

[3] 70 Fed Reg. 24574 (May 10, 2005).

[4] *Id.*

nanoscale materials; chemical characterization and nomenclature of nanoscale materials for regulatory purposes; and the identification of interested stakeholders.

Following the June 23, 2005 public meeting, EPA asked the National Pollution Prevention and Toxics Advisory Committee ("NPPTAC") to assist OPPT with developing an approach to assessing potential risks from nanoscale materials.[5] The newly created Interim Ad Hoc Work Group on Nanoscale Materials ("Work Group") was tasked with providing input to the NPPTAC on four issues: (1) options for possible elements of EPA's voluntary pilot program for existing chemical nanoscale materials; (2) approaches that may be appropriate for putting such a voluntary pilot program in place; (3) consideration of issues that may be relevant to the review of new chemical nanoscale materials under TSCA; and (4) consideration of other relevant issues raised in stakeholder input provided at EPA's June 23, 2005, public meeting as well as written comments to the docket. Over the summer and through the fall of 2005, the Work Group met many times and discussed issues relevant to the development of a voluntary pilot program on nanoscale materials.

In September 2005, the Work Group presented its *Overview of Issues for Consideration* ("Overview of Issues") document for discussion at the September 29, 2005 NPPTAC public meeting. Following the public meeting, the document was further reviewed and discussed at the NPPTAC public meeting on October 13-14, 2005. The November 22, 2005, version of the document reflects input from the entire NPPTAC.[6] It was formally offered to EPA for its consideration to facilitate the development of a voluntary program for engineered nanoscale materials referred to then as the Nanoscale Materials Voluntary Program ("NVP").

The Overview of Issues document provides that the "overall goal of EPA's program regarding engineered nanoscale materials should focus on addressing the potential risks of such materials to human health and the environment, thereby giving the public reasonable assurances of safety concerning such materials."[7] Some NPPTAC members questioned the inclusion of the expression "reasonable assurances of safety" on grounds that it could be interpreted as suggesting a standard different from the "may present an unreasonable risk" standard under TSCA's statutory language. The NPPTAC ultimately agreed that the "assurances of safety" language as an "overall goal" of the NVP was not likely to supplant the TSCA legal standard, and that it fairly articulated the overall goal of EPA's program regarding engineered nanoscale materials.

According to the Overview of Issues document, the NVP was intended to encompass engineered nanoscale materials now in or "soon to enter commerce." The "soon to enter commerce" language

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[5] NPPTAC is a national advisory body intended to provide advice, information, and recommendations on the general policy and operation of programs managed by OPPT in performing its duties and responsibilities under TSCA and the Pollution Prevention Act. Before it was dissolved in 2006, the NPPTAC provided "a forum for public discussion and the development of independent advice to the EPA Administrator by taking advantage of the experience, strengths and responsibilities of a broad range of Agency constituents and stakeholders. In addition, Federal Agency representatives or national experts will serve as technical advisors to the NPPTAC."

[6] The Overview of Issues document is organized into six sections and includes two Annexes: Section I - Introduction; Section II - General Goal for EPA's Program Regarding Engineered Nanoscale Materials; Section III - Voluntary Program, which includes four subsections: III.A. - Intended Outcomes for a Voluntary Program, III.B. - Voluntary Program Description, III.C. - Benefits and Incentives for Participation in a NVP, and III.D. - Evaluation of the Voluntary Program and Follow-Up; Section IV - Regulatory Approaches for Addressing Potential Risks of Engineered Nanoscale Materials; Section V - Implementation Approach; and Section VI - Issues for Further Consideration. Annex A addresses remaining issues from the overview document, which consists of a single issue involving nanomaterial dispersive uses and handling as hazardous materials. Annex B includes a schematic of the NVP along with a commitment timeline. The document is available at NPPTAC, Overview Document on Nanoscale Materials [hereinafter "Overview of Issues document"], Nov. 22, 2005, http://www.epa.gov/oppt/npptac/pubs/nanowgoverviewdocument20051125.pdf (last visited Dec. 3, 2007).

[7] Overview of Issues document at 2.

invited considerable discussion within the NPPTAC, as this description is inherently subjective. After discussion, "soon to enter commerce" was defined as "applying to pre-commercial new and existing chemical engineered nanoscale materials for which there is clear commercial intent on the part of the developer, excluding such materials that are only at the research stage, or for which commercial application is more speculative or uncertain."[8]

Under the NVP, participants would volunteer one or more specific engineered nanoscale materials that they are developing, producing, processing, or using, but need not necessarily volunteer all of their materials. The specific information elements and management practices called for were to be identified by the time the voluntary program was announced, but remained undefined in the Overview of Issues document. For each identified information element, participants would be expected to provide to EPA all information possessed by the submitter. Information provided by participants relevant to understanding and addressing the potential risks of engineered nanoscale materials would be made publicly accessible, limited as appropriate under TSCA by protections applicable to confidential business information ("CBI").

A core element of the NVP as described in the Overview of Issues document was reporting existing information, defined to include all information in the possession of the submitting entity. The information reported on each volunteered nanoscale material would include the following: material characterization (report existing material characterization information on engineered nanoscale materials); hazard information (report existing information on hazards, i.e., environmental fate and toxicity studies); use and exposure potential (report existing information about use and exposure potential); and risk management practices (report existing information about risk management and other protective measures implemented now or available to be applied to engineered nanoscale materials, and to products and wastes containing such materials).

Participation under the NVP could be achieved by opting into either or both of two programs: a Basic Program and an In-Depth Program. Participation in the Basic Program would include a risk management component that consists of a participant's agreement to implement basic risk management practices or other environmental or occupational health protection controls (e.g., worker training; hazard communication (material safety data sheets ("MSDS")); use of available engineering controls; provision of personal protective equipment; product labeling; customer training; and waste management practices. Participants also would describe their experience in implementing, and their degree of satisfaction with, Basic Program risk management practices.

The In-Depth Program was intended to attract organizations, consortia of organizations, and/or other entities interested in participating beyond the Basic Program. Participants would agree to generate new information about the hazards and risks (including reduction of risk) of a particular engineered nanoscale material, as well as identifying, implementing, and expanding, as needed, risk management measures appropriate for a given life-cycle phase of such substance.[9] Under the In-Depth Program, volunteers

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[8] *Id*. at 3.

[9] According to the Overview of Issues document:

> The In-Depth Program would be expected to focus on a more limited number of engineered nanoscale materials, generating and reporting more in-depth information as identified by EPA as necessary to allow the Agency to conduct a full risk assessment of the identified materials and associated uses. For each volunteered material, producers, processors, users, and researchers and/or consortia of such entities would submit Basic Program information and would concurrently begin to generate the additional, more in-depth information, although it is expected that it will take longer to generate the new information. In-depth information on the engineered nanoscale materials would be submitted on a prescribed set of elements, developed by EPA in advance of program launch, on material characterization, human health hazard, environmental hazard, and release and exposure. The information would be generated with an aim to avoid redundancy and ensure efficient use of resources.

would also agree to work to extend application of protective risk management practices identified by EPA along their supply chains, and to conduct monitoring of workplaces, environmental releases, and worker health.

Importantly, the NPPTAC envisioned, and the Overview of Issues document expressed, the NPPTAC's view that a combination of voluntary and regulatory approaches is needed to address the potential risks of nanoscale materials. The list in the document includes near-term, medium-term, and longer-term approaches. Near-term approaches include: defining "new" engineered nanoscale materials; specifying information needed to evaluate properly PMN (and associated exemption) notification submissions of engineered nanoscale materials; ensuring public availability of information about environmental health and safety effects of engineered nanoscale materials consistent with TSCA approaches, while addressing CBI concerns; initiating activities to utilize TSCA Section 8(a) and 8(d) or other authorities to complement the NVP to ensure that EPA obtains needed information about engineered nanoscale materials to inform the Program Evaluation; and coordinating work/responsibilities between EPA and other agencies (e.g., the Food and Drug Administration and the Consumer Product Safety Commission) to ensure appropriate coverage of engineered nanoscale materials.

Medium-term approaches include the following: considering whether engineered nanoscale materials added to the TSCA Inventory should be identified as such, and if they should be tracked as a separate category to monitor and enable analysis of the performance of EPA's engineered nanoscale materials program; revisiting, and revising as needed, current PMN exemptions (e.g., low volume exemption ("LVE"), low release and low exposure exemption ("LoREX"), polymer)) and reporting thresholds (e.g., for reporting under the Inventory Update Rule ("IUR")) available under TSCA to reflect the novel or enhanced properties of engineered nanoscale materials; and utilizing TSCA authorities, as necessary, to ensure that EPA obtains needed information about engineered nanoscale materials to inform the program evaluation.

Finally, longer-term approaches identified in the document include the following: possibly developing one or more Significant New Use Rules ("SNUR") for new nanoscale uses of existing materials; promulgating one or more test rules under TSCA Section 4 to obtain further appropriate information needed to evaluate engineered nanoscale materials; and implementing TSCA Section 6 or other risk reduction actions for engineered nanoscale materials found to present an unreasonable risk.

The NPPTAC also encouraged EPA to conduct public scientific peer consultations with specialized scientists to assist in assessing the elements to be included in the Basic and In-Depth Programs, review and consider new scientific developments, and otherwise assess the value and integrity of the NVP. Since 2005, OPPT has convened two scientific peer consultations. The first was October 19-20, 2006, and focused on risk management practices for nanoscale materials.[10] The second was convened on September 6-7, 2007, and focused on materials characterization.[11]

Timing considerations for the NVP are set forth in considerable detail in the Overview of Issues document. NPPTAC urged EPA to provide additional opportunities to sign up to ensure new entities are included in the program and to include newer materials that may enter commerce. NPPTAC envisioned a six- to 12-month sign-up period, and suggested a three-month period for Basic Program participants to submit existing information and apply basic risk management practices. NPPTAC also urged EPA to avoid inadvertently rewarding late sign-ups by providing for a second sign-up period. Non-participants in the program were encouraged to submit information on an ongoing basis. The Overview of Issues

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Id. at 6.

[10] 71 Fed. Reg. 58601 (Oct. 4, 2006).

[11] 72 Fed. Reg. 45244 (Aug. 13, 2007).

document also includes a catalogue of issues NPPTAC urged EPA to consider as it proceeds in exploring the regulatory implications of nanoscale materials.[12]

III. CONCEPT PAPER FOR THE NANOSCALE MATERIALS STEWARDSHIP PROGRAM UNDER TSCA

OPPT officially responded to the NPPTAC Overview of Issues document in July 2007, in the form of a draft document—the Concept Paper. OPPT issued, at the same time, its draft TSCA Inventory Paper discussed separately below. EPA developed the Concept Paper and its accompanying Annexes "to outline [EPA's] initial thinking on the design and development" of the NMSP, which will "complement and support [EPA's] new and existing chemical efforts on nanoscale materials" and "help address some of the issues identified in EPA's Nanotechnology White Paper."[13] EPA states in the Concept Paper that the NMSP has the following specific objectives: to help EPA assemble existing data and information from manufacturers and processors of existing chemical nanoscale materials; to identify and encourage the use of risk management practices in developing and commercializing nanoscale materials; to encourage the development of test data needed to provide a firmer scientific foundation for future work and regulatory/policy decisions; and to encourage responsible development.[14] Annex A of the Concept Paper (Description of Nanoscale Materials for Reporting) contains "clarifications and descriptions" of various key terms used throughout the Concept Paper, including "engineered," "nanoscale," "engineered nanoscale material," and "nanotechnology."

According to the Concept Paper, EPA intends that the NMSP will include, but not be limited to, engineered nanoscale materials manufactured or imported for commercial purposes within the meaning of 40 C.F.R. Section 720.3(r). Importantly, EPA explains that participation in the NMSP "would not relieve or replace any requirements under TSCA that a manufacturer, importer, or processor of nanoscale materials may otherwise have."[15]

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[12] The issues list includes the following: Distinguishing Between "New" and "Existing" Chemical Nanoscale Materials—How might EPA distinguish between new and existing nanoscale materials?; Enhanced Properties—Is there a role for enhanced properties in drawing a distinction between "new" and "existing" nanoscale materials?; Inventory of Engineered Nanoscale Materials—Should EPA build/publish an inventory of nanoscale materials?; IUR—If EPA undertakes to flag nanoscale materials, should EPA make special efforts to obtain reporting on such nanoscale materials?; Public Access of Information—At what level of detail should information be provided to the public?; Data Management for Submitted Information—What types of information on nanoscale materials should be included in the NVP?; Labeling/Material Safety Data Sheets—EPA may regulate new chemical nanoscale materials by requiring specific MSDS language; Data Compensation—How can information reported under the NVP be shared among stakeholders while seeking to preserve a data submitter's claim to data compensation and at the same time meeting needs for potentially limiting the use of and public access to such information?; PMN Data Requirements—What information should accompany PMN submissions for new nanoscale materials?; Supply Chain—What factors might different actors in a nanomaterial supply chain—producers, processors, manufacturers of articles that incorporate nanoscale materials—consider in deciding whether to participate in the NVP individually or in a consortium with others in their supply chain?; Exemptions—Should EPA revisit the applicability of PMN exemptions on nanoscale materials?; EPA Resources—What steps is OPPT taking to allow it to deal with nanoscale materials?; Aggregation and Agglomeration of Nanoscale Materials—Should the potential of nanoscale materials to aggregate, disaggregate, or agglomerate affect how their risks ought to be considered?; Retaining Samples of Nanoscale Materials as an Element under the NVP—Should NVP participants be encouraged to retain a sample of the material for which the company has submitted data to the EPA?; Further Define and Clarify Attributes of the In-Depth Program—How would the In-Depth Program differ from the Basic Program?; Small Business Considerations and Concerns—What assistance could EPA (and voluntary program participants) provide to small businesses regarding understanding and implementing of: TSCA requirements; information provision under the NVP; and risk management practices to protect worker health and the environment?

[13] Concept Paper at 1-2.

[14] *Id*.

[15] *Id*. at 2.

With respect to participation in the NMSP, EPA foresees involvement by persons or entities that do or intend to do any of the following, with the corresponding intent to offer a commercially available product: manufacture or import engineered nanoscale materials; physically or chemically modify an engineered nanoscale material; physically or chemically modify a non-nanoscale material to create an engineered nanoscale material; or use engineered nanoscale materials in the manufacture of a product.[16] Both "new" and "existing" (for purposes of TSCA Section 5) engineered nanoscale materials can be included in the NMSP.

Similar to the NPPTAC proposal, EPA notes that it is considering a two-part NMSP: a Basic Program that would request the reporting of "all known or reasonably ascertainable information regarding specific nanoscale materials"; and an In-Depth Program in which additional data would be developed and submitted to EPA over a longer timeframe.[17] Annex B (Data Elements) delineates the types of data that participants in the Basic Program would be expected to report. Submitters would be encouraged, but not required, to submit their data through a data submission form that EPA has prepared.[18] Data claimed as CBI will be protected "in the same manner as CBI submitted under TSCA in accordance with procedures in 40 CFR parts 2 and 720,"[19] and EPA encourages NMSP participants both "to give careful consideration to what they will and will not claim [as] CBI" and "to make as much data as possible available to the public."[20]

Similar to the NPPTAC proposal, NMSP participants would agree to implement a risk management program, as well as "agree to consider information provided by EPA that is relevant to [nanoscale material] risk management . . . and to provide information about the risk management practices and other aspects of their risk management program that are relevant to nanoscale materials."[21]

The In-Depth Program would be informed by the Basic Program's results, and would involve a subset of the information reported under the Basic Program "in a greater amount of detail."[22] EPA states that "[i]n-depth data development would likely apply to a smaller set of representative nanoscale materials designated for further evaluation by mutual agreement of EPA and participants, with input from stakeholders."[23]

EPA notes its intent to use the data from the NMSP "to gain an understanding of which nanoscale materials are produced, in what quantities, how they are used, and the data that is available for such materials."[24] The data will assist EPA scientists in making human health and environmental risk determinations, and may be used to "[i]dentify the data that are missing to conduct an informed risk assessment of a specific nanoscale material" and "[i]dentify nanoscale materials or categories of nanoscale materials that may not warrant future concerns or actions, or should otherwise be treated as a lower priority for further consideration."[25] Significantly, EPA explains that if information submitted by an NMSP participant "indicates that the participant is manufacturing a nanoscale material that is reportable under [TSCA] section 5 . . . as a new chemical substance, EPA will immediately inform the participant of that situation and the applicable TSCA requirements."[26]

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16 *Id.*
17 *Id.* at 3.
18 The draft submission form is available at http://www.epa.gov/opptintr/nano/nmsp-icr-reportingform.pdf.
19 Concept Paper at 13.
20 *Id.* at 4.
21 *Id.*
22 *Id.* at 5.
23 *Id.*
24 *Id.*
25 *Id.* at 6.
26 *Id.*

Roughly one year after commencement of the Basic Program, EPA "may" publish an interim report summarizing "the types of data available, the reasons some data were reported as not being available, additional data that would be needed for a better risk assessment and any activities for which data are being used."[27] Two years after the launch of the NMSP, EPA "will" issue a more detailed evaluation of the program and simultaneously "determine the future direction of the basic reporting phase as well as in-depth data development."[28]

IV. PUBLIC COMMENT

This relatively detailed summary of the original 2005 NPPTAC Overview of Issues document and OPPT's 2007 Concept Paper is necessary for understanding the range of issues now being debated among nanoscale material stakeholders. As described below, the passage of time, changes in the scope and structure of the voluntary program, and the perception that EPA lacks a sense of urgency regarding the need for a voluntary program have caused stress fractures in the delicate alliance that existed two years ago among diverse stakeholders regarding the prompt need for and development of a voluntary reporting program for nanoscale materials.

Oral remarks on the Concept Paper presented at a public meeting on August 2, 2007, and written comments submitted thereafter reflect a house divided. Unlike the public meeting on June 23, 2005, where diverse stakeholders expressed remarkable and near unanimous support for a voluntary reporting program, the August 2, 2007, public meeting confirmed that the honeymoon was over. The most critical comments came from Environmental Defense ("ED"), which expressed concern over EPA's decision to jettison "key elements of the NPPTAC proposal" and the nearly two-year delay in issuing essentially a new framework that is "quite similar to that proposed by NPPTAC." Key elements of the NPPTAC proposal that EPA "jettisoned," according to ED, include the absence of deadlines for entities to sign up and submit information, or to apply basic risk management practices, and the absence of any "regulatory backstop." ED criticized the NPPTAC document's proposal for the identification of a "near-term need" to provide, as noted in the Overview of Issues document, "a combination of voluntary and regulatory approaches . . . to address the potential risks of nanoscale materials," including "initiating activities to utilize TSCA Section 8(a) and 8(d) or other authorities to complement the NVP to ensure that [EPA] obtains needed information about engineered nanoscale materials to inform the Program Evaluation."[29]

ED also expressed its concern over EPA's apparent reluctance to consider developing TSCA reporting rules by noting the tepid response to voluntary programs similar to the NMSP in the United Kingdom and in Denmark. According to ED, the United Kingdom's Voluntary Reporting Scheme ("VRS") has reportedly yielded fewer than ten participants. Similarly, the Danish voluntary program "yielded so little response and so little information that it did not warrant publishing." ED offered in its comments a detailed explanation why it decided to withdraw its support from the NMSP and to support instead the issuance of a TSCA Section 8(a) rule, altered as necessary to ensure small- and medium-sized enterprises ("SMEs") are included within the scope of any such rule, and identified the categories of information that EPA should consider requesting under TSCA Section 8(d).

Terry Davies, Senior Advisor to the Project on Emerging Nanotechnologies of the Woodrow Wilson International Center for Scholars ("PEN"), offered similar views. Davies urged EPA to get on with the voluntary program, criticized EPA for its apparent lack of urgency, and urged it to create a program that

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[27] *Id.*

[28] *Id.* Annex C of the Concept Paper (OPPT TSCA Framework) contains a summary of the TSCA regulatory framework, while Annex D (Issues and Challenges) discusses various issues and challenges regarding nanotechnology and nanoscale materials that OPPT in particular, and EPA more generally, faces.

[29] Overview of Issues document at 9.

has "concrete deadlines for implementing the program, receiving submissions, and ultimately ending [the] voluntary program."

Industry by and large continued to offer support for the concept of a voluntary program, but urged EPA to move forward and to do so with relatively ambitious deadlines. The American Chemistry Council Nanotechnology Panel, for example, urged EPA to allow entities three months from the official start of the NMSP to submit information, and six months from then for EPA to review, assess, and report out on the materials submitted under the Basic Program. This stands in stark contrast to the Concept Paper's proposal, where OPPT stated that it "may" publish an interim report approximately a year after initiation of the basic reporting phase of the NMSP, and will issue a more detailed evaluation of the program two years after initiation.

The NanoBusiness Alliance similarly expressed its support for the NMSP. It cautioned EPA, however, to be mindful of the burdens a voluntary program places on small businesses.

The Dow Chemical Company expressed its support for the NMSP, subject to minor suggested changes, but interestingly urged EPA to "use its significant new use rule ("SNUR") authority as appropriate to ensure that it can conduct risk reviews of existing nanomaterials, or categories of existing nanomaterials, which are likely to be significant in terms of their potential impact on health and the environment and which qualify as new in some appropriate way."[30] Dow's comments include a cogent and detailed explanation for its recommendation, and requested that EPA consider issuing a SNUR for categories of existing nanomaterials.

V. DRAFT TSCA INVENTORY PAPER

A threshold question nanoscale material manufacturers must ask before commencing commercial manufacture is whether the nanoscale material is "new" and thus subject to TSCA reporting requirements, or "existing" and thus not subject to reporting. Whether a chemical substance is new is a function of its listing on the TSCA Inventory, a listing of chemicals in commerce.[31] If a nanoscale substance is listed on the Inventory, EPA considers it existing and no new chemical reporting requirement applies. If the substance is not Inventory-listed, EPA considers the substance "new" and, unless a PMN exemption applies, the manufacturer must submit a PMN to EPA at least 90 days before commencing commercial manufacture or import.[32]

EPA's draft TSCA Inventory Paper "describes how EPA currently determines whether a nanoscale substance is a 'new' chemical only for the purposes of the [TSCA] Inventory."[33] EPA cautions that its approach to the "new" versus "existing" chemical distinction, which is so crucial to the PMN requirement set forth in TSCA Section 5(a), does not "establish[] a precedent on how nanotechnology issues arising under other EPA programs, other Federal Government agencies, or other federal statutes will be addressed."[34]

EPA reaffirms in the TSCA Inventory Paper its policy not to use particle size to distinguish, for Inventory purposes, substances that are known to have the same molecular identity. EPA indicates that it "views molecular identity as being based on such structural and compositional features as the types and number of atoms in the molecule, the types and number of chemical bonds, the connectivity of the atoms

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30 Comments of The Dow Chemical Company (Sept. 5, 2007) at 1.

31 *See* 40 C.F.R. § 720.25.

32 TSCA § 5(a), (c), 15 U.S.C. § 2604(a), (c); 40 C.F.R. § 720.75. Not discussed in this article are several important PMN exemptions, including the exemption for chemical substances having no separate commercial purpose, the polymer exemption, and the research and development exemption.

33 TSCA Inventory Paper at 1.

34 *Id.*

in the molecule, and the spatial arrangement of the atoms within the molecule," and that "chemical substances that differ in any of these structural and compositional features . . . have different molecular identities."[35] Importantly, EPA states that substances have different molecular identities when they: (1) have different molecular formulas; (2) have the same molecular formulas but different atom connectivities; (3) have the same molecular formulas and atom connectivities but different spatial arrangements of atoms; (4) have the same types of atoms but different crystal lattices; (5) are different allotropes of the same element; or (6) have different isotopes of the same elements.

EPA concludes the TSCA Inventory Paper by reiterating what has been its mantra for some time now: manufacturers or importers of nanoscale substances are "encourage[d] . . . to contact the [OPPT] New Chemicals Program to arrange a pre-notice consultation or to submit a request for an Inventory search under the *bona fide* intent to manufacture provision in 40 C.F.R. [Section] 720.25."[36]

Comments on the TSCA Inventory Paper varied. Many, particularly industry groups, supported EPA's interpretation. Others, including the National Institute for Occupational Safety and Health ("NIOSH"), expressed concern with EPA's decision not to consider particle size "in its decision criteria for determining if a nanoscale material is considered a new chemical for the TSCA Inventory."[37] According to NIOSH, "[r]educing the particle size to the nanoscale can result in unique or enhanced properties of the nanoscale substance, which can also alter or increase the biological activity and potential toxicity. Thus, the hazard potential of a nanoscale form of a substance may differ substantially (qualitatively and/or quantitatively) from the partent/bulk materials that may be listed on the Inventory."[38]

Some expressed support with EPA's general view, but disagreement with particular aspects of the guidance. For example, the Consumer Specialty Products Association ("CSPA") took umbrage with EPA's position that chemical substances have different molecular identities for TSCA Inventory purposes when they "have different isotopes of the same elements," citing the now popular administrative decision in *Concord Trading Corporation*.[39] CSPA cited *Concord* as a repudiation of the notion that differences in isotopic distribution in chemicals sharing the identical molecular structure is a legitimate basis upon which to consider the substances different for TSCA Inventory purposes.

VI. WHERE WE ARE NOW?

There is still much support for a voluntary reporting program. Time is running out, however, and EPA needs to get on with launching the program as soon as possible to generate public trust and confidence, and provide stakeholders with a structured opportunity to share needed information with EPA quickly.

Because of what some consider the passage of an excessive amount of time since the NPPTAC proposal and the critical need for EPA to obtain, review, and assess information on nanoscale materials as quickly as possible, EPA and industry stakeholders have a lot riding on the success of the NMSP. Detractors of the voluntary approach may have already concluded that no level of participation is sufficient to redeem the NMSP. If it continues to lack some of the elements ED and others regard as essential, the final program, even with robust participation, may be written off by some as too little, too late. Others will see the launch of the NMSP as a sensible and relatively expedient means for EPA to

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[35] *Id.* at 3.
[36] *Id.* at 6.
[37] Comments of the National Institute for Occupational Safety and Health (Sept. 7, 2007) at 4 (EPA-HQ-OPPT-2004-0122-0078.1).
[38] *Id.*
[39] Comments of the Consumer Specialty Products Association (Sept. 10, 2007) at 2-3 (EPA-HQ-OPPT-2004-0122-0076.1).

obtain information from nanotechnology stakeholders in the most pragmatic and efficient way possible. Those committed to the responsible development of nanotechnology should consider participating in one or both components of the program. Failure to do so may bode badly for nanotechnology and telegraph the wrong message to the public.

Additionally, nanotechnology stakeholders should encourage others in the nanotechnology community to participate. It is incumbent upon nanoscale material producers and other stakeholders committed to the responsible development of nanotechnology to promote the NMSP, spread the word, and encourage broad participation. Robust participation in the NMSP will help demonstrate to the public and others that those engaged in the manufacture, distribution, and processing of nanoscale materials are interested in providing EPA with the information it needs to understand and assess nanoscale materials, and to ensure that EPA has information on which to base appropriate risk management decisions. The demand for mandatory reporting measures and regulatory limitations on the manufacture of nanoscale materials can be expected to increase, making it considerably more difficult for nanoscale manufacturers and others to propose innovative governance mechanisms that EPA and other government agencies should utilize to identify and apply risk mitigation measures where appropriate. As noted, the NPPTAC proposal anticipated EPA's reliance upon other, more traditional regulatory mechanisms, such as TSCA Section 8(a) and 8(d) rules, to augment its voluntary data and information gathering efforts. There is considerable value in deferring more targeted mandatory information collection efforts until information and data from voluntary efforts are submitted and reviewed, thus informing EPA's judgment on what to seek and from which entities.