

Washington Watch

Nanoscale Materials and TSCA: EPA's NPPTAC Recommends a Framework for a Voluntary Program

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With uncharacteristic speed and remarkable clarity, the U.S. Environmental Protection Agency (EPA) National Pollution Prevention and Toxics Advisory Committee (NPPTAC) forwarded to EPA Administrator Stephen L. Johnson on November 22, 2005, its document entitled *Overview of Issues for Consideration by NPPTAC*.

The Overview of Issues document sets forth NPPTAC's "analysis and views" on a framework for a voluntary program on existing engineered nanoscale materials. The framework is intended to complement the new nanoscale chemicals requirements promulgated under the Toxic Substances Control Act (TSCA).

This column describes the voluntary nanoscale program outlined in the overview document, and discusses some of the challenging policy and technical issues facing EPA in implementing the program and regulating (under TSCA) new engineered nanoscale materials consisting of chemical substances. A prior installment of this column offers additional background on issues surrounding nanoscale materials.¹

Background: The Promises and Pitfalls of Nanotech

EPA is very much aware of the promise of nanotechnology, and equally aware of potential risks to human health and the environment posed by engineered nanoscale materials. The Agency program office now most engaged in the regulatory implications of engineered nanoscale materials is EPA's Office of Pollution Prevention and Toxics (OPPT), the office tasked with implementing TSCA and regulating existing and new chemical substances. Since engineered nanoscale materials consisting of new chemical substances are subject to EPA approval before they are manufactured or imported into the United States, EPA's authority under TSCA is very much in the regulatory foreground.

EPA formally initiated its nanoscale materials TSCA regulatory explorations on May 10, 2005, when OPPT issued a *Federal Register* notice announcing its decision to convene a public meeting to assess the feasibility and wisdom of establishing a voluntary program on existing nanoscale materials consisting of chemical substances.²

The decision to convene such a meeting and to develop a voluntary reporting program was prompted, in part, by growing recognition that:

- engineered nanoscale materials consisting of chemical substances are finding their way into many commercial applications, including coatings, clothing, computers, cosmetics, and medical devices,

- some nanoscale materials have entered one or more of EPA's various regulatory review processes, and
- the Agency needs a comprehensive and cogent risk assessment process that is able to identify, characterize, and manage risks that may be associated with nanoscale materials consisting of chemical substances.

While much has been written about the inherent promise of nanotechnology, particularly the use of nanoscale materials for environmental remediation, much less is known about the human health and environmental effects of engineered nanomaterials and structures.

What is known has given some cause for concern. According to a recent paper prepared by the International Life Sciences Institute Research Foundation/Risk Science Institute, "the existing research raises some concerns about the safety of nanomaterials and has led to increased interest in studying the toxicity of nanomaterials for use in risk assessment and protection of human health and the environment."³

EPA is also aware of critically important legal/regulatory policy issues under TSCA with significant implications that need to be resolved. For example, much of the appeal of engineered nanoscale materials is their ability to impart novel physical and chemical properties that enhance certain functionalities and improve commercial appeal. Nano-sizing a material may enhance its conductivity, reactivity, luminescence, or some other physical or chemical attribute.

A core issue that OPPT is now trying to address involves the difference between new and existing substances under TSCA. "Existing" chemical substances (i.e., listed on the TSCA Inventory) may be nano-engineered to impart unique physical or other characteristics that may cause the nanoengineered substance to pose risks that are not associated with its bulk form. The issue is when might these characteristics or other changes to the chemical substance cause the substance to be sufficiently different from its bulk counterpart to make it a "new" chemical such that TSCA Section 5 is triggered, giving the Agency authority to obtain pre-market approval of the nanoengineered chemical.

EPA and others question, however, whether the Agency actually has sufficient information to make distinctions between "new" and "existing" nanoscale materials for TSCA regulatory and definitional purposes. This is one of the many reasons EPA is seeking to develop quickly a voluntary nanomaterials program.

Many believe that it is important that EPA demonstrate clearly its ability under TSCA to review and assess nanoscale materials and ensure that they pose no unreasonable risk to human health and the environment, as TSCA requires. Without sufficient toxicological and environmental fate and monitoring data, however, making this finding is challenging.

Many also believe that it is important that EPA demonstrate its ability to review new engineered nanoscale substances competently and consistent with its mandate under TSCA in order to preserve TSCA's integrity. After all, TSCA's core provisions pertinent in this regard

were drafted almost 30 years ago, well before nanotechnology was known to allow the manipulation of matter at dimensions of one to 100 nanometers.

EPA's abilities under TSCA are also under renewed scrutiny and TSCA is being compared to the European Union's (EU's) new Registration, Evaluation, and Authorization of Chemicals (REACH) program, which many believe allows for a more thorough review of new chemicals as a condition of pre-market approval, and continued marketing in the case of existing chemicals. The contrast between TSCA and REACH will make it all the more important for EPA to demonstrate that its existing authorities are sufficient to achieve EPA's overarching goal under the Voluntary Nanomaterials Program, namely that of providing the public with an assurance of safety with respect to these materials.

EPA and Nanomaterials

EPA's keen interest in nanotechnology and nanoscale materials spans across several Agency program offices, and several initiatives are underway.

Office of Research and Development

The Office of Research and Development (ORD) has been closely following developments in nanotechnology, and is funding nanotechnology research through the ORD/National Center for Environmental Research Science to Achieve Results (STAR) grant program and the Small Business Innovative Research (SBIR) program.

Air Regulatory Offices

EPA's Office of Air and Radiation/Office of Transportation and Air Quality reviews nanomaterial registration applications pursuant to Clean Air Act (CAA) Section 211. This section provides the Agency with authority to designate any mobile source fuel or additive for registration under CAA Section 211(b).

Section 211(b)(1)(B) authorizes EPA to require health effects testing for certain fuels and fuel additives. At least one manufacturer has made application for registration of a diesel additive containing cerium oxide, which is represented as being based on nanotechnology. The application is presently being reviewed by EPA.

Office of Solid Waste and Emergency Response

The Office of Solid Waste and Emergency Response (OSWER) is also keenly interested in nanotechnology. The ability of some nanosized materials (such as iron nanoparticles) to remediate environmental contamination is well publicized. In addition, nanosized sensors are believed to hold great promise for the improved detection and tracking of contaminants.

In these respects, nanotechnology is critically important to EPA. Programmatically, OSWER is very interested in progressing the development of nanotechnologies that are believed capable of hastening the detection and cleanup of environmental contaminants.

Science Policy Council

In December 2004, EPA's Science Policy Council (SPC) charged a cross-Agency nanotechnology work group with describing the issues EPA must address to ensure that society accrues the important benefits that nanotechnology may offer to environmental protection, while also understanding the potential health and environmental risks from exposure to nanomaterials. The draft SPC white paper was released to the public for comment in December 2005.⁴

The white paper begins with an introduction that describes what nanotechnology is, why EPA is interested in it, and what opportunities and challenges exist with respect to nanotechnology and the environment. It then discusses the potential environmental benefits and applications of nanotechnology, with a strong emphasis on environmental stewardship and sustainability.

The paper then provides a brief review of statutory mandates, followed by a review of research needs relating to both the environmental applications and the implications of nanotechnology. The paper concludes with recommendations for Agency decision-makers on next steps in addressing science policy issues and research needs.

Office of Pollution Prevention and Toxics

As noted above, the EPA program office that is out in front on nanotech issues is OPPT. This office relies upon TSCA for its legal authority to review and approve new nanoscale materials and, if appropriate, establish limits on the manufacture of existing nanoscale materials consisting of chemical substances.

In the May 10, 2005, *Federal Register* notice, EPA acknowledged that nanoscale materials consisting of new chemical substances are subject to notification requirements under TSCA Section 5, and that the manufacturer of a new chemical substance must submit a pre-manufacture notice (PMN), including toxicity and other data, to EPA at least 90 days before production of the chemical is to begin. New chemicals generally are those not listed on the Inventory maintained under TSCA Section 8(b). In the notice, the Agency also acknowledged, however, that nanoscale materials consisting of existing chemical substances "may enter commerce without notification to EPA."⁵ The Agency'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 nanoscale materials;
- chemical characterization and nomenclature of nanoscale materials for regulatory purposes; and
- the identification of interested stakeholders.

Comments on these topics, and others, were presented at a June 23, 2005, public stakeholder meeting. Following the meeting, EPA decided to add “nanotechnology” to NPPTAC’s agenda.

NPPTAC and Its Work

Scope of the Committee

NPPTAC is a national advisory body that was created 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 (PPA). According to EPA’s website,⁶ the committee:

provides 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.

Much of NPPTAC’s work is conducted through work groups. Currently, NPPTAC has several such groups: the High Production Volume (HPV) Program Work Group, the Pollution Prevention Work Group, the Tribal Issues Work Group, and the Broader Issues Work Group. In addition, as discussed in the next section, it has a newly created Interim Ad Hoc Work Group on Nanoscale Materials.

The Interim Ad Hoc Work Group on Nanoscale Materials

Over the summer and fall of 2005, the Ad Hoc Work Group met and discussed issues relevant to the development of a voluntary pilot program on nanoscale materials. The Work Group was tasked with providing input to NPPTAC on four specific issues:

- options for possible elements of EPA’s voluntary pilot program for existing chemical nanoscale materials;
- approaches that may be appropriate for putting such a voluntary pilot program in place;
- consideration of issues that may be relevant to the review of new chemical nanoscale materials under TSCA; and
- consideration of other relevant issues raised in stakeholder input provided at EPA’s June 23, 2005, public meeting, as well as in written comments to the docket.

The Nanotech Work Group's "Overview of Issues" Document

The Interim Ad Hoc Work Group on Nanoscale Materials prepared a draft "Overview of Issues" document and presented it for discussion at a NPPTAC public meeting held on September 29, 2005. Following that meeting, the document was further reviewed and discussed at a NPPTAC public meeting held on October 13-14, 2005.

The November 22, 2005, version of the document reflects input from the entire NPPTAC. It was formally offered to EPA for its consideration in order to facilitate the development of a voluntary program for engineered nanoscale materials, referred to as the Nanoscale Materials Voluntary Program (NVP).

The Overview of Issues document is organized into six sections, and includes two Annexes. The sections are:

- Section I -- Introduction
- Section II -- General Goal for EPA's Program Regarding Engineered Nanoscale Materials
- Section III -- Voluntary Program, including four subsections:
 - Section III.A. -- Intended Outcomes for a Voluntary Program
 - Section III.B. -- Voluntary Program Description
 - Section III.C. -- Benefits and Incentives for Participation in the NVP
 - Section 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
- Section VI -- Issues for Further Consideration

Annex A addresses "remaining issues" from the overview document (in this case, 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 Overview of Issues document is a "must read" for anyone wishing to keep abreast of regulatory initiatives involving nanoscale materials. There is no attempt here to describe the voluntary program outlined in the document in significant detail; such a description would far exceed the space allotted to this column. Key provisions and issues are briefly outlined below, however.

The Nanoscale Materials Voluntary Program

The Overview 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.”

Inclusion of the expression “reasonable assurances of safety” was questioned by some NPPTAC members on the grounds that it could be interpreted as suggesting a standard different from the “may present an unreasonable risk” test under TSCA’s statutory language. NPPTAC ultimately agreed that the “assurances of safety” language as an “overall goal” of the NVP was not reasonably likely to supplant the TSCA legal standard and that it fairly articulated the aims of EPA’s program regarding engineered nanoscale materials.

Scope of the Program

The NVP is intended to encompass engineered nanoscale materials that are now in or “soon to enter” commerce. The “soon to enter commerce” language invited considerable discussion, given that this description is inherently subjective.

After debate, “soon to enter” 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.”

Elements of the Program

The Interim Ad Hoc Work Group on Nanoscale Materials consistently expressed its view that program participants should be offered the choice of participating in either a “basic” program or a more “in-depth” program that includes all the elements of the basic program, along with commitments to generate and report more in-depth information and to implement more in-depth risk management practices.

Both of the proposed programs, Basic and In-Depth, are intended to be voluntary and participation in either would, according to NPPTAC, offer benefits for those willing to provide information and agree to implement appropriate risk management practices. 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 would be clearly identified by the time the voluntary program is announced, although they currently are undefined. For each identified information element, participants are expected to provide EPA with all information possessed by the submitter.

Information provided by participants relevant to understanding and addressing the potential risks of engineered nanoscale materials will be made publicly accessible, limited as appropriate by protections applicable to confidential business information as described under TSCA.

Basic Program Participation

Participation in the Basic Program of the NVP would consist of the following three sets of activities for each volunteered engineered nanoscale material:

- reporting existing material characterization information on the material, as well as existing information characterizing hazard, use, and exposure potential, and risk management practices;
- filling gaps in basic information (about material characteristics only); and
- implementing basic risk management practices.

A core element of the NVP is reporting existing information, which refers to all information in the possession of the submitting company. The information reported on each volunteered nanoscale material would include the following:

- **Material Characterization:** Existing material characterization information on engineered nanoscale materials.
- **Hazard Information:** Existing information on hazards (i.e., environmental fate and toxicity studies).
- **Use and Exposure Potential:** Existing information about use and exposure potential.
- **Risk Management Practices:** 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.

The submission of new types of data (including cellular, mechanistic, -omics, and human exposure) is also encouraged in order to provide EPA with a range of test types that will allow it to identify the sorts of data that are most useful for assessing nanoscale material toxicity and risk.

If elements of a baseline set of material characterization information are missing, voluntary program participants are expected to generate the missing data. The baseline would consist of the following basic material characterization information: chemical composition (including impurities), aggregation/agglomeration state, physical form, concentration, size distribution and/or surface area, and solubility. It is believed that most producers, processors, users, and researchers already have this type of information about materials characteristics, and that this commitment would result in only a minimal additional burden.

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 and hazard communication, such as use of MSDSs); use of available engineering controls; and actions such as provision of personal protective equipment, product labeling, customer training, and waste management. Participants are also expected to describe their experience in implementing, and their degree of satisfaction with, Basic Program risk management practices.

In-Depth Program Participation

The In-Depth Program is for organizations, or consortia of organizations and/or entities, that are interested in participating beyond the Basic Program. Participants would agree to generate new information about the hazards and risks (including ways to reduce risk) associated with a particular engineered nanoscale material. They would also identify, implement, and expand (as needed) risk management measures appropriate for a given life cycle phase of the substance. 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.

Under the In-Depth Program, volunteers would also work to extend application of protective risk management practices identified by EPA along their supply chains, and would conduct monitoring of workplaces, environmental releases, and worker health.

Program Evaluation and Follow-up

An aspect of the NVP that attracted considerable attention was program evaluation. The program is intended to be time-limited, and it is expected that EPA will determine a point in time at which it will conduct a full-scale program evaluation to assess at least the following: the degree to which the program is meeting its goals, the rate of participation, the amount and quality of the information generated by program participants, the adequacy and potential effectiveness of

existing risk management practices, and the lessons and conclusions that can be drawn from the program experience.

NPPTAC members, and especially members of the Interim Ad Hoc Work Group on Nanoscale Materials, expressed keen interest in ensuring not only that the program get off the ground, but also that it meet the Agency's intended goals within a reasonable period of time.

NPPTAC's Vision: Voluntary and Regulatory Approaches to Nanotech Risk

NPPTAC envisions a combination of voluntary and regulatory approaches for addressing potential risks from engineered nanoscale materials. The list includes near-term, medium-term, and long-term approaches, as discussed below.

Near-Term

- Defining “new” engineered nanoscale materials, and specifying information needed to properly evaluate PMN (and associated exemption) submissions on engineered nanoscale materials.
- Ensuring public availability of information about the environmental, health, and safety effects of engineered nanoscale materials consistent with TSCA approaches, while addressing confidential business information concerns.
- Initiating activities to utilize TSCA Sections 8(a) and 8(d) or other authorities to complement the NVP in order to ensure that EPA obtains the information about engineered nanoscale materials that is needed to inform the program evaluation.
- Coordinating work and responsibilities among EPA and other agencies (e.g., the U.S. Food and Drug Administration and the U.S. Consumer Product Safety Commission) to ensure appropriate coverage of engineered nanoscale materials.

Medium-Term

- Considering whether engineered nanoscale materials that are added to the Chemical Substances Inventory should be identified as such, and whether they should be tracked as a separate category in order to monitor and enable analysis of the performance of EPA's engineered nanoscale materials program.
- Revisiting, and revising as needed, current exemptions (e.g., the low volume exemption, or LVE, the low release and exposure exemption, or LoREX, and the polymer exemption) and reporting thresholds (e.g., for reporting under the Inventory Update Rule, or IUR) available under TSCA to reflect the novel or enhanced properties of engineered nanoscale materials.

- Utilizing TSCA authorities, as necessary, to ensure that the Agency obtains the information needed about engineered nanoscale materials in order to inform the program evaluation.

Long-Term

- Possibly developing one or more Significant New Use Rules (SNURs) for new nanoscale uses of existing materials.
- Promulgating one or more test rules under TSCA Section 4 in order to obtain further appropriate information needed to evaluate engineered nanoscale materials.
- Implementing TSCA Section 6 or other risk reduction actions for engineered nanoscale materials found to present an unreasonable risk.

Other measures that have been noted include, but are not limited to: ensuring the development of additional information, and ensuring implementation of the control measures that EPA determines are needed to identify and manage potential risks from engineered nanoscale materials that are now in, or soon will enter, commerce.

Scientific Peer Consultation

NPPTAC encouraged EPA to conduct public scientific peer consultations with specialized scientists in order 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.

NVP Implementation Timing

The timing of the NVP is set forth in considerable detail in the Overview document. NPPTAC urged EPA to provide additional opportunities for organizations to sign up for the program in order to ensure that new entities are included, and to encompass newer materials that may be entering commerce soon. NPPTAC envisions a six- to twelve-month sign-up period.

NPPTAC urged EPA to avoid inadvertently rewarding late signups by providing for a second sign-up period. Additionally, non-participants in the program would be encouraged to submit information on an ongoing basis.

Issues for Further Consideration

As noted, the Overview of Issues document outlines a voluntary program. As good as it is, the document barely scratches the surface of EPA's interest in obtaining an understanding regarding the risks and benefits of nanotechnology.

NPPTAC catalogued a few of the more prominent issues that it has urged EPA to consider as it proceeds in exploring the regulatory implications of nanoscale materials. 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 the Agency make special efforts to obtain reporting on such nanoscale materials?
- **Public Access to 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 and 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 preserving 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 nanomaterials supply chain (such as producers, processors, and manufacturers of articles that incorporate nanoscale materials) consider in deciding whether to participate in the NVP, either individually or as part of 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 itself 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 EPA?
- **Further Defining and Clarifying 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 implementation of: TSCA requirements; information provision under the NVP; and risk management practices for protecting worker health and the environment?

Discussion: Thoughts on the NVP

The approach to a voluntary program envisioned in the Overview of Issues document is thoughtful and well-considered, and the document represents a useful first attempt at addressing the potential risks posed by nanoscale materials. The November transmittal of the Overview of Issues document to EPA Administrator Johnson is only the first of many steps, however, each of which presents new challenges and opportunities for EPA and other stakeholders.

Perhaps a key challenge is the need for Bush Administration support to progress the NVP. In order to initiate the NVP, EPA likely will be required to prepare an Information Collection Request (ICR) and obtain approval of it by the Office of Management and Budget (OMB). Some speculate that OMB may not fully appreciate the critical need for the NVP as a means of enabling EPA to obtain information necessary to facilitate its understanding of nanoscale materials and to hasten the development of suitable risk assessment tools and methodologies as part of the TSCA program.

The United States is in a global competition over the rapid development of nanotechnology. Some believe that the “regulation” of nanoscale materials, or even the perception of regulation, could be interpreted as a competitive disadvantage. OMB might be tempted to disapprove “regulation,” and thus disfavor the NVP and any forthcoming ICR to facilitate its development.

Stakeholders need to communicate their support for the NVP and emphasize the many upsides the program offers. For example, many believe that a more accurate view is that the success of nanotechnology rests upon the public’s acceptance of it as a viable and safe technology, and that EPA must be firmly engaged in assessing the risks and benefits of what nanoengineered materials have to offer. This necessarily means that the Agency must be engaged in review and approval of the products of nanotechnology that fall within the jurisdictional boundaries of the statutes EPA is charged with implementing.

The NVP will enable the Agency to obtain and review information pertinent to assessing the risks of nanoscale materials consisting of chemical substances. The program is thus a useful -- if not essential -- first step in providing the public with some assurances that EPA is engaged in the review and assessment of potential risks posed by existing nanoscale materials. In this regard, the NVP offers tremendous opportunities for EPA and other nanotechnology stakeholders.

Another challenge facing the Agency, as well as other stakeholders who wisely believe their fate is inexorably tied to the success of the NVP, is promoting participation in the program by a commercially diverse range of stakeholders. Because of the number and importance of small and medium enterprises (SMEs) in the nanotechnology area, it is critically important to attract non-traditional stakeholders as participants.

While the chemical community is very familiar with voluntary initiatives such as the HPV Program and the Voluntary Children's Chemical Evaluation Program (VCCEP), it is likely that the small startup businesses that populate the nanotechnology field are much less aware of these programs. Moreover, SMEs are expected to be less familiar with regulatory requirements that arise under TSCA and related legal authorities.

For all these reasons, EPA and other stakeholders must engage in non-traditional means to communicate with and reach out to these new stakeholders, promoting the NVP in ways that secure their participation. This will not be easy, and more traditional stakeholders in the chemical community will need to do their part to ensure participation by less traditional colleagues.

It goes without saying that all of EPA's NVP efforts will need to be undertaken with the expectation that no new resources will be provided to the Agency to assist it in administering the program. In these days of declining budgets, EPA is constantly challenged to do more with less, and the inclusion of all things nano in the Agency's growing portfolio of emerging issues is no exception.

This reality makes it all the more important for members of the more established business community to participate actively and creatively. They will need to work with EPA and other federal and state agencies to build the public's confidence in nanotechnology and ensure that any risks that nanotech might inspire are identified and managed early and comprehensively.

The need to harmonize and prioritize research initiatives is also critically important. Public and private research on the environmental, health, and safety implications of nanotechnology is ongoing, and care must be taken to ensure that initiatives are not duplicative or unnecessary.

Similarly, it is essential to ensure that research is properly focused on nanoscale materials and on exposure scenarios that most accurately depict real-world exposure opportunities if limited resources are to be directed toward outcomes that will provide the most benefit.

In this regard, the release of the first inventory of government-supported research on the health and environmental impacts of nanotechnology is expected provide significant assistance. This inventory (released in late 2005) was created by The Woodrow Wilson International Center for Scholars Project on Emerging Nanotechnologies.⁷ It is intended to offer policymakers, researchers, corporations, and others “their first opportunity to better assess publicly funded research” regarding the effect of nanomaterials on human health and the environment.⁸

The parallels between the emergence of nanotechnology today and biotechnology a decade or so ago have been made many times in the recent past. The touting of biotechnology as a panacea for many problems was done in the absence of a comprehensive communications strategy helping the public understand the science and value of biotechnology. This invited the public backlash that ensued in the absence of a thoughtful and well-conceived strategy for communicating the risks and benefits of the technology.

If past is prologue, the proponents of nanotechnology would do well to learn from these mistakes. They will need to communicate -- at every step of the way -- the need for appropriate transparency, risk communication, inclusiveness, and coordination between and among the diverse stakeholders in the nanotechnology area.

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Notes

¹ See Bergeson, L.L. (2005, autumn). Washington Watch: EPA Considers How Best to Regulate Nanoscale Materials. *Environmental Quality Management*, 15(1), 81-89.

² 70 Fed. Reg. 24574 (May 10, 2005).

³ Principles for Characterizing the Potential Human Health Effects from Exposure to Nanomaterials: Elements of a Screening Strategy. *Particles and Fibre Toxicology*, available at <http://www.particleandfibretoxicology.com/content/2/1/8>.

⁴ 70 Fed. Reg. 75812 (December 21, 2005).

⁵ 70 Fed. Reg. at 24574.

⁶ The site is available at <http://www.epa.gov/opptintr/npptac/>.

⁷ See <http://www.wilsoncenter.org>.

⁸ The inventory is available at <http://www.nanotechproject.org/index.php?id=18>.