Interim Ad Hoc Work Group on Nanoscale Materials
National Pollution Prevention and Toxics Advisory Committee (NPPTAC)
U.S. Environmental Protection Agency

Overview of Issues for Public Discussion and Consideration by NPPTAC

9/21/05

I. INTRODUCTION

About two decades ago, research indicated that certain engineered nanoscale materials exhibit unexpectedly unique and novel properties. The existence of structures at the nanoscale level may confer a distinct set of physical, chemical, and biological properties. Engineered nanoscale materials are being used to improve existing products and are expected to create breakthroughs that could lead to the efficient use of resources necessary for this and future generations. EPA is interested in whether commercial activities of engineered nanoscale materials may present a potential risk to human health and the environment because of their unique physical structure and consequent properties. Therefore, EPA is considering how best to evaluate the risks associated with engineered nanoscale materials and how to manage those risks.[1]

On June 23, EPA held a public meeting to discuss a potential voluntary pilot program for reporting information pertaining to existing chemicals that are engineered nanoscale materials, and the information needed to adequately inform the conduct of the pilot program. Some public comments registered the need for a regulatory approach in addition to conducting a voluntary program. The Agency plans to move forward to develop elements of a voluntary reporting program for engineered nanoscale materials, and has asked for input from the NPPTAC on options for a voluntary pilot program and issues that may be relevant to the review of new engineered nanoscale materials under TSCA.

NPPTAC formed an Interim Ad Hoc Work Group on Nanoscale Materials to provide input to the NPPTAC for consideration at its October 2005 meeting. The Work Group charge is the development of informed discussion on the following topics:

- 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.
- 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.

The Work Group met via several conference calls in August and September 2005 to prepare for a September 29 public session to obtain broad stakeholder input. The ten Work Group members represented small and large companies, environmental NGOs and an animal welfare organization.

[1] For an announcement of the June 23 public meeting see: Federal Register / Vol. 70, No. 89 / Tuesday, May 10, 2005 / Notices.

The purpose of this overview document is to provide a basis for discussion of some common elements of a potential voluntary pilot program that might receive broad support, to begin consideration of regulatory actions that could be undertaken, and to flag issues for input and further discussion. This document has been developed for the purpose of public discussion at the September 29 public session and should not be construed as a consensus statement by the Nano Work Group.

This Overview Document contains, in Section V and in the attached Issues Annex (Annex A), lists of issues that would benefit from public discussion. Section V lists issues that have not been discussed by the Work Group; the Issues Annex describes issues that have received considerable discussion by the Work Group members who held a range of views on the topic. These issues would also benefit from further discussion during the September 29 public session. In the text below, locations where the issues of the Issues Annex could be most usefully addressed are marked in bold as, for example, "**Issue #1**", "**Issues #2**", etc.

II. GENERAL GOAL FOR EPA'S PROGRAM REGARDING ENGINEERED NANOSCALE MATERIALS

The overall goal of EPA's program regarding engineered nanoscale materials should **[Issue #1: Assurances for the Public]**. This overall goal should be executed by: a) building a baseline of information on the engineered nanoscale chemical substances, including their physical and chemical characteristics, and information on their use(s), exposure potential, and effects on human health and the environment, the tools and methods used to collect that information, and the risk management practices that are being implemented for such substances, and b) prompting implementation of appropriate risk assessment and risk management practices needed to reduce risk of potential exposures to an engineered nanoscale material during its lifecycle. With that information in hand and basic risk assessment and risk management practices in place, EPA should focus on establishing the means to assure that engineered nanoscale materials are being responsibly developed and commercialized.

Voluntary and regulatory (under TSCA) measures are being developed by EPA, in conjunction with public input. These include, for example, the NVPP; efforts to distinguish new versus existing chemical nanoscale materials; decisions on new chemical nanoscale materials notified to EPA; and possible section 8(a)/8(d) reporting rules. The voluntary pilot program, as described below, should provide statutory protections for confidential business information, and EPA should apply a "may present an unreasonable risk" test when offering its views on specific submissions.

III. VOLUNTARY PILOT PROGRAM

The NVPP is intended to encompass engineered nanoscale materials now in or soon to enter commerce and the approaches under the NVPP are intended to be available to both "new" and "existing" chemical nanoscale materials, regardless of whether they would otherwise qualify for various exemptions, or fall below reporting or notification thresholds, now applicable under TSCA provisions. This scope would apply without prejudice as to whether such distinctions, exemptions, or thresholds do or should apply in other contexts beyond the duration of a voluntary pilot program. Participation in the NVPP does not supersede, rather it complements, the new chemical notification requirements for new chemical nanoscale materials.

In this context "soon to enter commerce" is 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.

III.A. Intended Outcomes for a Voluntary Program

New chemical nanoscale materials fall within the scope of EPA's regulatory program under TSCA section 5. EPA has started a public discussion regarding a voluntary pilot program that would include existing and new chemical nanoscale materials.

Building on the general goals of EPA's overall program for engineered nanoscale materials[2], the Work Group identified a range of potential intended outcomes for a nanoscale materials voluntary pilot program (NVPP), including:

1. Give EPA, and the public to the extent possible recognizing legitimate CBI issues, a better understanding of the types of engineered nanoscale materials; the physical, chemical, hazard and exposure characteristics of such substances; the volume of such substances; and the uses of such substances;
2. Help EPA develop capacity and a process to identify and assess risks of engineered nanoscale materials;
3. Help EPA determine what information it needs about engineered nanoscale materials and articulate those information needs to industry and other stakeholder groups;
4. Help EPA understand what risk management practices are being used at production, processing, use and disposal stages, and what additional risk management practices need to be implemented;
5. Prompt or reinforce the implementation of risk management practices; and
6. Provide the information and experience needed to develop an overall approach to the treatment of nanoscale chemical substances under TSCA that builds public trust in nanoscale materials while enabling innovation and responsible development.

EPA might pursue a variety of actions in response to information it receives from participants. Short of a situation in which submitted information indicates an "unreasonable risk of injury to human health or the environment", in which case EPA would take actions prescribed by TSCA, EPA could pursue a range of actions, including:

1. EPA could develop a detailed and focused program for information gathering;
2. EPA could develop a process for risk assessment and risk management;

[2] For purposes of the NVPP, engineered nanoscale materials include materials with one or more dimensions between 1 and 100 nm, that are in commerce or soon to enter commerce. Examples include, but are not limited to: nanoscale particles, fullerenes ("buckyballs"), nanotubes, nanowires, quantum dots, and nanoscale titania and other nanoscale materials that may be derived from natural sources and are further processed for use. Naturally-occurring materials that are not the result of a manufacturing process are excluded. This definition is not intended to preclude submission of information about naturally-occurring or un-intentionally-produced nanoscale materials that is relevant to understanding potential risks of engineered nanoscale materials.

3. EPA could assess the potential risks of engineered nanoscale materials;
4. EPA could develop and call for implementation of control measures to address potential risks;
5. EPA could provide a response to information supplied by a participant to encourage greater understanding and efforts by the participant consistent with the general outcomes described above

III.B. Voluntary Pilot Program Description

EPA should establish a NVPP that offers participants the opportunity to participate in a basic program, or in a more in-depth program that includes all the elements of the basic program, as well as the commitment to generate and report more in-depth information, and implement more in-depth risk management practices. EPA should develop these programs to encourage broad participation from producers[3], processors, users, and researchers, while assuring that EPA receives relevant information and achieves implementation of risk management practices adequate to achieving the overall goals stated above. Submitters of notifications on new chemical nanoscale materials could also have the opportunity to commit under the NVPP to meet the basic or in-depth program elements as a complement to meeting new chemical regulatory requirements.

Both of the programs are voluntary and participation in either would provide specific benefits for those willing to provide information and agree to implement appropriate risk management practices. 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.[4] The specific information elements and management practices called for would be clearly identified by the time the voluntary program is announced. For each identified information element, participants are 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 will be made publicly accessible, limited as appropriate by protections applicable to confidential business information (as described under TSCA). A schematic of the proposed NVPP is provided in Annex B.

[Issue #2: Sequencing and Duration of Programs]

Basic Program Participation

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

1. Reporting existing (hereinafter meaning all information possessed by the submitter) material characterization information on the material in commerce and materials soon to enter commerce, as well as existing information characterizing hazard, use and exposure potential, and risk management practices;
2. Filling in gaps in basic information about material characteristics ONLY; and
3. Implementing basic risk management practices.

[3] For the purpose of this document, the term "producers" includes manufacturers and importers.
[4] The benefits and incentives (see Section III.C.) available for a participant could reflect the actual extent of its participation.

The general goal in designing the Basic Program would be to ensure broad participation by organizations that are able to provide relevant information to EPA.

Reporting Existing Information
A core element of the voluntary pilot program is focused on ***reporting existing information***, meaning all information in possession of the submitting company**.** The information reported on each volunteered material would include:

- **Material Characterization:** Report existing material characterization information on engineered nanoscale materials in commerce and materials soon to enter commerce.
- **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.
- **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.

The submission of new types of data (including cellular, mechanistic, -omics, and human exposure) should be encouraged to provide the EPA with the range of test types that will allow them to identify the most useful ones for assessing nanoscale material toxicity and risk.

Filling Gaps in Basic Information about Material Characteristics ONLY
If some elements of a baseline set of material characterization information (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) are missing, the participant in the voluntary program is expected to generate the missing information. If the physical form or state of the nanoscale material varies throughout its lifecycle (for example, solubilized particles in solvent during manufacture versus agglomerates in solidified product versus some other form after disposal) then this should be indicated and the material's characterization data, that is submitted should be linked with the appropriate state of the nanoscale material. It is expected that most producers, processors, users, and researchers already have the requested information about materials characteristics. This commitment would result in only a minimal additional burden.

Implementing Appropriate Basic Risk Management Practices
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 (MSDS); use of available engineering controls; provision of personal protective equipment product labeling, customer training, waste management practices, etc.). Participants should 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) who are interested in participating beyond the Basic Program, by generating 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.

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 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 materials 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 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.

[Issue #3: Dispersive Uses and Handling as Hazardous Materials]

III.C. Benefits and Incentives for Participation in a NVPP

The NVPP needs to be structured to achieve a high level of participation and cooperation by stakeholders. A high level of participation and cooperation will provide the public with greater assurance that engineered nanoscale materials will be managed in a responsible and accountable manner. This is an important benefit of participation in the NVPP, because producers, processors, users, and researchers are seeking public understanding and acceptance of engineered nanoscale materials. Participation in a program designed with broad stakeholder input and reflective of a range of needs and perspectives can provide companies with a concrete means to demonstrate their individual and collective commitment to responsible nanotechnology development. Participation also provides an opportunity to help determine the best ways to evaluate and address the potential risks of engineered nanoscale materials.

Another major benefit of participation in the NVPP should be the opportunity it presents to facilitate interaction with a broader community for shared learning and experience and to offer participants access to resources and expertise to help them implement the program. The NVPP could especially encourage small companies to participate by joining with others, e.g., in consortia with their customers, to share resources and work together to satisfy the program elements. It could also facilitate access to particular expertise (e.g., on industrial hygiene) to help implement the program in their companies or institutions.

To provide additional benefits for participation in the NVPP, EPA should consider offering incentives to participants. Incentives could be differentiated between levels of participation (e.g., Basic vs. In-Depth Program Participation). Incentives might include, among others:

- EPA could provide feedback regarding volunteers' submissions.
- Participants would not be required to respond to any forthcoming TSCA Sections 8(a) or (d) reporting requirements specific to engineered nanoscale materials, except to the extent that the reporting requirements include data not previously submitted under the voluntary program.
- Submitters of Premanufacture Notifications (or the notices required for the applicable exemptions from the PMN requirements) that provide in their submissions all of the information called for under the NVPP and agree to implement its risk management provisions would also be deemed NVPP participants for that PMN upon their request. Submitters could also indicate that they wish to handle the PMN under the "in-depth" program and would be so recognized. EPA would consider this status in its review of PMN information submitted by NVPP participants and may take additional steps (e.g., fast track) in the future.
- **[Issue #4: Safe Harbor]**
- Participants should be authorized to state their participation in the NVPP in various promotional contexts, but not on individual products.
- EPA would maintain a website that lists program participants by name.
- In promoting outreach for participation, EPA would list, with participant permission, program participants by name (including in ads, public service announcements, or other materials intended to promote participation).
- EPA would use its best efforts to promote harmonization of information and notification requirements among federal agencies (e.g., FDA, NIOSH, OSHA, etc.) and internationally (e.g., OECD member countries).
- EPA could provide companies, particularly small companies, with assistance in navigating the regulatory system.

III.D. Evaluation of the Voluntary Program and Follow-Up

The NVPP should be considered an important step in assisting EPA to assess and address potential risks of engineered nanoscale materials and to achieve the overall goal set out in Section II. Therefore, the program (or at least its initial phases) should be designed as a time-limited project and evaluated by the EPA after a defined period to determine its degree of success in meeting these objectives, what lessons can be drawn from the experience, and what next steps are appropriate. The program could be designed with objectives, milestones, and regular reviews to drive success, while maintaining consistency. This would allow flexibility in evaluating needs for change and identification of lessons learned sooner rather than later, including identification of needs, means, and methods to solicit more participation.

The program will require a reasonable period of time in order to attract participants, collect data and encourage appropriate research. It is expected that EPA will determine a point in time (e.g., at 24 months) when it should conduct a full-scale program evaluation to assess:

- The degree to which the program is meeting or has achieved the overall goal of the program and its other objectives;

- The rate of participation;
- The amount and quality of information generated by the 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, for example:
  - Characteristics of nanoscale substances that should be considered in risk assessment and risk management;
  - Which, if any, regulatory changes are needed to address nanoscale materials; and
  - Risk management practices appropriate to nanoscale substances.

Information needed for this evaluation should largely come directly from the information submitted by the program participants, but may need to be augmented with interviews with participants and other appropriate stakeholders.

Based upon these findings EPA should determine whether to continue, expand or discontinue the program and what additional steps should be taken as follow-up.

IV. REGULATORY APPROACHES FOR ADDRESSING POTENTIAL RISKS OF ENGINEERED NANOSCALE MATERIALS

A combination of voluntary and regulatory (under TSCA) measures are being developed by EPA in support of the goal of responsible development of nanoscale materials. The details of a regulatory program under TSCA have not been discussed by the Work Group. It has been suggested that possible elements of a regulatory approach under TSCA might include:

1. Defining "new" engineered nanoscale materials, specifying information needed to properly evaluate PMN (and associated exemption) notification submissions of engineered nanoscale materials, and possibly developing one or more Significant New Use Rules (SNURs) for new nanoscale uses of existing materials. Engineered nanoscale materials added to the Chemical Substances Inventory should be identified as such, and could be tracked as a separate category to monitor and enable analysis of the performance of the engineered nanoscale materials program.
2. Promulgating TSCA Section 8a and 8d rules to ensure that the Agency obtains existing information from all producers about engineered nanoscale materials.[5]
3. Promulgating one or more test rules under TSCA Section 4 to obtain further appropriate information needed to evaluate engineered nanoscale materials.
4. Implementing TSCA Section 6 actions for engineered nanoscale materials found to present an unreasonable risk.
5. Developing a TSCA Section 12 export notification and tracking system.

[5] To ensure that EPA is able to obtain as much information as possible, EPA might consider measures that allow it to issue TSCA Section 8(a) and 8(d) rules as quickly as possible. EPA could initiate consultations with the Small Business Administration (SBA) to determine how best to adjust the definition of "small manufacturer exemption" under TSCA Section 8(a), as codified in the C.F.R. Section 704.3 and 704.5(f). EPA should also consider whether it should develop a nanoscale material-specific Section 8(a) rule, with revised thresholds for small manufacturers, to achieve the Program's goals. EPA should also consider waiving the exemption under TSCA Section 8(d) for chemicals not listed on the TSCA Inventory to achieve the Program's goals.

6. Ensuring public access to information about environmental health and safety effects of commercialized engineered nanoscale materials, while addressing confidential business information concerns.
7. Coordinating jurisdictional issues between EPA and other agencies (e.g., FDA and CPSC), and coordinating EPA and other agencies' programs' to ensure appropriate coverage of engineered nanoscale materials.
8. Revisiting, and revising as needed, current exemptions (e.g., LVE, LoREX, polymer) and reporting thresholds (e.g., for reporting under the IUR) available under TSCA to reflect the novel or enhanced properties of engineered nanoscale materials.

Other measures may include, but are not limited to, ensuring the development of additional information (through both the private sector and publicly accessible institutes and laboratories, such as the National Toxicology Program and other federal agencies) and implementation of control measures that EPA determines are needed to identify and manage potential risks of engineered nanoscale materials now in or soon to enter commerce.

V. ISSUES FOR FURTHER CONSIDERATION

There are many issues that require careful thought and consideration. A preliminary list of issues for further consideration is presented below. This list is not exhaustive, and is intended only to flag issues that would benefit from public discussion and input.

1. Distinguishing "new" and "existing" chemical nanoscale materials
2. Exemptions
3. Supply Chain
4. Data Compensation
5. Public access to information
6. New/Enhanced Properties
7. Inventory Update Rule
8. Possible NCAN (analog to Microbial Commercial Activities Notices (MCANs), a specialized reporting system)
9. PMN Data Requirements
10. Role of SNURs/Test Rules
11. Inventory of engineered nanoscale materials
12. Export notification and tracking
13. Labeling/Material Safety Data Sheets

14. Safe harbor for participants

15. EPA Resources

16. Data management for submitted information

17. Submission of information on “categories”

18. Aggregation of nanoscale materials

19. Retaining samples of nanoscale materials as an element under the NVPP

20. Further define and clarify attributes of the In-depth Program

21. Defining whether there should be further benefits to In-Depth program participation, for instance EPA acting “faster” on PMN submissions

22. Small Business considerations and concerns

ANNEX A: ISSUES FROM OVERVIEW DOCUMENT

NPPTAC formed an Interim Ad Hoc Work Group on Nanoscale Materials (Nano Work Group) to provide input to the NPPTAC for consideration at its October 2005 meeting. The Nano Work Group charge is the development of informed discussion on the following topics:

- 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.
- 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.

A range of issues, program elements and approaches to program implementation have been discussed by the Nano Work Group and are presented in the Overview Document. The issues and questions presented in this Issues Annex have been discussed by Work Group members, who have voiced a range of opinions on these issues. These issues have also emerged as key for further discussion, and would benefit from public discussion. These issues are presented below in the order addressed in the Overview Document, and potentially useful locations to address these issues are marked "**Issue #1**", "**Issue #2**", etc., in the Overview Document. In addition, in the Overview Document, Section V. lists issues that would benefit from public discussion, but *have not* been discussed extensively by the Work Group. It should be noted that many other ideas and options for discussion may be generated at the public session.

II. General Goals for EPA's Program Regarding Nanoscale Materials

Issue #1: Assurances for the Public

A variety of potential phrases on public assurances have been raised and discussed, including those below. Should a goal statement for the EPA's overall program, as started in the Overview Document, be included and should it include one of the following phrases:

"The overall goal of EPA's program regarding engineered nanoscale materials should focus on addressing the potential risks of such materials,

a) giving the public reasonable assurances of safety concerning such materials"?
b) assuring the public that the potential human health and environmental effects of nanoscale chemical substances are considered and addressed appropriately as such substances are developed and commercialized"?
c) giving the public a reasonable assurance that nanoscale materials are safely and responsibly managed"?

III. Voluntary Pilot Program

Issue #2: Sequencing and Duration of Programs

Voluntary and regulatory measures are being developed by EPA. Three questions arise regarding the sequencing of the various programs:

a) In the NVPP, should the Basic Program be initiated concurrently with the In-depth Program, or should the In-depth Program be launched following the Basic Program?
b) Should the development of regulatory approaches be initiated concurrently with the NVPP, or following the NVPP?
c) What should be the specific duration of the NVPP?

Issue #3: Dispersive Uses and Handling as Hazardous Materials

As additional commitments for Basic Program participants of the NVPP, should they be expected to:

a) refrain from introducing into commerce any products that involve dispersive uses of engineered nanoscale materials, until and unless they have developed and provided to EPA hazard and exposure information sufficient to allow it to identify, assess and address the lifecycle risks of the nanomaterials in products; and
b) handle all nanomaterials as hazardous materials, and manage all wastes containing such materials as hazardous wastes, until and unless they have developed and provided to EPA hazard and exposure information sufficient to allow it to identify, assess and address the lifecycle risks of the nanomaterials and wastes in manufacturing, or
c) commit to no additional agreements.

Issue #4: Safe Harbor

What kinds of safe harbor clarification for future actions should the agency provide NVPP participants?

a) Should EPA be expected to develop guidance (with public comment) regarding TSCA section 8(e) submissions for nanoscale materials, and as part of this effort consider safe harbor elements?
b) Should EPA develop an approach for dealing with situations where a person, in the course of NVPP participation, identifies and voluntarily discloses a potential violation under TSCA?
c) Safe harbor clarifications need to be further discussed and defined, and should not be included at this time.

ANNEX B: SCHEMATIC OF PROPOSED NVPP