Concept Paper for the Nanoscale Materials Stewardship Program under TSCA

Purpose: EPA has developed this draft concept paper including Annexes A-D to outline its initial thinking on the design and development of a Stewardship Program for nanoscale materials under the Toxic Substances Control Act (TSCA) (15 USC 2601). EPA will publish a Federal Register notice announcing the availability of this document and related documents (TSCA Inventory Status of Nanoscale Substances – General Approach, and a proposed Information Collection Request) for public comment. EPA also intends to conduct a public meeting to receive further input and comment on all aspects of the Stewardship Program. EPA will also collaborate with other agencies in the development of the program as appropriate.

1) Introduction and Summary

There is a growing class of materials commonly referred to as engineered nanoscale materials. Materials having structures with dimensions in the nanoscale (approximately 1-100 nanometers (nm)), also known as nanoscale materials or nanoscale substances, may have organizations and properties different than the same chemical substances with structures at a larger scale (See Annex A for a description of these terms).

Nanoscale materials that meet the TSCA section 3(2)(A) definition of "chemical substance" are subject to TSCA. TSCA provides EPA with a strong framework for ensuring that new and existing chemical substances are manufactured and used in a manner that protects human health and the environment**.** For more details on EPA's current oversight of nanoscale materials please consult the TSCA Framework Document. (Annex C)

EPA is developing a Nanoscale Materials Stewardship Program ("the program") to complement and support its new and existing chemical efforts on nanoscale materials. The program is intended to include but not limited to engineered nanoscale materials manufactured or imported for commercial purposes as defined in 40 CFR 720.3(r).

The program is intended to:

- Help the Agency assemble existing data and information from manufacturers and processors of existing chemical nanoscale materials;
- Identify and encourage use of risk management practices in developing and commercializing nanoscale materials; and
- Encourage the development of test data needed to provide a firmer scientific foundation for future work and regulatory/policy decisions.

- Encourage responsible development. [1]

This paper outlines proposed ideas for reporting on existing nanoscale materials in commerce, developing data on representative nanoscale materials and identifying risk management practices. The paper describes who may wish to participate and the reporting expectations for participants. It also generally describes what EPA intends to do with the data, what the program could entail, and why someone would choose to participate. It also describes the potential benefits of participation. These benefits include applying a stewardship approach to identify and adopt environmental health and safety practices throughout an industrial supply chain.

The stewardship program would help address some of the issues identified in EPA's Nanotechnology White Paper. The White Paper describes the issues that EPA should consider to ensure that society benefits from advances such as environmental protection that nanotechnology may offer, and to understand the environmental health and safety implications of nanoscale nanomaterials.

Participation in the program would not relieve or replace any requirements under TSCA that a manufacturer, importer, or processor of nanoscale materials may otherwise have.

2) Who would participate?

EPA envisions participation in the program by persons or entities that do or intend to do any of the following, with the 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
- Use engineered nanoscale materials in the manufacture of a product

The program is intended to encompass a broad range of participants who manufacture, process, use, or import types of nanoscale materials for commercial purposes as described above. Both new and existing substances (as determined by the status of the substance on the TSCA inventory of chemical substances), regardless of whether they qualify for exemptions or fall below a reporting or a notification threshold can be included in the

[1] One approach for describing 'responsible development' has been offered by the National Research Council (NRC) in the context of its first triennial review of the National Nanotechnology Program as required under Section 5(a) of the 21st Century Nanotechnology Research and Development Act. In that review, the NRC characterizes 'responsible development' "..as the balancing of efforts to maximize the technology's positive contributions and minimize its negative consequences. Thus, responsible development involves an examination both of applications and of potential implications. It implies a commitment to develop and use technology to help meet the most pressing human and societal needs, while making every reasonable effort to anticipate and mitigate adverse implications or unintended consequences." *A Matter of Size: Triennial Review of the National Nanotechnology Initiative*, The National Academies Press, p. 73 (2006)

program. Participation in the program would be voluntary. It will be left to the individual company to determine its suitability for participation. EPA is considering a program in two parts. One part, a "basic" program, would request participants to report all known or reasonably ascertainable information regarding specific nanoscale materials. The other part, an "in-depth" portion, would entail development of data as described in section 4. EPA expects that participants in the basic program could forward information as soon as the program is developed. Participants in the in-depth program would develop a plan and submit data over a longer period.

Annex A of this document gives further description and examples on who may wish to report and what materials they would report. The description of who would report is not meant to be exclusive.

3) Information to be Reported as Part of the Basic Program

The types of data that EPA has identified to be reported are detailed in Annex B of this document. These data include information on material characterization, hazard, use, potential exposures, and risk management practices. EPA intends to conduct a scientific peer consultation on material characterization to receive views and comments on the type of material characterization information to be reported for nanoscale materials. EPA will announce that meeting in a separate Federal Register notice. Also attached is a draft form for submission of the data. Participants would be encouraged but not required to use this form to submit information to the program. This form and the types of data to be reported are based on EPA's Premanufacture Notice Form and the information reported to EPA for new chemical substances under TSCA. EPA has also identified additional information that may be pertinent to nanoscale materials. More information is available about the data to be reported in the proposed Information Collection Request for the program.

EPA will request that participants provide all the information described in Annex B and the draft reporting form to the extent it is known or reasonably ascertainable. EPA is not requesting that participants develop additional data. If the information identified is not available or applicable to the nanoscale substance, participants simply would not submit those data. However, it would be informative for respondents to describe to EPA why the information is not available or applicable. EPA also encourages participants in the basic program to provide additional data as it becomes available. Each nanoscale material should be reported separately. If using the form, one form would be submitted for each nanoscale material. Participants who wish to identify nanoscale materials collectively will be requested to describe the parameters that form the basis for grouping.

As noted earlier, participation in the stewardship program would not relieve or replace any requirements under TSCA that a manufacturer, importer, or processor of nanoscale materials may otherwise have. If a manufacturer of a nanoscale material that is a new chemical substance under TSCA submits a premanufacture notification to EPA, they may also participate in the stewardship program by submitting the information to the program.

Alternatively, the manufacturer may notify EPA of the PMN submission of a nanoscale material it wants to include in the program.

Confidential Business Information (CBI)

Recognizing this is a program which involves voluntary submissions of information, EPA is advising potential participants in the stewardship program that submission of information under the program will constitute consent for the Agency to disclose this information as if it had been submitted under TSCA. Claims of confidentiality will therefore be handled pursuant to 15 U.S.C. section 2613 and 40 CFR parts 2 and 720. EPA has a long history of successfully handling and protecting TSCA CBI information.

EPA encourages participants to give careful consideration to what they will and will not claim CBI. EPA encourages participants to make as much data as possible available to the public. EPA will protect information claimed as CBI in accordance with procedures in 40 CFR parts 2 and 720. Under some circumstances, EPA may, where possible, share aggregated data with the public. To achieve EPA's mission of protecting human health and the environment, EPA has long been committed to integrating, in a meaningful way, the knowledge and opinions of others into its decision-making processes. As presented in EPA's Public Involvement Policy (Final May 2003), EPA believes that "effective public involvement can both improve the content of the Agency's decisions and enhance the deliberative process." One important aspect of EPA's strong commitment to transparency is involving stakeholders and the public in its decision-making processes.

Risk Management Practices

Participants in the basic program would agree to implement a risk management program that includes consideration of the nanoscale material(s). Participants would also agree to consider information provided by EPA that is relevant to risk management for nanoscale materials and to provide information about the risk management practices and other aspects of their risk management program that are relevant to nanoscale materials. On October 19-20, 2006, EPA conducted a scientific peer consultation on Risk Management Practices to receive public input in the development of these considerations. EPA will include input from this scientific peer consultation when developing risk management considerations (Final Meeting Summary Report, http://www.epa.gov/opptintr/nano/nanopublicmeetingsummaryfinaloct2006.pdf). EPA encourages anyone with additional information on risk management practices for nanoscale materials to submit the information to EPA. New information that EPA receives in the program or is available from other sources may result in EPA amending the information it considers relevant to risk management practices for nanoscale materials. EPA expects to further develop and communicate details on risk management practices following public comment but prior to initiation of the program.

4) In-depth Data Development

The program outlined above is the structure of a basic reporting phase. It identifies data that participants would submit if they are in the participant's possession or reasonably ascertainable as defined in 40 CFR720.3(p). The data and experience generated by the basic reporting phase including input from the program evaluation of the basic reporting phase will help to inform the types of in-depth data to be developed. In-depth data development could begin at any time and would entail a certain subset of those data in a greater amount of detail. In-depth data development could also include additional data if they are identified.

In-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. For example, EPA and program participants could review existing data, conduct preliminary assessments, and identify additional data needed to better characterize hazard, risk, and exposure issues for the material. Once these needs are identified, a plan of action would be agreed upon that could include:

- Characterizing the physical/chemical properties of the material;
- Testing for health and environmental hazards;
- Monitoring or estimating exposures and releases;
- Determining fate and transport characteristics;
- Evaluating the effectiveness of protective equipment or engineering controls;
- Developing a model worker education program; and
- Other evaluations agreed to under the plan of action.

In some cases, a particular company may choose to do one or more aspects of the plan, or a consortia of companies and other stakeholders may work together to implement aspects of the plan. The last three bullets above are specific examples where input from OSHA and NIOSH would be valuable. At the completion of the plan, EPA and participants, with input from stakeholders, would again meet to review the information gathered; conduct final assessments; and consider any further action. Any step that would go beyond what is called for in the plan would be considered on a case-by-case basis.

5) What Does EPA Plan To Do With the Data?

EPA will use the data 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. EPA scientists will use data collected through this program, where appropriate, to aid in determining how and whether certain nanoscale materials or categories of nanoscale materials may present risks to human health and the environment.

EPA may also use the information submitted to the program to make the following determinations:

- Identify the data that are missing to conduct an informed risk assessment of a specific nanoscale material. EPA may contact participants on a case-by-case basis to clarify if further data are available or why certain data were unavailable or not submitted.

- Identify 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.

If the data is confidential business information, it may also be used by other Federal agencies that have TSCA CBI clearance, in accordance with CBI procedures. Non-confidential portions of this information may be used by the public, academics, states, local and tribal government, as well as foreign governments and international organizations.

If the hazard, exposure, and risk data submitted by a participant indicate that potential risks may exist for a specific nanoscale material, the data will be used by EPA and the participant to determine the appropriate action necessary to avoid or mitigate the risks. EPA will address that situation on a case-by-case basis.

If the data submitted by a participant indicates that the participant is manufacturing a nanoscale material that is reportable under section 5 of TSCA (15 USC 2613) as a new chemical substance, EPA will immediately inform the participant of that situation and the applicable TSCA requirements (See Annex C for further discussion on TSCA Framework).

EPA may publish a summarized interim report approximately one year after initiation of the basic reporting phase of the program. The report will summarize to the extent possible considering CBI claims, 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.

EPA will also develop a more detailed report and evaluation of the program two years after initiation of the program. This report will also address any program evaluation criteria EPA develops based on public comment as well as how the stewardship program addressed the objectives identified in section 6 below. At that time EPA will determine the future direction of the basic reporting phase as well as in-depth data development..

After public comment and further development of the stewardship program, EPA will present a more detailed description of what it expects to do with the data received in the NMSP.

6) Why should I participate?

In the introduction to this paper EPA identified several objectives of the program:

- Help the Agency assemble existing data and information from manufacturers and processors of existing chemical nanoscale materials;
- Identify and encourage use of risk management practices in developing and commercializing nanoscale materials; and
- Encourage the development of test data needed to provide a firmer scientific foundation for future work and regulatory/policy decisions: and
- Encourage responsible development. [1]

EPA believes that participation in the program will encourage responsible development of nanoscale materials and will benefit all stakeholders. Development and sharing of data on nanoscale materials to the fullest extent possible will enhance each stakeholder's ability to make informed decisions regarding nanoscale materials. Applying a stewardship approach will help participants to identify and adopt environmental health and safety practices throughout an industrial supply chain. EPA is committed to an open and transparent process in the development and implementation of the stewardship program.

EPA is seeking comments and ideas on incentives for participation in the program and how it can identify and reach out to the many small and medium sized nanotechnology businesses. Many of these entities have limited experience with TSCA and limited resources to devote to environmental programs, including the stewardship program. EPA is considering a series of workshops for such businesses, to inform them of TSCA requirements as well as the stewardship program.

ANNEX A

Description of Nanoscale Materials for Reporting

1 Scope

1.1 Included Substances

The Nanoscale Materials Stewardship Program (hereafter "the Program") is intended to encompass any substance in a form with one or more dimensions in the nanoscale that has been manufactured or imported for commercial purposes. Under TSCA, commercial purposes also include research and development when there is a clear commercial intent. The program is open to both new and existing substances (as determined by the status of the substance on the TSCA inventory of chemical substances), regardless of whether they may qualify for any exemptions or fall below a reporting or a notification threshold.

1.2 Participants

EPA envisions participation in the program by persons or entities that do any of the following, with the intent to offer a commercially available product:

1. Manufacture or import engineered nanoscale materials
2. Physically or chemically modify an engineered nanoscale material
3. Physically or chemically modify a non-nanoscale material to create an engineered nanoscale material
4. Use engineered nanoscale materials in the manufacture of a product

1.3 Breadth

The program is intended to encompass a broad range of types of nanoscale materials and participants. Participation is voluntary. It will be left to the individual company to determine its suitability for and extent of participation.

2 Clarifications and Descriptions

2.1 "Engineered Nanoscale Material"

No official U.S. Government definition exists for the terms "engineered nanoscale material" and "nanoscale." The description given herein should not be considered to be definitive for any purpose other than for EPA's Nanoscale Materials Stewardship Program; this definition is only applicable within the context of the Program as a guideline for determining if a material is appropriate for inclusion in the Program.

Briefly, an "engineered nanoscale material" is any particle, substance, or material that has been engineered to have one or more dimensions in the nanoscale.

2.1.1 "Engineered"

The term "engineered" is intended to mean that the material is 1) purposefully produced and 2) purposefully designed to be a nanoscale material. The material may be produced from a "bottom-up" (i.e., through a process that causes atoms, ions, and/or molecules to bind together to form larger materials; e.g., Chemical Vapor Deposition) or a "top-down" (i.e., through a process that breaks down a macroscale material; e.g., ball milling) technique.

2.1.2 "Nanoscale"

The term "nanoscale" is generally used to refer to the scale measured in nanometers (1×10^{-9} meters). For the purposes of the Program, nanoscale is the size range between the atomic/molecular state and the bulk/macro state. This is generally, but not exclusively, below 100 nm and above 1 nm. Materials engineered to be in this size range can exhibit novel or enhanced properties.

2.1.3 Number of dimensions

For the purpose of the Program, any substance engineered with one or more dimensions in the nanoscale may be appropriate for inclusion in the program.

2.1.3.1 One-dimensional nanoscale materials

The category of "one-dimensional nanoscale materials"—that is, materials that have one dimension in the nanoscale and two dimensions larger than the nanoscale—may be divided into two:

1. Particles
2. Films and coatings.

One-dimensional nanoscale materials that exist as particles (for example, those having dimensions such as 50 nm x 1 μm x 1 μm) may be appropriate for inclusion in the Program.

It is generally assumed that films and coatings are not commercially available as such (that is, as a solid, thin sheet), but rather are available in a to-be-applied state (e.g., a mixture, solution or suspension, such as paint, that is to be applied to a surface) or are applied to another product, which is itself commercially available. To-be-applied films and coatings may also be divided into two categories:

1. Those containing engineered nanoscale materials
2. Those that do not contain engineered nanoscale materials (e.g., a chemical that will self-assemble into a one-dimensional nanoscale film or coating upon application and treatment)

To-be-applied films and coatings in the first category (containing engineered nanoscale materials) are intended to be included in the Program. To-be-applied films and coatings in the second category (not containing engineered nanoscale materials) are not intended to be included in the Program.

Products that have an already-applied nanoscale film or coating are not intended to be included in the Program.

2.2 "Nanotechnology"

There are three terms regarding "nanotechnology / nanotechnologies" that may be considered in the context of the Program: one developed by the International Standards Organization (ISO), one developed by the American Society for Testing and Materials (ASTM), and the other by the U. S. Government's National Nanotechnology Initiative (NNI).

The scope of the Program is tied to engineered nanoscale materials and not to the definition of nanotechnology. However, nanoscale materials are expected to be created by nanotechnology, and, as such, it may be instructive to consider these definitions in determining whether a material is an engineered nanoscale material.

2.2.1 ISO identified the scope of its technical committee, TC 229, as:

> Standardization in the field of nanotechnologies that includes either or both of the following:
>
> 1. Understanding and control of matter and processes at the nanoscale, typically, but not exclusively, below 100 nanometers in one or more dimensions where the onset of size-dependent phenomena usually enables novel applications.
> 2. Utilizing the properties of nanoscale materials that differ from the properties of individual atoms, molecules, and bulk matter, to create improved materials, devices, and systems that exploit these new properties.
>
> Specific tasks include developing standards for: terminology and nomenclature; metrology and instrumentation, including specifications for reference materials; test methodologies; modeling and simulation; and science-based health, safety and environmental practices.

2.2.2 NNI description of "nanotechnology"

The NNI has described nanotechnology in the following way:

> Nanotechnology is the understanding and control of matter at dimensions of roughly 1 to 100 nanometers, where unique phenomena enable novel applications. Encompassing nanoscale science, engineering and technology, nanotechnology

involves imaging, measuring, modeling, and manipulating matter at this length scale. (http://nnco5.nano.gov/html/facts/whatIsNano.html)

2.2.3 ASTM definition of "nanotechnology"

ASTM defines nanotechnology as:

> A term referring to a wide range of technologies that measure, manipulate, or incorporate materials and/or features with at least one dimension between 1 and 100 nanometers. Such applications exploit the properties, distinct from bulk/macroscopic systems, of nanoscale components.

3 Examples

The list of examples given herein should not be considered exhaustive, but rather, should serve as guidance in determining whether a material is appropriate for inclusion in the Program.

3.1 Examples of materials that would be appropriate for inclusion in the Program:

- Metal (e.g., Au, Ag, etc.) or metal oxide (e.g., TiO_2, SiO_2) nanoparticles, quantum dots, nanotubes, nanowires, etc., including those with core-shell structures (e.g., SiO_2 coated with Au)
- Carbon fullerenes ("buckyballs") and nanotubes (i.e., C_n, where $n \geq 28$)
- Polymeric dendrimers (three dimensional polymers)
- Materials derived from natural sources and further processed to produce nanoscale-sized materials

3.2 Examples of materials that would not be appropriate for inclusion in the Program:

- Materials that have one or more dimensions smaller than the nanoscale and/or are commonly considered organic molecules that only extend into the nanoscale by virtue of having approximately 10 or more atoms covalently bonded in a chain or a planar network. Examples:
  1. Polymers or oligomers, particularly linear or planar polymers, wherein one or two dimensions may be in the nanoscale or larger. Polymers are explicitly excluded, when enough polymeric units or polymer molecules are bound together to create macroscale materials. E.g., polyethylene, polystyrene, polyvinyl alcohol, polydimethylsiloxane.
     a. Exceptions may be made when conditions of polymerization or post-reaction processing have created free particles that otherwise fit the general description "engineered nanoscale material."
     b. Exceptions will be made for polymeric dendrimers
  2. Heavy Fuel Oils
  3. Organic dyes

- Materials that only exist as a nanoscale material when in solution should not be included. Examples:
  1. Surfactant micelles
  2. Salts
  3. Soluble linear or planar polymers

- Biological materials (e.g. DNA, RNA, proteins). (The National Institutes of Health (NIH) has issued a corollary that generally excludes purely biological materials from the definition of nanotechnology while acknowledging that many biological materials fall within the range of the nanoscale.)

- Materials that would be regulated solely by statutes other than TSCA would not be included in the program. If such materials are submitted to the Program, the submitter will be advised to also contact the appropriate office or other Federal agency. Examples:
  1. Materials that would fall under the authority of FDA (intended food additives, pharmaceuticals, medical devices, cosmetics)
  2. Materials that would fall under the authority of FIFRA (intended pesticides)
  3. Explosives
  4. Certain radioactive materials

3.3 Examples of size-dependent, novel, or enhanced properties:

- Surface area that is dramatically increased in comparison to the bulk material
- Reactivity that dramatically differs from the molecular or bulk material
- Solubility or suspend-ability that differs dramatically in comparison to molecular or bulk material
- Absorption, transmission, emission, and/or fluorescence spectra that differ substantially in wavelengths and/or intensity from the molecular or bulk material
- Paramagnetism
- Ability to cross typical physiological barriers, such as skin, blood-brain barrier, placenta, and cell membranes
- Toxicity that differs from the bulk material
- Characteristics (e.g., strength, absorption of light) of a macroscale material (e.g., composite) that differ markedly when it is made from the nanoscale material

ANNEX B

DATA ELEMENTS

1. General Notes

Participation in the Program is voluntary. EPA would request that all relevant information that is known or reasonably ascertainable by the participant be submitted. EPA would also encourage participants in the basic program to provide additional data as it becomes available. EPA will protect information claimed as CBI in the same manner as CBI submitted under TSCA in accordance with procedures in 40 CFR parts 2 and 720

A data submission form has been developed for the Program, which is based on the standard PMN submission form. Submitters are encouraged but not required to use this form to submit information to the Program.

2. Types of Data

The types of data being collected in the Program fall into these broad categories:

1. General information about the submitter
2. General / identifying information about the substance
3. Production, importation, and use information
4. Exposure information
5. Risk management practices
6. Hazard information
7. Pollution Prevention information
8. Physical and chemical properties

2.1. General Information about the Submitter

- Company name and contact information
- Name and contact information of authorized official, agent, and technical contact, as appropriate

2.2 General / identifying information about the substance

- Chemical name
- Common or trade name
- Molecular formula and structure
- Chemical identity (e.g. CAS number)
- Reactants / monomers
- Impurities and byproducts resulting from manufacture, process, use or disposal

2.3 Production / importation information

- Total amount of substance to be manufactured / imported
- Amount of substance manufactured / imported for each use category
- Operational description

- Current state of manufacture / importation and commercial availability

2.4 Exposure information and risk management practices
(**includes input from the October 2006 EPA Risk Management Practices for Nanoscale Materials Scientific Peer Consultation**)

- Overview of the lifecycle
    - All facilities and processes used in manufacturing and processing
    - All uses including expected consumer uses
    - Disposal of byproducts and end products
- Number of people (e.g. workers, consumers) who may be exposed
- Activities resulting in exposure
- Duration of exposure
- Environmental releases including amounts and medium of release
- Environmental fate and transport
- Exposure monitoring techniques and data
- Control technology and rationale for their use at each release point
- Data and measurement methods of waste treatment or purification efficiency studies
- Additional procedures or equipment intended to mitigate exposures
- Worker training
- Hazard communication (e.g. MSDS)
- Engineering controls and rationale for their use
- Personal protective equipment (PPE) and rationale for their use
- Cleaning, reuse, and disposal of equipment, including engineering controls and PPE

2.5 Hazard information including any test data on:

- Health/environmental effects
- Bioaccumulation / biomagnification
- Biodegradation
- Fate and transport

2.6 Pollution prevention information

- Information that may be used to assess overall net reductions in toxicity or environmental releases and exposures

2.7 Physical and chemical properties

2.7.1 Properties found on standard PMN form

- Physical state
- Vapor pressure
- Density
- Solubility in water or other solvents
- Melting temperature
- Boiling/sublimation temperature

- Spectra
- Dissociation constant
- Octanol/water partition coefficient
- Henry's Law constant
- Volatilization from water and soil
- pH
- Flammability / Explodability
- Adsorption coefficient

2.7.2 Properties specific to nanoscale materials:
(**will include input from future EPA Materials Characterization scientific peer consultation **).

- General description of unique or enhanced properties related to nanosize
- Crystal structure
- Agglomeration state/dispersion state
- Particle size, shape, and mass
- Surface area, charge, and chemical composition
- Porosity
- Diffusion
- Gravitational settling
- Sorption
- Wet and dry transport
- Influence of Redox and photochemical reaction
- Mobility through soil

2.7.3 Obtaining the data

- Methods and equipment used to obtain data
- Cost of obtaining the data
- Reasons for not collecting data

ANNEX C

OPPT TSCA Framework

TSCA is a multi-media statute bridging the more narrow focus of media specific statutes. TSCA applies to "chemical substances." Nanoscale materials which meet the TSCA definition of "chemical substances" are subject to TSCA. For the purposes of the Concept Paper, "nanoscale materials" refers to chemical substances where one or more dimensions are in the length scale of approximately 1 to 100 nanometers (i.e., nanosized). They may also exhibit unique properties that are different from those exhibited by the same substances as bulk material and are usually the result of deliberate control of matter to produce the substance at the nanoscale. Several provisions of TSCA make it an effective EPA tool for assessing and managing potential risks of nanoscale materials.

TSCA authorizes EPA to:

- Receive notifications, assess, and manage risks of new chemicals, i.e., those chemicals not currently in commerce, which are not on the TSCA Chemical Substances Inventory. (TSCA §5).
- Manage existing chemicals which present "unreasonable risks," which is a standard under which EPA considers both costs and benefits of a proposed action. (TSCA §6).
- Define through rulemaking "significant new uses" of chemical substances and require notification to the Agency prior to such "significant new uses." EPA then has an opportunity to assess and manage risks associated with those notified uses in a manner similar to that used for new chemicals. (TSCA §5(a)(1)(B)).
- Receive statutorily required notifications of "substantial risk" information from chemical manufacturers, processors, and distributors. (TSCA §8(e)).
- Require manufacturers and processors of chemical substances to submit lists or copies of reasonably ascertainable health and safety studies (TSCA §8(d)).
- Require manufacturers and processors to develop new test data on chemicals. (TSCA §4).
- Require manufacturers and processors to report information on chemical use and exposures and other information. (TSCA §8(a)).

"Chemical substance" as defined under TSCA does not include certain substances in specified circumstances such as drugs and pesticides as defined under other authorities when manufactured, processed or distributed in commerce for use as drugs or pesticides (TSCA §3(2)(b)).

1. New Chemicals

TSCA §5 facilitates EPA consideration of potential health and environmental risks before a chemical substance is manufactured for commercial purposes. TSCA §5 requires persons to give EPA a 90-day advance notice of their intent to manufacture or import a new substance not listed on the TSCA Inventory. TSCA §5 also authorizes EPA to

designate a specific use of a new chemical as a "significant new use" through a significant new use rule (SNUR). In addition to requirements and procedures for the submission of Premanufacture Notices (PMNs), exemption notices can also be submitted under certain circumstances. These exemptions include among others: (1) a low volume exemption (LVE), (2) a low release and exposure exemption (LoREx), (3) a polymer exemption, (4) exemption for R&D purposes, and (5) a test marketing exemption (TME).

For any new chemical submission a review is conducted by EPA. During this review, additional information may be requested from the submitter as appropriate (e.g., material characterization, engineering controls and on-site treatment information) to help in assessing potential risk from manufacture and use of the new chemical. Because use of current modeling tools may be limited for some nanoscale materials, qualitative assessments would be prepared by EPA where appropriate. The need and options for possible control measures of the new nanoscale material are presented at an OPPT Decision Meeting. Decisions on each submission are determined on a case-by-case basis, using the criteria in TSCA §5 and in the relevant EPA regulations at 40 CFR parts 720, 721 and 723.

2. Existing Chemicals

Chemical substances listed on the TSCA Inventory are considered to be "existing chemicals" (including new chemicals that have been reviewed by EPA, manufactured, and then added to the Inventory). Under TSCA section 6, EPA has the authority to prohibit or limit the manufacture, import, processing, distribution in commerce, use, or disposal of a chemical if there is a reasonable basis to conclude that the chemical "presents or will present an unreasonable risk" of injury to health or the environment. "Unreasonable risk" is a risk-benefit standard. In order to regulate under section 6, EPA must consider the effects of the substance on human health and the environment, the benefits of the substance and the availability of substitutes, and the reasonably ascertainable economic consequences of the contemplated action. Section 6(a) of TSCA requires that the Administrator use the "least burdensome" regulatory measures that protect adequately against risk.

Reporting on Significant New Uses

EPA can also issue a SNUR for an existing chemical substance. To promulgate such a SNUR, EPA needs to find that a use or uses of an existing chemical substance, in this case a nanoscale material, constitutes a significant new use. This involves considering a series of statutory factors in the context of the chemical substance (e.g., projected volume of manufacturing and processing; extent to which a use changes the type, form, or magnitude and duration of exposure; the reasonably anticipated manner and methods of manufacturing, processing, etc.). In developing such a regulation, EPA also typically considers potential hazards or risks and might identify testing that would help to characterize the health or environmental effects of the chemical substance. The effect of such SNURs is to funnel subject chemical substances into a notification and review process that, as a starting point, is similar to that used for new chemicals but can be

tailored to meet the needs of the new use. Regulatory actions (including testing and control measures) similar to those for new chemicals can be taken if the appropriate regulatory findings are made.

Reporting on Production and Use Information and Health and Safety Information

As an alternative or in addition to the use of SNURs, EPA can issue a TSCA section 8(a) rule to obtain reporting of information on, among other things, the manufacture or processing of an existing chemical. EPA could also consider issuing a TSCA section 8(d) rule to obtain reporting on existing health and safety information on nanoscale materials**.**

Reporting of Information on Substantial Risks

Section 8(e) of TSCA requires that chemical manufacturers, processors, and distributors notify EPA of information that "reasonably supports the conclusion that a chemical substance or chemical mixture presents a substantial risk of injury to human health or the environment." Section 8(e) reports most often contain toxicity data or product/environmental contamination data but may also contain information on exposure, environmental persistence or actions being taken to reduce human health and environmental risks. The information submitted may be either full reports of studies known to the submitter or summarized results on commercial or research & development chemicals. TSCA section 8(e) data are made publicly available (excluding any Confidential Business Information).

ANNEX D

Issues and Challenges

A. Definitions of Nanotechnology and Nanoscale Materials.

The NNI describes nanotechnology as "The understanding and control of matter at dimensions of roughly 1 to 100 nanometers, where unique phenomena enable novel applications." Although the various agencies and departments participating in the NNI have made use of this definition, there are potentially a number of challenges to be worked out in attempting to determine whether, and if so how, to apply it for regulatory or other programmatic purposes, e.g., what the terms "unique phenomena" and "novel applications" mean. In addition, other bodies such as the American Society for Testing and Materials Nanotechnology Committee (ASTM E56), the American National Standards Institute- Nanotechnology Standards Panel (ANSI-NSP), and the U.S. Technical Advisory Group to the Technical Committee on Nanotechnology of the International Standards Organization (US TAG to ISO TC 229) are working on nanotechnology definitions. In December 2006, ASTM issued standard terminology relating to nanotechnology. At some point it may be appropriate for EPA to offer one or more definitions, possibly accompanied by guidance, for programmatic and/or regulatory purposes.

B. Limitations of Current Knowledge Base.

The knowledge base of nanotechnology environmental health and safety implications is limited. A combination of approaches is being utilized to help fill the gaps (identified through such sources as the EPA White Paper and NNI research strategy). These include research under the NNI, testing by National Toxicology Program, National Institute of Environmental Health Sciences, National Institute of Occupational Safety and Health and others, Science To Achieve Results grants and budding in-house programs in ORD, academic and corporate research. This would also include possible testing and/or other data submissions required by OPPT under the new chemicals program or other means and testing by other countries which is shared with the US (e.g. via the Organisation for Economic Co-operation and Development (OECD)). However, at present the lack of a robust dataset leads to challenges in the risk assessment of and decision-making on nanoscale materials.

C. Inventory Status.

It will be important for the Agency to determine the extent of coverage of nanoscale materials by the new chemicals provisions of TSCA. The PMN provisions of TSCA offer a solid foundation for review and decision-making on nanoscale materials. However, questions have been raised regarding the extent to which nanoscale materials have molecular identities that are the same as or different from those of chemicals listed on the TSCA Inventory. Such information would be valuable for the Agency in determining the scope of any program that might be desirable in addition to the review of

nanoscale materials under Section 5 of TSCA. It would also be helpful to industry to assist in determining compliance. The draft EPA document, TSCA Inventory Status of Nanoscale Substances – General Approach, presents for comment EPA's current views regarding this issue.

D. International.

A number of international activities are occurring in parallel to OPPT activities, for example the development of voluntary programs in the United Kingdom and Germany, work under the OECD Working Party on Manufactured Nanomaterials to harmonize test guidelines and burden-share the costs of testing nanoscale materials, and standards-setting work under ISO. It will be important for OPPT to stay abreast of, and where appropriate provide leadership to certain aspects of this work. Many of the results, e.g., in the development of OECD test guidelines and ISO standards, may have an impact on OPPT's work on nanotechnology including the stewardship program.

E. Data Scope Issues.

When receiving or requiring data, e.g., from manufacturers, there is a wide variety of data that could be requested. For example, the International Life Sciences Institute report, (ILSI 2005)[2] a report developed by an expert working group sponsored by EPA to develop a screening strategy for the hazard identification of engineered nanomaterials, lists some 30 possible endpoints just for material characterization. It will be important for OPPT to define appropriate data sets or tiers of data that would be useful to better understand nanoscale materials, including material characterization, human health hazard, environmental hazard, release and fate, and exposure.

F. Testing and Test Guidelines.

It is not clear whether existing TSCA or OECD methods and test guidelines need to be modified for use with nanoscale materials. Existing methods may in some cases need to be validated, and newer methods, such as work in advancing *in vitro* methodologies, may be desirable. Specific materials characterizations issues for nanoscale materials could come up in this context. A certain amount of this work will likely take place under the OECD Working Party on Manufactured Nanomaterials, but certain aspects should also be addressed by EPA. The EPA Science Policy Council White Paper addresses a number of these areas, including chemical identification and characterization, environmental fate, environmental detection and analysis, potential releases and human exposures, human

[2] ILSI 2005 - International Life Sciences Institute (ILSI) Research Foundation/Risk Science Institute, Principals for Characterizing the Potential Human Health Effects From Exposure to Nanomaterials: Elements of a Screening Strategy. Particle Fibre Toxicol. 2:8

health effects and ecological effects. It will also be important to look for opportunities to develop predictive models.

G. Risk Assessment Methodology.

At present, the state of the art of assessing the risk of nanomaterials is still evolving. This capacity will need to rely on continuous improvement based on practical experience reviewing nanoscale materials (e.g., as new chemical submissions) and review and consideration of the efforts of others (e.g., in the published literature, through the OECD, and to the extent such reviews are undertaken by other programs or agencies). Where feasible, initiatives should be undertaken to help further build this capacity. For example, ORD and OPPT are jointly producing risk assessment case studies on selected nanoscale materials.

H. Pollution Prevention Benefits

A number of nanoscale materials are likely to have environmental benefits, including pollution prevention benefits. It will be important for OPPT to appropriately recognize the emerging pollution prevention opportunities presented by nanotechnology. In this regard a joint OPPT/ORD conference on the pollution prevention benefits of nanotechnology is being planned and will be announced in the Federal Register.

I. Materials Characterization

As already described in paragraph E, further work remains to be done in identifying the characteristics by which nanoscale materials or subgroups of nanoscale materials will be described. These characteristics will be important for identifying various forms of nanoscale materials and the appropriate methods to measure, evaluate, and test them.