

## ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPPT-2004-0122; FRL-8344-5]

### Nanoscale Materials Stewardship Program

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice.

**SUMMARY:** This document describes the design and format of EPA's Nanoscale Materials Stewardship Program ("the program") for nanoscale materials under the Toxic Substances Control Act (TSCA). On July 12, 2007, EPA sought public comment on a concept paper that outlined its initial thinking on the design and development of the program, and several related documents. Based on ideas in the concept paper, written public comments, comments at public meetings, and scientific peer consultations on material characterization and risk management practices, EPA has developed this document to provide the final description and format of the program. EPA will consider refinements to the program over time based on experience and additional feedback from participants.

**FOR FURTHER INFORMATION CONTACT:** For general information contact: Colby Lintner, Regulatory Coordinator, Environmental Assistance Division (7408M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 554-1404; e-mail address: [TSCA-Hotline@epa.gov](mailto:TSCA-Hotline@epa.gov).

For technical information contact: James Alwood, Chemical Control Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 564-8974; e-mail address: [alwood.jim@epa.gov](mailto:alwood.jim@epa.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. General Information

###### A. Does this Action Apply to Me?

You may be potentially affected by this action if you manufacture, import, process, or use nanoscale materials that are chemical substances subject to the jurisdiction of TSCA. Potentially affected entities may include, but are not limited to:

- Chemical manufacturers (NAICS code 325), e.g., persons manufacturing, importing, processing, or using chemicals for commercial purposes.

- Petroleum and coal product industries (NAICS code 324), e.g., persons manufacturing, importing, processing, or using chemicals for commercial purposes.

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected, such as researchers who develop and/or study nanoscale materials. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. To determine whether you or your business may be affected by this action, you should carefully examine the descriptions in Unit II. If you have any questions regarding the applicability of this action to a particular entity, consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

###### B. How Can I Get Copies of this Document and Other Related Information?

1. *Docket.* EPA has established a docket for this action under docket identification (ID) number EPA-HQ-OPPT-2004-0122. All documents in the docket are listed in the docket's index available at <http://www.regulations.gov>. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available electronically at <http://www.regulations.gov>, or, if only available in hard copy, at the OPPT Docket. The OPPT Docket is located in the EPA Docket Center (EPA/DC) at Rm. 3334, EPA West Bldg., 1301 Constitution Ave., NW., Washington, DC. The EPA/DC Public Reading Room hours of operation are 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding Federal holidays. The telephone number of the EPA/DC Public Reading Room is (202) 566-1744, and the telephone number for the OPPT Docket is (202) 566-0280. Docket visitors are required to show photographic identification, pass through a metal detector, and sign the EPA visitor log. All visitor bags are processed through an X-ray machine and subject to search. Visitors will be provided an EPA/DC badge that must be visible at all times in the building and returned upon departure.

2. *Electronic access.* You may access this **Federal Register** document electronically through the EPA Internet under the "**Federal Register**" listings at <http://www.epa.gov/fedrgstr>.

## II. Nanoscale Materials Stewardship Program Introduction

EPA is implementing its Nanoscale Materials Stewardship Program "the program" to complement and support its new and existing chemical efforts on nanoscale materials under the Toxic Substances Control Act (TSCA) (15 U.S.C. 2601). The program is to include but is not limited to engineered nanoscale materials (also known as nanoscale materials or nanoscale substances) manufactured or imported for commercial purposes as defined in 40 CFR 720.3(r).

With this document, EPA is inviting interested parties to participate in a "basic" program by submitting existing data on the engineered nanoscale materials they manufacture, import, process, or use. To help participants compile existing data and provide available information in a consistent format, EPA has developed an optional form for participants to use. The Agency is also inviting interested parties to participate in an "in-depth" program to test engineered nanoscale materials they manufacture, import, process, or use.

EPA intends to publish a summarized interim report approximately 1 year after the initiation of the program that will be based on data reported during the first 6 months of the basic program. EPA will then develop a more detailed report that reflects its evaluation of the program approximately 2 years after initiation of the program.

##### A. Background

The Nanoscale Materials Stewardship Program is intended to:

- Help the Agency gather existing data and information from manufacturers, importers, processors, and users of existing chemical nanoscale materials to build EPA's knowledge base in this area.
- Identify and encourage use of risk management practices in developing and commercializing nanoscale materials.
- Encourage the development of additional test data needed to provide a firmer scientific foundation for future work and regulatory/policy decisions.
- Encourage responsible development of nanoscale materials.

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 (Public Law 108–153). 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.” (Ref. 1)

On July 12, 2007, EPA released for public comment a Concept Paper for the Nanoscale Materials Stewardship Program under TSCA, (“concept paper”), a draft TSCA Inventory Status of Nanoscale Substances—General Approach, (“TSCA Inventory Paper”) (72 FR 38083) (FRL–8139–2), and a proposed Information Collection Request (ICR) (72 FR 38079) (FRL–8140–2) regarding the stewardship program. Based on the information in those documents and public comments, EPA is announcing the final format of the stewardship program.

This document describes the process for reporting on existing chemical nanoscale materials under the program, reporting on risk management practices for those nanoscale materials, and developing data on representative nanoscale materials. This document also describes the factors that interested parties could consider in deciding whether to participate in the program, what EPA will do with the data, and how it will report on and evaluate the program. It also describes the potential benefits, incentives, and EPA outreach activities that could affect participation in the program.

EPA reminds participants that participation in the program does not relieve or replace any requirements under TSCA that a manufacturer, importer, processor, or user of nanoscale materials may otherwise have.

EPA received numerous public comments supporting the stewardship program. Several commenters did not support developing a voluntary program because they wanted EPA to focus on issuing TSCA regulations regarding nanoscale materials. Other commenters asked EPA to consider issuing regulations under TSCA while implementing the program; they mentioned using information gathering authorities under section 8 of TSCA or its significant new use authority under

section 5(a)(2) of TSCA. One specific commenter noted that the National Pollution Prevention and Toxics Advisory Committee (NPPTAC) overview document (Ref. 2) recommended that EPA initiate activities to utilize TSCA section 8(a) and 8(d) to complement any voluntary program it considers. While implementing the program, EPA will continue to consider, as appropriate, the timing and use of all of its authority under TSCA for nanoscale materials.

EPA also received numerous public comments either supporting or not supporting the approach outlined in the TSCA Inventory Paper. Commenters who did not support EPA’s approach stated, among other things, that the Agency should consider physical characteristics when determining new versus existing chemical nanoscale materials under TSCA. However, the information provided by commenters has in large part already been considered by EPA, and did not, in the Agency’s judgment, compel modification of the basic approach described in the TSCA Inventory Paper as previously issued for comment. Therefore, this approach will remain unchanged. EPA has developed a response to comments document for the public comments received regarding the TSCA Inventory Paper that is available in the public docket for this announcement.

EPA received several public comments on changes it should make to the concept paper, including definitions, materials that should or should not be included in the program, types of participants, and additional data elements that could be reported under the program. Rather than revise the concept paper EPA will continue to use it as a description of who EPA envisions participating and what nanoscale materials they would report, and has referenced the concept paper in the following paragraphs.

EPA received only a few minor comments on the ICR, which only resulted in minor amendments to the ICR that did not affect the overall substance of the ICR. For example, EPA amended the worksheet to the optional form by listing additional physical and chemical properties that could be relevant to nanoscale materials, and revised the form to clarify instructions and the presentation of requested information. The revised ICR was submitted to OMB for approval and underwent additional public comment as part of its submission to OMB under the Paperwork Reduction Act (72 FR 63175, November 8, 2007) (FRL–8493–

9). The ICR is discussed in more detail in Unit III. of this document.

### *B. Program Participants*

The program encompasses participants who manufacture, process, use, or import nanoscale materials for commercial purposes, including those who:

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

Others, including researchers who develop or study engineered nanoscale materials may also participate. Any participation in the program is voluntary. Both new and existing chemical substances (as determined by the status of the substance on the TSCA inventory of chemical substances) can be included in the program, regardless of whether they qualify for exemptions from TSCA new chemical reporting.

Annex A of the concept paper further describes and provides examples regarding who could report and the types of materials that could be reported. The description is not meant to be exclusive. EPA received public comments on changes it should make to Annex A of the concept paper, including definitions or materials that should or should not be included in the program. EPA has not attempted to make definitive boundaries for reporting nanoscale materials under the program. The Agency has given examples and definitions in the concept paper to describe those nanoscale materials that may be reported under the program. EPA encourages anyone who manufactures, imports, processes, or uses nanoscale materials as described in Annex A of the concept paper and has pertinent information as described in Annex B of the concept paper or the ICR to participate in the program. If you have further questions please consult the person listed as the technical contact under **FOR FURTHER INFORMATION CONTACT**.

### *C. Program Components*

EPA will implement the program in two parts. One part, a basic program, invites participants to report all known or reasonably ascertainable information regarding specific nanoscale materials, including risk management practices. Under the basic program EPA encourages participants to forward available data on nanoscale materials to

the Agency within 6 months of today's announcement of the program. Data received within the 6-month period will be used in preparing the interim report on the program. Participants may continue to submit new data that become available on any nanoscale material reported to EPA during the initial 6-month period. Participants may also identify additional nanoscale materials for which they may choose to submit information under the basic program.

The other part, an in-depth program, entails development of data. EPA is inviting participation in the in-depth program through this notice. Participants in the in-depth program would develop a plan and submit data over a longer period of time to be determined in the plan. EPA intends to conduct both the basic and in-depth program for the next 2 years although it may make adjustments or decide on future steps or direction of the program at an earlier point as sufficient experience is gained. For example, some testing initiated under the in-depth program is likely to extend beyond the 2-year point.

1. *Basic program.* The types of data that EPA has identified for reporting are detailed in Annex B of the concept paper and the ICR. These data include information on material characterization, hazard, use, potential exposures, and risk management practices. On September 6–7, 2007, (Ref. 3), EPA conducted a public scientific peer consultation on material characterization to receive views and comments on the type of material characterization information to be reported for nanoscale materials under the stewardship program. Comments from the scientific peer consultation and other public comments generally agreed with the types of data detailed in Annex B of the concept paper and the ICR. Several commenters also noted that not all data would be applicable to all nanoscale materials. EPA agrees and expects that participants will submit only data that are pertinent to their particular nanoscale materials.

Participants may provide data in any format or on any form that they choose; however, EPA has also developed an optional data submission form for participants. The optional form was developed based on the Agency's Premanufacture Notice (PMN) Form (EPA Form No. 7710–25) that is used for reporting to EPA regarding new chemical substances under TSCA. The optional form is designed for manufacturers and importers of chemical substances and EPA does not expect that researchers or other

interested parties will fill out the entire form. The optional form identifies additional physical and chemical properties that may pertain to characterizing and evaluating nanoscale materials. Participants are encouraged but not required to use this form to submit information to EPA. Based on EPA's experience with the PMN form, it will be easier for EPA to evaluate the information if the optional reporting form is used.

Several commenters stated that filling out the entire form could be a burden, especially to small and medium-sized businesses not familiar with TSCA. While participants are encouraged to submit as much data and explanation as possible, they are not required to fill out the entire form to participate in the program. Nonetheless, the more complete the information provided to EPA, the greater benefit to both EPA and program participants (who may receive feedback from the Agency). More information is available about the data to be reported in the ICR for the program.

EPA invites participants to provide the information described in Annex B of the concept paper, the ICR, and the reporting form to the extent it is known or reasonably ascertainable to them. EPA is not requesting that participants in the basic program develop additional data. If the information identified is not available or applicable to the nanoscale material, participants would not submit those data. EPA encourages participants in the basic program to provide additional data if and when they become available. It would also be informative for participants to describe why information is not available or applicable. EPA requests that each nanoscale material be reported separately. If using the form, one form would be submitted for each nanoscale material. Participants who wish to identify nanoscale materials collectively, e.g. submit one form for a group of similar nanoscale materials, are requested to describe the parameters that form the basis for grouping.

EPA received numerous public comments regarding the need to establish target dates for submission of data under the program, noting that some participants in voluntary initiatives often wait until the latter stages of the program before submitting data or otherwise participating. Commenters suggested targets ranging from 3 to 9 months for submitting data under the basic program while allowing for a more flexible approach under the in-depth program. In response to these public comments, EPA is establishing a target of 6 months from today for

participants to report under the basic program. In conducting its interim evaluation as described in Unit II.F., EPA intends to consider only data reported within the first 6 months of the program. In addition, the more data EPA receives during this 6-month period the easier it will be to fully integrate those data into the more comprehensive 2-year report. Data submitted during the first 6 months of the program will be a factor when the Agency considers whether to use regulatory information gathering authority under TSCA.

As noted earlier, participation in the stewardship program does not relieve or replace any requirements under TSCA that a manufacturer, importer, processor, or user of nanoscale materials may otherwise have. Manufacturers or importers who want further guidance on determining the Inventory status of specific nanoscale materials or submitting PMNs should consult the person listed as the technical contact under **FOR FURTHER INFORMATION CONTACT**. Where, for example, there is a requirement to submit a PMN, participation in the program would not satisfy this requirement; a separate PMN would need to be filed. If a manufacturer of a nanoscale material that is a new chemical substance under TSCA submits a premanufacture notification to EPA, they are encouraged to also participate in the stewardship program by submitting that information to EPA. Alternatively, the PMN submitter may simply notify EPA of the PMN submission of a nanoscale material it wants to include in the stewardship program.

2. *In-depth program.* The data and experience generated by the basic program, including input from the interim program evaluation will help to inform the types of in-depth data that need to be developed. In-depth data development will likely apply to a smaller set of representative nanoscale materials designated for further evaluation by participants who agree to sponsor the development of data for a particular nanoscale material. EPA and the sponsor(s) would sort through the data development approach and elements. For example, EPA and the sponsor(s) can review existing data, conduct preliminary assessments, and identify additional data needed to better characterize hazard, risk, and exposure issues for the material. Once testing has been identified, and considering input from stakeholders, EPA and the sponsor(s) will jointly develop a plan of action that could include:

- Characterizing the physical/chemical properties of the material.

- Testing for health and environmental hazards.
- Determining fate and transport characteristics.
- Monitoring or estimating exposures and releases.
- Evaluating the effectiveness of engineering controls and protective equipment.
- Developing a model worker education program.
- Other evaluations and/or actions as appropriate.

In some cases, a particular sponsor may choose to implement one or more aspects of the plan, or a consortium of sponsors and other stakeholders may work together to implement aspects of the plan. The last three bullets are specific examples of areas where input from the Occupational Safety and Health Administration and the National Institute of Occupational Safety and Health would be valuable. At the completion of the plan, EPA and sponsors, considering input from stakeholders, will again review the information gathered; conduct final assessments; and consider any further action.

Entities who want to participate in the in-depth program would notify EPA as described further in Unit II.H. As soon as potential sponsors are identified, EPA will coordinate the process for in-depth data development. EPA will begin to coordinate meetings for the in-depth program 90 days after announcement of the program. To avoid duplication of testing, the in-depth program will be coordinated with EPA's research program, other federal testing and research programs, and internationally through the Organization for Economic Cooperation and Development's Working Party on Manufactured Nanomaterials. EPA will also coordinate with the Canadian government to encourage participation of Canadian companies in the in-depth program or participation of American companies in Canadian data development activities which will allow joint development and sharing of data by both countries.

#### D. CBI

Recognizing that this is a program that involves voluntary submissions of information and that the application of TSCA to all the data submitted in connection to the program cannot be determined in advance, EPA is advising participants in the stewardship program that submission of information under the program will constitute consent for the Agency to treat this information as if it had been submitted under TSCA. Claims of confidentiality will therefore be handled in accordance with 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 information they will and will not claim as CBI. EPA encourages participants to make as much data as possible available to the public. The more information that is available to the public, the more transparent EPA will be able to be in demonstrating benefits and knowledge learned from the stewardship program. Under some circumstances, EPA will also, where possible, share aggregated data with the public. One important aspect of EPA's strong commitment to transparency is involving stakeholders and the public in its programs and processes.

With permission of the submitting company, EPA would also share CBI with other governments who agree to protect the information from disclosure in an appropriate manner. EPA has included a box to check on the reporting form if participants are willing to allow such sharing. EPA would contact a participant before releasing any data and provide the reasons for doing so. One possible purpose for sharing data would be to improve consistency of approaches among trading partners while protecting CBI and maintaining a consistently high level of health and environmental protection. If the data are 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 governments, as well as foreign governments and international organizations.

#### E. Risk Management Practices

The objectives of typical risk management programs are to consider alternatives to minimize or eliminate exposures and releases of hazardous materials. In its ("Approaches to Safe Nanotechnology - An Information Exchange with NIOSH"), NIOSH stated in the executive summary: "Given the limited amount of information for determining if engineered nanoparticles pose an occupational health risk, it is prudent to take precautionary measures to minimize worker exposures" (Ref. 4). Recognizing the uncertainties surrounding the evolving science and technology of nanoscale materials, EPA also encourages use of exposure mitigation practices for nanoscale materials.

EPA invites each participant in the basic program to submit available data on risk management practices for nanoscale materials it manufactures, imports, processes, or uses. A participant who has already developed a risk management plan is invited to include the plan as part of its submission under the basic program. EPA encourages participants who do not have a risk management plan to consider developing one. Participants will find information describing risk management practices on page 13, section II.C. of the optional reporting form. Participants could also consider information that is relevant to risk management practices for nanoscale materials in the report of the public scientific peer consultation on risk management practices EPA conducted in October 2006. EPA included input from this scientific peer consultation when developing risk management considerations (See the Final Meeting Summary Report, <http://www.epa.gov/optintr/nano/nanopublicmeetingsummaryfinaloct2006.pdf>). EPA is not prescribing specific risk management practices that would be used for all nanoscale materials.

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.

#### F. EPA Use of the Data

EPA will use the data from the stewardship program to gain a better understanding of the nature of nanoscale materials that are produced; the quantities in which they are produced; how they are or will be used; any hazards, exposures, or releases associated with those materials; and how these hazards are being addressed. 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 use the data for a variety of purposes including building new assessment methods and models or incorporating the data into existing models with regard to hazard, exposure, and fate. The data will help increase EPA's capacity to assess benefits from nanoscale materials. As EPA reviews specific data that are submitted it may find other uses for the data.

EPA will also evaluate the information submitted under the program to make the following determinations:

- Identify the data that may be useful to evaluate 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 any additional risk management practices for participants to consider.
- Identify nanoscale materials or categories of nanoscale materials that warrant future concerns or actions based on existing information, or should be treated as a lower priority for further consideration.

If the hazard, exposure, and fate data submitted by a participant indicate that potential risks may exist for a specific nanoscale material, EPA may work with the participant to determine possible actions to avoid, reduce, or mitigate potential risks.

If the data submitted by a participant indicate that the participant is manufacturing a nanoscale material that is reportable under section 5 of TSCA (15 U.S.C. 2613) as a new chemical substance, EPA will inform the participant of that situation, the applicable TSCA requirements, and the TSCA section 5 enforcement policy (<http://www.epa.gov/compliance/resources/policies/civil/tscatsec5erpamend-060889.pdf>). EPA encourages manufacturers, importers, and processors of nanoscale materials to consult with EPA regarding questions of the TSCA Inventory status of such materials before beginning commercial activity. EPA will work with program participants who also have reporting requirements under section 5 of TSCA to minimize or eliminate duplicative reporting of the same information.

EPA intends to publish an interim report approximately 1 year after announcement of the program. The purpose of the report would be to describe participation in the basic component of the program during its first 6 months. The report would summarize, to the extent possible, considering CBI claims, who reported, the types of data available, the reasons some data were reported as not being available, additional data that would be useful to improve risk assessment and any activities for which data are being used. The report is expected to address only the data received within 6 months of this announcement of the program. As suggested by several commenters, EPA will also issue quarterly updates on the OPPT nanotechnology website (<http://epa.gov/oppt/nano/index.htm>)

regarding the number of submissions received and any activity under the in-depth program.

EPA also intends to develop a more detailed report and evaluation of the program approximately 2 years after announcement of the program. This report will describe how the stewardship program addressed the objectives identified in Unit II.A. EPA welcomes suggestions for criteria to evaluate the program. At the time of the 2-year report, EPA intends to determine the future direction of the basic reporting phase as well as in-depth data development, although it may make adjustments or decide on future steps at an earlier point as sufficient experience is gained. This would also include consideration of information gathering authorities under TSCA.

#### G. Benefits of Participation

EPA believes that participation in the stewardship 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 develop appropriate environmental health and safety plans in their workplaces as well as throughout an industrial supply chain. EPA is committed to an open and transparent process in the development and implementation of the stewardship program.

EPA sought comments and ideas on incentives for participation in the stewardship program and how it could identify and reach out to the many small and medium sized nanotechnology businesses. Many of these entities have limited experience with TSCA and may have limited resources for participation in a voluntary stewardship program. EPA will use information from its own small business office to meet with small and medium sized nanotechnology companies to assist these companies with understanding TSCA and participating in the stewardship program.

EPA received two comments that participants in the stewardship program who become aware they should have submitted a PMN for a nanoscale material submitted to the program, be allowed to submit a PMN without penalty. Several commenters also suggested that program participants should be exempt from future EPA reporting requirements EPA may issue for nanoscale materials. EPA will not

exempt anyone from TSCA requirements for participating in the program.

EPA will also acknowledge participants in the program on EPA's OPPT webpage, provided the participants have not claimed their identity as CBI or otherwise object to such acknowledgement.

#### H. How to Participate

EPA encourages anyone with further questions to consult the person listed as the technical contact under **FOR FURTHER INFORMATION CONTACT**. Send submissions for the basic program, requests to participate in the in-depth program, or any other input regarding the program to these addresses:

- *Mail*: Document Control Office (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001, ATTN: Nanoscale Materials Stewardship Program.

- *Hand Delivery*: OPPT Document Control Office (DCO), EPA East Bldg., Rm. 6428, 1201 Constitution Ave., NW., Washington, DC. The DCO is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the DCO is (202) 564-8930. Such deliveries are only accepted during the DCO's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

*Instructions*: Clearly mark any documents as pertaining to the Nanoscale Materials Stewardship Program. If you are claiming information as CBI or other information whose disclosure is restricted by statute you must clearly label the information that is CBI. If you are using the reporting form follow the instructions on the reporting form. If information is claimed as confidential, a sanitized version (including attachments) should be provided. Do not submit information that you consider to be CBI or otherwise protected through regulations.gov or e-mail. If you submit an electronic submission, EPA recommends that you include your name and other contact information in the body of the submission and with any disk or CD-ROM you submit. If EPA cannot read your submission due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your submission. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. Given security measures for mail, EPA does not recommend mail for a disk or CD-ROM because the equipment used to

scan the mail may destroy the disk or CD-ROM.

### III. Paperwork Reduction Act Notice

The Office of Management and Budget (OMB) has approved the information collection activities associated with the Nanoscale Materials Stewardship Program (NMSP) under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.* and has assigned OMB control number 2070-0170. EPA has prepared an Information Collection Request (ICR) that describes the information collection activities and EPA's estimated burden, which is summarized in this unit. The ICR is identified by EPA ICR No. 2250.01. A copy of the ICR and public comments (described in Unit II.A. of this document) are available under Docket ID No. EPA-HQ-OPPT-2007-0572.

As described in more detail in the ICR, the annual burden for this collection of information is estimated to average 154.3 hours per response for the basic NMSP, and 2,500 hours for the in-depth NMSP, based on 240 responses for the basic NMSP and 15 responses for the in-depth NMSP. According to the PRA, "burden" means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this collection activity appears in this document, in the **Federal Register** document announcing the approval of the ICR, and on the optional collection instrument or form.

### IV. Statutory and Executive Order Reviews

This document describes the design and format of EPA's Nanoscale Materials Stewardship Program, which is a voluntary program to collect data for nanoscale materials under TSCA. This action is not a regulatory action or a significant guidance document under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993), as amended by Executive Order 13422 on January 18, 2007 (72 FR 2763). As such, this action does not require review by OMB under Executive Order 12866.

In addition, Executive Orders 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997) and 13211, entitled *Actions Concerning Regulations that Significantly Affect Energy Supply, Distribution, or Use* (66

FR 28355, May 22, 2001), do not apply to this action because it is not "economically significant" as defined by section 3(f) of Executive Order 12866. Nor does this action establish an environmental standard that may have a negatively disproportionate effect on children, or otherwise have any significant adverse effect on the supply, distribution, or use of energy.

This action is not subject to the notice-and-comment requirements under the Administrative Procedure Act or any other statute. As such, it is not subject to the provisions of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*). Further, today's action is expected to only have a limited impact because only entities that volunteer to participate in the NMSP will be impacted.

Based on EPA's experience with review of PMNs; State, local, and Tribal governments have not been impacted by these activities, and EPA does not have any reason to believe that any State, local, or Tribal government would be impacted by this action. As such, the Agency concludes that this action will not have substantial direct effects on the States or on the relationship between the national government and the States or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Nor does this action significantly or uniquely affect the communities of tribal governments as specified by Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR 27655, May 10, 1998). In addition, EPA has determined that this action would not impose any enforceable duty, contain any unfunded mandate, or otherwise have any affect on small governments subject to the requirements of sections 202, 203, 204, or 205 of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104-4).

This action does not involve any technical standards that require the Agency's consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note).

This action will not have an adverse impact on the environmental and health conditions in low-income and minority communities. Therefore, under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994), the Agency is not

required to and has not considered environmental justice-related issues.

### V. References

1. A Matter of Size: Triennial Review of the National Nanotechnology Initiative, The National Academies Press. p. 73 (2006).
2. NPPTAC 2005. Overview of Issues for Consideration by NPPTAC. Document ID EPA-HQ-OPPT-2002-0001-0068. <http://www.regulations.gov/fdmspublic/component/main>.
3. Material Characterization of Nanoscale Materials; Notice of Public Meeting, August 13, 2007 (72 FR 45244) (FRL-8144-1).
4. NIOSH 2007. National Institute for Occupational Safety and Health, December 2007, Approaches to Safe Nanotechnology—An Information Exchange with NIOSH. <http://www.cdc.gov/niosh/topics/nanotech/safenano/summary.html>.

### List of Subjects

Environmental protection, Chemicals, Hazardous substances, Nanoscale materials.

Dated: January 22, 2008.

**James B. Gulliford,**

*Assistant Administrator, for Prevention, Pesticides and Toxic Substances.*

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## FEDERAL COMMUNICATIONS COMMISSION

[WT Docket No. 08-7; DA 08-78]

### Comment Sought on Petition for Declaratory Ruling That Text Messages and Short Codes Are Title II Services or Are Title I Services Subject to Section 202 Non-Discrimination Rules

**AGENCY:** Federal Communications Commission.

**ACTION:** Notice.

**SUMMARY:** In this document, comment is sought on a December 11, 2007 petition for declaratory ruling (Petition) filed by Public Knowledge, Free Press, Consumer Federation of America, Consumers Union, EDUCAUSE, Media Access Project, New America Foundation, and U.S. PIRG (Petitioners). The Petitioners ask the Federal Communications Commission (Commission) to clarify the regulatory status of text messaging services, including short-code based services sent from and received by mobile phones, and declare that these services are governed by the anti-discrimination