# SUPPORTING STATEMENT FOR AN INFORMATION COLLECTION REQUEST (ICR)

# 1. IDENTIFICATION OF THE INFORMATION COLLECTION

**1(a) Title of the Information Collection** 

Title: Information Collection in Support of EPA's Stewardship Program for Nanoscale Materials

EPA ICR No.: 2250.01

OMB Control No.: 2070-new

#### **1(b) Short Characterization**

EPA intends to initiate a voluntary information collection to assemble existing data and information from manufacturers, importers, and processors of nanoscale materials. EPA also intends to collaborate with manufacturers, importers, and processors of nanoscale materials, in an effort to generate more detailed information of certain specific nanoscale materials. Under this second effort OPPT and industry will work together to generate data and analyses that will more fully characterize certain nanoscale materials, and to increase understanding of the environmental health and safety implications of manufactured nanoscale materials.

These data will inform the process by which EPA establishes appropriate chemical management efforts to protect human health and the environment from unreasonable risk from nanoscale materials. This collection will facilitate and support EPA's Stewardship Program for Nanoscale Materials which is a comprehensive stewardship program with industry and the interested public committed to the safe manufacture, processing, distribution, use, storage and disposal of nanoscale materials.

# 2. NEED FOR AND USE OF THE COLLECTION

# 2(a) Need/Authority for the Collection

Nanoscale materials or nanomaterials are chemical substances organized in structures in the scale of approximately 1 to 100 nanometers, and may have different organizations and properties than the same chemical substances in a larger size. Nanoscale materials can be found in electronics, sunscreens, cosmetics, automotive and medical products as well as paints and coatings, metal-cutting tools, sports equipment, stain-free clothing and mattresses, and ink. (NNI 2006) Only in the last several years have these substances been introduced into commerce in any significant degree. There are estimated to be hundreds of nanotechnology products already on the market. The National Science Foundation predicts that the market for nanotech products and services will reach \$1 trillion by 2015. It is expected to transform virtually every aspect of the economy and life.

Some nanoscale materials are recognized as new chemical substances subject to notification requirements under section 5 of TSCA because they are not contained on the TSCA Inventory. Therefore, they are subject to review for potential human health and environmental risks before they are manufactured and enter commerce. Other nanoscale materials have the same molecular identity as chemical substances which are already on the TSCA Inventory and as such are not subject to new chemical notification. The application of TSCA §5 new chemical authorities to nanoscale materials is currently under consideration within EPA. The Agency has authority under TSCA §8(a) to collect information regarding chemicals already in commerce. While the stewardship program is focused on those nanoscale materials already in commerce it could also include nanoscale materials that would be reportable to EPA under section 5 of TSCA. Participation in the voluntary stewardship program will not relieve manufacturers, importers, and processors of their obligations under TSCA or other applicable statutes.

It is recognized that some of these substances, because of their small size, exhibit novel and enhanced properties not present in substances of larger dimensions. It is also widely recognized that there is limited data available on these types of substances. As of this date, there has been no other effort to systematically collect such comprehensive information .

To assist in assessing health and environmental effects of these nanoscale materials in commerce, EPA is creating the Stewardship Program for Nanoscale Materials. EPA's Stewardship Program for Nanoscale Materials is intended to:

- Encourage responsible development of nanoscale materials;
- Help the Agency assemble existing data and information from manufacturers and processors of existing chemical nanoscale materials;
- Identify and encourage use of a basic set 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.

This voluntary information collection will provide EPA baseline information on nanoscale materials in commerce.

#### 2(b) Use/Users of the Data

The information collected through the stewardship program will provide important baseline information on health and environmental effects, exposures, risks, management practices, and data needs that will assist EPA and others in properly assessing and managing risks related to nanoscale materials. Non-confidential portions of this information will also be made available to help the public understand how nanoscale materials are being used. Data collected through this stewardship program will be used by EPA scientists to assist in determining how and whether certain nanoscale materials may present risks to human health and the environment. If the hazard, exposure, and risk data submitted by participants indicate that potential unreasonable risks may exist, the data will be used by EPA and the manufacturer to determine the appropriate action necessary to avoid or mitigate the risks. Furthermore, such information could be used for risk management, hazard communication and right-to-know purposes, and product labels. EPA may also use the information to identify nanoscale materials that may not warrant future concerns or actions, or should otherwise be treated as a lower priority for further consideration.

The data may also be used by other Federal agencies. 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.

# 3. NON-DUPLICATION, CONSULTATIONS, AND OTHER COLLECTION CRITERIA

#### **3(a) Non-Duplication**

There has been no other effort to systematically collect such comprehensive information.

#### **3(b)** Public Notice Required Prior to ICR Submission to OMB

Prior to submission to OMB, this ICR will be made available to the public for comment through a <u>Federal Register</u> notice. The public will have 60 days to provide comments. The comments received will be given consideration when completing the supporting statement that is submitted to OMB.

# **3(c) Consultations**

OPPT held a public meeting on June 23, 2005 to discuss a potential voluntary pilot program for certain nanoscale materials and the information needed to adequately inform the conduct of the pilot program. On November 23, 2005, the National Pollution Prevention and Toxics Advisory Committee (NPPTAC) provided to EPA for consideration an Overview Document on Nanoscale Materials (NPPTAC 2005). While the June 23, 2005, public meeting and the NPPTAC Overview Document elicited broad stakeholder support for the idea of a stewardship program, these public processes have also identified specific issues relevant to the program that EPA is still considering.

As a result EPA intends to hold public peer consultations on materials characterization and risk management practices as described in the NPPTAC Overview Document. EPA will also hold a general public meeting during the ICR process to obtain further public input on any aspect of this information collection request and the stewardship program.

#### **3(d) Effects of Less Frequent Collection**

The frequency of the submission of information under this voluntary information collection request is not under the Agency's control. Manufacturers, importers, and processors of nanoscale materials will determine whether to submit information under this program. Less

frequent collection would mean respondents would not submit data at all. However, submission of this data will allow EPA to better carry out its mandate to protect the public from unreasonable risks to health and the environment.

# 3(e) Compliance with General OMB Guidelines

This collection of information is consistent with all OMB guidelines under 5 CFR 1320.6.

# **3(f) Confidentiality**

EPA expects that some of the information submitted to EPA in response to the information request will be claimed confidential. If respondents wish to claim information submitted as confidential business information (CBI), they may do so. Respondents may claim all or part of a document confidential if there is a legitimate need to do so as described in 40 CFR part 2. 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 will follow the procedures for handling CBI as set forth in the TSCA CBI Protection Manual (October 2003 edition), which calls for careful protection of CBI. EPA will disclose information that is covered by a claim of confidentiality only to the extent permitted by, and in accordance with, the procedures in 40 CFR part 2.

# **3(g) Sensitive Questions**

The information requested under the stewardship program does not include questions of a sensitive nature.

# **3(h) Electronic Reporting.**

Submitters are asked to provide information electronically by putting their information on a CD, which they would then mail or otherwise deliver to EPA. Because of time constraints, security issues related to the electronic transfer of CBI and potential expenses for both the EPA and the possible reporters, it is not feasible to devise a direct electronic submission scheme for this collection.

# 4. THE RESPONDENTS AND THE INFORMATION REQUESTED

# 4(a) Respondents/SIC Codes

Respondents affected by the collection activity may include, but are not limited to the following NAICS groups, 325 (Chemical Manufacturing) and 324 (Petroleum and Coal Products). The North American Industrial Classification System (NAICS) codes have been provided to indicate which entities might be affected by this information collection activity. This listing is not intended to be exhaustive and other types of entities not listed in this table could also be affected.

#### **4(b) Information Requested**

EPA is requesting that respondents provide all the information described below to the extent it is known or reasonably ascertainable. EPA is not requesting that respondents develop additional data for this information collection request. If the information requested 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:

- 1. Company name and other identifying information, address of company and site, technical contact and related information.
- 2. Common or trade name of chemical. Chemical identity and molecular structure of substance.
- 3. The following physical and environmental fate properties and information would be helpful to characterize the nanoscale material where relevant and reasonably ascertainable:

Physical state	Vapor pressure
Density	Solubility in water or other solvents
Melting temperature	Boiling/sublimation temperature
Spectra	Dissociation constant
Particle size distribution	Octanol/water partition coefficient
Henry's Law constant	Volatilization from water
pH	Volatilization from soil
Flammability	Explodability
Adsorption coefficient	Shape
Agglomeration state/dispersion state	
Crystal structure	
Chemical composition – including s	patially averaged (bulk) and spatially resolved
heterogeneous composition	
Surface area	Surface chemistry
Surface charge	Porosity

- 4. Description of all uses including expected consumer uses.
- 5. Estimate of the total amount of substance to be manufactured/imported including the amounts for each use category.
- 6. Description of byproduct resulting from manufacture, process, use or disposal of chemical.
- 7. For each type of workplace in the lifecycle, the same information requested on pp. 8-10 of the EPA PMN form (7710-25) would be helpful for releases and exposures, with the following additions.

8. In addition to the above properties and information the following physical properties would be helpful for understanding and assessing exposures and releases:

surface reactivity	average particle weight
average particle surface area	rate of sorption
aggregation	rate of diffusion
wet and dry transport	rate of gravitational settling
bioaccumulation/biomagnification	biodegradation
particle count	rate of deposition
surface/volume ratio	average aerodynamic diameter
mobility through soil	
influence of Redox and photochemical 1	reaction

- 9. A brief overview of the lifecycle including all workplaces that manufacture, process, or use the nanoscale chemical and all expected consumer uses.
- 10. For each release point for which control technology is used, rationale for selecting the control, and, if available, data and measurement methods of waste treatment or purification efficiency studies for the nanoscale material.
- 11. Regarding worker exposure information, personal or area monitoring data (in mass concentrations, surface area per mass, number of particles, etc.) for the nanoscale material, including the measurement method(s) used to generate the data.
- 12. For each protective equipment or engineering control listed as worker protection, rationale for selecting the protective equipment or engineering controls, and data (and methods used to generate the data) that were used in making the selection or that may help to indicate the effectiveness of the protective equipment or engineering controls.
- 13. Information on cleaning/ reuse/ disposal of used protective equipment (gloves, respirator cartridges, etc.).
- 14. Additional procedures or other equipment intended to mitigate exposures to the nanoscale material.
- 15. Description of worker training and hazard communication (MSDS, other) specific to the nanoscale material.
- 16. Estimate of the total number of individuals other than workers exposed to the chemical and duration of exposure.
- 17. Manner or method of disposal for consumer use of products containing the nanoscale material.
- 18. Any test data in the submitter's possession regarding information on health/environmental effects, environmental fate, worker safety, and material characterization, including any data related to characterization of the nanoscale material in the subject organism and test medium.

To facilitate this information collection request, EPA has developed a form based on the PMN reporting form (EPA Form 7710-25). Copies of both the PMN form and the proposed form for this information collection request are attached. It is not essential that respondents use the proposed form. By supplying the information described in the form to the extent it is known or reasonably ascertainable, respondents do not incur the burden of providing unnecessary information. In addition, many of the potential respondents are familiar with the PMN form, thus further reducing the reporting burden.

EPA has limited the level of detail of information described in the form to the information which would be most useful in facilitating EPA's to evaluation of the potential risks of the nanoscale material. However, respondents may include additional or optional information that they believe EPA should consider when evaluating the nanoscale material. For example, respondents may identify pollution prevention techniques being employed by the submitter that may be relevant to the Agency's assessment. EPA encourages submitters to provide information on the benefits of the nanoscale material in comparison to existing chemical substances including macroscale forms of the same chemical substance, information on the substitutes, and any additional information available to them on waste management techniques.

# 4(c) The In-Depth Program

The information collection described in 4(b) will provide EPA, respondents, and the public with baseline information on nanoscale materials' properties, details on their production and use, and descriptions of existing risk management practices. In an effort to generate a more detailed view of certain specific nanoscale materials following an analysis of data from the basic program, EPA is proposing to collaborate with some respondents in an in-depth program. This second program, which builds on data from the basic program, will allow OPPT and respondents to work collaboratively to generate data and analyses that will more fully characterize the nanoscale materials in commerce, and to develop insights into the nanotechnology industry as a whole.

The primary purpose of the in-depth program is to generate human health hazard, environmental hazard, release, and exposure data on particular nanoscale materials in commerce. EPA, respondents and other stakeholders will then use these data to help assess hazard, exposure, and ultimately, risk in the context of the entire product chain and life-cycle. This evaluation will assist EPA, respondents, and others in working towards a suite of protective risk management practices and developing better risk-assessment protocols, tools, and methodologies.

As envisioned, the data needed to meet the goals for such a program could require testing for material characterization, health and environmental hazard testing, monitoring of exposures and releases, and testing of protective equipment. EPA would determine the specific data needs and regimen of testing in consultation with respondents and with input from other stakeholders.

OPPT has experience with similar collaborative chemical evaluation programs, such as the Voluntary Children's Chemical Evaluation Program (VCCEP). The VCCEP enlisted sponsors for 20 chemicals, and features three tiers of testing and analysis. Under the VCCEP process, a peer consultation is conducted by a group of scientific experts on each tier of data submitted by a sponsor. EPA considers the results of the peer consultation when announcing whether additional higher tier information is needed. OPPT also manages the High Production Volume (HPV) Challenge program, under which chemical producers submit a base set of testing data on chemicals produced at or above a one-million-pounds-per-year threshold.

# 4(d) Basic Outline of the In-Depth Program

Participation in the in-depth program will be determined by the mutual interest of EPA and the participants. Respondents may volunteer nanoscale materials for the program, and EPA may also identify specific nanoscale materials of interest. The criteria for consideration could include: production volume, potential for exposure, life-cycle/disposal considerations, data gaps (or conversely, the availability of data), the potential for information gathered on one nanoscale substance to shed light on others, and any other criteria that could affect either the risk profile of the nanoscale substance or the ability of EPA to effectively oversee other TSCA applications. For example, a particular type of carbon nanotube (CNT) that has been well-characterized and subject to health testing, and that also appears in many products, may be a good candidate because data may be transferable to other types of CNTs. A widely-used nanoparticle that is not well understood from a risk perspective may also be considered for the in-depth program.

Once candidates are identified, respondents producing the candidate nanoscale substance could join as either individuals or consortia. EPA envisions somewhere between five and 25 participants, depending on OPPT's resources and respondents' interest in pursuing the program.

Companies or consortia joining the program would meet and correspond with EPA to conduct preliminary assessments using available information, and to identify outstanding data needs. When these needs are identified, a plan of action would be developed in consultation with EPA and with input from other stakeholders.

Examples of elements that could be included in an action plan:

- Characterizing the physical/chemical properties of the material;
- Testing for health and environmental hazards;
- Monitoring or estimating exposures and releases;
- Evaluating the effectiveness of protective equipment and treatment technologies; and/or
- Developing a worker education program.

To minimize costs and burden, the elements in an action plan should coincide with any ongoing research, whether sponsored by EPA or by private groups. EPA would also consider testing of an individual substance that is representative of a class or classes of nanoscale materials.

At the completion of the action plan, EPA and participants with input from other stakeholders will again meet to review the information gathered; conduct further assessments; develop and apply appropriate risk-management measures for the substance; and consider any further action. Any further action beyond what is called for in the action plan, would be considered on a case-by-case basis.

The goal of the in-depth program would be to cooperate with participants in assessing hazard, exposure, and ultimately, risk in the context of the entire product chain and life-cycle,

and as a result of these assessments, to work towards a suite of protective risk management practices.

# 5. THE INFORMATION COLLECTED - AGENCY ACTIVITIES, COLLECTION METHODOLOGY, AND INFORMATION MANAGEMENT

# 5(a) Agency Activities

Under this stewardship program, EPA will perform the following activities:

- review the data submitted;

- analyze submissions for confidentiality and provide appropriate protection for confidential data;

- file and store submissions;

- use the data to inform the assessment and management of any risks from nanoscale materials; and

- provide an aggregated report of the data submitted.

# 5(b) Collection Methodology and Management

EPA encourages submission of data by electronic means as described in 3(h) above. EPA believes electronic submission reduces the reporting burden on industry, because it is intended to reduce both the cost and the time required to enter, review, edit and transmit the data. Electronic submission may also improve data quality because it facilitates correcting incorrect data or adding omitted data. There is no other new technology applicable to the collection of this information that would minimize the collection burden, nor has EPA been able to identify a more efficient, less expensive or more flexible means of obtaining the data.

# 5(c) Small Entity Flexibility

The reporting elements associated with the stewardship program are applicable to all affected entities, regardless of size of business. However, EPA provides specialized assistance to respondents, particularly to small entities. TSCA section 26(d) established the TSCA Assistance Office, now known as the Environmental Assistance Division (EAD), to provide technical and other non-financial assistance to manufacturers, importers and processors of chemical substances. Moreover, EPA has taken certain steps to minimize for all respondents the reporting burden associated with this collection. Finally, EPA will provide the services of pre-notice communications coordinators and other personnel to assist persons in a comprehensive manner for purposes of submitting information for nanoscale materials in the stewardship program.

# 5(d) Collection Schedule

Does not apply. The submission of information under this collection is initiated by the respondents.

# **6** ESTIMATING THE BURDEN AND COST OF THE COLLECTION

# 6(a) Nanoscale Materials Stewardship Program (Basic Program)

## 6(a)(1) Estimates of Respondent Burden

Participants in the basic Nanoscale Materials Stewardship Program (NMSP) will be asked to undertake the following activities:

- Review the NMSP data request;
- Determine which provisions are applicable to their activities; and
- Gather and submit information regarding the identified data elements.

Each of these activities may require efforts by employees in three broad labor classifications (managerial, technical, and clerical). Costs for each activity are calculated by estimating the labor hours required in each labor category and multiplying those burdens by the wage rate for each labor category. These costs are then multiplied across all of the respondents expected to submit information under the NMSP.

The methodology and calculations used in this analysis assume that the employee responsible for collecting, filling out, and submitting the requested information has a reasonable level of familiarity with the company and knowledge of operations at the site. It is assumed that for most entities these tasks are similar to other employee duties that require familiarity with EPA, State, and other Federal agency requests for chemical information and does not require additional familiarization or training to comply. In addition, this analysis focuses on the marginal costs of submitting information for this specific request and not the total costs to the company to comply with a range of other Federal and State environmental, health, and safety regulations (e.g., initial employee training, costs associated with collecting and storing records or file maintenance) or accounting requirements that rely on this type of information. EPA cautions that these assumptions and burden estimations may not be appropriate for the many small businesses in the nanotechnology industry, or other businesses that may not have prior experience with the chemical regulatory system.

# **Respondent Activities**

Section 5 of Toxic Substance Control Act (TSCA) provides EPA with the authority to review the potential health and environmental risks associated with any new chemical substance. EPA's main tool for this review is the premanufacture notification (PMN) process, which requires any manufacturer or importer of a substance not listed on the TSCA Chemical Substance Inventory (i.e., a "new" chemical) to file a PMN at least 90 days prior to beginning manufacture or importation. Since much of the information that EPA expects will be useful in assessing the potential risk from nanoscale materials is similar to the information collected in the PMN, EPA is utilizing a modified version of the PMN form to collect NMSP data. Table 1 lists the reporting elements being collected, along with EPA's estimated burden for providing this information. In estimating

Reporting Element	Clerical	Technical	Managerial	Total	Source
1 General instructions & manager certification; Submitter information	2.5	2	1	5.5	
<sup>2</sup> Chemical identity info	2	7.5	1	10.5	RIB, 1994
3A Physical properties	0.5	2	0.5	3	
3B Additional physical properties	1	4	1	6	*
4 Description of uses	0.75	3	1.5	5.25	
5 Amount of substance to be manufactured/imported	0.75	1	1.5	3.25	RIB, 1994
6 Description of byproducts	0	0.5	0	0.5	
7 Human exposure and environmental release	5.5	52	9.5	67	
8 Physical properties related to understanding and assessing exposures and releases	1	4	1	6	
9 Overview of the lifecycles	1	10	2	13	
<sup>10</sup> Release point control technology	0.2	2	0.4	2.6	
11 Worker exposure information	0.2	2	0.4	2.6	
12 Protective equipment or engineering control	0.2	2	0.4	2.6	
13 Information on cleaning/reuse/disposal of used protective equipment	0.1	1	0.2	1.3	
14 Additional procedures or other equipment intended to mitigate exposures to nanoscale materials	0.1	1	0.2	1.3	*
15 Description of worker training and hazardous communication specific	0.1	1	0.2	1.3	
16 Number of individuals other than workers exposed to the chemical and duration of exposure	0.1	1	0.2	1.3	
17 Manner or method of disposal for consumer use of products	0.2	2	0.4	2.6	
18 Test data in the submitter's possession of information on health/environmental effects	1.7	4.5	11	17.2	TSCA 8(d) ICR, 2006
Total	17.9	102.5	32.4	152.8	

# Table 1. Industry Burden Estimates for NMSP Basic Program Reporting Elements

\* Based on professional judgment

the burdens for this Information Collection Request (ICR), EPA assumed the high end of the burden range estimated in the PMN regulatory impact assessment for those reporting elements that are identical to the PMN form (RIB 1994). To estimate the burdens for most of the remaining elements, the Agency consulted in-house experts from the New Chemicals Program who are responsible for PMN review, and other Agency staff working with the nanotech industry. The estimates for reporting elements 3b and 8-17 are thus based on best professional judgment (BPJ).

For reporting element 18, the submitter is requested to provide any test data in its possession that indicates the environmental or health effects of the chemical, and a description of any other data known to the submitter concerning the environmental or health effects of the chemical. For this element, the Agency utilized the burden estimates from the TSCA Section 8(d) ICR, which covers the Health and Safety Data Reporting Rule (EPA 2006).

In summary, the estimated burden per respondent to participate in the NMSP is 152.8 hours.

# 6(a)(2) Estimates of Respondent Cost

## **Derivation of Appropriate Wage Rates**

Loaded wage rates for managerial, technical, and clerical personnel are derived by combining data on wages and fringe benefits with estimates of overhead rates. EPA selected average wage rates for managerial, technical, and clerical labor from the most-recent unpublished Bureau of Labor Statistics (BLS) data for manufacturing sectors made available to EPA (BLS 2005).

The cost of fringe benefits (such as paid leave and insurance) specific to each labor category are from unpublished BLS data made available to EPA (BLS 2005). An additional loading factor of 17 percent is applied to wages to account for overhead. The fringe benefits loading factor and the overhead loading factor are then added to the base wage to calculate a fully loaded wage rate.

Labor Category	Loaded Hourly Rate (\$2005)
Managerial	\$63.61
Technical	\$53.02
Clerical	\$26.37

Table 2. Industry Labor Category and Loaded Hourly Rate

Table 3 combines the estimated burdens from Table 1 with the fully loaded wage rates listed in Table 2 to estimate the cost to industry of collecting and submitting the data identified in the basic NMSP. As seen in Table 3, the total estimated cost per response is \$7,968. These estimates are in 2005 dollars.

#### **Estimation of the Number of NMSP Participants and Responses**

Nanotechnology is not identified as a separate industry within the North American Industrial Classification System (NAICS). Rather, nanotechnology encompasses a range of technologies that are deployed across a broad spectrum of industries including:

- Electronics
- Health Sciences
- Materials
- Environment
- Energy

			Ног	ırs*		Cost*			
						С Т М т			Total
Repo	orting Element	С	Т	Μ	Total	@\$26.37/hr	@\$53.02/hr	@\$63.61/hr	(\$2005)
	General instructions & manager								
	certification; Submitter information	2.5	2	1	5.5	\$65.93	\$106.04	\$63.61	\$236
2	Chemical identity info	2	7.5	1	10.5	\$52.74	\$397.65	\$63.61	\$514
3A	Physical properties	0.5	2	0.5	3	\$13.19	\$106.04	\$31.81	\$151
3B	Additional physical properties	1	4	1	6	\$26.37	\$212.08	\$63.61	\$302
	Description of all uses including								
	expected consumer uses	0.75	3	1.5	5.25	\$19.78	\$159.06	\$95.42	\$274
	Estimate of total amount of substance to be manufactured/imported including the amount of use in each use category	0.75	1	1.5	3.25	\$19.78	\$53.02	\$95.42	\$168
6	Description of byproduct resulting from manufacture, process, use, or disposal of chemical	0	0.5	0	0.5	\$0.00	\$26.51	\$0.00	\$27
	Human exposure and environmental	0	0.5	0	0.5	\$0.00	\$20.51	\$0.00	\$Z1
	release	5.5	52	9.5	67	\$145.04	\$2,757.04	\$604.30	\$3,506
	Physical properties related to	5.5	52	9.5	07	\$14J.04	\$2,737.04	\$004.30	\$5,500
	assessing exposures and releases	1	4	1	6	\$26.37	\$212.08	\$63.61	\$302
	Overview of the lifecycles	1	10	2	13	\$26.37	\$530.20	\$127.22	\$684
-	Release point control technology	0.2	2	0.4	2.6	\$5.27	\$106.04	\$25.44	\$137
	Worker exposure information	0.2	2	0.4	2.6	\$5.27	\$106.04	\$25.44	\$137
	Protective equipment or engineering	0.2	2	0.4	2.0	ψ5.27	ψ100.04	φ23.44	ψ137
	control	0.2	2	0.4	2.6	\$5.27	\$106.04	\$25.44	\$137
	Information on cleaning/reuse/disposal of used protective equipment	0.1	1	0.2	1.3	\$2.64	\$53.02	\$12.72	\$68
	Additional procedures or other equipment intended to mitigate exposures to nanoscale materials	0.1	1	0.2	1.3	\$2.64	\$53.02	\$12.72	\$68
	Description of worker training and hazardous communication specific	0.1	1	0.2	1.3	\$2.64	\$53.02	\$12.72	\$68
16	Number of individuals other than workers exposed to the chemical								
	and duration of exposure	0.1	1	0.2	1.3	\$2.64	\$53.02	\$12.72	\$68
	Manner or method of disposal for	0.2	2	0.4	26	\$5.07	\$106.04	\$25 11	¢127
18	consumer use of products Test data in the submitter's possession of information on	0.2	2	0.4	2.6	\$5.27		\$25.44	\$137
	health/environmental effects	1.7	4.5	11	17.2	\$44.83	\$238.59	\$699.71	\$983
Tota	1	17.9	102.5	32.4	152.8	\$472.02	\$5,434.55	\$2,060.96	\$7,968

# Table 3. Respondent Burden and Cost for NMSP Basic Program Reporting Elements

C = clerical labor; T = technical labor; and M = managerial labor.

Entities potentially eligible to participate in the voluntary program may include, but are not limited to, the following NAICS industries, 325 (Chemical Manufacturing) and 324 (Petroleum and Coal Products). This list is not intended to be exhaustive, but rather provides an indication of the kinds of industries that may be involved in the manufacture or importation of nanoscale materials.

Because the nanotech "industry" is not well defined, there are few reliable estimates of its overall size and composition. EPA reviewed numerous data sources on the nanotech industry and made an estimate of the overall size of the industry based on data from the National Science Foundation (NSF). The NSF estimates are based on industry surveys by a nanotech market research firm. NSF estimates that in 2005 there were some 1,455 companies involved in nanotechnology worldwide. Of these, NSF estimates that 42 percent are involved in the manufacturing or application of nanoscale materials (Roco 2005). The remainder of the industry is composed of specialized service providers (legal, financial), research organizations and trade associations, government entities and equipment vendors. Thus, based on these data sources the total universe of companies manufacturing and applying nanotech was about 600 firms in 2005 (1,455 x 0.42 = 611).

Not all of the nanoscale materials manufactured, imported, or used by these firms will constitute "chemical substances" according to the TSCA definition. TSCA applies to chemical substances exclusive of the following in the circumstances specified in TSCA section 3::

- Pesticides
- Tobacco and tobacco products
- Nuclear material
- Firearms and ammunition
- Food and food additives
- Drugs and medical devices
- Cosmetics.

In its 2006 review of nanotech consumer products already on the market, the Woodrow Wilson International Center's Project on Emerging Nanotechnologies estimates that approximately one-third of existing products would fall under TSCA regulatory purview (if they were considered "new chemicals"), with most of the remainder falling under the regulatory authority of the Food and Drug Administration (e.g., sunscreens and other health and beauty aids; medical devices) and the Consumer Product Safety Commission (e.g., garments; sporting goods) (Wilson Center 2006). However, it is important to note that this review focused on products, not raw materials, and that some of the products that would potentially be excluded from TSCA regulation may themselves be based on materials that *would* be considered new chemicals under TSCA. Further, the inventory covers only consumer products and excludes many industrial applications of nanotech already in use. For these reasons, EPA believes the Wilson Center's estimate that one-third of nanotech products currently on the market would potentially be regulated under TSCA is probably not a useful indicator for this ICR.

According to the National Center for Manufacturing Sciences, 80 percent of nanotechnology manufacturers are small businesses with less than 20 staff (NCMS 2006). If this distribution is representative of the firms that could potentially participate in the NMSP, then the universe of potential participants includes roughly 480 small businesses (600 x 0.8) and 120

large businesses. For purposes of this ICR, EPA estimates that the program participation rate for large nanotech businesses will be greater than that for small businesses. A number of factors will probably contribute to this, including large companies' enhanced familiarity with the chemical regulatory program and EPA, and their superior resources and staff expertise. EPA has used a participation rate of 50 percent for large businesses and 25 percent for small businesses for this ICR. These voluntary participation rates results in responses from 60 large businesses and 120 small businesses over the three-year ICR period.

EPA further assumes that each large company participating will submit information on two nanoscale substances and each small business participating will submit information on one nanoscale substance. EPA's experience suggests that large businesses tend to account for a majority of the PMNs submitted each year and it is expected that large businesses will submit information on nanoscale substances more frequently than small businesses. Over the three-year ICR period, EPA thus anticipates 120 submissions from large businesses and 120 submissions from small businesses.<sup>1</sup>

# 6(a)(3) Total Respondent Burden and Cost (Basic Program)

Table 4 summarizes the total number of responses and respondent burdens and costs associated with the NMSP. The total burden for 240 responses is 36,672 hours, and the total respondent cost is \$1.9 million.

Table 4. NMSP Basic Program I	<b>Respondent</b> Cost	and Burden
Item	Burden (hrs)	<b>Cost (\$)</b>
Burden and Cost per Response	152.8	\$7,968
No. of Responses	240	
Total	36,672	\$1,912,320

# 6(a)(4) Agency Burden and Costs (Basic Program)

This section estimates the burden and cost that will be incurred by EPA in connection with the NMSP. As the Agency developing, implementing, and operating the program, EPA will undertake a number of activities, including:

- Conducting pre-notice consultations;<sup>2</sup>
- Reviewing and discussing submissions;
- Filing and storing submissions;
- Analyzing requests for confidentiality and providing appropriate protection; and
- Writing a summary report of the NMSP basic program.

#### **Agency Burdens**

EPA estimated the Agency burdens associated with the NMSP basic program based upon the burdens estimated for the PMN program (RIB 1994). These burdens are shown in Table 5 below. It is important to note that while EPA is using the PMN costs as a template for the review

<sup>&</sup>lt;sup>1</sup> 60 large businesses will submit two responses each and 120 small businesses will submit one response each.

<sup>&</sup>lt;sup>2</sup> Note: there is no corresponding burden for industry.

of NMSP submissions, the actual review will likely differ in form and substance from the PMN review. However, EPA expects the general steps involved for the review will be similar. For the NMSP basic program, EPA assumes that 100 percent of submissions will require each of these steps. As shown in the table, EPA's estimated burden per submission is 22.2 hours. EPA also estimates a one-time burden of 300 hours to write a summary report on the NMSP basic program (not shown in Table 5).

#### **Agency Costs**

The costs associated with Agency activities undertaken in support of the NMSP are estimated by multiplying Agency burdens from Table 5 by an appropriate government employee wage rate (RIB 1994). EPA assumes that these activities are accomplished by a GS-13, Step 5 federal employee (RIB 1994). The 2006 hourly wage rate for this labor category in the Washington, DC locality is \$42.00 per hour (OPM 2006). EPA applied a factor of 1.6 (RIB 1994) to obtain a fully loaded labor rate (i.e., including fringe benefits and overhead) of \$67.20 per hour. The total agency cost per response is \$1,492, as shown in Table 6.

Review Step	Description	Burden (Hours)
1 Pre-notice consultations	These discussions allow potential submitters and the Agency to communicate any issues pertaining to the submission.	4.8
2 Administrative prescreen / notice receipt	The Agency performs an administrative review of each submission to verify information received and logs the receipt of data.	4.8
and Search	An Agency chemist conducts an initial chemistry review and prepares a summary report, during which the physiochemical properties of the substance have been verified. This report is presented at a CRSS meeting, where the chemistry needed for subsequent hazard and risk assessments is discussed and evaluated by Agency staff.	5
4 Engineering and exposure identification	The Agency also reviews the areas of environmental fate, human toxicity, and ecological effects by reviewing submitted data and researching other published research.	3
5 Structure Activity Team (SAT)	Base on the information gathered in previous steps, the Agency convenes a SAT meeting to assess the potential hazards and risk of the substance and assign a level of concern.	1.2
6 Exposure and Fate Evaluation	During this phase of the Agency's review, staff estimates the degree of human exposure and environmental exposure.	1.6
7 Focus Meeting	The Agency characterizes and discusses the risk posed by the substance and determines the risk of the substance.	1.8
Total		22.2

Table 5. Agency Activities and Estimated Burden per Response

Note: Does not include one-time costs associated with preparing a summary report on the NMSP (estimated at 200 hours)

Table 6. Agency Burden and Comparison			<b>D</b>
I ADIE 6 AGENCY BURDEN AND C	ASIS DEL RESUMSE	I Inder the NWNP	Rasic Program

Review Step	Hours	Total Cost (\$2006)
1 Prenotice consultations	4.8	\$ 322.56
2 Administrative prescreen / notice receipt	4.8	\$ 322.56
3 CRSS	5.0	\$ 336.00
4 SAT	1.2	\$ 80.64
5 Engineering/Exposure	3.0	\$ 201.60
6 Exposure/Fate	1.6	\$ 107.52
7 Focus Meeting	1.8	\$ 120.96
Total	22.2	\$1,491.84

Note: Assumes review activities are accomplished by GS-13, Step 5 employee at a loaded rate of \$67.20/hr. Does not include one-time costs associated with preparing a summary report on the NMSP (estimated at 200 hours).

# **Total Agency Burdens and Costs**

EPA multiplied the Agency burden and cost per response shown in Table 6 by the expected number of submissions shown in Table 4. The total burden and costs shown in Table includes that associated with the one-time Summary Report on the NMSP. The total agency burden is 5,628 hours and the total Agency cost is \$378,202.

Table 7. Agency Burden and Cost Associa	ated with the NMSP Basic Program
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	Burden per	Cost per	No. of	Total	<b>Total Cost</b>
Item	Response	Response	Responses	Burden	(\$2006)

Agency review and response	22.2	\$1,492	240	5,328	\$358,080
Summary Report			1	300	\$20,160
Total	22.2	\$1,492		5,628	\$378,240

## 6(a)(5) Total Annual Burden and Cost Estimates

The total estimated industry burden, from Table 4, is 36,672 hours and the total estimated costs are \$1.9 million. The total estimated Agency burden for administering the NMSP, from Table 7, is 5,628 hours and the total estimated cost is \$378,240

As shown in Table 8, over the three-year ICR period the total combined burden (industry and Agency) is estimated at 42,300 hours and the total combined cost (industry and Agency) is estimated at \$2.29 million. On an annual basis, the combined industry and Agency burden is 14,100 hours and the combined industry and Agency cost is \$763,520.

	Total (3 Years)		Annual		
Entity Type	Burden (Hours)	Cost	Burden (Hours)	Cost	
Industry	36,672	\$1,912,320	12,224	\$637,440	
Agency	5,628	\$378,240	1,876	\$126,080	
Total	42,300	\$2,290,560	14,100	\$763,520	

 Table 8. NMSP Basic Program Burden and Costs for Industry and Agency

# 6(b) In-Depth Nanoscale Materials Stewardship Program

#### 6(b)(1) Estimates of Respondent Burden (In-Depth Program)

The In-Depth NMSP will apply to a smaller set of nanoscale materials designated for further evaluation by mutual agreement of EPA and NMSP participants. Under the In-Depth NMSP, EPA and participants would 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 developed in consultation with EPA and other stakeholders that could include:

- Characterizing the physical/chemical properties of the material;
- Testing for health and environmental hazards;
- Monitoring or estimating exposures, releases, and fate;
- Evaluating the effectiveness of protective equipment; and/or
- Developing a model worker education program.

At the completion of the action plan, all stakeholders would again meet to review the information gathered; conduct final assessments; develop and apply appropriate risk management measures for the substance; and consider any further action. Any step that would go beyond what is called for in the action plan, would be considered on a case-by-case basis.

Because the number of participating groups is unknown, and the program's particulars will differ for each of the substances, it is not possible at this time to accurately estimate the costs and burdens for the In-Depth Program. Nevertheless, EPA believes its experience with the Voluntary Children's Chemical Evaluation Program (VCCEP) sheds some light on the potential costs and burdens. For example, participants in the VCCEP conducted assessments that could also occur under the In-Depth NMSP. While the hazard assessments under the VCCEP involved a very specific set of tests which would not be applicable to substances enrolled in the In-Depth NMSP, OPPT does have estimates of costs for most tests that might be conducted as part of the In-Depth program (although it is important to note that lab testing costs are not considered reporting burdens for ICR purposes).

As a preliminary estimate, EPA assumes 15 substances will take part in the In-Depth NMSP over the first three years of this ICR. As currently envisioned, each substance will require an action plan, and preliminary and final assessments. The program could also call for a suite of risk-management practices and sundry action items, which would likely be formalized in a final summary document.

For the purposes of this ICR, the elements of the In-Depth NMSP must be divided into *reporting* burdens and *non-reporting* burdens. Only reporting (that is, paperwork) burdens are relevant to the ICR requirements of the Paperwork Reduction Act. The testing costs associated with conducting the hazard assessments are not paperwork burdens, but the preparation and submittal to EPA of robust summaries of test results are. Additional paperwork burdens include preparing and submitting additional assessments, the action plan, and any summary documents. Efforts expended to participate in meetings are not considered part of the reporting burden, nor is the implementation of any risk-management measures.

#### **Hazard Assessments**

EPA is not able to accurately estimate the number of hazard tests or even the type of hazard testing that would be included under the In-Depth NMSP, as these tests will be determined by a variety of factors unknown at this time. In light of previous experience, EPA conservatively assumes that participants will prepare robust summaries of five hazard tests per substance, which will cover both the initial and final hazard assessments. EPA estimates that robust summaries require 15 hours of technical time and 5 hours of clerical time each. Assuming 15 substances are enrolled in the program, a total of 75 robust summaries will be prepared, representing a total burden of 1,500 hours (see Table 9).

#### **Exposure Assessments**

Preliminary and final exposure assessments could be developed for each substance. In the ICR for the VCCEP, EPA estimated a respondent burden of 500 hours (425 technical hours, 50 clerical, and 25 managerial) for a Tier 1 exposure assessment. A preliminary exposure assessment for the In-Depth NMSP will likely be similar in nature and scope to the Tier 1 VCCEP assessment, thus EPA assumes a similar burden of 500 hours per substance. A final exposure assessment will likely be more complex, and EPA assumes the burden will be similar to the 1,000 hours estimated for the VCCEP Tier 2 exposure assessment (850 technical, 100 clerical, 50 managerial). EPA further assumes that the burden estimates for these assessments include the paperwork burden associated with summarizing any monitoring or exposure testing conducted. Assuming 15 substances, the exposure assessments would represent a burden of 22,500 hours (see Table 9).

#### **Risk Assessments**

Preliminary and final risk assessments could also be developed for each substance under the In-Depth NMSP. In the ICR for the VCCEP, EPA estimated the respondent burden for a Tier 1 risk assessment at 300 hours (255 technical, 30 clerical, and 15 managerial). A final risk assessment will again likely correspond to a VCCEP Tier 2 risk assessment, with an estimated respondent burden of 500 hours (425 technical, 50 clerical, 25 managerial). Assuming 15 substances, the risk assessments would represent a burden of 12,000 hours (see Table 9).

#### **Action Plans and Final Summary**

EPA assumes that the action plans and agreed-upon risk management measures will be presented in summary documents, likely produced by the participants. Therefore, EPA is estimating that these documents combined will require a respondent burden of 100 hours (85 technical, 10 clerical, 5 managerial). These burdens are detailed in Table 9.

-	Hours per Response					
Program Element	Technical	Clerical	Managerial	Total		
Robust summaries			_			
(hazard assessments)*	15	5	0	20		
Exposure assessments	Prelim: 425	Prelim: 50	Prelim.: 25	Prelim: 500		
	Final: 850	Final: 100	Final: 50	Final: 1,000		
	Total: 1,275	Total: 150	Total: 75	Total: 1,500		
Risk assessments	Prelim: 255	Prelim: 30	Prelim: 15	Prelim: 300		
	Final: 425	Final: 50	Final: 25	Final: 500		
	Total: 680	Total: 80	Total: 40	Total: 800		
Action plans and summary	85	10	5	100		

# Table 9. Respondent Burdens for the In-Depth NMSP Reporting Elements

\* Burden estimates are per robust summary. As indicated in the text, EPA estimates an average of five robust summaries may be developed per substance.

#### 6(b)(2) Estimates of Respondent Cost (In-Depth Program)

Table 10 combines estimates of respondent burden with appropriate industry labor rates (from Table 2) to estimate the respondent cost of the In-Depth NMSP reporting elements.

# Table 10. Respondent Cost for the In-Depth NMSP Reporting Elements

-	Labor Cost per Response					
Program Element	Technical (\$53.02/hr)	Clerical (\$26.37/hr)	Managerial (\$63.61/hr)	Total (\$)		
Robust summaries						
(hazard assessments)*	\$795	\$132	\$0	\$927		
Exposure assessments	\$67,601	\$3,956	\$4,771	\$76,328		
Risk assessments	\$36,054	\$2,110	\$2,544	\$40,708		
Action plans and summary	\$4,507	\$264	\$318	\$5,089		

\* Cost estimates are per robust summary. As indicated in the text, EPA estimates an average of five robust

summaries may be developed per substance.

## 6(b)(3) Total Respondent Burden and Cost (In-Depth Program)

The total burden and cost per respondent are estimated by multiplying the burdens and costs per reporting element by the number of elements per response. As shown in Table 11, the estimated burden per response is 2,500 hours and the total estimated cost per response is \$126,760.

Table 11. Respondent Burden and Cost for the In	n-Depth NMSP Reporting Elements
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	Burden and	l Cost per		<b>Burden and Cost Per</b>		
	Element		No. of Elements	Response		
<b>Reporting Element</b>	Burden	Cost	per Response	Burden	Cost	
Robust summaries	20	\$927	5	100	\$4,635	
(hazard assessments)*						
Exposure assessments	1,500	\$76,328	1	1,500	\$76,328	
Risk assessments	800	\$40,708	1	800	\$40,708	
Action plans and	100	\$5,089	1	100	\$5,089	
summary						
Total				2,500	\$126,760	

The total burdens and costs for all respondents are estimated by multiplying the burdens and costs per respondent by the number of respondents (15). As shown in Table 12, the total estimated respondent burden is 37,500 hours and the total estimated respondent cost is \$1.9 million.

	<b>Burden and Cost per</b>			<b>Burden and Cost Per</b>	
	Resp	onse	No. of	Response	
<b>Reporting Element</b>	Burden	Cost	Responses	Burden	Cost
Robust summaries	100	\$4,635		1,500	\$69,525
(hazard assessments)					
Exposure assessments	1,500	\$76,328		22,500	\$1,144,920
Risk assessments	800	\$40,708	15	12,000	\$610,620
Action plans and	100	\$5,089		1,500	\$76,335
summary					
Total	2,500	\$126,760		37,500	\$1,901,400

# Table 12. Total Respondent Burden and Cost for the In-Depth NMSP

Costs and burdens of participation in the program may be shared by multiple companies working through consortia, as is the case with several current EPA-sponsored chemical testing programs. And it important to again note that participants will likely incur other costs, such as costs for testing and risk-management measures, that are not included in the reporting burdens estimated in this ICR.

# 6(b)(4) Agency Burden and Costs (In-Depth Program)

This section estimates the burden and cost that will be incurred by EPA in connection with the In-Depth NMSP. Agency burdens for managing and participating in the In-Depth NMSP are assumed to require a similar amount of staff time and a similar labor mix as the

VCCEP. In the ICR for the VCCEP, EPA estimated an Agency burden of 1,100 hours per year, divided among GS-11, GS-14, and GS-15 level employees. Based on the number of expected responses to the VCCEP (209) versus the number of expected responses to the In-Depth NMSP (15), EPA assumes the In-Depth NMSP will be proportionally less burdensome for the Agency. Thus the Agency burden is estimated at 650 hours annually, as detailed in Table 13. The Agency cost associated with this burden is \$45,778.

Table 13. Agency I	<b>Burden and Cost for</b>	the In-Depth NM	SP	
Itom	CS 15 Stop 1	CS 14 Stop 1	CC 11	Ston

Item	GS-15	, Step 1	GS-14	, Step 1	GS-11,	Step 1		
Labor rate (\$/hr)	\$82	2.43	3 \$70.08		\$41.60		Total	
	Hours	Cost	Hours	Cost	Hours	Cost	Hours	Cost
Hours and cost	295	\$24,317	235	\$16,469	120	\$4,992	650	\$45,778

Note: Agency personnel hourly wage rates are taken from the OMB pay tables for Washington, DC. 60% is added to the base wage to account for fringe and overhead

#### 6(b)(5) Total Annual Burden and Cost Estimates (In-Depth Program)

Over the three-year ICR period the total combined burden (industry and Agency) for the In-Depth NMSP is estimated at 38,150 hours and the total combined cost (industry and Agency) is estimated at \$1.95 million. On an annual basis, the combined industry and Agency burden is 12,717 hours and the combined industry and Agency cost is \$649,059. These totals are shown in Table 14.

#### Table 14. In-Depth NMSP Burdens and Costs, Total and Annual

	Total (	(3 Years)	Annual		
	Burden		Burden		
Entity Type	(Hours)	Cost	(Hours)	Cost	
Industry	37,500	\$1,901,400	12,500	\$633,800	
Agency	650	\$45,778	217	\$15,259	
Total	38,150	\$1,947,178	12,717	\$649,059	

# 6(c) Total and Annual Burden and Cost Estimates, Basic NMSP and In-Depth NMSP

As shown in Table 15, the total combined burden (industry and Agency) for both the Basic NMSP and In-Depth NMSP is estimated at 80,450 hours and the total combined cost (industry and Agency) is estimated at \$4.24 million. On an annual basis, the combined burden (industry and Agency) for both the NMSP and In-Depth NMSP is estimated at 26,817 hours and the combined cost (industry and Agency) is estimated at \$1.41 million.

Table 15, 10	Table 15, Total and Annual Duruen and Cost, Dasic Mulsi and In-Depth Mulsi							
Entity	Basic	NMSP	In-Dept	th NMSP	Total			
Туре	Burden	Cost	Burden Cost		Burden	Cost		
			Total, 3 Year.	5				
Industry	36,672	\$1,912,320	37,500	\$1,901,400	74,172	\$3,813,720		
Agency	5,628	\$378,240	650	\$45,778	6,278	\$424,018		
Total	42,300	\$2,290,560	38,150	\$1,947,178	80,450	\$4,237,738		
			Annual					
Industry	12,224	\$637,440	12,500	\$633,800	24,724	\$1,271,240		

#### Table 15. Total and Annual Burden and Cost, Basic NMSP and In-Depth NMSP

Agency	1,876	\$126,080	217	\$15,259	2,093	\$141,339
Total	14,100	\$763,520	12,717	\$649,059	26,817	\$1,412,579

#### **6(d)** Changes in Burden Estimates

This is a new ICR; therefore there is no change in burden estimates from that previously approved by OMB.

#### 6(e) Burden Statement

The annual public burden for this collection of information is estimated to average 51 hours per response for the Basic NMSP, and 833 hours for the In-Depth NMSP. According to the Paperwork Reduction Act, "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 numbers for EPA's regulations in title 40 of the CFR, after appearing in the Federal Register, are listed in 40 CFR part 9 and included on the related collection instrument or form, if applicable.

To comment on the Agency's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden, including the use of automated collection techniques, EPA has established a public docket for this ICR under EPA Docket ID No. EPA-HQ-OPPT-2007-0572, which is available for public viewing online at www.regulations.gov. The Pollution Prevention and Toxics 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.

An electronic version of the public docket is available through Regulations.gov at http://www.regulations.gov. Use this tool to submit or view public comments, access the index listing of the contents of the public docket, and to access those documents in the public docket that are available electronically. Once in the system, select "search," then key in the docket ID number identified above. Also, you can send comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street, NW, Washington, DC 20503, Attention: Desk Office for EPA. Please include the EPA Docket ID No. EPA-HQ-OPPT-2007-0572 in any correspondence.

# REFERENCES

BLS 2006. U.S. Bureau of Labor Statistics. *May 2005 National Industry-Specific Occupational Employment and Wage Estimates: Sectors 31, 32, and 33 – Manufacturing*. May 24, 2006, http://www.bls.gov/OES/current/naics2\_31-33.htm

BLS 2005a. Unpublished *Employer Costs for Employee Compensation* (ECEC) data received by Carol Rawie, US EPA, from Raphael Branch, US Bureau of Labor Statistics, September 16, 2005. The data is not seasonally adjusted (email from Raphael Branch to Carol Rawie, November 17, 2005).

EPA 2006. TSCA Section 8(d) ICR for the Health and Safety Data Reporting Rule.

EPA 2002. Supporting Statement for a Request for OMB Review under the Paperwork Reduction Act: Data Submissions for the Voluntary Children's Chemical Evaluation Program, April. http://www.epa.gov/EPA-TOX/2002/April/Day-16/o-t9221.htm

NCMS 2006. National Center for Manufacturing Sciences, 2005 NCMS Survey of Nanotechnology in the U.S. Manufacturing Industry: Abstract, National Science Foundation, March 6, 2006.

NNI 2006. National Nanotechnology Initiative, Nanotech Facts, Application and Products, August 22, 2006. http://www.nano.gov/html/facts/appsprod.html

NPPTAC 2005. Overview of Issues for Consideration by NPPTAC. Document ID EPA-HQ-OPPT-2002-0001-0068. http://www.regulations.gov/fdmspublic/component/main

OPM 2006. Salary Table 2006 DCB, for the Locality Pay Area of Washington-Baltimore-Northern Virginia, DC-MD-PA-VA-WV. U.S. Office of Personnel Management. http://www.opm.gov/oca/06tables/html/dcb\_h.asp

RIB 1994. Regulatory Impacts Branch. *Regulatory Impact Analysis of Amendments to Regulations for TSCA Section 5 Premanufacture Notifications*. Washington, DC: U.S. EPA/OPPT/EETD/RIB, September 9, 1994.

Roco 2005. M.C. Roco, "Nanotechnology," National Science Foundation, presented at 2<sup>nd</sup> Annual International Symposium on Nanotechnology and Occupational Health, University of Minnesota, October 3, 2005. http://www.nsf.gov/crssprgm/nano/reports/nni\_05\_1003\_minn\_tutoria.pdf

Wilson Center 2006. Woodrow Wilson International Center, Project on Emerging Nanotechnologies. Nanotech Consumer Products Inventory. March 10, 2006. http://www.nanotechproject.org/index.php?id=46

# ATTACHMENTS

All attachments are included in the electronic docket (EPA Docket ID No. EPA-HQ-OPPT-2007-0572) at www.regulations.gov, unless otherwise noted.

ATTACHMENT A - Nanoscale Materials Stewardship Program Data Submission Form