

**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 has established a voluntary information collection to assemble existing data and information from manufacturers, importers, and processors of nanoscale materials regulated under the Toxic Substances Control Act (TSCA). EPA will also 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 to increase understanding of the environmental health and safety implications of manufactured nanoscale materials.

This collection of information 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 includes industry and the interested public in characterizing the safe manufacture, processing, distribution, use, storage, recycling, 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 to a significant degree. There are estimated to be hundreds of nanotechnology products already on the market. The National Science Foundation predicts that the market worldwide for nanotechnology products and services will reach \$1 trillion by 2015. Nanotechnology 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 TSCA §5 because they are not listed on the TSCA Inventory. Therefore, they are subject to review under TSCA for potential human health and environmental

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risks before they are manufactured and enter commerce. Other nanoscale materials have the same molecular identity as chemical substances 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 nanoscale materials already in commerce, it could also include nanoscale materials that would be reportable to EPA under TSCA §5. It is important to note that participation in the voluntary stewardship program will not relieve manufacturers, importers, or 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 comprehensive information on the properties and characteristics of nanoscale materials.

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.

## **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.

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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 information about nanoscale materials.

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

On July 12, 2007 (72 FR 38079), EPA sought public comment on the draft ICR, and received four comments in response.

One commenter supported the estimates in the ICR but noted that the estimates of the number of NMSP participants and responses may be too high and that EPA should not measure success of the program based on the estimated number of participants. As the commenter did not offer any basis for an alternative estimate, EPA is retaining the estimates as proposed. The estimates are based on the best available information to EPA. Because those estimates are based on market information for all nanotechnology firms and assumed a certain percentage have nanoscale materials that could be reported under the program, EPA acknowledges that they could be an overestimate.

Two commenters noted that the proposed reporting form could be a considerable burden to fill out especially for smaller entities. When developing the optional form, EPA considered that it might not be suitable for all participants, especially smaller entities with limited information and resources, which is why the form was proposed as an optional tool to facilitate reporting, as opposed to requiring participants to use it. EPA also intended that a participant would not complete each element of the form – just complete those elements that were relevant to their material. EPA believes that the form helps participants more easily identify the type of information that may be submitted, and provides a vehicle for organizing and submitting the information. As such, EPA will continue to make the form available for use as proposed and will also make it clearer to participants that use of the form is optional. While EPA encourages participants to use the form, participants may report data in any format they choose. In addition, anyone who uses the form is not required to fill out the entire form. They may fill in only the information that is available to them.

Another commenter asserted that because EPA will use the data collected under the NMSP to determine which chemicals need to be regulated and which do not, the data had to meet the Data Quality Act Guidelines and other EPA Quality System standards. The commenter also stated that by making the data submitted publicly available to the extent that they are not protected from release as CBI, the Agency was required to ensure that the data meet the EPA Information Quality Guidelines. As previously stated, EPA intends to use the data collected under the NMSP to gain an understanding of which nanoscale materials are produced, in what quantities they are produced, how they are used, and the data that is available for such materials.

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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 will use the data to build new assessment models or incorporate the data into existing models with regard to hazard, exposure, and fate. EPA will also increase its capacity to assess benefits from nanoscale materials. As with any data submitted to EPA, other uses of the data may arise from reviews and the Agency is no way restricted from using the data for other purposes. To the extent applicable, EPA intends to ensure that EPA's use of the data collected under the NMSP complies with EPA's Information Quality Guidelines.

Based on these comments, EPA has estimated additional burden to account for the development of a fact sheet or other outreach materials to lend assistance to small business participants in the stewardship program. EPA has modified Table 8 in Section 6(a)(5) of this ICR to reflect an increase in burden for the first year of the program and less burden in the last two years, because EPA is encouraging reporting within the first six months of the announcement of the program. This change does not reflect a change in the total burden estimate. EPA has also updated some burden estimates and wage rates to reflect the most recent available information which resulted in minor changes to the total burden estimate.

On July 12, 2007 (72 FR 38083), EPA also sought public comment on a Concept Paper for the NMSP and a document entitled "TSCA Inventory Status of Nanoscale Materials - General Approach.". EPA received twenty-six comments on these documents. Comments on these documents are available in at [www.regulations.gov](http://www.regulations.gov) under Docket ID No. EPA-HQ-OPPT-2004-0122. EPA is in the process of developing a document that will build on the Concept Paper but provides more details for the NMSP. Copies of the July drafts of these documents are also in the docket for this ICR.

### **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). The June 23, 2005, public meeting and the NPPTAC Overview Document elicited broad stakeholder support for the idea of a stewardship program which identified specific issues relevant to the program that EPA is considering.

As described in the NPPTAC Overview Document, EPA held a public scientific peer consultation on risk management practices for nanoscale materials on October 19-20, 2006 and on material characterization for nanoscale materials on September 6-7, 2007. The approach is consistent with OMB Memorandum dated September 19, 2007 "Updated Principles for Risk Analysis." EPA also conducted another public meeting on August 2, 2007 to obtain comments and input on all aspects of the NMSP. The reports from all of these meetings are available in Docket ID No. EPA-HQ-OPPT-2004-0122 and on OPPT's Nanotechnology under the Toxic Substances Control Act webpage at <http://epa.gov/oppt/nano/index.htm>. EPA considered all of the comments and input from these meetings when designing and structuring the NMSP, including this ICR.

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

There is no set frequency of submission under this voluntary information collection request. Participants in the voluntary program (i.e., the manufacturers, importers, and processors of nanoscale materials) will determine whether and when to submit information under this program, including whether to submit all of the information at once or to submit it in stages. The Agency believes that this flexibility is important for such a program, given its voluntary nature. As such, there is no less frequent collection option for the Agency to consider.

### **3(e) Compliance with General OMB Guidelines**

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

### **3(f) Confidentiality**

If respondents wish to claim information submitted as confidential business information (CBI), they may do so at the time of submission. 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, with any claims of confidentiality 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 deliver to EPA. Because of time constraints, security issues related to the electronic transfer of CBI, and potential expenses for EPA and respondents, it is not feasible to devise a direct electronic submission scheme for this voluntary collection effort.

## **4. THE RESPONDENTS AND THE INFORMATION REQUESTED**

### **4(a) Respondents/SIC Codes**

Potential participants in the stewardship program and respondents affected by the collection activity in this ICR may include, but are not limited to the following groups, using the North American Industrial Classification System (NAICS) codes, Chemical Manufacturing (Code 325) and Petroleum and Coal Products (Code 324).

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

EPA is establishing two information collection levels for the stewardship program. The first level is referred to as the “basic program”, and the second level is referred to as the “in-depth program.” These levels differ with regard to the information requested and the participants. Although all participants are expected to provide the information requested for the basic program, only some of the participants are expected to volunteer for the in-depth program. The information requested for the basic program is discussed in section 4(b)(i), and the information requested for the in-depth program is discussed in section 4(b)(ii) of this ICR.

#### **4(b)(i) Basic Program**

EPA is requesting that respondents provide all the information described below to the extent it is known or reasonably ascertainable by them. EPA is not requesting that respondents develop additional data for the basic program.. 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. Information requested includes:

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	Explosibility
Adsorption coefficient	Shape
Agglomeration state/dispersion state	
Crystal structure	
Chemical composition – including spatially averaged (bulk) and spatially resolved heterogeneous composition	
Surface area	Surface chemistry
Surface charge	Porosity

4. Description of all uses including expected consumer uses.

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5. Estimate of the total amount of substance to be manufactured/imported including the amounts for each use category.
6. Description of byproducts and impurities resulting from manufacture, process, use, recycling, or disposal of the chemical.
7. For each type of workplace in the lifecycle, the same information requested on pp. 8-10 of the EPA PMN form (EPA Form No. 7710-25) would be helpful for releases and exposures.
8. In addition to the properties and information identified in item 3 above, 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 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, the rationale for selecting the control, and, if available, data and measurement methods of waste treatment or purification efficiency studies for the nanoscale material including any analytical methods used.
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, the 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 recycling or 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 an optional form for participants to use, which is based on the PMN reporting form (EPA Form No. 7710-25). Copies of both the PMN form and the optional form for this information collection request are attached to this ICR. It is not essential that respondents use the optional form provided. 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, and may therefore find the optional form helpful in providing the requested information under the NMSP.

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 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 recycling and waste management techniques.

#### **4(b)(ii) The In-Depth Program**

The information collection described in 4(b)(i) 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. The in-depth 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.

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 could join at any given time, depending on OPPT's resources and respondents' interest in pursuing the in-depth 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;
- Assessing the ability to recycle the nanoscale material and/or the products containing the nanoscale material at their end-of-life; 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 the testing of an individual substance that is representative of a class or classes of nanoscale materials.

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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 submission of the information on a CD-ROM reduces the reporting burden on industry, because it is intended to reduce both the cost and the time required to enter, review, and edit the data. Submission of the information electronically may also improve data quality because it facilitates correcting incorrect data or adding omitted data. The Agency believes that this approach is the most effective way of submitting the data requested under this ICR, and that it minimizes the collection burden for the participant and for EPA to process and manage the data submitted.

### **5(c) Small Entity Flexibility**

Participation in the stewardship program is voluntary, and there is nothing that would obligate a small business to participate. If a small business does choose to participate, 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**

While the submission of information under this collection is initiated by the respondents, EPA will encourage respondents to complete basic reporting (as described in section 4(b)(i) of this ICR) within six months of the announcement of the start of the voluntary program. This will enable EPA to report on the response and the progress of the stewardship program, and to begin to evaluate data received, and make further decisions or adjustments regarding the stewardship program.

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

The estimated burden and costs are presented in two parts to reflect the two information collection levels for the stewardship program described in section 4(b) of this ICR. The basic program and the in-depth program differ with regard to the information requested and the potential participants. Although all participants are expected to provide the information requested for the basic program, only some of the participants are expected to volunteer for the in-depth program.

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

#### **6(a)(1) Estimates of Respondent Burden (Basic Program)**

Participants in the basic reporting component of the 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 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 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 under the stewardship program and not

the total costs for 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 the assumptions and burden estimations provided in this ICR may not be appropriate for businesses that may not have prior experience with the chemical regulatory system.

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 used the information collection activities and estimates from the ICR related to the PMN form as a baseline for this ICR, and used the PMN form as a model for creating the optional form that is being made available for the participants in the stewardship program.

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

Reporting Element	Hours				Source
	Clerical	Technical	Managerial	Total	
1 General instructions & manager certification; Submitter information	2.5	2	1	5.5	(a)
2 Chemical identity info	2	7.5	1	10.5	
3A Physical properties	0.5	2	0.5	3	
3B Additional physical properties	1	4	1	6	(b)
4 Description of uses	0.75	3	1.5	5.25	(a)
5 Amount of substance to be manufactured/imported	0.75	1	1.5	3.25	
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	(b)
9 Overview of the lifecycles	1	10	2	13	
10 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	1.5	7.2	10	18.7	(c)
<b>Total</b>	<b>17.7</b>	<b>105.2</b>	<b>31.4</b>	<b>154.3</b>	--

(a) EPA, 1994

(b) Based on best professional judgment

(c) TSCA 8(d) ICR (EPA 2006); see Table 1<sup>1</sup>

<sup>1</sup> Estimates exclude burdens for robust summary of studies and any post-reporting follow-up to ongoing studies (lines 6 and 8 in Table 1 of the TSCA 8(d) ICR).

In estimating the burdens for this 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 (EPA 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 provide the basic reporting elements is 154.3 hours.

### **6(a)(2) Estimates of Respondent Cost (Basic Program)**

#### **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. The basic methodology is described more fully in *Wage Rates for Economic Analysis of the Toxics Release Inventory Program* (EPA 2002). Average wages and fringe benefits for managerial, professional/technical, and clerical labor<sup>2</sup> were taken from the Bureau of Labor Statistics (BLS) *Employer Costs for Employee Compensation* (ECEC) data for December 2006, for the manufacturing industries (BLS 2007). The cost of fringe benefits (such as paid leave and insurance) specific to each labor category is taken from the same BLS series. 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.

The data used to calculate the wage rates and the results are shown in Table 2. The estimated fully loaded wage rates are \$65.36 per hour for managerial staff, \$54.65 per hour for technical staff, and \$27.00 per hour for clerical staff.

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<sup>2</sup> BLS uses the Standard Occupational Classification system. A crosswalk between EPA labor categories is as follows: EPA Managerial = BLS Management, business, and financial; EPA Technical = BLS Professional and related; Clerical = BLS Office and administrative support.

**Table 2. Industry Labor Category and Loaded Hourly Rate**

<b>Labor Category</b>	<b>Wages<sup>a</sup></b>	<b>Fringe Benefits<sup>a</sup></b>	<b>Overhead (17% of base wage)<sup>b</sup></b>	<b>Loaded Wage Rate (2006 \$)</b>
Managerial	\$39.77	\$18.83	\$6.76	\$65.36
Technical	\$32.38	\$16.77	\$5.50	\$54.65
Clerical	\$16.07	\$8.20	\$2.73	\$27.00

<sup>a</sup> Source: BLS 2007.

<sup>b</sup> Source: EPA 2002.

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 \$8,279. These estimates are in 2006 dollars.

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

Reporting Element	Hours*				Cost*			
	C	T	M	Total	C	T	M	Total (2006\$)
					@\$27.00/hr	@\$54.65/hr	@\$65.36/hr	
1 General instructions & manager certification; Submitter information	2.5	2	1	5.5	\$67.50	\$109.30	\$65.36	\$242.16
2 Chemical identity info	2	7.5	1	10.5	\$54.00	\$409.88	\$65.36	\$529.24
3A Physical properties	0.5	2	0.5	3	\$13.50	\$109.30	\$32.68	\$155.48
3B Additional physical properties	1	4	1	6	\$27.00	\$218.60	\$65.36	\$310.96
4 Description of all uses including expected consumer uses	0.75	3	1.5	5.25	\$20.25	\$163.95	\$98.04	\$282.24
5 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	\$20.25	\$54.65	\$98.04	\$172.94
6 Description of byproduct resulting from manufacture, process, use, or disposal of chemical	0	0.5	0	0.5	\$0	\$27.33	\$0.00	\$27.33
7 Human exposure and environmental release	5.5	52	9.5	67	\$148.50	\$2,841.80	\$620.92	\$3,611.22
8 Physical properties related to assessing exposures and releases	1	4	1	6	\$27.00	\$218.60	\$65.36	\$310.96
9 Overview of the lifecycles	1	10	2	13	\$27.00	\$546.50	\$130.72	\$704.22
10 Release point control technology	0.2	2	0.4	2.6	\$5.40	\$109.30	\$26.14	\$140.84
11 Worker exposure information	0.2	2	0.4	2.6	\$5.40	\$109.30	\$26.14	\$140.84
12 Protective equipment or engineering control	0.2	2	0.4	2.6	\$5.40	\$109.30	\$26.14	\$140.84
13 Information on cleaning/reuse/disposal of used protective equipment	0.1	1	0.2	1.3	\$2.70	\$54.65	\$13.07	\$70.42
14 Additional procedures or other equipment intended to mitigate exposures to nanoscale materials	0.1	1	0.2	1.3	\$2.70	\$54.65	\$13.07	\$70.42
15 Description of worker training and hazardous communication specific	0.1	1	0.2	1.3	\$2.70	\$54.65	\$13.07	\$70.42
16 Number of individuals other than workers exposed to the chemical and duration of exposure	0.1	1	0.2	1.3	\$2.70	\$54.65	\$13.07	\$70.42
17 Manner or method of disposal for consumer use of products	0.2	2	0.4	2.6	\$5.40	\$109.30	\$26.14	\$140.84
18 Test data in the submitter's possession of information on health/environmental effects	1.5	7.2	10	18.7	\$40.50	\$393.48	\$653.60	\$1,087.58
<b>Total</b>	<b>17.7</b>	<b>105.2</b>	<b>31.4</b>	<b>154.3</b>	<b>\$477.90</b>	<b>\$5,749.18</b>	<b>\$2,052.30</b>	<b>\$8,279.38</b>

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

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

NMSP is a voluntary program. So the number of participants or potential responses to the information collection request is as yet undetermined. The Agency's estimate, therefore, is

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based on several assumptions. Although it is likely that these assumptions may have resulted in an overestimate, as suggested by one commenter on the draft ICR, the Agency believes that the estimates are reasonable given the current status of this new voluntary program.

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

Because the nanotech “industry” is not well defined, few reliable estimates of its overall size and composition exist. 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 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 estimated to about 600 firms in 2005 ( $1,455 \times 0.42 = 611$ ).

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 incorporate materials that *would* be considered new chemicals under TSCA. Further, the Wilson Center 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, there are a total of 600 nanotechnology manufacturers where 80 percent 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' familiarity with the chemical regulatory program and EPA, as well resources and staff availability. Further, 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 be more likely to volunteer to submit information on nanoscale substances than small businesses. Also, EPA assumes that each large company participating will submit information on two nanoscale substances and that each small business participating will submit information on one nanoscale substance. 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 that each small business participating will submit information on one nanoscale substance. As a result, over the three-year ICR period, EPA estimates 120 submissions from large businesses and 120 submissions from small businesses for a total of 240 submissions.<sup>3</sup>

Since EPA is encouraging submissions to be reported within the first six months of the program, EPA is allocating the number of submissions by year as follows:

- Year 1: 60% (240 \* 60% = 144)
- Year 2: 30% (240 \* 30% = 72)
- Year 3: 10% (240 \* 10% = 24)

#### **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 basic program of NMSP. The total burden for 240 responses is 36,552 hours (154.3 hours per response \* 240 responses), and the total respondent cost is \$1.99 million (\$8,279 per response \* 240 responses). Table 4 breaks down the total burden and cost by year.

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<sup>3</sup> 60 large businesses will submit two responses each and 120 small businesses will submit one response each.

**Table 4. NMSP Basic Program Respondent Cost and Burden**

<b>Year</b>	<b>No. of Responses</b>	<b>Burden per Response (hours)</b>	<b>Total Response Burden (hours)</b>	<b>Cost per Response (\$2006)</b>	<b>Total Response Cost (\$2006)</b>
1	144	154.3	22,219	\$8,279	\$1,192,176
2	72		11,110		\$596,088
3	24		3,703		\$198,696
<b>Total</b>	<b>240</b>		<b>37,032</b>		<b>\$1,986,960</b>

**6(a)(4) Estimated Agency Burden and Costs (Basic Program)**

This section estimates the burden and cost that will be incurred by EPA in connection with the basic reporting component of the NMSP. As the Agency develops, implements, and operates the program, EPA will undertake a number of activities, including:

- Conducting pre-submission consultations
- Developing a fact sheet and other outreach materials
- Reviewing and discussing submissions
- Filing and storing submissions
- Analyzing requests for confidentiality and providing appropriate protection
- Writing a summary report of the NMSP basic program.

**Agency Burdens**

EPA estimated the Agency burdens associated with the NMSP basic program are based upon the burdens estimated for the PMN program (EPA 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 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 Table 5, EPA’s estimated burden per submission is 22.2 hours. EPA also estimates a one-time burden of 60 hours to develop and distribute a fact sheet about the NMSP and 300 hours to write a summary report on the NMSP basic program (not shown in Table 5). Burden for the fact sheet and outreach material is allocated to Year 1, while the burden for the summary report is split between years 2 and 3.

**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. EPA assumes that these activities are accomplished by a GS-13, Step 5 federal employee (EPA 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 (EPA 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.

**Table 5. Agency Activities and Estimated Burden per Response**

<b>Review Step</b>	<b>Description</b>	<b>Burden (Hours)</b>
1 Pre-submission consultations	These discussions allow potential submitters and the Agency to communicate any issues pertaining to the submission.	4.8
2 Administrative prescreen / submission receipt	The Agency performs an administrative review of each submission to verify information received and logs the receipt of data.	4.8
3 Chemical Review and Search Strategy (CRSS)	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 Structure Activity Team (SAT)	Based 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.	3
5 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.	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
<b>Total</b>		<b>22.2</b>

Note: The table does not include one-time costs associated with preparing and distributing a fact sheet regarding NMSP and a summary report on the NMSP (estimated at 360 hours).

**Table 6. Agency Burden and Costs per Response Under the NMSP Basic Program**

<b>Review Step</b>	<b>Hours</b>	<b>Total Cost (2006\$)</b>
1 Pre-submission consultations	4.8	\$322.56
2 Administrative prescreen / submission 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
<b>Total</b>	<b>22.2</b>	<b>\$1,491.84</b>

Note: Assumes activities are accomplished by GS-13, Step 5 employee at a loaded rate of \$67.20/hr. Calculations do not include one-time Agency costs.

**Total Agency Burdens and Costs (Basic Program)**

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 Tables 7 and 8 include one-time costs (e.g., outreach materials and summary report). The total agency burden is 5,688 hours and the total Agency cost is \$380,952.

**Table 7. Agency Burden Associated with the NMSP Basic Program**

Year	No. of Responses	Burden per Response (hours)	Total Response Burden (hours)	Burden for One Time Tasks	Total Burden
1	144	22.2	3,197	60	3,257
2	72		1,598	150	1,748
3	24		533	150	683
<b>Total</b>	<b>240</b>		<b>5,328</b>	<b>360</b>	<b>5,688</b>

**Table 8. Agency Cost Associated with the NMSP Basic Program**

Year	No. of Responses	Cost per Response (hours)	Total Response Cost (hours)	Cost for One Time Tasks	Total Burden (2006\$)
1	144	\$1,492	\$214,848	\$4,032	\$218,880
2	72		\$107,424	\$10,080	\$117,504
3	24		\$35,808	\$10,080	\$45,888
<b>Total</b>	<b>240</b>		<b>\$358,080</b>	<b>\$24,192</b>	<b>\$382,272</b>

**6(a)(5) Total Annual Burden and Cost Estimates for the Basic Program**

The total estimated industry burden, from Table 4, is 37,032 hours and the total estimated costs are \$1.99 million. The total estimated Agency burden for administering the NMSP, from Table 7, is 5,688 hours and, from Table 8, the total estimated cost is \$382,272.

Over the three-year ICR period the total combined burden (industry and Agency) is estimated at 42,720 hours and the total combined cost (industry and Agency) is estimated at \$2.37 million. In Table 9, the annual burden and cost are presented for each year of the ICR.

**Table 9. NMSP Basic Program Burden and Costs for Industry and Agency**

Entity Type	Year 1		Year 2		Year 3		Total	
	Burden (Hours)	Cost	Burden (Hours)	Cost	Burden (Hours)	Cost	Burden (Hours)	Cost
Industry	22,219	\$1,192,176	11,110	\$596,088	3,703	\$198,696	37,032	\$1,986,960
Agency	3,257	\$218,880	1,748	\$117,504	683	\$45,888	5,688	\$382,272
<b>Total</b>	<b>25,476</b>	<b>\$1,411,056</b>	<b>12,858</b>	<b>\$713,592</b>	<b>4,386</b>	<b>\$244,584</b>	<b>42,720</b>	<b>\$2,369,232</b>

## **6(b) Nanoscale Materials Stewardship In-Depth 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 specific in-depth program's elements 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 (EPA 2002). 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, the Agency 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 the generation and submission of data, 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 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 each robust summary requires 15 hours of technical time and 5 hours of clerical time each. This estimate results in 20 hours per robust summary (see Table 10). Assuming 15 substances are enrolled in the program, which on average will include five robust summaries, a total of 75 (i.e., 15 \* 5) robust summaries will be prepared. Total burden related to robust summaries per substance is 1,500 (75 \* 20) hours.

**Table 10. Respondent Burdens for the In-Depth NMSP Reporting Elements**

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

\* Burden estimate is per robust summary. The Agency expects an average of five robust summaries to be developed per substance.

### 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 hours, and 25 managerial hours) 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 hours, 100 clerical hours, 50 managerial hours). EPA further assumes that the burden estimates for these assessments include the paperwork burden associated with summarizing any monitoring or exposure testing conducted. As presented in Table 10, total burden related to exposure assessments per substance is 1,500 hours.

### 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 hours, 30 clerical hours, and 15 managerial

hours). 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 hours, 50 clerical hours, 25 managerial hours). The risk assessments represent a burden of 800 hours per substance (see Table 10).

### **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 hours, 10 clerical hours, and 5 managerial hours) per substance. These burdens are detailed in Table 10.

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

Table 11 combines estimates of respondent burden (Table 10) with appropriate Industry labor rates (from Table 2) to estimate the respondent cost of the In-Depth NMSP reporting elements.

**Table 11. Respondent Cost for the In-Depth NMSP Reporting Elements**

<b>Program Element</b>	<b>Labor Cost per Element</b>			<b>Total Cost (2006\$)</b>
	<b>Clerical (\$27.00/hr)</b>	<b>Technical (\$54.65/hr)</b>	<b>Managerial (\$65.36/hr)</b>	
Robust summaries (hazard assessments)*	\$135	\$820	\$0	\$955
Exposure assessments	\$4,050	\$69,679	\$4,902	\$78,631
Risk assessments	\$2,160	\$37,162	\$2,614	\$41,936
Action plans and summary	\$270	\$4,645	\$327	\$5,242

\* 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 12, the estimated burden per response is 2,500 hours and the total estimated cost per response is \$130,584.

**Table 12. Respondent Burden and Cost for the In-Depth NMSP Reporting Elements**

Reporting Element	Burden and Cost per Element		No. of Elements per Response	Burden and Cost Per Response	
	Burden	Cost		Burden	Cost
Robust summaries (hazard assessments)*	20	\$955	5	100	\$4,775
Exposure assessments	1,500	\$78,631	1	1,500	\$78,631
Risk assessments	800	\$41,936		800	\$41,936
Action plans and summary	100	\$5,242		100	\$5,242
<b>Total</b>				<b>2,500</b>	<b>\$130,584</b>

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 13, the total estimated respondent burden is 37,500 hours and the total estimated respondent cost is \$1.96 million.

**Table 13. Total Respondent Burden and Cost for the In-Depth NMSP**

Reporting Element	Burden and Cost per Response		No. of Responses	Total Burden and Cost	
	Burden	Cost		Burden	Cost
Robust summaries (hazard assessments)	100	\$4,775	15	1,500	\$71,625
Exposure assessments	1,500	\$78,631		22,500	\$1,179,465
Risk assessments	800	\$41,936		12,000	\$629,040
Action plans and summary	100	\$5,242		1,500	\$78,630
<b>Total</b>	<b>2,500</b>	<b>\$130,584</b>		<b>37,500</b>	<b>\$1,958,760</b>

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. Again it is important to 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 14. The Agency cost associated with this burden is \$45,778.



**Table 14. Agency Burden and Cost for the In-Depth NMSP**

Item	GS-15, Step 1		GS-14, Step 1		GS-11, Step 1		Total	
	Hours	Cost	Hours	Cost	Hours	Cost		
Labor rate (\$/hr)	\$82.43		\$70.08		\$41.60			
Hours and cost	295	\$24,317	235	\$16,469	120	\$4,992	<b>650</b>	<b>\$45,778</b>

Note: Agency personnel hourly wage rates are taken from the 2006 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 \$1.96 million. On an annual basis, the combined industry and Agency burden is 12,717 hours and the combined industry and Agency cost is \$668,179. These totals are shown in Table 15.

**Table 15. In-Depth NMSP Burdens and Costs, Total and Annual**

Entity Type	Total (3 Years)		Annual	
	Burden (Hours)	Cost	Burden (Hours)	Cost
Industry	37,500	\$1,958,760	12,500	\$652,920
Agency	650	\$45,778	217	\$15,259
<b>Total</b>	<b>38,150</b>	<b>\$2,004,538</b>	<b>12,717</b>	<b>\$668,179</b>

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

As shown in Table 16, the total combined burden (industry and Agency) for both the Basic NMSP and In-Depth NMSP is estimated at 80,393 hours and the total combined cost (industry and Agency) is estimated at \$4.34 million. Table 17 lists the burden and cost on an annual basis, the combined burden (industry and Agency) for both the NMSP and In-Depth NMSP (based on Tables 9 and 15).

**Table 16. Total Burden and Cost, Basic NMSP and In-Depth NMSP**

Entity Type	Basic NMSP		In-Depth NMSP		Total	
	Burden	Cost	Burden	Cost	Burden	Cost
Industry	37,032	\$1,986,960	37,500	\$1,958,760	74,532	\$3,945,720
Agency	5,688	\$382,272	650	\$45,778	6,338	\$428,050
<b>Total</b>	<b>42,720</b>	<b>\$2,369,232</b>	<b>38,150</b>	<b>\$2,004,538</b>	<b>80,870</b>	<b>\$4,373,770</b>

**Table 17. Annual Burden and Cost, Basic NMSP and In-Depth NMSP, by Year**

Entity Type	Year 1		Year 2		Year 3		Total	
	Burden (Hours)	Cost	Burden (Hours)	Cost	Burden (Hours)	Cost	Burden (Hours)	Cost
Industry	34,719	\$1,845,096	23,610	\$1,249,008	16,203	\$851,616	74,532	\$3,945,720
Agency	3,474	\$234,139	1,965	\$132,763	900	\$61,147	6,339	\$428,049
<b>Total</b>	<b>38,193</b>	<b>\$2,079,235</b>	<b>25,575</b>	<b>\$1,381,771</b>	<b>17,103</b>	<b>\$912,763</b>	<b>80,871</b>	<b>\$4,373,769</b>

#### **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 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 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](http://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.

## **7 REFERENCES**

The following is a list of the documents that are specifically referenced in this document, along with information about where to access the documents directly (copies are available in the docket for this ICR, or online as listed in the reference):

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EPA 2002. U.S Environmental Protection Agency. 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>

EPA 2002. U.S. Environmental Protection Agency. *Wage Rates for Economic Analysis of the Toxics Release Inventory Program*. Office of Environmental Information, Environmental Analysis Division, Analytical Support Branch. June 10, 2002.

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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](http://www.opm.gov/oca/06tables/html/dcb_h.asp)

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](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>

## **8 ATTACHMENTS TO THE SUPPORTING STATEMENT**

The attachments listed below can be found in the docket for this ICR, which is accessible electronically through [www.regulations.gov](http://www.regulations.gov) under Docket ID No. EPA-HQ-OPPT-2007-0572.

<u>Attachment</u>	<u>Description</u>
A	TSCA Section 5 authority
B	TSCA Section 8 authority
C	Optional Reporting Form for NMSP Base Program
D	Premanufacture Notice Submission Form (Already Approved under 2070-0012)