

January 12, 2017

**1 Supporting Statement for a Request for OMB Review under
The Paperwork Reduction Act**

11. IDENTIFICATION OF THE INFORMATION COLLECTION

1(a) Title of the Information Collection

**TITLE: Final Rule Related Addendum to the Existing EPA ICR Entitled:
Chemical-Specific Rules, Toxic Substances Control Act Section 8(a)**

EPA ICR No.: 2517.02 OMB Control No: 2070-0194

1(b) Short Characterization

This information collection request (ICR) addendum covers reporting and recordkeeping requirements for persons who manufacture or process chemical substances as nanoscale materials and is related to a final rule issued under the authority of section 8(a) of the Toxic Substances Control Act (TSCA). This ICR addendum will revise the existing approved ICR to incorporate reporting and recordkeeping requirements in the TSCA section 8(a) rule for Certain Nanoscale Materials, identified under RIN 2070-AJ54.

TSCA section 8(a) authorizes the Administrator of the EPA to promulgate rules that require persons who manufacture or process chemical substances and mixtures, or who propose to manufacture or process chemical substances and mixtures, to maintain such records and submit such reports to EPA as may be reasonably required. Information that may be collected under TSCA section 8(a) includes, but is not limited to, chemical names, categories of use, production volume, byproducts of chemical production, existing information on health and environmental effects, exposure information, and disposal information. This information is collected by the Office of Pollution Prevention and Toxics (OPPT) and may be used by other EPA offices and/or Federal agencies to ensure knowledge of specific practices that may affect human health and the environment.

Under TSCA section 8(a), EPA is establishing reporting and recordkeeping requirements for certain chemical substances as nanoscale materials. The rule requires that persons who manufacture or process these nanoscale materials notify EPA of certain information which includes production volume, methods of manufacture and processing, exposure and release information, and available health and safety information. The reporting of these activities will provide EPA with an opportunity to evaluate the information and consider appropriate action under TSCA to reduce any risk to human health or the environment. The information will also inform EPA's assessments of new chemical nanoscale materials submitted to EPA under section 5 of TSCA.

TSCA 8(a)(5) requires that 8(a) reporting, to the extent feasible, shall not be unnecessary or duplicative, shall minimize the cost of compliance on small manufacturers and processors, and

Addendum to EPA ICR No. 1198.10; OMB Control No. 2070-0067

shall apply to those persons likely to have information relevant to the effective implementation of TSCA. As noted in the response to comments several elements of the final rule address duplicative reporting such as the exemption for chemical substances that are nanoscale materials that have already been reported under section 5 of TSCA and for the exemption for information already submitted under the Nanoscale Materials Stewardship Program. The response also explains why the final rule does not duplicate chemical data reporting (CDR) under 40 CFR part 711. EPA's economic analysis demonstrated that the final rule would not have a significant adverse economic impact on a substantial number of small entities. The rationale is presented in the small entity impact analysis that EPA prepared for this action as part of the Agency's economic analysis in the public docket for the final rule. The rule focuses on manufacturers and processors of chemical substances as nanoscale materials with unique and novel properties which are the persons likely to have relevant information on nanoscale materials in commerce.

EPA's OPPT, other EPA Offices and/or other Federal agencies will generally be the primary groups for which information will be collected. However, to the extent that reported information is not considered to be confidential business information (CBI), environmental groups, environmental justice advocates, state and local government entities and other members of the public will have access to this information for their own use.

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 a wide variety of products, including electronics, automotive products, paints and coatings, metal-cutting tools, sports equipment, stain-free clothing and mattresses, and ink. There are hundreds of products already on the market that utilize nanoscale materials. 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.

Some nanoscale materials are recognized as new chemical substances subject to notification requirements under TSCA section 5 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. EPA has identified over 180 nanoscale materials submitted as new chemicals under TSCA since January 2005. 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 Agency has authority under TSCA §8(a) to collect information regarding chemical substances in commerce.

EPA developed a voluntary Nanoscale Materials Stewardship Program ("NMSP" or "the program") to complement and support its regulatory activities on nanoscale materials. For more details on the NMSP and to read the program's interim report, consult the EPA website at <http://epa.gov/oppt/nano/stewardship.htm>. EPA initiated the NMSP to quickly learn about commercially available nanoscale materials by gathering existing data and information from

Addendum to EPA ICR No. 1198.10; OMB Control No. 2070-0067

manufacturers, processors, and users of nanoscale materials. In the January 2009 interim report, EPA identified data gaps for existing nanoscale material production, uses, and exposures, based on the information EPA received through the NMSP prior to the report publication. For example, EPA estimated that companies provided information on only about 10 percent of the nanomaterials that may be commercially available.

EPA is issuing this rule to address some of the data gaps identified in the NMSP interim report. The reporting of information associated with nanoscale materials will provide EPA with data needed to determine appropriate action(s) under TSCA to reduce any risk to human health or the environment.

The legal authority for this information collection is TSCA section 8(a), U.S.C. 2607(a). Some TSCA section 8(a) chemical-specific rules have been codified at 40 CFR 704, subpart B; see Attachment 2.

2(b) Use/Users of the Data

The information collected through the rule 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. Information collected through this rule 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 information 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 information 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, CONSULTATION, AND OTHER COLLECTION CRITERIA

3(a) Non-Duplication

Section 8(a)(5) of TSCA states, “the Administrator shall, to the extent feasible... not require reporting which is unnecessary or duplicative.” The NMSP described above is the only other effort that EPA has identified to systematically collect such comprehensive information. In the 8(a) rule persons that participated in the NMSP are not required to report any information already submitted to EPA. The rule also indicates that any person who submitted a TSCA new

Addendum to EPA ICR No. 1198.10; OMB Control No. 2070-0067

chemical notice on or after January 1, 2005 under 40 CFR part 720 or 723 for a nanoscale material subject that would be subject to the rule does not need to submit a report for the nanoscale material previously submitted.

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

1 In proposing this ICR addendum, EPA provided a 120-day public notice and comment period that coincided with the comment period for the proposed 8(a) rule.

3(c) Consultations

During the comment period EPA contacted stakeholders and solicited comment on the estimates and findings in the ICR.

1 3(d) Effects of Less Frequent Collection

The 8(a) rule requires reporting only once for existing nanoscale materials and for new discrete nanoscale materials before they are manufactured or processed.

3(e) General Guidelines

This information collection activity is necessary to implement the statutory requirements of section 8(a) of TSCA and is consistent with the requirements of 5 CFR 1320.6.

3(f) Confidentiality

Submitters may designate information as confidential, trade secret or proprietary. EPA has implemented procedures to protect any confidential, trade secret or proprietary information from disclosure. These procedures comply with EPA's confidentiality regulation, 40 CFR Part 2, Subpart B.

3(g) Sensitive Questions

This section is not applicable. TSCA section 8(a) reporting rules do not include any questions of a sensitive nature.

4. THE RESPONDENTS AND THE INFORMATION REQUESTED

4(a) Respondents/North American Industrial Classification System (NAICS) Codes

Respondents affected by this collection activity primarily include those businesses that fall under NAICS codes 325, Chemical Manufacturers and Processors, and 324110, Petroleum Refineries. 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

4(b)(i) Data Items

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

1. Company name and other identifying information, address of company and site, technical contact and related information.
2. Common or trade name of the chemical substance.
Chemical identity and molecular structure of substance.
3. The following physical and environmental fate properties:

- 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 spatially averaged (bulk) and spatially resolved heterogeneous composition
- Surface area Surface chemistry
- Surface charge Porosity
- 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

Addendum to EPA ICR No. 1198.10; OMB Control No. 2070-0067

4. Description of all uses including expected consumer uses.
5. Estimate of the total amount of the chemicals substance to be manufactured including the amount for each use category.
6. Description of byproducts and impurities resulting from manufacture, process, use or disposal of the chemical substance.
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. A brief overview of the lifecycle including all workplaces that manufacture, process, or use the chemical substance and all expected consumer uses.
9. 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 chemical substance.
10. Regarding worker exposure information, personal or area monitoring data (in mass concentrations, surface area per mass, number of particles, etc.) for the chemical substance, including the measurement method(s) used to generate the data.
11. 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.
12. Information on cleaning/reuse/disposal of used protective equipment (gloves, respirator cartridges, etc.).
13. Additional procedures or other equipment intended to mitigate exposures to the chemical substance.
14. Description of worker training and hazard communication (MSDS, other) specific to the chemical substance.
15. Estimate of the total number of individuals other than workers exposed to the chemical substance and duration of exposure.
16. Manner or method of disposal for consumer use of products containing the chemical substance.
17. Any information in the submitter's possession regarding health or environmental effects, environmental fate, worker safety, and material characterization, including any information related to characterization of the chemical substance in the subject organism and test medium.

Addendum to EPA ICR No. 1198.10; OMB Control No. 2070-0067

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 form for this information collection request are attached. 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 chemical substance. However, respondents may include additional or optional information that they believe EPA should consider when evaluating the chemical substance. 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 chemical substance 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(b)(ii) Respondent Activities

Activities a respondent may be required to perform as a result of TSCA section 8(a) chemical-specific rule are as follows:

Managerial Labor

- Identify listed chemical substances;
- Assign principal technical contact person;
- Identify by-product; impurities; physical properties
- Review marketing data;
- Research the date of the initiation of manufacture of the chemical substance;
- Research occupational exposure, environmental release, health and environmental information, disposal methods; risk management practices; and
- Process, compile, and review information for accuracy, substantiate a claim of confidential business information.

Technical Labor

- Identify chemical and trade name and chemical composition;
- Identify by-product; impurities; physical properties
- Describe use of the chemical substance;
- Report quantity manufactured;
- Research workplace exposures, environmental releases, health and environmental information, and disposal methods; risk management practices; and
- Provide occupational description.

Clerical Labor

- Format research on occupational exposures, environmental releases, health and environmental information; risk management practices;
- Format attachments;
- Prepare notice; and
- Recordkeeping.

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

5(a) Agency Activities Inventory

EPA will perform the following activities:

- review the information 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 information submitted.

5(b) Collection Methodology and Management

An improved information technology to minimize burden of a TSCA section 8(a) chemical-specific rule has not been found. EPA has not been able to identify a more efficient, less expensive, or more flexible means of obtaining the required information than the one currently being used. To the extent information is not CBI, all information collected is made available to the public through the public docket office. EPA is requiring firms to submit this information on one standard reporting form. TSCA section 8(a) chemical-specific rules typically require one-time reporting. As future data needs arise, EPA will consider the use of other types of reporting methods. EPA believes the flexibility already allowed in the reporting structure significantly eases burden.

5(c) Small Entity Flexibility

The rule would exempt some small manufacturers and processors. However, as described in the rule some small manufacturers and processors would be required to report and keep records. Based on EPA's economic analysis for the rule, EPA has determined that the rule is not expected to have a significant adverse economic impact on a substantial number of small entities. All respondents to TSCA section 8(a) chemical-specific rules, including small businesses, are granted flexibility in their reporting methods.

5(d) Collection Schedule

This is a one-time collection of information. Respondents will have one year to collect and submit information for existing nanoscale materials and will normally report 135 days before

new discrete forms of reportable nanoscale materials are intended to be manufactured or processed.

6. ESTIMATING THE BURDEN AND COST OF THE COLLECTION

This section presents the burden and cost estimates incurred by all affected entities over the first three years of the rule as a result of the reporting requirements for certain nanoscale materials under the authority of section 8(a) of TSCA. This supporting statement provides burden and cost estimates for the information collection and is incremental to the burden already accounted for in the existing, approved ICR, *Information Collection Request for Chemical Specific Rules, Toxic Substances Control Act Section 8(a) EPA ICR No: 1198.10, OMB Control No: 2070-0067*. All costs are presented in year 2015 dollars. The information collection requires reporting at the company level. EPA estimates that a total of 165 nanomaterial manufacturers (who respond each year) and 2,186 nanomaterial processors (over three years), for a total of 2,681 total respondents (over three years), will respond to this information collection.

Burden and cost calculations are based on the assumption that EPA will receive 3,129 reports in the first three years of the rule. Each report is for a single nanomaterial/company combination. Each nanomaterial manufacturer is expected to submit an average of 4.67 reports in the first year and 0.52 reports in subsequent years. Each nanomaterial processor is expected to submit an average of one report per year. The average annual burden per respondent is estimated to be approximately 169 hours over the three year period.

6(a) Estimating Respondent Burden

The rule requires manufacturers, importers, and processors of certain nanoscale materials to incur costs associated with rule familiarization, preparation of reports, CBI claim substantiation, and recordkeeping. While firms are expected to incur some recurring costs associated with maintaining their records, these costs are expected to be minimal; as a result, all costs are assumed to be one-time costs. In addition, rule familiarization costs are only incurred in the first year of the rule for manufacturers because the same manufacturers are estimated to respond each year.

Companies will be required to report a variety of information about nanoscale materials including chemical identity, physical properties, human exposure and environmental release, production technology, and information on the nanomaterial's effects on health and the environment. Five procedural tasks are considered in the estimation of respondent burden. The four respondent activities include: rule familiarization; form completion; CBI claim substantiation; form submission; and recordkeeping. Rule familiarization requires that reporting entities learn the 8(a) rule and its various requirements. Entities must then complete a form providing the information listed above. If the submitter claims certain data elements as CBI, they must substantiate the claim by proving certain information supporting the need to keep the information confidential. The fourth task requires reporting businesses to submit electronically to EPA via CDX, EPA's electronic system for environmental data exchange. Lastly, entities must maintain records of the reported information. Table 1 provides a detailed description of the related Information Collection that corresponds to each activity.

Addendum to EPA ICR No. 1198.10; OMB Control No. 2070-0067

Table 1: Cross-walk between Industry Activities and Related Information Collections (ICs)

Activity	Description	Related IC(s)
Rule Familiarization	Site staff must familiarize themselves with the requirements of the rule. This entails reading the rule, understanding the various reporting and administrative requirements, and determining the manner in which the reporting requirements will be met.	Rule Familiarization
Preparation of Reports (Form Completion and Form Submission)	Site staff must collect all required information regarding nanomaterial information, production technologies, and health/environmental impacts, including information to substantiate any claims of data confidentiality. Firms are required to submit one form for each nanomaterial. The information must be collected and reviewed internally before submission.	Prepare Report, CBI Claim Substantiation, Electronic Submission
Recordkeeping	Respondents must keep records supporting their submissions.	Prepare and Submit Report, and Maintain Records - Partial Report Prepare and Submit Report, and Maintain Records- Full Report

EPA calculated burden estimates for each element of the collection form based on the *Supporting Statement for EPA ICR No. 2250.01: Information Collection in Support of EPA’s Stewardship Program for Nanoscale Material, OMB Control No 2020-0003* (EPA, 2007), economic analyses for other rules with similar requirements (such as the Premanufacture Notification Electronic Reporting final rule); the *Supporting Statement for EPA ICR No. 1665.12: Renewal of Existing Information Collection Request for Confidentiality Rules* (EPA, 2013); and EPA’s best professional judgment. More detailed information on the derivation of these estimates is found in the *Economic Analysis for the Final TSCA Section 8(a) Reporting Requirements for Certain Chemical Substances as Nanoscale Materials* (EPA, 2016).

Table 2 provides a summary of typical respondent burden by respondent type for rule familiarization (one-time burden per firm), completion of a report, CBI claim substantiation, and recordkeeping. EPA estimates the total burden for one firm to complete one form to be approximately 140 hours including rule familiarization and recordkeeping. Burden for electronic submission is presented in Table 3 and varies whether the company is registering for the first time (assumed for all firms in the first year) with CDX or has previously registered with CDX (assumed for nanomaterial manufacturers in years 2 and 3). Not all respondents will perform all activities related to electronic reporting in all years. Each of the 165 nanomaterial manufacturers is expected to submit an average of 4.67 reports in the first year and 0.52 reports in all subsequent years, for a total of approximately 943 reports over the three year period. EPA estimates that 1,788 nanomaterial processors will submit one report each in the first year and an additional 199 nanomaterial processors in each of the years two and three submitting one report each for a total of 2,186 reports.

Addendum to EPA ICR No. 1198.10; OMB Control No. 2070-0067

Table 2: Industry Burden, by Activity for Rule Familiarization, Form Completion, and Recordkeeping

Activity	Clerical Burden (hours)	Technical Burden (hours)	Managerial Burden (hours)	Attorney Burden (hours)	Total Burden (hours)
	(a)	(b)	(c)	(d)	(e) = (a)+(b)+(c)+(d)
RULE FAMILIARIZATION (One-time burden)					
Staff Reviews Rule 8(a) and its Various Requirements	0	0.55	0.27	0	0.82
Total	0	0.55	0.27	0	0.82
FORM COMPLETION					
Submitter Information	0	2	1	0	3
Chemical Identity Information	0	7.5	1	0	8.5
Physical Properties	0	2	0.5	0	2.5
Additional Physical Properties	0	4	1	0	5
Description of Uses	0	3	1.5	0	4.5
Amount of Substance to be Manufactures / Imported	0	1	1.5	0	2.5
Description of Byproducts	0	0.5	0	0	0.5
Human Exposure and Environmental Release	0	52	9.5	0	61.5
Physical Properties Related to Understanding and Assessing Exposures and Release	0	4	1	0	5
Overview of Lifecycles	0	10	2	0	12
Release Point Control Technology	0	2	0.4	0	2.4
Worker Exposure Information	0	2	0.4	0	2.4
Protective Equipment or Engineering Control	0	2	0.4	0	2.4
Information on Cleaning / Reuse / Disposal of Used Protective Equipment	0	1	0.2	0	1.2
Additional Procedures or Other Equipment to Mitigate Exposure to Nanoscale Materials	0	1	0.2	0	1.2
Description of Worker Training and Hazardous Communication	0	1	0.2	0	1.2
Number of Individuals Other than Workers Exposed to the Chemical or Duration of the Exposure	0	1	0.2	0	1.2
Manner or Method of Disposal for Consumer Use of Products	0	2	0.4	0	2.4
Information in the Submitter's Possession of Information on Health / Environmental Effects	0	7.2	10	0	17.2
Total	0	105.2	31.4	0	136.6
CBI CLAIM SUBSTANTIATION					
Gather and prepare information to substantiate a claim of data confidentiality	0	0	0.75	0.75	1.5
Total	0	0	0.75	0.75	1.5
RECORDKEEPING					
Maintain Records of Collected Information	0.5	0.5	0		1
Total	0.5	0.5	0		1
BURDEN PER REPORT (including one-time rule familiarization)					

Addendum to EPA ICR No. 1198.10; OMB Control No. 2070-0067

Total	0.5	106	32	1	140
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Addendum to EPA ICR No. 1198.10; OMB Control No. 2070-0067

Table 3: Industry Burden, by Activity for Electronic Reporting

Activity	Clerical Burden (hours)	Technical Burden (hours)	Managerial Burden (hours)	Number of Annual Activities	Total Burden (hours)
	(a)	(b)	(c)	(d)	(e) =[(a)+(b)+(c)]*d
<i>ELECTRONIC REPORTING</i>					
First-time registration					
CDX Registration	0.00	0.67	0.17	1.00	0.84
Electronic Subscriber Agreement/ Electronic Signature	0.00	0.00	0.25	1.00	0.25
Help Desk	0.00	0.24	0.06	1.00	0.30
Problem Resolution	0.00	1.00	0.00	0.03	0.03
Total First Time Burden per firm					1.42
Subsequent registration					
CDX Registration	0.00	0.67	0.17	0.10	0.08
Electronic Subscriber Agreement/Electronic Signature	0.00	0.00	0.25	0.10	0.03
Help Desk	0.00	0.24	0.06	0.10	0.03
Report Compromised Signature	0.00	0.00	0.40	0.01	0.00
Problem Resolution	0.00	1.00	0.00	0.03	0.03
Total Subsequent Burden per firm					0.17

6(b) Estimating Cost

To estimate costs, EPA multiplies burden estimates by standard wage rates for managerial, technical, and clerical levels developed from information published by the Bureau of Labor Statistics (BLS) and a method outlined in the document *Wage Rates for Economic Analyses of the Toxics Release Inventory Program* (EPA, 2002b). Wage data for these three occupational categories was gathered for manufacturing industries from *Employer Costs for Employee Compensation Supplemental Tables: December 2006 – March 2016* (BLS, 2016a). Additionally, wage rates for attorney level were gathered from the *BLS Occupational Employment Statistics (OES) May 2015 National Industry-Specific Occupational Employment and Wage Estimates* (BLS, 2016b).

The cost of fringe benefits, such as health insurance and vacation, is taken for each labor category from the same ECEC series. Following the methodology outlined in (EPA, 2002b), fringe benefits are calculated as a percentage of total wages for each category. Since the fringe benefits for attorneys were not available from the BLS report, EPA applied the managerial fringe benefit to wage ratio to this wage as well. EPA added 17 percent to the wages in each category to account for overhead, based on information provided by the chemical industry and chemical industry trade associations in the *Revised Economic Analysis for the Amended Inventory Update Rule: Final Report* (EPA, 2002a) and *Wage Rates for Economic Analyses of the Toxics Release Inventory Program* (2002b). The wages for each of the three categories were then multiplied by benefits and overhead factors to estimate loaded, annual salaries in year 2015 dollars. Table 4 contains the loaded wage rates for the managerial, technical and clerical occupation categories.

Table 4: Derivation of Loaded Wage Rates for the Private Manufacturing Sector in 2015\$

Labor Category	Wage	Fringe Benefits	Fringes as % of Wage	Overhead % of Wage ³	Fringe + Overhead Factor	Loaded Wages
	(a)	(b)	(c) = (b)/(a)	(d)	(e)=(1)+(c)+(d)	(f) = (a) x (e)
Attorney¹	\$65.51	\$32.65	49.84%	17%	1.67	\$109.29
Managerial²	\$48.66	\$24.25	49.84%	17%	1.67	\$81.18
Technical²	\$44.06	\$24.34	55.24%	17%	1.72	\$75.89
Clerical²	\$19.91	\$10.37	52.08%	17%	1.69	\$33.66

Sources: ¹BLS Occupational Employment Statistics (OES) May 2015 National Industry-Specific Occupational Employment and Wage Estimates (BLS, 2016b) ²Employer Costs for Employee Compensation Supplementary Tables: December 2006-March 2016, US Bureau of Labor Statistics (BLS, 2016a)
³An overhead rate of 17 percent was estimated based on industry data gathered for the *Revised Economic Analysis for the Amended Inventory Update Rule: Final Report* (EPA, 2002a) and *Wage Rates for Economic Analyses of the Toxics Release Inventory Program*. (EPA, 2002b)

Table 5 contains the cost per activity of completing a form for one respondent. Burden hours presented in Table 2 were multiplied by the corresponding loaded wage rate in Table 4. EPA estimates that the total cost for reviewing the rule and completing and submitting one report with recordkeeping is approximately \$10,794 in the first year and approximately \$10,730 in each of years 2 and 3 of the ICR. Because the same nanomaterial manufacturers are estimated to submit reports in each year of the ICR, first year costs include rule familiarization while subsequent year costs do not. Because new processors are estimated to report in each of the years of the ICR they will undertake rule familiarization each of the years and costs for that group will be \$10,794 per report each year.

Addendum to EPA ICR No. 1198.10; OMB Control No. 2070-0067

Electronic reporting costs are presented in Table 6. Because not all firms are expected incur all costs, the number of annual activities per firm may be less than one. Electronic reporting costs for first time registrants are estimated to be \$110.31 per firm and subsequent year costs are to be \$13.41 per firm. Because the same nanomaterial manufacturers are reporting each year, they are expected to incur \$110.31 the first year and \$13.41 in subsequent years, while processors, who are new respondents each year, are expected to incur \$110.31 per firm each year. More information on the derivation of these costs is found in the *Economic Analysis for the Final TSCA Section 8(a) Reporting Requirements for Certain Chemical Substances as Nanoscale Materials* (EPA, 2016).

Table 5: Industry Cost, by Activity

Activity	Clerical Burden (at \$33.66/hour)	Technical Burden (at \$75.89/hour)	Managerial Burden (at \$81.18/hour)	Attorney Burden (at \$109.29/hour)	Total Cost	
	(a)	(b)	(c)	(d)	(e) = (a)+(b)+(c)+(d)	
RULE FAMILIARIZATION (first year only)						
Total	\$0.00	\$41.74	\$21.92	\$0.00	\$63.66	
FORM COMPLETION						
Total	\$0.00	\$7,984	\$2,549	\$0.00	\$10,533	
CBI CLAIM SUBSTANTIATION						
Total	\$0.00	\$0	\$61	\$82	\$143	
RECORDKEEPING						
Total	\$16.83	\$37.95	\$0.00	\$0.00	\$54.78	
TOTAL BURDEN PER REPORT						
Year 1 Totals	\$16.83	\$8,063	\$2,632	\$82	\$10,794	
Year 2 and 3 Totals	\$16.83	\$8,022	\$2,610	\$82	\$10,730	

Notes: Numbers may not add due to rounding.

Year 2 and 3 totals assume that rule familiarization does not occur. Because there are new processors estimated to report each year, the cost for those entities is equal to year one costs.

Addendum to EPA ICR No. 1198.10; OMB Control No. 2070-0067

Table 6: Industry Cost for Electronic Reporting

Activity	Clerical Cost (at \$33.66/hour)	Technical Cost (at \$75.89/hour)	Managerial Cost (at \$81.18/hour)	Number of Annual Activities	Total Cost
	(a)	(b)	(c)	(d)	(e) =[(a)+(b)+ (c)]*d
<i>ELECTRONIC REPORTING</i>					
First-time registration					
CDX Registration	\$0.00	\$50.85	\$13.80	1	\$64.65
Electronic Subscriber Agreement/ Electronic Signature	\$0.00	\$0.00	\$20.30	1	\$20.30
Help Desk	\$0.00	\$18.21	\$4.87	1	\$23.08
Problem Resolution	\$0.00	\$75.89	\$0.00	0.03	\$2.28
Total First Time Cost per firm					\$110.31
Subsequent registration					
CDX Registration	\$0.00	\$50.85	\$13.80	0.10	\$6.47
Electronic Subscriber Agreement/Electronic Signature	\$0.00	\$0.00	\$20.30	0.10	\$2.03
Help Desk	\$0.00	\$18.21	\$4.87	0.10	\$2.31
Report Compromised Signature	\$0.00	\$0.00	\$32.47	0.01	\$0.32
Problem Resolution	\$0.00	\$75.89	\$0.00	0.03	\$2.28
Total Subsequent Cost per firm					\$13.41

Note: Numbers may not add due to rounding.

6(c) Estimating Agency Burden and Cost

EPA is responsible for the following activities associated with administering the section 8(a) rule:

- Industry and public assistance;
- Data processing and systems support;

Costs related to EPA activities that involve using the data are not included. The Frank R. Lautenberg Chemical Safety for the 21st Century Act was signed into law on June 22, 2016, and became immediately effective. EPA has estimated the Agency burden resulting from the new requirements in the act for substantiation of CBI claims made as a result of this rule. EPA will further refine these estimates when it revises the cost and estimates for the ICR for 40 CFR part 2 based on the new CBI substantiation requirements.

Agency personnel are responsible for all tasks associated with the rule, and none of the work is estimated to be completed by contractor staff. EPA labor costs are based on annual federal wage rates published by the Office of Personnel Management for the Washington-Baltimore-Northern Virginia, DC-MD-PA-VA-WV Locality Pay Area for 2015 (OPM, 2015). Wages are presented in terms of GS-level and step. A federal GS-13, Step 5 employee will conduct the collection and administrative activities under the rule. A federal GS-14, Step 5 will assist with the review of the CBI claim substantiations. Unloaded wage rates for 2015 for both of

Addendum to EPA ICR No. 1198.10; OMB Control No. 2070-0067

these employees are presented in Table 7. Following the methodology outlined in *Instructions for Preparing Information Collection Requests (ICRs)* (EPA, 1992), EPA added 60 percent to the wage rate to account for fringe benefits and overhead costs. Table 7 derives the loaded wage rates for Agency staff at the GS-13 Step 5 level.

Table 7: Derivation of Loaded Agency Wage Rates (2015\$)

Labor Category	Pay Grade	Annual Salary	Overhead and Fringe Benefits (% of wages)	Overhead and Fringe Benefit Cost	Total
Technical Labor	GS 13 Step 5	\$102,932	60%	\$61,759	\$164,691
Attorney Labor	GS 14 Step 5	\$121,635	60%	\$72,981	\$194,616

Source: The unloaded Federal salary for 2015 is from the Office of Personnel Management salary table for Washington-Baltimore-Northern Virginia (OPM, 2015).

Table 8 contains the burden and cost per report for all EPA staff activities. All activities performed by EPA staff are dependent on the number of reports submitted to EPA. The burden for industry and public assistance is approximately 1.25 hours per report and the total cost per report is approximately \$99. The burden for data processing and systems support is approximately 3.13 hours and the cost per-report is approximately \$247. The total burden for review of CBI claim substantiations is approximately 2 hours and the cost per report is approximately \$179. The burden and cost of processing each form is derived in the *Economic Analysis for the Final TSCA Section 8(a) Reporting Requirements for Certain Chemical Substances as Nanoscale Materials* (EPA, 2016).

Table 8: EPA Staff Burden and Cost of Processing One Report

EPA Activity	Technical Labor		Attorney Labor		Total Labor Cost	
	Burden (Hours)	Cost	Burden (Hours)	Cost	Burden	Cost
Industry/Public Assistance	1.25	\$99	0	\$0	1.25	\$99
Data Processing and Systems Support Personnel	3.13	\$247	0	\$0	3.13	\$247
Review of CBI claim substantiations	0.5	\$39	1.5	\$140	2	\$179
Total, per report	4.88	\$385	1.5	\$140	6.38	\$525

Note: Some burden estimate subtotals may not calculate due to rounding of unit burden estimates.

6(d) Bottom-Line Industry Burden and Cost Estimates

This section describes the estimated total social paperwork burden and cost of the section 8(a) rule over its first three years.

Addendum to EPA ICR No. 1198.10; OMB Control No. 2070-0067

Respondent tally

EPA estimated the number of U.S.-based nanomaterials manufacturers, importers, processors, and distributors using three sources:

- Lux Research: *Nanotech Report*TM, 5th ed. (2007)
- BCC Research: *Nanotechnology: A Realistic Market Assessment* (2008)
- Nanowerk: *Company & Labs Directory* (2009)

Once the universe of U.S. nanomaterial manufacturers, importers, processors, and distributors was estimated, EPA then calculated the number of companies that would be subject to the rule. EPA estimated that approximately 165 nanomaterial manufacturing firms will be subject to the section 8(a) information collection. Each nanomaterial manufacturing firm is expected to submit an average of 4.67 reports in the first year and 0.52 reports in subsequent years. EPA estimates that there will be 1,788 processors subject to the rule in the first year, and 199 in each of the subsequent years of the rule. More information of the derivation of these numbers can be found in the *Economic Analysis for the Final TSCA Section 8(a) Reporting Requirements for Certain Chemical Substances as Nanoscale Materials* (EPA, 2016).

Affected firms would incur burden and cost due to the electronic reporting requirements. This includes costs in the first year to complete a subscriber agreement and register with CDX. New processors will also incur these costs in subsequent years. Some nanomaterial manufacturers will incur CDX costs in subsequent years due to employee turnover or compromised electronic signatures; therefore, response rate for some activities will vary across years. Tables 9 and 10 show the number of responses for the various activities for the three years for manufacturers and processors, respectively.

Table 9: Number of Responses per Activity - Manufacturers

Activity	Total Number of Companies	Number of Responses/ Respondent	Total Number of Responses
Year 1			
Rule Familiarization	165	1	165
Form Completion	165	4.67	771
CBI Substantiation	165	4.67	771
Electronic Submission	165	1	165
Recordkeeping	165	4.67	771
Years 2 and 3			
Rule Familiarization	165	0	0
Form Completion	165	0.52	86
CBI Substantiation	165	0.52	86
Electronic Submission	165	1	165
Recordkeeping	165	0.52	86

Table 10: Number of Responses per Activity - Processors

Activity	Total Number of Companies	Number of Responses/ Respondent	Total Number of Responses
Year 1			
Rule Familiarization	1,788	1	1,788
Form Completion	1,788	1	1,788
CBI Substantiation	1,788	1	1,788
Electronic Submission	1,788	1	1,788
Recordkeeping	1,788	1	1,788
Years 2 and 3			
Rule Familiarization	199	1	199
Form Completion	199	1	199
CBI Substantiation	199	1	199
Electronic Submission	199	1	199
Recordkeeping	199	1	199

Tables 11 and Table 12 present the total estimated respondent burden and costs for nanomaterial manufacturers and processors, respectively, in the first year and subsequent years. As presented in Table 11, EPA estimates the total industry burden for a total of 165 nanomaterial manufacturers to be approximately 131,597 hours and the total cost to be approximately \$10.1 million over three years. For the 2,186 nanomaterial processors (1,788 + 199 +199) affected over the three years of the ICR, the burden is estimated to be approximately 308,969 hours and the cost is estimated to be approximately \$23.8 million. These estimates are presented in Table 12.

Addendum to EPA ICR No. 1198.10; OMB Control No. 2070-0067

Table 11: Total Estimated Annual Respondent Burden and Cost Associated with this ICR Addendum (Manufacturers)

Year	Number of Firms	Reports per Firm	Rule Familiarization (per Firm)		Form Completion, CBI Substantiation, and Recordkeeping (per Report)		Electronic Reporting (per Firm)		Burden Per Firm	Cost Per Firm	Total Number of Reports	Total Manuf. Burden	Total Manuf. Cost (Millions 2015\$)
			Burden	Cost	Burden	Cost	Burden	Cost					
1	165	4.67	0.82	\$63.66	139	\$10,730	1.42	\$110.30	652	\$50,285	771	107,616	\$8.30
2	165	0.52	0	\$0	139	\$10,730	0.17	\$13.41	73	\$5,593	86	11,991	\$0.92
3	165	0.52	0	\$0	139	\$10,730	0.17	\$13.41	73	\$5,593	86	11,991	\$0.92
Total, three years:											943	131,597	\$10.14

Table 12: Total Estimated Annual Respondent Burden and Cost Associated with this ICR Addendum (Processors)

Year	Number of Firms	Reports per Firm	Rule Familiarization (per Firm)		Form Completion, CBI Substantiation, and Recordkeeping (per Report)		Electronic Reporting (per Firm)		Burden Per Firm	Cost Per Firm	Total Number of Reports	Total Processor Burden	Total Processor Cost (Millions 2015\$)
			Burden	Cost	Burden	Cost	Burden	Cost					
1	1,788	1.00	0.82	\$63.66	139	\$10,730	1.42	\$110	141	\$10,904	1,788	252,716	\$19.50
2	199	1.00	0.82	\$63.66	139	\$10,730	1.42	\$110	141	\$10,904	199	28,127	\$2.17
3	199	1.00	0.82	\$63.66	139	\$10,730	1.42	\$110	141	\$10,904	199	28,127	\$2.17
Total, three years:											2,186	308,969	\$23.8

Addendum to EPA ICR No. 1198.10; OMB Control No. 2070-0067

Table 13 presents the estimated total and average annual burden and cost associated with this ICR addendum. EPA estimates the annual average burden and cost over three years at approximately 147,000 hours and \$11 million dollars, respectively, with a total burden of approximately 441,000 hours and \$34 million over the three year period.

Table 13: Estimated Annual Average Burden and Cost Associated with this ICR Addendum

Year	Respondents	Responses per Respondent	Burden per Response	Total Number of Responses	Total Burden Hours	Total Costs Millions 2015\$
Manufacturers						
1	165	4.67	140	771	107,616	\$8.30
2	165	0.52	139	86	11,991	\$0.92
3	165	0.52	139	86	11,991	\$0.92
Average	165	1.9	139	314	43,866	\$3.38
Processors						
1	1,788	1	141	1,788	252,716	\$19.50
2	199	1	141	199	28,127	\$2.17
3	199	1	141	199	28,127	\$2.17
Average	729	1	141	729	102,990	\$7.95
All Respondents						
Total	2,681	-	-	3,129	440,566	\$33.98
Average per Year	894	1.17	140	1,043	146,855	\$11.33

Notes: Values may not calculate due to rounding.

Addendum to EPA ICR No. 1190.10; OMB Control No. 2070-0067

Multiplying the average responses per respondent (1.17) by the average burden per response (140) gives an average burden per respondent of 164 hours.)

Agency Tally

Table 14 presents the Agency costs in the first year. EPA multiplied the costs per report by the total number of reports to calculate the total burden and cost associated with the number of reports EPA expects to be submitted. The total Agency burden for year one is approximately 11,208 hours with an estimated cost of \$0.88 million.

Table 14: Total Cost and Burden of Agency Activities in the First Year (2015\$)

Activity	Staff	Total Burden per Activity (Hours)	Total Number of Units	Total Cost per Activity (2015\$)	Total Burden (Hours)	Total Cost (Millions 2015\$)
Industry/Public Assistance	EPA Employee (GS 13 Step 5)	1.25	2,559	\$98.64	3,199	\$0.25
Data Processing and System Support Personnel		3.13	2,559	\$247.00	8,010	\$0.63
Review of CBI Claim Substantiations		0.5	2,559	\$39.46	1,280	\$0.10
Review of CBI Claim Substantiations	EPA Employee (GS 14 Step 5)	1.5	2,559	\$139.88	3,839	\$0.36
Total Cost and Burden					16,326	\$1.34

Note: Some burden estimate subtotals may not calculate due to rounding of unit burden estimates.

Addendum to EPA ICR No. 1190.10; OMB Control No. 2070-0067

Table 15 presents the Agency costs associated with the rule in the second and third year. EPA multiplied the costs per report by the total number of reports to calculate the total burden and cost associated with the number of reports EPA expects to be submitted. The total Agency burden for the second and third year is approximately 1,818 hours and the total cost is \$0.15 million.

Table 15: Total Cost and Burden of Agency Activities in the Second and Third Year (2015\$)

Activity	Staff	Total Burden per Activity (Hours)	Total Number of Units	Total Cost per Activity (2015\$)	Total Burden (Hours)	Total Cost (Millions 2015\$)
Industry/Public Assistance	EPA Employee (GS 13 Step 5)	1.25	285	\$98.64	356	\$0.03
Data Processing and System Support Personnel		3.13	285	\$247.00	892	\$0.07
Review of CBI Claim Substantiations		0.5	285	\$39.46	143	\$0.01
Review of CBI Claim Substantiations	EPA Employee (GS 14 Step 5)	1.5	285	\$139.88	428	\$0.04
Total Cost and Burden					1,818	\$0.15

Note: Some burden estimate subtotals may not calculate due to rounding of unit burden estimates.

6(e) Reasons for Change in Burden

EPA estimates that industry will incur an increase of 146,855 hours in annual burden for a total burden of 147,130 hours. This increase is solely due to program changes that result from the new reporting requirements for manufacturers, importers, processors, and distributors of certain nanoscale materials.

Table 16: Total Estimate of Annual Burden Hours and Annualized Cost Comparisons

	Annual Burden Hours
Current OMB Inventory	275
Change in Burden due to Adjustments	0
Change in Burden due to Program Changes	146,855
Total Change in Burden	146,855
Total Burden	147,130

6(f) Burden Statement

The annual public burden for this collection of information is estimated to average approximately 164 hours per respondent over the three year period. 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. For this collection it includes the time needed to review and understand instructions; prepare and submit reports (including searching data sources); complete and review the collection of information; transmit the information; and keep records.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this information collection appears above. The OMB control numbers for EPA's regulations in title 40 of the CFR, after appearing in the Federal Register when approved, are listed in 40 CFR Part 9, are displayed either by publication in the Federal Register or by other appropriate means, such as on the related collection instrument or form, if applicable. The display of OMB control numbers in certain EPA regulations is consolidated in 40 CFR Part 9.

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 docket for this ICR under Docket ID No. EPA-HQ-OPPT-2010-0572 which is available for public viewing at the Pollution Prevention and Toxics Docket in the EPA Docket Center (EPA/DC), EPA West, Room B102, 1301 Constitution Ave., NW, Washington, DC. The EPA Docket Center Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Reading Room is (202) 566-1544 and the telephone number for the Pollution Prevention and Toxics Docket is (202) 566-0280.

An electronic version of this docket is available at <http://www.regulations.gov/>. Use the federal government wide electronic docket and comment system at www.regulations.gov to submit or view public comments, access the index listing of the docket contents, and to access those documents in the docket that are available electronically. Once in the system, select “advance 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-2010-0572 and OMB control number 2070-0194 in any correspondence.

7. Sources

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