Supporting Statement for an Information Collection Request (ICR) Under the Paperwork Reduction Act (PRA)

1. EXECUTIVE SUMMARY

1(a). Identification of the Information Collection – Title and Numbers

Chemical-Specific Rules under the Toxic Substances Control Act Section 8(a); Certain Nanoscale Materials

ICR Numbers: EPA ICR No.: 2517.03; OMB Control No.: 2070-0194.

EPA Form Numbers: EPA Form 9600-07: TSCA §8(a) Reporting for Chemical Substances when Manufactured or Processed as Nanoscale Materials: Data

Submission Form

Docket ID Number: EPA-HQ-OPPT-2010-0572.

1(b). Docket Information

The information collection request (ICR) that explains the information collection activities and related burden and cost estimates, as well as other supporting documents related to the ICR, are available in the docket established for this ICR. The docket can be viewed online at http://www.regulations.gov or in person at the EPA Docket Center, West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC. The telephone number for the Docket Center is (202) 566-1744. For additional information about EPA's public docket, visit http://www.epa.gov/dockets.

1(c). ICR Status

Under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 et seq., 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 control number issued by the Office of Management and Budget (OMB). The OMB control numbers 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 for certain EPA regulations is consolidated in 40 CFR part 9.

Before submitting an ICR to OMB for review and approval under the PRA, an agency must solicit comments pursuant to PRA §3506(c)(2)(A) and 5 CFR 1320.8(d)(1). After considering comments received on the draft ICR, the agency must submit the ICR to OMB for review and approval according to the procedures prescribed in 5 CFR 1320.12. In announcing the submission of the final ICR to OMB for review and approval, the agency must provide another opportunity for public review and comments on the revised ICR pursuant to 5 CFR 1320.12(c).

This is an ICR renewal for the information collection activities that are currently approved by OMB for:

OMB Control No. 2070-0194; EPA ICR No. 2517.02; entitled "Addendum to the Existing

EPA ICR Entitled: Chemical-Specific Rules, Toxic Substances Control Act Section 8(a)", approved through August 31, 2020.

1(d). Abstract

This information collection request (ICR) covers reporting and recordkeeping requirements for persons who manufacture or process chemical substances as nanoscale materials under the authority of section 8(a) of the Toxic Substances Control Act (TSCA).

Legal authority: The Toxic Substances Control Act (TSCA) section 8(a), U. S. C. 2607 and implementing regulations in 40 CFR part 704.20. More details are provided in Unit 2(a) of this Supporting Statement.

Respondents/affected entities: Entities potentially affected by this ICR include persons persons who manufacture or process chemical substances as nanoscale materials as defined in the final rule codified at 40 CFR part 704.20.

Respondent's obligation to respond: Responses are mandatory under TSCA (see also 40 CFR part 704.20).

Confidentiality of responses: Respondents may claim all or part of a document submitted to be as confidential. 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 TSCA section 14 and 40 CFR part 2.11

Estimated total number of potential respondents: 285 per year

Frequency of response: On occasion.

Estimated total annual burden hours: 40,089 hours. Burden is defined at 5 CFR 1320.3(b).

Estimated total annual costs: \$3,067,546, includes no annualized capital investment or maintenance and operational costs.

Changes in the estimates: There is decrease of 26,861 hours in the total estimated respondent burden compared with that identified in the ICR currently approved by OMB. This decrease reflects EPA's expectation of decreased submissions. In the previous ICR period, the rule required an initial one-time reporting on current nanomaterials, while the reporting covered in this period only requires the reporting of new nanomaterials. Furthermore, burden estimates assume that the same manufacturers will report each year and, therefore, will have already undertaken rule familiarization in the previous ICR period. Wage rates were also updated to reflect 2018 dollars.

2. NECESSITY OF THE INFORMATION COLLECTION

2(a). Related Legal and/or Administrative Requirements

The related legal authority is The Toxic Substances Control Act (TSCA) section 8(a), U. S. C. 2607 and implementing regulations in 40 CFR part 704.20

In addition, the EPA has developed guidance and other materials that are available at https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/control-nanoscale-materials-under#info rule.

The following provides a general overview for requirements covered in this ICR:

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

- 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.

2(b). Necessity of the Information 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 200 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. The reporting of information associated with these 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.

Recordkeeping and reporting requirements are necessary to ensure effective implementation.

2(c). Uses, Users, and Purpose of the Information Collection

The information collected 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, CONSULTATIONS, 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 rule indicates that any person who submitted a TSCA new 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 and Consultations

In renewing this ICR, EPA provided notice in the Federal Register of January 28, 2020 (85 FR 4982; FRL-10003-00) of a 60-day public notice and comment period. In addition to the public notice and comment period, EPA consulted with potential ICR respondents and data users according to OMB regulations, at 5 CFR 1320.8(d)(1). EPA contacted the following stakeholders who had already submitted notifications under this rule or had commented on the rule and ICR when they were proposed:

Mike Walls, American Chemistry Council, Inc.

Melissa Hockstad, American Cleaning Institute

Tim A. Brown, Esq., Consumer Specialty Products Association

William Carteaux, Society of the Plastics Industry, Inc.

Bill Allmond, Society of Chemical Manufacturers and Affiliates Formerly the Synthetic Organic Chemical Manufacturers Association. (SOCMA)

Vincent Caprio, Nano Business Commericalization Association

Jake Vandevort, Titanium Dioxide Stewardship Council

Julia Rege, Association of Global Automakers, Inc.

Sanjay Baliga, SEMI

EPA contacted these stakeholders via email on January 30, 2020 seeking comments on additional specific questions about the ICR and supporting documents. EPA received no comments regarding any of the supporting documents for the ICR including this supporting statement.

3(c). Small Entity Flexibility

The regulation exempts some small manufacturers and processors. However, as described in the regulation some small manufacturers and processors would be required to report and keep records. All respondents to TSCA section 8(a) chemical-specific rules, including small businesses, are granted flexibility in their reporting methods.

3(d). General PRA Related 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 1320.5(d)(2). Firms are required to maintain records for three years. EPA requires reporting only once for manufacturers and processors for new discrete nanoscale materials before they are manufactured or processed.

1 3(e). Effects of Less Frequent Collection

EPA requires reporting only once for manufacturers and processors for new discrete nanoscale materials before they are manufactured or processed.

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. AGENCY ACTIVITIES, COLLECTION METHODOLOGY, AND INFORMATION MANAGEMENT

4(a). Agency Activities

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.

4(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.

4(c). Collection Schedule

This is a one-time collection of information. Respondents will normally report 135 days before new discrete forms of reportable nanoscale materials are intended to be manufactured or processed but no later than 30 days after forming that intent.

5. The RESPONDENTS AND INFORMATION COLLECTION (IC) ACTIVITIES

For each respondent category, this section of the ICR describes the respondents, the information collection activities and related estimates for burden and costs associated with those activities.

5(a). Methodology for Estimating Respondent Burden and Costs

This information collection request (ICR) specifies the 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).

The North American Industrial Classification System (NAICS) codes associated with industries most likely affected by the paperwork requirements are described below:

325	Chemical Manufacturers and Processors
325130	Synthetic Dye and Pigment Manufacturing
324110	Petroleum Refineries
325180	Other Basic Inorganic Chemical Manufacturing

331221	Rolled Steel Shape Manufacturing
334413	Semiconductor and Related Device Manufacturing
335991	Carbon and Graphite Product Manufacturing
423220	Home Furnishing Merchant Wholesalers
423330	Roofing, Sliding, and Insulation Material Merchant Wholesalers
423510	Metal Service Centers and Other Metal Merchant Wholesalers

5(b). Burden and Cost Estimates

IC #1: Manufacturer Form Completion, CBI Substantiation, Form Submission and Recordkeeping_

Respondent NAICS Codes

325	Chemical Manufacturers and Processors
325130	Synthetic Dye and Pigment Manufacturing
324110	Petroleum Refineries
325180	Other Basic Inorganic Chemical Manufacturing
331221	Rolled Steel Shape Manufacturing
334413	Semiconductor and Related Device Manufacturing
335991	Carbon and Graphite Product Manufacturing
423220	Home Furnishing Merchant Wholesalers
423330	Roofing, Sliding, and Insulation Material Merchant Wholesalers
423510	Metal Service Centers and Other Metal Merchant Wholesalers

Information Collection Activities

Manufacturers will complete four procedural tasks: form completion, CBI claim substantiation, form submission and recordkeeping. EPA estimates a total of 165 nanomaterial manufacturers will respond each year. It is expected that the same 165 manufactures will submit 0.52 reports per year on average. All of the following estimates of burden hours take into account the expectation that each manufacturer will submit 0.52 reports per year.

Form completion involves the time and cost for providing the information listed above. It is estimated that it will take manufactures approximately 71 hours per year for form completion. If a manufacturer claims certain data elements as CBI, they must substantiate the claim by providing certain information to support the need to keep information confidential. It is estimated that it will take a manufacturer approximately 0.78 hours per year to substantiate a CBI claim. Form submission involves the time to electronically submit the report to EPA via CDX, EPA's electronic system for environmental data exchange. Because the same manufacturers are expected to report each year, it is estimated to take 0.17 hours per year to electronically submit the report. Recordkeeping involves the time taken to maintain records of the reported information. It is estimated to take approximately a half hour per year for a manufacturer to maintain its records of the information reported.

The total burden is estimated to be approximately 73 hours per year per manufacturer. There are no material costs associated with this collection.

IC#1. Manufacturer Form Completion, CBI Substantiation, Form Submission and Recordkeeping Citation: 40 CFR 704.20						
Data Element 3-year Total Responses 3-year Total Burden (hours) Material s Total Cost (\$)						
Form Completion	257.4	35,161	N/A	\$2,686,999		
CBI Substantiation	257.4	386	N/A	\$38,322		
Form Submission (Electronic Reporting)	495	84.15	N/A	\$6,574		
Recordkeeping	257.4	257	N/A	\$14,134		
3-1	ear Grand Total	35,888		\$2,746,028		
	11,963		\$915,343			

Total responses, burden and cost estimates are based on the expectation that 165 manufactures will submit 0.52 responses each year over the three-year period.

IC #2: Processor Form Completion, CBI Substantiation, Form Submission and Recordkeeping_

Respondent NAICS Codes

325	Chemical Manufacturers and Processors
325130	Synthetic Dye and Pigment Manufacturing
324110	Petroleum Refineries
325180	Other Basic Inorganic Chemical Manufacturing
331221	Rolled Steel Shape Manufacturing
334413	Semiconductor and Related Device Manufacturing
335991	Carbon and Graphite Product Manufacturing
423220	Home Furnishing Merchant Wholesalers
423330	Roofing, Sliding, and Insulation Material Merchant Wholesalers
423510	Metal Service Centers and Other Metal Merchant Wholesalers

Information Collection Activities

Based on the rule requirements, processors will complete five procedural tasks: rule familiarization, form completion, CBI claim substantiation, form submission and recordkeeping.

It is expected that 199 new processors will submit one report each year and, therefore, engage in rule familiarization. Rule familiarization involves the time and cost required for processors to review the rule and set up procedures for meeting the requirements. EPA estimates that the one-time burden related to learning the rule and setting up compliance procedures is 0.82 hours.

Values may not sum due to rounding.

Form completion involves the time and cost for providing the information listed above. It is estimated to take 136.6 hours per year to complete the form. If a processor claims certain data elements as CBI, it must substantiate the claim by providing certain information to support the need to keep information confidential. It is estimated to take 1.5 hours per year for a processor to substantiate a CBI claim. Form submission involves the time to electronically submit the report to EPA via CDX, EPA's electronic system for environmental data exchange. Because it is expected that new processors will submit the form each year, it is estimated to take 1.42 hours per year for a processor to register and submit the form. Recordkeeping involves the time taken to maintain records of the reported information. It is estimated to take one hour per year for a processor to maintain its records of the information reported.

The total burden is estimated to be 141 hours per year per processor. There are no material costs associated with this collection.

IC#2. Processor Form Completion, CBI Substantiation, Form Submission and Recordkeeping Citation: 40 CFR 704.20					
Data Element	3-Year Total Responses	3-Year Total Burden (hours)	Materials	Total Cost (\$)	
Rule Familiarization	597	490	N/A	\$37,641	
Form Completion	597	81,550	N/A	\$6,232,083	
CBI Substantiation	597	896	N/A	\$88,881	
Form Submission (Electronic Reporting)	597	848	N/A	\$65,222	
Recordkeeping	597	597	N/A	\$32,781	
3-1	ear Grand Total	84,380		\$6,456,609	
	Annual Total	28,127		\$2,152,203	

Total responses, burden and cost estimates are based on the expectation that 199 processors will submit one response each year over the three-year period.

Values may not sum due to rounding.

6. ESTIMATING BURDEN AND COST OF THIS COLLECTION

6(a). Total Estimated Respondent Annual Burden and Costs

IC Summary Table						
IC Category Annual Annual Burden (hours) Annual Cost (\$)						
IC 1: Manufacturers	86	11,963	\$915,343			
IC 2: Processors	199	28,127	\$2,152,203			
Total	285	40,089	\$3,067,546			

6(b) Changes in the Estimates

The annual burden from the previously approved ICR was146,855 hours. The total annual burden requested for this ICR is 40,089 hours, or a decrease of 106,766 hours from the previous total burden. The difference between the current burden request and the previously approved requests are due to adjustments in EPA's estimates of the burden. Several adjustments to the estimates were made, including:

- In the previous ICR period, the rule required an initial one-time reporting on current nanomaterials, while the reporting covered in this period only requires the reporting of new nanomaterials. Therefore, a large portion of the adjustment in estimates stems from the decrease in the number of submissions expected after the initial one-time reporting on current nanomaterials.
- Burden estimates include a one-time burden that firms incur to become familiar
 with the rule and its various requirements. In the first year of the rule, the
 manufacturers that submitted reports incurred the one-time rule familiarization
 burden. EPA assumes that the same manufacturers will submit reports on new
 nanomaterials during subsequent years and do not need to familiarize
 themselves with the rule. Therefore, part of the decrease in burden estimates,
 relative to the previous ICR period that included the first year of the rule, is due to
 the same manufacturers submitting reports without incurring the rule
 familiarization burden.

The total annual cost burden of the previously approved ICR was \$33,978,455. The total annual cost requested for this ICR is \$3,067,546. The difference of \$30,910,909 between the current cost burden request and the previously approved requests are due primarily to adjustments in EPA's estimates of the burden. In addition to the adjustments listed above, the wage rates were revised to reflect 2018 dollars for this information collection request.

6(c) PRA Burden Statement

The annual public burden for this collection of information, which is approved under OMB Control No. 2070-0194, is estimated to average approximately 141 hours per response.

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. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information. 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 are listed in 40 CFR Part 9 and 48 CFR Chapter 15.

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 Docket ID Number EPA-HO-OPPT-2010-0572, which is available for online viewing at www.regulations.gov, or in person viewing at the EPA Docket Center (EPA/DC), EPA West, Room 3334, 1301 Constitution Avenue, NW, Washington, D.C. 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) 566-1744. An electronic version of the public docket is available at www.regulations.gov. This site can be used 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. When 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, D.C. 20503, Attention: Desk Officer for EPA. Please include the EPA Docket ID Number EPA-HQ-OPPT-2010-0572 and OMB Control Number 2070-0194 in any correspondence.

ATTACHMENT A

Supporting Attachment: Burden Calculation

This document serves the purpose of supporting the burden calculations included in the ICR renewal. EPA estimates that a total of 165 nanomaterial manufacturers will submit 0.52 responses per year and 199 nanomaterial processors will submit one response per year in each year of the ICR period, for a total of 285 reports per year and 855 reports over the three-year period. Table 1 shows the yearly number of responses for the various activities for manufacturers and processors, respectively.

Table 1: Annual Number of Responses per Activity

Activity	Manufacturers		Proce	Total Number of	
Activity	Total Number of Companies	Number of Responses/ Respondent	Total Number of Companies	Number of Responses/ Respondent	Responses (per year)
Rule Familiarization	165	0	199	1	199
Form Completion	165	0.52	199	1	285
CBI Substantiation	165	0.52	199	1	285
Electronic Submission	165	1	199	1	364
Recordkeeping	165	0.52	199	1	285

Estimating Respondent Burden

Table 2 provides a summary of typical respondent burden by activity for rule familiarization, completion of a report, CBI claim substantiation, and recordkeeping. Because it is expected that the same manufacturers will report each year, manufacturers do not have to undertake rule familiarization. On the other hand, it is expected that new processors will report each year and, therefore, undertake rule familiarization.

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)
Rule Familiarization	0	0.55	0.27	0	0.82
Form Completion	0	105.2	31.4	0	136.6
CBI Claim Substantiation	0	0	0.75	0.75	1.5
Recordkeeping	0.5	0.5	0	0	1
Total Burden per Report	0.5	106.25	32.42	0.75	140

Values may not sum due to rounding.

The burden associated with electronic submission is presented in Table 3. This burden depends on whether a firm is registering for the first time with CDX or has previously registered with CDX.

Table 3: Industry Burden, by Activity for Electronic Reporting

Tuble 5. Industry Burden, by	Clerical	Technical	Managerial	Number of	m.in.i
Activity	Burden	Burden	Burden	Annual	Total Burden
-	(hours)	(hours)	(hours)	Activities	(hours)
First-time registration					
CDX Registration	0.00	0.67	0.17	1.00	0.84
Electronic Subscriber	0.00	0.00	0.25	1 00	0.25
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 1	First Time Bur	den per firm	1.42
Subsequent registration					
CDX Registration	0.00	0.67	0.17	0.10	0.08
Electronic Subscriber	0.00	0.00	0.25	0.10	0.03
Agreement/Electronic Signature	0.00	0.00	0.25	0.10	0.05
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					

EPA estimates the total burden for one firm to complete one form to be approximately 141 hours including rule familiarization and electronic reporting.

Given the expectation that the same manufacturers will submit 0.52 reports per year, the burden per year per manufacturer is estimated by:

Form Completion, CBI Claim Substantiation and Recordkeeping E-Reporting Annual Burden per Manufacturer = 0.52 [136.6 + 1.5 + 1] + 0.17 = 72.5.

Therefore, the total annual burden across all 165 manufacturers is estimated by:

Annual Manufacturer Burden = $165 \times 72.5 = 11,962.83$ Given the expectation that each new processor will submit one report per year, the burden per year per processor is estimated by:

Form Completion,
Rule CBI Claim Substantiation
Familiarization and Recordkeeping E-Reporting
Annual Burden per Processor = 0.82 + 136.6 + 1.5 + 1 + 1.42 = 141.34.

Therefore, the total annual burden across all 199 processors is estimated by:

Annual Processor Burden = $199 \times 141.34 = 28,126.66$

Table 4 summarizes the annual and total burden over the course of the ICR to manufactures, processors and industry as a whole based on the above estimates.

Table 4: Total Industry Burden

IC Category	Annual Burden (hours)
IC 1: Manufacturers	11,963
IC 2: Processors	28,127
Total Industry Burden	40,089 hours

Estimating Cost

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. EPA estimates that the total cost for a new firm to review the rule, complete, and submit one report with record keeping is approximately \$10,815. Because new processors are estimated to report each year, they will undertake rule familiarization and first-time registration for electronic reporting. Because the same manufacturers are expected to submit reports each year, their cost for submitting one report would be approximately \$10,656 when excluding the cost burden associated with rule familiarization and accounting for a lower burden associated with electronic reporting for subsequent submissions.

Table 5: Industry Cost, by Activity (2018\$)

Activity	Clerical Burden (\$34.50/hour)	Technical Burden (\$75.32/hour)	Managerial Burden (\$80.09/hour)	Attorney Burden (\$118.42/hour)	Total Cost
Rule Familiarization	\$0.00	\$41.43	\$21.62	\$0.00	\$63.05
Form Completion	\$0.00	\$7,924	\$2,515	\$0.00	\$10,439
CBI Claim Substantiation	\$0.00	\$0.00	\$60.07	\$88.82	\$148.88
Recordkeeping	\$17.25	\$37.66	\$0.00	\$0.00	\$54.91
Total Burden per Report	\$17.25	\$8,003	\$2,597	\$88.82	\$10,706

Values may not sum due to rounding.

Estimates for manufacturer totals assume that rule familiarization does not occur. Because there are new processors estimated to report each year, the cost for those entities includes rule familiarization.

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 \$109.25 per firm and subsequent year costs are to be \$13.28 per firm. Because the same nanomaterial manufacturers are reporting each year, they are expected to incur a cost of \$13.28 per firm per year, while processors, who are new respondents each year, are expected to incur \$109.25 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 6: Industry Cost for Electronic Reporting (2018\$)

Activity	Clerical Cost (\$34.50/hour)	Technical Cost (\$76.32/hour)	Managerial Cost (\$80.09/hour)	Number of Annual Activities	Total Cost
	ELEC	TRONIC REPO	RTING		
First-time registration					
CDX Registration	\$0.00	\$50.46	\$13.62	1	\$64.08
Electronic Subscriber Agreement/ Electronic Signature	\$0.00	\$0.00	\$20.02	1	\$20.02
Help Desk	\$0.00	\$18.08	\$4.81	1	\$22.89
Problem Resolution	\$0.00	\$75.32	\$0.00	0.03	\$2.26
Total First Time Cost per firm					
Subsequent registration					
CDX Registration	\$0.00	\$50.46	\$13.62	0.10	\$6.41
Electronic Subscriber Agreement/Electronic Signature	\$0.00	\$0.00	\$20.02	0.10	\$2.00
Help Desk	\$0.00	\$18.08	\$4.81	0.10	\$2.29
Report Compromised Signature	\$0.00	\$0.00	\$32.04	0.01	\$0.32
Problem Resolution	\$0.00	\$75.32	\$0.00	0.03	\$2.26
		Total Su	ibsequent Cos	st per firm	\$13.28

Values may not sum due to rounding.

Given the expectation that the same manufacturers will submit 0.52 reports each year, the annual cost per manufacturer is estimated by:

Form Completion, CBI Claim
Substantiation and Recordkeeping E-Reporting

Annual Cost per Manufacturer = 0.52(10,439+148.88+54.91)+13.28=\$5,547.53.

Therefore, the annual cost across all 165 manufacturers is estimated by:

Annual Cost & Manufacturers = $165 \times 5,547.53 = $915,342.6$.

Given the expectation that each new processor will submit one report per year, the annual cost per processor is estimated by:

Rule Form Completion, CBI Claim
Familiarization Substantiation and Recordkeeping E-Reporting

 $Annual Cost \ per \ Processor = 63.05 + 10,439 + 148.88 + 54.91 + 109.25 = $10,815.09.$

Therefore, the annual cost across all 199 processors is estimated by:

Annual Cost & Processor = $199 \times 10,815.09 = \$2,152,203$.

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Table 7 summarizes the annual and total cost over the course of the ICR to manufactures, processors and industry as a whole based on the above estimates.

Table 7: Total Industry Cost (2018\$)

IC Category	Annual Cost		
IC 1: Manufacturers	\$915,343		
IC 2: Processors	\$2,152,203		

Total Industry Burden	\$3,067,546
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Estimating Agency Burden and Cost

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 2018 (OPM, 2018). 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 2018 for both of these employees are presented in Table 8. 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 8 derives the loaded wage rates for Agency staff at the GS-13 Step 5 and GS-14 Step 4 levels.

Table 8: Derivation of Loaded Agency Wage Rates (2018\$)

Labor Category	Pay Grade	Annual Salary	Overhead and Fringe Benefits (% of wages Control of the control of		Total	Hourly Rate
Technical Labor	GS 13 Step 5	\$109,900	60%	\$65,940	\$175,840	\$84.54
Attorney Labor	GS 14 Step 5	\$129,869	60%	\$77,181	\$207,050	\$99.54

Source: The unloaded Federal salary for 2018 is from the Office of Personnel Management salary table for Washington-Baltimore-Northern Virginia (OPM, 2018).

Table 9 provides the total annual cost and burden of Agency activities based on the loaded wages derived in Table 8. The annual burden to the Agency is estimated to be 1,818 hours and the total burden to the Agency over the three-year period of the ICR is estimated to be 5,454 hours. The annual cost of the Agency is estimated to be \$160,200 and the total cost to the Agency over the three-year period is estimated to be \$480,600.

Table 9: Total Annual Cost and Burden of Agency Activities (2018\$)

Activity	Staff	Total Burden per Activity (hours)	Total Number of Units	Annual Burden (hours)	Annual Cost (Thousands)
Industry/Public Assistance		1.25	285	356	\$30,100
Data Processing and System Support Personnel	EPA Employee (GS 13 Step 5/ \$84.54/hour)	3.13	285	892	\$75,400
Review of CBI Claim Substantiations	ф04.54/ nom)	0.5	285	143	\$12,100
Review of CBI Claim Substantiations	EPA Employee (GS 14 Step 5/ \$99.54/hour)	1.5	285	428	\$42,600
		1,818 hours	\$160,200		
Total Cos	st and Burden	5,454 hours	\$480,600		

Values may not sum due to rounding.

References

U.S. Office of Personnel Management. (2018). *Salary Table 2018- DCB, Washington-Baltimore-Northern Virginia*, *DC-MD-PA-VA-WV*. Retrieved September 18, 2019 from Pay & Leave: Salaries & Wages: https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2018/DCB.pdf.

U.S. EPA, (2009). *ICR Handbook EPA's Guide to Writing Information Collection Requests under the Paperwork Reduction Act of 1995*. Revised 10/2009 Washington, D.C.: U.S. EPA, Office of Environmental Information.

ATTACHMENT B

WAGE RATE CALCULATIONS

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 2019* (U.S. BLS, 2019). Additionally, wage rates for the attorney level were gathered from the *BLS Occupational Employment Statistics (OES) May 2018 National Industry-Specific Occupational Employment and Wage Estimates* (U.S. BLS, 2018).

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 (U.S. EPA, 2002), fringe benefits are calculated as a percentage of total wages for each category. Since the fringe benefits for attorney 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* (Rice, 2002). The wages for each of the four categories were then multiplied by benefits and overhead factors to estimate loaded, annual salaries in year 2018 dollars. Table 1 contains the loaded wage rates for the attorney, managerial, technical and clerical occupation categories.

Table 1: Derivation of Loaded Wage Rates for the Private Manufacturing Sector in 2018\$

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)
Attorney ¹	\$72.21	\$33.94	47%	17%	1.64	\$118.42
Managerial ²	\$48.73	\$23.08	47%	17%	1.64	\$80.09
Technical ²	\$44.35	\$24.43	55%	17%	1.72	\$75.32
Clerical ²	\$20.77	\$20.77	49%	17%	1.66	\$34.50

Sources: ¹ Bureau of Labor Statistics Occupational Employment Statistics (OES) May 2018 National Industry-Specific Occupational Employment and Wage Estimates (U.S. BLS, 2018)

²Employer Costs for Employee Compensation Supplementary Tables: December 2006 – March 2019 (U.S. BLS, 2019).

³An overhead rate of 17 percent was estimated 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* (U.S. EPA, 2002) and *Wage Rates for Economic Analyses of the Toxics Release Inventory Program.* (Rice, 2002)

References

- Rice, C. (2002). *Wage Rates for Economic Analysis of the Toxic Release Inventory Program*. Washington, D.C.: U.S. EPA, Office of Pollution Prevention and Toxics, Economics and Policy Analysis Branch.
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