

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

EXECUTIVE SUMMARY

Identification of the Information Collection – Title and Numbers

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

EPA ICR No.: 2517.04

OMB Control No.: 2070-0194

Docket ID No.: EPA-HQ-OPPT-2010-0572

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).

Summary Total Burden and Costs

Information Collection	Annual Number of Respondents	Responses per Respondent	Annual Number of Responses	Annual Time Burden (Hours)	Annual Cost Burden (Dollars)
Form Completion, Confidential Business Information (CBI) Substantiation, Form Submission, Recordkeeping, and Rule Familiarization (Manufacturers & Processors)	5.3	1.7	9	959	\$69,280
Total Agency				236	\$23,956

SUPPORTING STATEMENT

1. Explain the circumstances that make the collection of information necessary. Identify any legal or administrative requirements that necessitate the collection. Attach a copy of the appropriate section of each statute and regulation mandating or authorizing the collection of information.

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 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:

As defined in 40 CFR 704.20(b), potential respondents include those who can reasonably ascertain that they are manufacturers (defined by statute to include importers) and/or processors of a discrete form of a reportable chemical substance or mixture. (Additional information about the entities identified as potential respondents for the EPA estimates in this ICR, see also the answer to Question 12).

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) (**Attachment A**) 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 (Safety Data Sheet (SDS), 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. Indicate how, by whom, and for what purpose the information is to be used. Except for a new collection, indicate the actual use the Agency has made of the information received from the current 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 275 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.

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. Describe whether, and to what extent, the collection of information involves the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses, and the basis for the decision for adopting this means of collection. Also describe any consideration of using information technology to reduce burden.

Manufacturers and processors of nano materials must submit information to the Agency electronically. To file electronically, submitters must use the EPA provided application. To access the application, users must register with EPA's Central Data Exchange (CDX). CDX is the Agency's portal for submitting information to EPA in a secure manner. When registering, a user will need to ensure they are registering for the Chemical Safety and Pesticide Programs (CSPP) data flow which will provide them access to the Chemical Information Submission System (CISS) where the submission can be accessed. (Note: Users who have previously registered with CDX are able to add "Submission for Chemical Safety and Pesticide Program (CSPP)" to their current registration.) This reporting tool is compatible with Windows, Mac, Linux, and UNIX based computers, and uses "Extensible Markup Language" (XML) specifications for efficient data transmission across the Internet (**Attachment B**).

4. Describe efforts to identify duplication. Show specifically why any similar information already available cannot be used or modified for use for the purposes described in Item 2 above.

Section 8(a)(5) of TSCA states, "the Administrator shall, to the extent feasible... not require reporting which is unnecessary or duplicative." The implementing regulations 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 that would be subject to the regulations does not need to submit a report for the nanoscale material information previously submitted.

5. If the collection of information impacts small businesses or other small entities, describe the methods used to minimize burden.

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.

6. Describe the consequence to Federal program or policy activities if the collection is not conducted or is conducted less frequently, as well as any technical or legal obstacles to reducing burden.

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

7. Explain any special circumstances that require the collection to be conducted in a manner inconsistent with OMB guidelines.

- a) requiring respondents to report information to the agency more often than quarterly;
- b) requiring respondents to prepare a written response to a collection of information in fewer than 30 days after receipt of it;
- c) requiring respondents to submit more than an original and two copies of any document;
- d) requiring respondents to retain records, other than health, medical, government contract, grant-in-aid, or tax records, for more than three years;
- e) in connection with a statistical survey, that is not designed to produce valid and reliable results that can be generalized to the universe of study;
- f) requiring the use of a statistical data classification that has not been reviewed and approved by OMB;
- g) that includes a pledge of confidentiality that is not supported by authority established in statute or regulation, that is not supported by disclosure and data security policies that are consistent with the pledge, or which unnecessarily impedes sharing of data with other agencies for compatible confidential use; or
- h) requiring respondents to submit proprietary trade secrets, or other confidential information unless the agency can demonstrate that it has instituted procedures to protect the information's confidentiality to the extent permitted by law.

The proposed collection does not create special circumstances requiring justification under 5 CFR 1320.5.

8. If applicable, provide a copy and identify the date and page number of publication in the Federal Register of the agency's notice, required by 5 CFR 1320.8(d), soliciting comments on the information collection prior to submission to OMB. Summarize public comments received in response to that notice and describe actions taken in response to the comments. Specifically address comments received on cost and hour burden.

Describe efforts to consult with persons outside EPA to obtain their views on the availability of data, frequency of collection, the clarity of instructions and recordkeeping, disclosure, or reporting format (if any), and on the data elements to be recorded, disclosed, or report.

Consultation with representatives of those from whom information is to be obtained or those who must compile records should occur at least once every 3 years - even if the collection of information activity is the same as in prior periods. There may be circumstances that may preclude consultation in a specific situation. These circumstances should be explained.

Pursuant to 5 CFR 1320.8(d), EPA published a notice in the Federal Register on February 1, 2024 (88 FR 6520), announcing the planned renewal of this information collection activity, soliciting public comment on specific aspects of the ICR and providing a 60-day public comment period.

The EPA also consulted 9 stakeholders, specifically asking them for their assessment of the regulatory burden estimates expressed by the Agency in this ICR (**Attachment C**).

Two stakeholders provided responses (**Attachment D**). The stakeholders consulted were:

- 1) American Chemistry Council
- 2) Nano Business Commercialization Association (NanoBCA)
- 3) American Cleaning Institute
- 4) Society of Chemical Manufacturers and Affiliates (SOCMA)
- 5) Association of International Automobile Manufacturers
- 6) Plastics Industry Association
- 7) BASF
- 8) Bergeson and Campbell Consortia Management LLC
- 9) Nanophase Technologies Corporation

Of those consulted, EPA received comments from NanoBCA and the American Cleaning Institute. The comments received were not substantive. The Agency thanks all

commenters for their comments and has considered them in developing this ICR (Attachment D).

9. Explain any decision to provide any payment or gift to respondents, other than remuneration of contractors or grantees.

This question is not applicable to this ICR.

10. Describe any assurance of confidentiality provided to respondents and the basis for the assurance in statute, regulation, or agency policy. If the collection requires a systems of records notice (SORN) or privacy impact assessment (PIA), those should be cited and described here.

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.

11. Provide additional justification for any questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private. This justification should include the reasons why the agency considers the questions necessary, the specific uses to be made of the information, the explanation to be given to persons from whom the information is requested, and any steps to be taken to obtain their consent.

No information of a sensitive or private nature is requested in conjunction with these information collection activities, and these information collection activities comply with the provisions of the Privacy Act of 1974 and OMB Circular A-108, as amended, "Responsibilities for the Maintenance of Records about Individuals by Federal Agencies."

12. Provide estimates of the hour burden of the collection of information.

- a) Indicate the number of respondents, frequency of response, annual hour burden, and an explanation of how the burden was estimated. Unless directed to do so, agencies should not conduct special surveys to obtain information on which to base hour burden estimates. Consultation with a sample (fewer than 10) of potential respondents is desirable. If the hour burden on respondents is expected to vary widely because of differences in activity, size, or complexity, show the range of estimated hour burden, and explain the reasons for the variance. Generally, estimates should not include burden hours for customary and usual business practices.
- b) If this request for approval covers more than one form, provide separate hour burden estimates for each form and aggregate the hour burdens.

- c) Provide estimates of annualized cost to respondents for the hour burdens for collections of information, identifying and using appropriate wage rate categories. The cost of contracting out or paying outside parties for information collection activities should not be included here. Instead, this cost should be included under ‘Annual Cost to Federal Government’

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.

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

Burden and Cost Estimates

Information Collection Activities

EPA received TSCA section 8(a) nanomaterials submissions from 37 different manufacturers and processors since 2017. Based on this observation, EPA estimates that a total of 5.3 respondents will submit responses per year. Given that the EPA received a total of 27 reports over the last three-year ICR period, EPA expects to receive 1.7 reports per respondent each year. Table 1 shows the yearly number of responses for the various nanoscale materials for manufacturers and processors combined.

Table 1: Responses during the current ICR period

Time period	Number of responses
Sep 2020 – Dec 2020	2
2021	10
2022	10
Jan 2023- Aug 2023	5
ICR period total	27

Estimating Respondent Burden

Table 2 shows the estimated burden for five activities necessary to submit a TSCA 8(a) nanomaterials report to the EPA for nanoscale manufacturers, processors as well as the average estimated burden for any given respondent. This is estimated by assigning equal weights to manufacturer and processor burdens. This assumption is made given that the expected number of nanoscale manufacturers and processors in the previous ICR renewal were about the same.

Table 2: Burden per year per respondent

Activity	Manufacturer burden (hours/year)	Processor burden (hours/year)	Weighted burden per respondent (hours/year)
Form completion	71	136.6	103.8
CBI substantiation	0.78	1.5	1.14
Form submission	0.17	1.42	0.80
Recordkeeping	0.5	1	0.75
Rule familiarization	0	0.82	0.41

Table 3 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 3: Industry Burden per year, by activity

Activity	Clerical Burden (hours)	Technical Burden (hours)	Managerial Burden (hours)	Attorney Burden (hours)	Total Burden (hours)
Rule Familiarization	0	0.28	0.14	0	0.41
Form Completion	0	79.93	23.87	0	103.8
CBI Claim Substantiation	0	0	0.57	0.57	1.14
Recordkeeping	0.375	0.375	0	0	0.75
Total Burden per Report	0.375	80.58	24.58	0.57	106.1

Values may not sum due to rounding.

The burden associated with electronic submission is presented in Table 4. This burden depends on whether a firm is registering for the first time with CDX or has previously registered with CDX. Approximately one-half of respondents (producers) will be first-time submitters while the other half (manufacturers) will be repeat submitters during the period covered by this ICR. The average form submission will therefore require 0.8 hours of labor.

Table 4: Industry Burden, by Activity for Electronic Reporting

Activity	Clerical Burden (hours)	Technical Burden (hours)	Managerial Burden (hours)	Number of Annual Activities	Total Burden (hours)
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

EPA estimates the total burden for one firm to complete one form to be approximately 106.9 hours including rule familiarization and electronic reporting.

Given the expectation that each respondent will submit 1.7 reports per year, the burden per year per respondent is estimated by: Form Completion, CBI Claim Substantiation, Recordkeeping, E-Reporting, and Rule familiarization.

$$\text{Annual Burden per respondent} = 1.7(103.8 + 1.14 + 0.75) + 0.80 + 0.41 = 180.88$$

Therefore, the total annual burden across all 5.3 respondents, that are expected per year, is estimated by:

$$\text{Total Annual Respondent Burden} = 5.3 \times 180.88 = 959 \text{ hours}$$

Estimating Cost

Table 5 contains the cost per activity of completing a form for one respondent. Burden hours presented in Table 3 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 \$13,072.

Table 5: Industry Cost, by Activity (2022\$)

Activity	Clerical Burden (\$33.76/hour)	Technical Burden (\$67.68/hour)	Managerial Burden (\$86.61/hour)	Attorney Burden (\$125.92/hour)	Total Cost
Rule Familiarization	\$0.00	\$18.61	\$11.69	\$0.00	\$30.30
Form Completion	\$0.00	\$5,410	\$2,067.38	\$0.00	\$7,477.38
CBI Claim Substantiation	\$0.00	\$0.00	\$49.37	\$71.77	\$121.14
Recordkeeping	\$12.66	\$25.38	\$0.00	\$0.00	\$38.04
Total Burden per Report	\$12.66	\$5,453.99	\$2,128.44	\$71.77	\$7,667

Values may not sum due to rounding.

Electronic reporting costs are presented in Table 6. Because not all firms are expected to 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 \$105.24 per firm and subsequent year costs are to be \$13.34 per firm. Approximately one-half of respondents (producers) will be first-time submitters while the other half (manufacturers) will be repeat submitters during the period covered by this ICR. The average labor cost for a form submission will therefore be \$59.29.

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 (2022\$)

Activity	Clerical Cost (\$33.76/hour)	Technical Cost (\$67.68/hour)	Managerial Cost (\$86.61/hour)	Number of Annual Activities	Total Cost
ELECTRONIC REPORTING					
First-time registration					
CDX Registration	\$0.00	\$45.35	\$14.72	1	\$60.07
Electronic Subscriber Agreement/ Electronic Signature	\$0.00	\$0.00	\$21.65	1	\$20.02
Help Desk	\$0.00	\$16.24	\$5.20	1	\$22.89
Problem Resolution	\$0.00	\$75.32	\$0.00	0.03	\$2.26
Total First Time Cost per firm					\$105.24
Subsequent registration					
CDX Registration	\$0.00	\$45.35	\$14.72	0.10	\$6.93
Electronic Subscriber Agreement/Electronic Signature	\$0.00	\$0.00	\$21.65	0.10	\$2.03
Help Desk	\$0.00	\$16.24	\$5.20	0.10	\$2.03
Report Compromised Signature	\$0.00	\$0.00	\$34.64	0.01	\$0.32
Problem Resolution	\$0.00	\$67.68	\$0.00	0.03	\$2.03
Total Subsequent Cost per firm					\$13.34

Values may not sum due to rounding.

Given the expectation that the same respondents will submit 1.7 reports each year, the annual cost per respondent is estimated by:

Form Completion, CBI Claim

$$\text{Annual Cost per Respondent} = 1.7(7,477.38 + 121.14 + 38.04) + 59.29 + 30.30 = \$13,072.$$

Therefore, the annual cost across all 5.3 respondents that are expected per year is estimated by:

$$\text{Total Annual Cost } \dot{\iota} \text{ Respondents} = 5.3 \times \$13,072 = \$69,280$$

13. Provide an estimate for the total annual cost burden to respondents or recordkeepers resulting from the collection of information.

- a) The cost estimate should be split into two components: (a) a total capital and start-up cost component (annualized over its expected useful life) and (b) a total operation and maintenance and purchase of services component. The estimates should take into account costs associated with generating, maintaining, and disclosing or providing the information. Include descriptions of methods used to estimate major cost factors

including system and technology acquisition, expected useful life of capital equipment, the discount rate(s), and the time period over which costs will be incurred. Capital and start-up costs include, among other items, preparations for collecting information such as purchasing computers and software; monitoring, sampling, drilling and testing equipment; and record storage facilities.

- b) If cost estimates are expected to vary widely, agencies should present ranges of cost burdens and explain the reasons for the variance. The cost of purchasing or contracting out information collections services should be a part of this cost burden estimate. In developing cost burden estimates, agencies may consult with a sample of respondents (fewer than 10), utilize the 60-day pre-OMB submission public comment process and use existing economic or regulatory impact analysis associated with the rulemaking containing the information collection, as appropriate.
- c) Generally, estimates should not include purchases of equipment or services, or portions thereof, made: (1) prior to October 1, 1995, (2) to achieve regulatory compliance with requirements not associated with the information collection, (3) for reasons other than to provide information or keep records for the government, or (4) as part of customary and usual business or private practices.

There are no operational and/or maintenance costs associated with this ICR.

14. Provide estimates of annualized cost to the Federal government. Also, provide a description of the method used to estimate cost, which should include quantification of hours, operational expenses (such as equipment, overhead, printing, and support staff), and any other expense that would not have been incurred without this collection of information. Agencies may also aggregate cost estimates from Items 12, 13, and 14 in a single table.

EPA will perform the following activities:

- review the information submitted;
- analyze submissions for CBI 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.

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.

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.

Estimating Agency Burden and Cost

Agency personnel are responsible for all tasks associated with the implementation of regulations, 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 2022 (OPM, 2022). 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. Loaded wage rates for 2022 for both 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 8 derives the loaded wage rates for Agency staff at the GS-13 Step 5 and GS-14 Step 4 levels.

Table 7: Loaded wages for EPA Staff and Attorney (2022\$)

Labor Category	Data Source for Wage Information	Wage (\$/hour)	Fringe Benefit	Fringes as % wage	Overhead as % wage	Fringe + Overhead Factor	Loaded Wage (\$/hr)
		(a)	(b)	(c) = (b) / (a)	(d)	(e) = (c) + (d) + 1	(f) = (a) * (e)
Staff	Annual federal staff cost: OPM Washington-Baltimore-Northern Virginia, DC-MD-PA-VA-WV area, GS-13 Step 5 pay rates ¹	\$60.83	Included in 60% overhead	N/A	60% ²	1.6	\$97.33
Attorney	Annual federal staff cost: OPM Washington-Baltimore-Northern Virginia, DC-MD-PA-VA-WV area, GS-14 Step 5 pay rates ¹	71.88	Included in 60% overhead	N/A	60% ²	1.6	\$115

Table 8 provides the total annual cost and burden of Agency activities based on the loaded wages presented in Table 7. The annual burden to the Agency is estimated to be 236 hours and the total burden to the Agency over the three-year period of the ICR is estimated to be 708 hours. The annual cost of the Agency is estimated to be \$23,956 and the total cost to the Agency over the three-year period is estimated to be \$71,868.

Table 8: Total Annual Cost and Burden of Agency Activities (2022\$)

Activity	Staff	Total Burden per Activity (hours)	Total Number of Units	Annual Burden (hours)	Annual Cost (Thousands)
Industry/Public Assistance	EPA Employee (GS 13 Step 5/ \$97.33/hour)	1.25	37	46.25	\$4,501.50
Data Processing and System Support Personnel		3.13	37	115.81	\$11,271.79
Review of CBI Claim Substantiations		0.5	37	18.50	\$1800.61
Review of CBI Claim Substantiations	EPA Employee (GS 14 Step 5/ \$115/hour)	1.5	37	55.50	\$6,382.50
Annual Cost and Burden				236 hours	\$23,956
Total Cost and Burden Over 3-Year ICR Period				708 hours	\$71,868

Values may not sum due to rounding.

15. Explain the reasons for any program changes or adjustments reported on the burden worksheet.

The annual burden in the previously approved ICR was 40,090 hours. The total annual burden to respondents requested for this ICR is 959 hours, or a decrease of 39,131 hours from the previous total annual burden. The total number of estimated responses from the previous ICR was 285, and the total estimated annual number of responses for this ICR is 9. The total annual cost of the previously approved ICR was \$3,067,546. The total annual cost to respondents requested for this ICR is \$69,280, a decrease of \$2,998,266 from the previous ICR total annual cost.

The difference between the current cost and burden estimates and the previous ICR estimates are due to adjustments in EPA's estimation methodology of the costs and burden. The two key adjustments that were made to the estimation methodology are as follows:

- In the previous ICR period, the burden estimates were based on expected submissions, not on actual submissions received by the agency, while the reporting covered in this period is based on actual submissions received by the agency. This significant change accounts for almost all the decrease in burden and cost estimates.
- In the previous ICR period, the burden was estimated separately for manufactures and processors, while the reporting covered in this period calculates a weighted burden for any given respondent without separating the manufacturers from the processors. This approach was deemed reasonable given that the agency received only 27 submissions related to TSCA 8(a) nanomaterials in the current three-year ICR period, which accounts for the decrease in number or responses.

In addition to the adjustments listed above, the wage rates were revised to reflect 2022 dollars for this information collection request.

16. For collections whose results will be published, outline the plans for tabulation and publication. Address any complex analytical techniques that will be used. Provide the time schedule for the entire project, including beginning and ending dates of the collection of information, completion of report, publication dates, and other actions.

This question is not applicable to this ICR.

17. If seeking approval to not display the expiration date for OMB approval of the information collection, explain the reasons why display would be inappropriate.

This question is not applicable to this ICR.

18. Explain each exception to the topics of the certification statement identified in "Certification for Paperwork Reduction Act Submissions."

EPA does not request an exception to the certification of this information collection.

SUPPLEMENTAL INFORMATION

PRA Burden Statement

This collection of information is approved by OMB under the Paperwork Reduction Act, 44 U.S.C. 3501 et seq. (OMB Control No. 2070-0194). Responses to this collection of information are mandatory for certain persons, as specified at 40 CFR Part(s) 704. 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 public reporting and recordkeeping burden for this collection of information is estimated to be 106.4 hours per response. Send comments on the Agency's need for this information, the accuracy of the provided burden estimates and any suggested methods

for minimizing respondent burden to the Information Engagement Division Director, U.S. Environmental Protection Agency (2821T), 1200 Pennsylvania Ave., NW, Washington, D.C. 20460. Include the OMB control number in any correspondence. Do not send the completed form to this address.”

You can also provide comments to the Office of Information and Regulatory Affairs, Office of Management and Budget via <http://www.reginfo.gov/public/do/PRAMain>. Find this particular information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function.

All comments received by EPA will be included in the docket without change, including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI), or other information whose disclosure is restricted by statute. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

LIST OF ATTACHMENTS

The attachments listed below can be found in the docket for this ICR. The docket for this ICR is accessible electronically through <https://www.regulations.gov> using Docket ID Number: EPA-HQ-OPPT-2010-0572.

Attachment	Description
A	EPA PMN Form 7710-25
B	EPA Form 9600-07
C	Consultation
D	Consultation Responses

REFERENCES

[15 USC 2607](#)

[40 CFR 704](#)

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- U.S. Office of Personnel Management. (2023). *Salary Table 2018- DCB, Washington-Baltimore-Northern Virginia, DC-MD-PA-VA-WV*. Retrieved January 9, 2024 from Pay & Leave: Salaries & Wages: https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/23Tables/html/DCB_h.aspx