

**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

Title: Procedures for Requesting a Chemical Risk Evaluation under TSCA

ICR Numbers: EPA ICR No.: 2559.03; OMB Control No.: 2070-0202.

EPA Form Numbers: n/a, Complete online.

Docket ID Number: EPA-HQ-OPPT-2016-0654

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 the rulemaking. 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., N.W., 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

This ICR renewal addresses the information collection activities that are contained in a final rule. 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).

1(d). Abstract

This ICR is related to a requirement contained in a final rule issued by EPA in June 2017 to implement new provisions outlined in the Frank R. Lautenberg Chemical Safety of the 21st Century Act which passed in June 2016. The final rule established the process the Agency adheres to in conducting risk evaluations under the Toxic Substances Control Act (TSCA) (**Attachment 2**). Chemicals that will undergo this evaluation include chemicals the Agency has

prioritized, as well as chemicals for which EPA has granted requests made by manufacturers to have the chemicals evaluated under EPA's risk evaluation process. The final rule outlined the criteria and information chemical manufacturers must provide for EPA to consider a chemical substance for risk evaluation. The information collection activities covered by this ICR renewal are those carried out by a chemical manufacturer in requesting a specific chemical risk evaluation under TSCA be conducted by EPA. This information is necessary in order for EPA to review information covered by chemical manufacturers and determine if the chemical substance is suitable for risk evaluation.

Legal authority: The Toxic Substances Control Act (TSCA), 15 U.S.C. § 2605(b).

Respondents/affected entities: Entities potentially affected by this ICR include persons that manufacture chemical substances and request a chemical be considered for risk evaluation by EPA.

Respondent's obligation to respond: Respondents are not obligated to respond or report to EPA. Submitting under this ICR is completely voluntary.

Confidentiality of responses: Responses may contain confidential business information but persons submitting a response are subject to EPA confidentiality regulations at 40 CFR part 2, subpart B. 11

Estimated total number of potential respondents: 5

Frequency of response: On occasion EPA, submission by manufacturer is completely voluntary.

Estimated total annual burden: 419.15 hours. Burden is defined at 5 CFR 1320.3(b).

Estimated total annual costs: \$283,570, which includes \$0 annualized capital or operation & maintenance costs.

Changes in the estimates: There is no change in hour or cost burden as compared with what is currently approved by OMB. There is an increase of \$709 in the total estimated labor costs, which reflects the increase in wage rates since the initial ICR.

2. NECESSITY OF THE INFORMATION COLLECTION

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

TSCA – Under section 6(b)(4) of TSCA (15 U.S.C. §2605(b)(4)), EPA is required to establish, by rule, a process to conduct risk evaluations. Specifically, EPA is directed to use this process to “determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation by the Administrator under the conditions of use.” (15 U.S.C. 85 §2605(b)(4)(A). Sections 6(b)(4)(A) through (H) enumerate the deadlines and minimum requirements, under TSCA, applicable to this process, including provisions that direct which chemical

substances must undergo evaluation, the development of criteria for manufacturer requested evaluations, the minimum components of an Agency risk evaluation, and the timelines for public comment and ultimate completion of the risk evaluation. Section 6(b)(4) authorizes EPA to:

- (1) Conduct risk evaluations pursuant to specific requirements in the statute and the promulgated risk evaluation rule on chemicals prioritized by the Agency or chemicals for which EPA has granted requests made by manufacturers to have the chemicals undergo EPA's risk evaluation;
- (2) Develop a process of risk evaluation;
- (3) Establish the form and manner and criteria that govern manufacturer requests that a substance they produce undergo EPA's risk evaluation; and
- (4) Make a final unreasonable risk determination on a chemical substance under the conditions of use

The final rule:

- 1) Established a process to conduct risk evaluations to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation, under the conditions of use;
- 2) Established the form and manner and criteria that govern manufacturer requests that a substance they produce undergo EPA's risk evaluation;
- 3) Enumerated the requirements and deadlines that must be adhered to in completing a risk evaluation; and
- 4) Provided opportunity for public comment during two stages of a risk evaluation process.

2(b). Necessity of the Information Collection

The information collection activities covered by this ICR are necessary in order for EPA to review information provided by chemical manufacturers and determine if the chemical substance is suitable for risk evaluation. Without collecting the information outlined in the final rule, there would not be a way for EPA to determine if enough data and information meeting the standards in section 21(h) available to perform a risk evaluation of the given chemical substance within the timeframe outlined in the new legislation.

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

EPA. This information collection provides EPA with information necessary to conduct a risk evaluation on a chemical substance and each submission request must comply with all procedures and criteria outlined in the final rule. A request meets EPA's criteria if it includes or references all the information necessary for the Agency to conduct a risk evaluation addressing all the circumstances constituting condition(s) of use of interest to the manufacturer(s), of the chemical substance within the meaning of TSCA section 33.

EPA uses this information collection to (1) determine if the criteria has been meet for risk evaluation requests and (2) conduct the risk evaluation if the request is granted.

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

3(a). Non-Duplication

The EPA's collection pursuant to the TSCA section 6(a) regulations do not duplicate any other collection. There is no other Federal program that requires the information collection activities related to the prohibitions under the final rule.

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

Prior to submission to OMB, this ICR renewal was made available to the public for comment through a January 28, 2020 Federal Register notice (85 FR 4981). The public had 60 days to provide comments. EPA received one public comment, which was considered in the development of this ICR renewal.

3(c). Consultations

Under 5 CFR 1320.8(d)(1) OMB requires agencies to consult with potential ICR respondents and data users about specific aspects of ICRs before submitting an original or renewal ICR to OMB for review and approval. EPA contacted the following four potential respondents:

- M. David Adenuga on behalf of ExxonMobil Chemical Company
- Eileen Conneely, American Chemistry Council High Phthalates Panel
- Michele Buckingham, Dow Silicones Corporation
- Karluss Thomas, American Chemistry Council's Silicones Environmental, Health, and Safety Center

A copy of the consultation communications is in the docket for this ICR (**Attachment 3**).

3(d). Effects of Less Frequent Collection

Due to the nature of the triggering events that initiate information collection activities included in this ICR, less frequent collection is not feasible. This ICR only applies to voluntary actions by chemical manufacturers. Submission of information thus is on an as-needed, on-occasion basis, as initiated by respondents. EPA cannot control when or how often respondents elect to submit a chemical substance for risk evaluation consideration. Less frequent collection would mean respondents not being required to submit data at all. However, without such data, EPA would not be able to consider chemical substances for risk evaluation at the request of chemical manufacturers as mandated in TSCA.

3(e). Small Entity Flexibility

EPA believes that the submission requirements do not unduly burden small businesses. EPA concludes that the final information collection request has no significant impacts on small entities subject to this ICR as firms self-select to report and when doing so less than one percent of the small businesses in the estimated universe of those potentially impacted are expected to have an impact of greater than 3 percent.

3(f). General PRA Related Guidelines

This ICR does not exceed the PRA guidelines at 5 CFR 1320.5.

3(g). Confidentiality

Large portions of the information required as part of the risk evaluation request submission may be considered by the submitter to be a trade secret, proprietary, or “confidential business information” (CBI). However, EPA requires the submission of such information because it is essential for providing a basis to determine unreasonable risk. EPA cannot draw conclusions or make assumptions concerning toxicological effects and potential risks without examining physicochemical structure, methods of production, byproducts, potential uses, exposure data, etc.

The Agency’s policies allow public involvement while preserving confidentiality. TSCA section 14(a) prohibits, except in limited circumstances, the disclosure of trade secret information. TSCA section 14(d) allows disclosure of health and safety studies, including underlying data, unless these studies disclose confidential process or mixture information. Under 40 CFR 720.85 and 720.87(See also 40 CFR part 2), when the specific chemical identity or use data are claimed confidential, the Agency requires the submitter to provide generic descriptions for inclusion in Federal Register notices and the public file. Additionally, the submitter must provide a “sanitized” copy of all health and environmental effects data, with confidential information deleted, for placement in the public docket. Within the Agency, only personnel with the required clearance may handle CBI.

Based on its experience, EPA expects that most information included in requests for risk evaluations notices will be CBI. EPA has developed an elaborate system to prevent unauthorized disclosure of CBI. This system includes procedures for logging material in and out of the Confidential Business Information Center (CBIC) at EPA headquarters and procedures for photocopying and transmitting CBI. These procedures apply to CBI submitted by manufacturers as well as CBI generated by EPA staff in the course of their review. Access to CBI is restricted to persons who need the information for their work. No one is allowed access to CBI without first undergoing instruction on procedures for handling CBI. Special procedures have been instituted to restrict access to computerized CBI. These procedures are detailed in the “TSCA CBI Protection Manual,” October 2003. EPA believes these procedures protect confidential information while providing the public with as much information as possible.

Any information being sent via Central Data Exchange (CDX) is transmitted using secure technologies to protect CBI. The software encrypts company submissions using a Federal Information Processing Standards (FIPS) compliant encryption module. The encryption module employs a public key algorithm which converts readable text into encrypted text. This public key is downloaded from CDX to the submission software, and the corresponding private key is sent to EPA’s New Chemical System (NCS). The encryption remains while the submission is transmitted via CDX to NCS. The file can be decrypted only with the NCS’s private key when it has reached its final destination. The NCS is the only party that possesses the private key, which converts the encrypted text back into readable text.

The same thing will occur for all correspondence going back to the submitter. The NCS and submission software are also provided with a set of public and private keys, so that correspondence containing any potential confidential business information will remain encrypted during transmission via CDX and can be opened only by the submitter within the appropriate software.

3(h). Sensitive Questions

The information collection activities do not include questions of a sensitive nature.

4. AGENCY ACTIVITIES, COLLECTION METHODOLOGY, AND INFORMATION MANAGEMENT

4(a). Agency Activities

In connection with administering the TSCA mandated review of chemical substances submitted by chemical manufacturers for risk evaluation consideration, EPA performs the following activities:

- Within 15 business days of receipt of a request EPA will notify the public of the request.
- Within 60 business days of receipt of a request EPA will public the request in the Federal Register and open a docket for no less than a 45 calendar day public commenter period. The notice will include the manufacturer request and any other conditions of use the Agency has determined should be considered in the risk evaluation.
- Within 60 business days of the end of the comment period the Agency will notify the requester of the decision to grant or deny the request. If the request is granted, the manufacturer has 30 days to withdraw the request, or the request will be granted and the Agency will move to initiate the risk evaluation.

4(b). Estimated Agency Costs

EPA estimates costs of \$2,494,096 to carry out the activities associated with the information collection activities covered by this ICR, the costs for the Agency to review and determine completeness of 5 manufacturer requested risk evaluations. In order to determine the total cost for the Agency, an average number of labor hours and contractor costs were calculated. The labor rate was assumed to be a fully loaded GS-13, step 5 employee in the Washington D.C. area of \$84.26 per hour. This cost includes an average labor time of 5,920 hours per chemical submitted by a manufacturer.

4(b)(i). Collection Schedule

Does not apply to this information collection. Submission of information under this collection is on an as-needed, on-occasion basis, initiated by the respondents.

4(b)(ii). Use of Technology to Facilitate Collection Activities

EPA makes use of existing technology to simplify the submission process. Respondents submit the initial request package and any supplemental information to the Agency via CDX. This is the same system used for section 5 submissions to EPA. Therefore, respondents may

already be familiar with the system and the system has the capabilities to receive and send information claimed as CBI.

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

The collection specifies submissions to EPA when a chemical manufacturer elects to submit a chemical substance for potential risk evaluation by the Agency. The North American Industrial Classification System (NAICS) codes associated with industries most likely affected by the paperwork requirements are described below:

3222	Converted Paper Products Manufacturing
3241	Petroleum and Coal Product Manufacturing
3251	Basic Chemical Manufacturing
3252	Resin, Synthetic Rubber, and Artificial Synthetic Fibers and Filaments Manufacturing
3255	Paint, Coating, and Adhesive Manufacturing
3256	Soap, Cleaning Compound, and Toilet Preparation Manufacturing
3259	Other Chemical Product and Preparation Manufacturing
3261	Plastics Product Manufacturing
3262	Rubber Product Manufacturing
3271	Clay Product and Refractory Manufacturing
3272	Glass and Glass Product Manufacturing
3273	Cement and Concrete Product Manufacturing

The final rule provides the information and criteria chemical manufacturers are required to meet when submitting a chemical substance to EPA for risk evaluation consideration. The submissions outlined in the final rule and covered by this ICR are completely voluntary and no chemical manufacturer is mandated to submit a chemical substance for risk evaluation consideration.

The rule requirements include the following:

(1) Name, mailing address, and contact information of the entity (or entities) submitting the request. If more than one manufacturer submits the request, all individual manufacturers must provide their contact information.

(2) The chemical identity of the chemical substance that is the subject of the request. At a minimum, this includes, all known names of the chemical substance, including common or trades names, CAS number, and molecular structure of the chemical substance. A request for risk evaluations of a category of chemical substances must include an explanation of why the category is appropriate under 15 U.S.C. 2625(c), and EPA will grant such request only upon determining that the requested category is appropriate for risk evaluation.

(3) The manufacturer must identify the circumstances on which they are requesting that EPA conduct a risk evaluation and include a rationale for why these circumstances constitute conditions of use.

(4) The request must also include a list of all the existing information that is relevant to whether the chemical substance, under the circumstances identified by the manufacturer(s), presents an unreasonable risk of injury to health or the environment. The list must be accompanied by an explanation as to why such information is adequate to permit EPA to complete a risk evaluation addressing the circumstances identified by the manufacturer(s). The request need not include copies of the information; citations are sufficient, if the information is publicly available. The request must include or reference all available information on the health and environmental hazard(s) of the chemical substance, human and environmental exposure(s), and exposed population(s), as relevant to the circumstances identified in the request. At a minimum, this must include all the following, as relevant to the circumstances identified:

- (A) The chemical substance's hazard and exposure potential;
- (B) The chemical substance's persistence and bioaccumulation;
- (C) Potentially exposed or susceptible subpopulations which the manufacturer(s) believes to be relevant to the EPA risk evaluation;
- (D) Whether there is any storage of the chemical substance near significant sources of drinking water, including the storage facility location and the nearby drinking water source(s);
- (E) The chemical substance's production volume or significant changes in production volume; and
- (F) Any other information relevant to the potential risks of the chemical substance under the circumstances identified in the request.

(5) The request must include a commitment to provide to EPA any referenced information upon request.

(6) Scientific information submitted must be consistent with the scientific standards in 15 U.S.C. 2615(h).

(7) A signed certification that all information contained in the request is accurate and complete, as follows:

I certify that to the best of my knowledge and belief:

1. The company named in this request manufactures the chemical substance identified for risk evaluation.
2. All information provided in the notice is complete and accurate as of the date of the request.
3. I have either identified or am submitting all information in my possession, control, and a description of all other data known to or reasonably ascertainable by me as required for this request under this part. I am aware it is unlawful to knowingly submit incomplete, false and/or misleading information in this request and there are significant criminal penalties for such unlawful conduct, including the possibility of fine and imprisonment.

(8) *Optional Elements*. A manufacturer may provide information that will inform EPA's determination as to whether restrictions imposed by one or more States have the potential to have a significant impact on interstate commerce or health or the environment, and that as a consequence the request is entitled to preference pursuant to 15 U.S.C. 2605(b)(4)(E)(iii).

(9) Confidential Business Information.

(A) Persons submitting a request under this subpart are subject to EPA confidentiality regulations at 40 CFR part 2, subpart B.

(B) In submitting a claim of confidentiality, a person must certify the accuracy of the following statements concerning all information claimed as confidential:

I hereby certify to the best of my knowledge and belief that all information entered on this form is complete and accurate. I further certify that, pursuant to 15 U.S.C. 2613(c), for all claims for confidentiality made with this submission, all information submitted to substantiate such claims is true and correct, and that it is true and correct that

(i) My company has taken reasonable measures to protect the confidentiality of the information;

(ii) I have determined that the information is not required to be disclosed or otherwise made available to the public under any other Federal law;

(iii) I have a reasonable basis to conclude that disclosure of the information is likely to cause substantial harm to the competitive position of my company; and

(iv) I have a reasonable basis to believe that the information is not readily discoverable through reverse engineering.

(C) Each claim of confidentiality, other than a claim pertaining to information described in TSCA section 14(c)(2), must be accompanied by a substantiation in accordance with 15 U.S.C. 2613.

(D) Manufacturers must supply a structurally descriptive generic name where specific chemical identity is claimed as CBI.

(E) Any knowing and willful misrepresentation, under this section, is subject to criminal penalty pursuant to 18 U.S.C. 1001.

Number of Entities Affected

EPA developed estimates for number of manufacturers who are likely to elect to submit a chemical substance for risk evaluation. Submissions of this nature are still new to the Agency therefore the actual number of expected submittals over time is still relatively unknown. However, EPA assumes 5 chemical manufactures may submit requests to the Agency in any given year. Once sufficient data based on the number of submissions received per year is available, this estimate will be revised as needed. The total number of entities affected by the recordkeeping and reporting requirements of the rule, therefore, is estimated to be 5 chemical manufacturers per year.

Rule Familiarization Burden

EPA assumes that each manufacturer who elects to submit a chemical substance for risk evaluation consideration is assumed to spend one hour becoming familiar with the requirements of the rule and developing an understanding of what actions are necessary to complete the forms and submission package.

CDX Electronic Reporting Burden

Manufacturers requesting a chemical substance be considered by EPA for risk evaluation are required to provide the submission package to the Agency via the CDX electronic system. While several manufacturers may be familiar with the CDX system and are registered users because the same system is used for new chemical submissions to the Agency (e.g., pre-manufacture notice, significant new use notice, low volume exemptions) there is no way to estimate which manufacturers submitting risk evaluation requests are familiar with CDX and which are new to the system. Therefore, EPA assumes submissions under this information collection are performed by new users of CDX which may result in an overestimate of burden.

The CDX electronic reporting burden includes registration to CDX, familiarization with the subscriber agreements, potential use of the help desk, and problem resolution. The burden estimates used in this ICR are based off of estimates in EPA ICR No 2502.02, resulting in a burden of 2.83 hours per respondent.

Submission Package Burden

Chemical manufacturers electing to request EPA consider a chemical substance for risk evaluation must provide a submission package including the following information: contact information of requesting entity(s), full chemical identity information, complete list of reasonably available information consistent with TSCA section 26(h) standards that is relevant to an unreasonable risk determination, addresses all the circumstances that constitute conditions of use, of interest to the manufacturer, within the meaning of TSCA section 3, contain a commitment to provide EPA any referenced information upon request of the Agency, and provide a signed certification that all information in the submission is accurate and complete.

While submissions of this nature have never been required or requested by EPA in the past, the Agency has performed similar tasks internally while conducting previous Risk Evaluations. The average contractor expense and labor time the Agency spends on the types of activities required to prepared the submission package covered by this ICR was used to develop the burden and cost estimates.

EPA estimates the cost of having a contractor conduct an in-depth literature review and screen the literature found for relevance costs an average of \$50,000 per chemical. In addition to the contractor cost, the manufacturer is expected to spend an average of 80 hours per chemical reviewing the data found during the literature, refining the searches as needed, and preparing the submission package. Therefore, the estimated burden for developing and submitting a risk evaluation request is 80 hours per respondent with an additional direct cost of \$50,000 per submission package.

Costs

EPA assumes a direct cost of \$50,000 per submission package for work performed by a contractor to assist the manufacturer in preparation activities such as literature reviews. Any fees to be collected as part of the risk evaluation requests will be covered under the fees rule required by TSCA and accompanying ICR. Labor costs are based on fully loaded wage rates.

The estimated wage for managerial professional (in the instance of this ICR a toxicologist) is \$80.09 per hour. More detail on the calculation of wage rates is presented in Appendix 1.

5(b). Information Collections

Information Collection Activities

The final rule provides the information and criteria chemical manufacturers are required to meet when submitting a chemical substance to EPA for risk evaluation consideration. The submissions outlined in the final rule and covered by this ICR are completely voluntary and no chemical manufacturer is mandated to submit a chemical substance for risk evaluation consideration.

Chemical manufacturers electing to request EPA consider a chemical substance for risk evaluation must provide a submission package including the following information:

- contact information of requesting entity(s),
- full chemical identity information,
- complete list of reasonably available information consistent with TSCA section 26(h) standards that is relevant to an unreasonable risk determination,
- addresses all the circumstances that constitute condition(s) of use, of interest to the manufacturer, within the meaning of TSCA section 3,
- contain a commitment to provide EPA any referenced information upon request of the Agency,
- and provide a signed certification that all information in the submission is accurate and complete.

A manufacturer may provide evidence to demonstrate that restrictions imposed by one or more States have the potential to have a significant impact on interstate commerce or health or the environment, and that as a consequence the request is entitled to preference pursuant to 15 U.S.C. 2605(b)(4)(E)(iii).

In submitting a claim of confidentiality, 461 a person must certify that all information entered on the form is complete and accurate and further certify that pursuant to 15 U.S.C. 2613(c), and for all claims for confidentiality made with this submission, all information submitted to substantiate such claims is true and correct.

Activities chemical manufacturers may be required to perform as a result of this final rule:

- Rule Familiarization.
 - o Familiarize themselves with the requirements of the rule and develop an understanding of what actions are necessary to complete the forms and the submission package. This entails reading the rule and understanding the procedures, requirements, criteria, and deadlines,
- Prepare Request.
 - o Collect all required information. The information must be collected and reviewed internally before submission.
 - o Complete the request.
 - o Complete the commitment to provide EPA with any referenced information upon request.

- o Complete and sign the certification.
- o Complete and sign the claim of confidentiality.
- Submit the request package to EPA.

IC# 1. Submission of a Chemical Manufacturer's Request							
Activity/Respondent	Number of Respondents	Responses per Respondent	Total Responses	Burden per Response (hours)	Direct Cost Per Submission	Total Burden (hours)	Cost
CDX Electronic Reporting Burden							
Chemical manufacturers submitting request	5	1	5	2.83	n/a	14.15	\$1,133
Rule Familiarization							
Chemical manufacturers submitting request	5	1	5	1	n/a	5	\$400
Literature Review and Package Preparation							
Chemical manufacturers submitting request	5	1	5	80	\$50,000	400	\$282,036
Total Burden for all Activities							
Chemical manufacturers submitting request	5	1	5	83.83	\$50,000	419.15	\$283,570
Total	5		5			419.15	\$283,570

6. ESTIMATING BURDEN AND COSTS OF THIS COLLECTION

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

Total Respondent Annual Burden and Cost							
Activity/Respondent	Number of Respondents	Responses per Respondent	Total Responses	Burden per Response (hours)	Direct Cost Per Submission	Total Burden (hours)	Cost
Chemical manufacturers submitting request	5	1	5	83.83	\$50,000	419.15	\$283,570
Total	5		5			419.15	\$283,570

6(b) Changes in the Estimates

There is no change in hour or cost burden as compared with what is currently approved by OMB. There is an increase of \$709 in the total estimated labor costs, which reflects the increase in wage rates since the initial ICR.

6(c) PRA Burden Statement

Under the PRA, burden is defined at 5 CFR 1320.3(b).

This an ICR renewal and the total burden requested for this ICR is 419.15 hours per year, which is a change of zero burden hours from the initial ICR. The total annual cost burden requested for this ICR is \$283,570, which is an increase of \$709. This increase results from an increase in industry wage rates since the previous approval of the ICR. Comments can be submitted regarding the accuracy of the provided burden estimates and any suggested methods for minimizing respondent burden, including the use of automated collection techniques. Comments, referencing Docket ID No. EPA-HQ-OPPT-2016-0654 and OMB Control No. 2070-0202 (EPA ICR No. 2559.03), may be submitted to EPA electronically through <http://www.regulations.gov> and to OMB, addressed to “OMB Desk Officer for EPA” and referencing OMB Control No. 2070-0202 (EPA ICR No. 2559.03), via email to oir_submission@omb.eop.gov.

References

U.S. Census Bureau (2012a). 2012 Statistics of U.S. Businesses- Number of Firms, Number of Establishments, Employment, Annual Payroll, and Estimated Receipts by Enterprise Employment Size for the United States, All Industries: 2012.

U.S. Census Bureau (2012b). Geographic Areas Series: U.S. Nonemployer Statistics 2012.

7. ATTACHMENTS TO THE SUPPORTING STATEMENT

Attachments to the ICR supporting statement are available in the public docket established for the rulemaking under docket identification number **EPA-HQ-OPPT-2016-0654**. These attachments are available for online viewing at <https://www.regulations.gov> or otherwise accessed as described in the following listing.

- Attachment 1:** Calculation of Wage Rates.
- Attachment 2:** Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act Final Rule
- Attachment 3:** Consultations with Potential Respondents