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

Title of the Information Collection:

Title:	TSCA Existing Chemical Risk Evaluation and Management; Generic ICR for Interviews and Focus Groups
EPA ICR Number:	2584.01
OMB Control Number:	2070-NEW
Docket ID Number:	EPA-HQ-OPPT-2018-0611
EPA Form Numbers:	NONE

Short Characterization/Abstract:

The Environmental Protection Agency (EPA or the Agency) intends to initiate a new voluntary information collection for chemical industry research involving focus groups, one-on-one interviews, and other structured discussions to provide more comprehensive and accurate information to inform the risk evaluation and risk management of existing chemicals as required under section 6 of the Toxic Substances Control Act (TSCA). In 2016, the Frank R. Lautenberg Chemical Safety for the 21st Century Act (LCSA), which updated TSCA, was signed into law. Under TSCA, EPA must prioritize chemical substances for risk evaluation; conduct risk evaluations to determine whether chemical substances present unreasonable risk; and manage any unreasonable risks found to be presented, all under strict statutory deadlines. Many of these chemicals may have multiple conditions of use that fall under EPA's authority under TSCA. Under TSCA, for each chemical substance evaluated, EPA must evaluate hazards and exposures.

EPA currently acquires data about chemicals under TSCA and other statutes. This information may include releases reported to the Toxics Release Inventory (TRI) (under the Emergency Planning and Community Right-To-Know Act), manufacturing (including importing) and processing information reported under the Chemical Data Reporting (CDR) rule (under TSCA section 8), and records of significant adverse reactions or notices of substantial risks submitted by chemical manufacturers, processors, or distributors under TSCA section 8. EPA also has authority under TSCA section 4 to require manufacturers and processors to conduct testing and submit data as well as other information collection authority under the statutes. EPA also uses information acquired by EPA under other statutes like the Clean Air Act and the Clean Water Act.

The purpose of this ICR is to help fill data gaps for EPA's risk evaluations and risk management of existing chemicals under section 6 of TSCA. In accordance with TSCA section 26, EPA must make TSCA section 6 risk evaluation and risk management decisions consistent with the best available science and based on the weight of the scientific evidence. To carry out its statutory obligations, EPA needs sufficient information about chemicals undergoing risk evaluation and risk management, including information related to the chemicals' conditions of use, hazards, exposures, potentially exposed or susceptible subpopulations, health and environmental effects, benefits, reasonably ascertainable economic consequences, alternatives, and other information. The collection of such information is subject to TSCA's strict statutory timeframes (set forth in section 6). Therefore, EPA is seeking approval for a generic information collection request (ICR) to conduct interviews and focus groups of chemical users, processors, distributors, manufacturers (including importers), and

recyclers, chemical waste handlers, consumers of chemical-containing products, employees who may be exposed to the chemical evaluated, state and local regulators, non-governmental organizations, industry experts, and knowledgeable members of the public (including potentially exposed or susceptible subpopulations) related to information collection for TSCA chemical risk evaluation and risk management.

As appropriate, under this ICR EPA would collect data in several ways, such as interviews and focus groups. This research would consist of open-ended structured discussions or interviews with individuals or small groups of individuals, and therefore can provide in-depth information. These information collection efforts are intended to supplement other reasonably available information on chemicals in commerce and will provide support for the Agency's policy and regulatory activities regarding existing chemicals under TSCA section 6. Data collected under this generic clearance may be used in several ways during the risk evaluation and risk management processes, including establishing generic scenarios, developing models of various conditions of use of chemicals evaluated under TSCA or their alternatives, pretesting survey questions, and providing important context for publicly available information already available to EPA. By learning more about the conditions of use, hazards, exposures, potentially exposed or susceptible subpopulations, health and environmental effects, benefits, reasonably ascertainable economic consequences, alternatives, and other information for chemicals being evaluated or regulated, EPA would be able to more precisely and effectively carry out its risk evaluation and risk management obligations under TSCA.

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.

Over the next several years, the Agency will prioritize chemicals, conduct risk evaluations, and take appropriate risk management actions to address any unreasonable risks identified from existing chemicals. Risk evaluation and risk management efforts under TSCA require detailed information about each chemical, including information about conditions of use (such as manufacturing, import, and processing), consumption, market for, exposure to, and substitutes for each chemical evaluated and, if warranted, regulated. Though some of this information may be available to EPA through CDR, TRI, other regularly collected government data, or industry submissions under TSCA section 8(e), the currently available information is not always of sufficient completeness or detail for EPA to effectively carry out the Agency's obligations, including meeting the requirements of sections 6(c) and 26, or the timeframes mandated for EPA in section 6.

EPA will use this generic ICR to conduct interviews and focus groups of chemical users, processors, distributors, manufacturers (including importers), and recyclers, chemical waste handlers, consumers of chemical-containing products, employees exposed to the chemical evaluated (including unions), state and local regulators, non-governmental organizations, industry experts, and knowledgeable members of the public (including potentially exposed or susceptible subpopulations) who may have relevant information and are not covered by current information collection requests. The Agency will use this information collection to inform the development of any future regulatory efforts and to integrate consistent, meaningful, and transparent information into risk evaluation and risk management actions. This information is critical for adequately identifying conditions of use, conducting hazard and exposure assessments, characterizing risks, ascertaining benefits of and substitutes for each substance, estimating the economic consequences of regulation, and developing

appropriate regulatory actions. Interviews and focus groups are important information-gathering tools that will allow EPA to address data gaps in current collections and more precisely evaluate and manage unreasonable risks from existing chemicals under TSCA.

Some stakeholders have recommended that EPA collect more detailed information for its risk evaluations and risk management efforts. For example, the American Chemistry Council (ACC) has asked EPA to "ensure that it is using high quality representative data that are reflective of current uses for the conditions of use that are of concern."[1] This generic ICR is designed to respond to these stakeholder comments and help EPA acquire more detailed data for its risk evaluations and risk management efforts.

Outreach and recruitment strategies for information collection under this generic ICR will depend on the chemical and affected industries, as well as the type of information we need to elicit and the types of stakeholders who may have relevant experience. EPA will design an outreach strategy to recruit knowledgeable and representative participants in a way that is analogous to how EPA recruits for Small Business Advocacy Review (SBAR) panels, but not limited to small businesses. This may include efforts like searches of EPA emission databases like the Toxics Release Inventory (TRI) or the National Emissions Inventory (NEI). We may also coordinate with industry trade associations and look at prior interactions with specific stakeholders in TSCA and non-TSCA contexts to identify subjects for interviews and focus groups under this generic ICR. We may also receive suggestions from the Small Business Administration, other parts of the EPA, and other governmental and non-governmental stakeholders.

This generic ICR will support EPA's systematic review process for TSCA risk evaluations. EPA's initial work on systematic review is described in the supplemental files for the scope documents for each of the first 10 chemicals evaluated for risks under TSCA section 6. The scope documents include the Strategy for Conducting Literature Searches and the Bibliography for each chemical. The systematic review process is outlined in EPA's *Application of Systematic Review in TSCA Risk Evaluations* (https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/application-systematic-review-tsca-risk-evaluations), including the general steps for collecting, evaluating and integrating data/information as well as specific guidance on how to assess the quality of data/information sources.

This data collection would be carried out in conjunction with other TSCA authorities under sections 4, 8, and 11, as appropriate, and would be a key part of how EPA meets its obligations under section 6 to evaluate chemicals in commerce and to address any unreasonable risks presented by these chemicals. The materials prepared for these discussions will fully conform to federal law – specifically the Privacy Act of 1974 (5 U.S.C. 552a), the Hawkins-Stafford Amendments of 1988 (P.L 100-297), and the Computer Security Act of 1987.

Information acquired from this collection will be used in a manner consistent with EPA's TSCA section 26(h) requirements to use information in a manner consistent with the best available science. Where reasonably possible and appropriate, EPA will supplement voluntary information collection[2]

[1] Comments of the American Chemistry Council on EPA's Proposed Rule: *Procedures for Chemical Risk Evaluation under the Amended Toxic Substances Control Act*, 82 Fed. Reg. 7562 (January 19, 2017); EPA-HQ-OPPT-2016-0654.
[2] Although participation in the information collection is voluntary, to the extent that information collected is obtainable under TSCA, that information may at a later point be deemed not voluntary for purposes of the application of the confidentiality provisions in TSCA Section 14.

with data collection from independent sources. When applicable, EPA will request that submitters provide full studies, as well as underlying data wherever reasonably available or obtainable.

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.

The information collected under this ICR will be an important part of EPA's risk evaluation and risk management processes, as required under section 6 of TSCA. In exposure assessments, data from this ICR could be used to (1) evaluate findings derived from modeled results and data from monitoring or enforcement activities, (2) help determine what data are needed to estimate exposures for evaluated conditions of use and (3) improve understanding of these conditions of use, allowing for more accurate characterization of risks. As part of risk management for any risks found to be unreasonable, EPA is required (under section 6(c)(2)) to, among other things, consider the costs and benefits of a proposed regulatory action and at least one alternative regulatory option, and in certain circumstances, consider, to the extent practicable, whether technically and economically feasible alternatives that benefit health or the environment will be reasonably available as a substitute. Data from this ICR will be used to help (1) determine and describe alternatives and (2) properly characterize the costs and benefits of each regulatory action and alternative actions. EPA will cite to information provided from this generic ICR as appropriate in risk evaluation and risk management documents.

While the information collected under this ICR could be used by OPPT, other EPA program offices are also potential users of data from this generic ICR to the extent these offices regulate chemicals and the chemical industry. Other federal agencies that regulate chemical manufacturing and use, such as the Occupational Safety and Health Administration (OSHA) and the Consumer Product Safety Commission (CPSC), may also use the information generated by this generic ICR. Additionally, interviews and focus groups conducted under this ICR could be used to inform survey questions or concepts (the subject of Part B of this ICR).

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.

In general, interviews and focus groups will either be held in person or by phone or video call as appropriate. Information gathered from interviews and focus groups will often be confirmed or supplemented by electronic submissions, often by email, to confirm information for rulemaking dockets. The use of information technology, including email and video calls, will be used as appropriate to reduce burden on respondents.

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.

Data generated from this generic ICR will assist EPA in identifying, evaluating and managing health and environmental risks of chemical substances. This voluntary collection will provide interested parties with a clear and effective way of communicating the nuances of their chemical

manufacture, processing, distribution, use, or disposal practices to EPA, and will provide EPA with details of and context for already existing chemical information, which will allow for more accurate risk evaluation and more effective risk management.

EPA has developed procedures that will be met to make sure that the information from this generic ICR pertaining to risk evaluation and risk management of chemicals under TSCA does not duplicate other activities or impose a burden on industry that outweighs the need for the data. These procedures are:

- utilization to the fullest extent of information already available to the Agency, including through databases such as CDR and TRI, and through reporting already required under TSCA section 8(e);
- consultation with other federal agencies to make sure that information requested does not duplicate information already in the possession of the federal government and that EPA can gain access to any relevant information held by other federal agencies;
- continuing use of public meeting and outreach opportunities;
- continuing evaluation of the information collection and management activities, including feedback from affected entities about burden estimates and methods for reducing burden; and
- careful management of the collected information, including appropriate dissemination within EPA to utilize all information to the fullest extent and avoid the need for additional collections.

This ICR will generally not be used for hazard information because hazard information is generally chemical- (and not use-) specific. In general, EPA will ask a single manufacturer or processor for hazard information about a chemical. Therefore, voluntary requests for hazard information will generally not require contacting more than nine respondents and therefore will not require the use of an ICR.

For conditions of use, exposure, and PESS information, the data/information collected from interviews and focus groups under this generic ICR may be used to fill important information gaps discovered during the systematic review process of each chemical risk evaluation. To avoid duplication, EPA will check a variety of use and exposure information sources before conducting surveys under this generic ICR. These sources include, but are not limited to, data from other EPA offices outside of OPPT and from other government sources like the National Institute of Occupational Safety and Health (NIOSH), OSHA, and the Agency for Toxic Substances and Disease Registry (ATSDR), as well as data from generally non-governmental sources like the American Conference of Governmental Industrial Hygienists (ACGIH) and other Organisation for Economic Co-operation and Development (OECD) countries. EPA will also conduct a literature search for relevant peer-reviewed and non-peer reviewed (gray) literature such as theses, dissertations, technical reports, guideline studies, conference proceedings, publicly-available industry reports, trade association resources and government reports. EPA may also contact a limited number of industry groups and others knowledgeable about conditions of use, exposure, and PESS information.

For alternatives and other information relevant to risk management, EPA will conduct an extensive review of relevant sources from the systematic review, as well as a systematic search of peer-reviewed and gray literature. Interviews and focus groups from this ICR may then be used to help fulfill the requirements of TSCA section 6(c)(2)(C) in instances where a certain type of risk management is expected, which requires that EPA consider “to the extent practicable, whether

technically and economically feasible alternatives that benefit health or the environment, compared to the use so proposed to be prohibited or restricted, will be reasonably available as a substitute when the proposed prohibition or other restriction takes effect."

It is not expected that any of the information to be submitted to EPA during these interviews or focus groups is duplicative or is already in the possession of the Federal Government. The agency anticipates that proposed interviews and focus groups could be used to address the needs of the Agency and significantly improve EPA's ability to refine its analysis and to evaluate and manage risks from chemicals evaluated under TSCA.

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

Information may be collected from small businesses, small organizations or small governmental jurisdictions as part of this information collection. None of these interviews or focus groups will be mandatory, and EPA will work to ensure flexibility for small businesses, small organizations, and small governmental jurisdictions.

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.

The information collection activities under this generic ICR will be ad hoc and will occur only on those occasions where information would be useful for EPA to evaluate and manage unreasonable risks of chemicals under TSCA, and the information is not in the possession of EPA after a comprehensive search of the relevant databases. As such, less frequent collection is not possible.

7. Explain any special circumstances that would cause an information collection to be conducted in a manner:

- **requiring respondents to report information to the agency more often than quarterly;**
- **requiring respondents to prepare a written response to a collection of information in fewer than 30 days after receipt of it;**
- **requiring respondents to submit more than an original and two copies of any document;**
- **requiring respondents to retain records, other than health, medical, government contract, grant-in-aid, or tax records, for more than three years;**
- **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;**
- **requiring the use of a statistical data classification that has not been reviewed and approved by OMB;**
- **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**
- **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.**

Information will be collected according to the guidelines in 5 CFR 1320. Participation will be voluntary under this generic ICR. There will be complete protection of any demographic

information collected from participants—full names, phone numbers, and addresses will not be associated with responses.

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 by the agency in response to these comments. Specifically address comments received on cost and hour burden.

Describe efforts to consult with persons outside the agency 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 reported.

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.

On August 5, 2019 (84 FR 38029), EPA sought comments on this ICR pursuant to 5 CFR 1320.8(d). EPA received 7 comments, which are available in the docket and summarized in Attachment A, along with EPA's responses to those comments.

Under 5 CFR 1320.8(d)(1), OMB requires agencies to consult with potential ICR respondents and data users about specific aspects of the ICR before submitting an ICR to OMB for review and approval. In accordance with this regulatory requirement, EPA submitted questions by e-mail to potential ICR respondents and data users. A copy of that email is included in Attachment B, along with the list of individuals contacted. EPA received 5 responses, which are available in the docket and summarized in Attachment A, along with EPA's responses to the feedback that was provided. Respondents may claim information submitted as part of an interview or focus groups as confidential. EPA will ask during the interview or focus group whether any information provided is confidential. EPA generally treats this information as obtained under TSCA, such that confidentiality claims are subject to the provisions of TSCA section 14. Information on the requirements for asserting confidential business information (CBI) claims under section 14 of TSCA can be found at https://www.epa.gov/tsca-cbi/making-cbi-claims-tsca-submissions. 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 the regulations at 40 CFR part 2, under which EPA will provide advance notice and an opportunity to object prior to public disclosure.

EPA intends to generate public versions of the information submitted as part of an interview or focus group. These versions will not include information claimed as confidential by the respondents. EPA may use information claimed as confidential in averages, ranges, aggregates, or in other ways that properly mask specific information claimed as confidential and/or a trade secret. If EPA receives a Freedom of Information Act request for the information, the Agency will determine whether the information is entitled to confidential treatment in accordance with TSCA Section 14 and procedures at 40 CFR part 2, as applicable. EPA will request that companies create sanitized versions of anything they submit in writing.

EPA takes stringent measures to protect CBI submitted in connection with TSCA pursuant to 40 CFR part 2 and the "TSCA CBI Protection Manual". These procedures include security clearances and training for all staff permitted to access TSCA CBI, storage of TSCA CBI in secured areas, computer security for TSCA CBI, secure methods for creating, transferring, and destroying TSCA CBI, and advance notice of disclosure to contractors (usually via the Federal Register) where such disclosure is authorized. In addition, each interview and focus group will fully conform to federal law – specifically the Privacy Act of 1974 (5 U.S.C. 552a), the Hawkins-Stafford Amendments of 1988 (P.L. 100-297), and the Computer Security Act of 1987.

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 questions will be asked that are of a personal or sensitive nature.

12. Provide estimates of the hour burden of the collection of information. The statement should:

- **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.**
- **If this request for approval covers more than one form, provide separate hour burden estimates for each form and aggregate the hour burdens.**
- **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'.**

The target population for the interviews and focus groups will vary by project and chemical, but may include chemical users, processors, manufacturers (including importers), recyclers, chemical waste handlers, consumers of chemical-containing products, employees who may be exposed to the chemical evaluated, state and local regulators, non-governmental organizations, industry experts, and knowledgeable members of the public (including potentially exposed or susceptible subpopulations). As such, there are no typical respondent NAICS codes and the respondents will vary depending on the conditions of use of each chemical under consideration.

There are no recordkeeping requirements associated with this generic ICR and potential respondent activities and information collected will vary based on the approach taken and the nature of the information needed.

Respondents will be asked to participate in a structured (in the case of focus groups, moderated) discussion concerning a chemical or chemicals being evaluated or managed under TSCA, which may include questions about the chemical's conditions of use, consumption, market, exposure, or substitutes, among other information.

Estimates of respondent burden were derived from projected interview and focus group usage over the next three years. To do this, EPA estimated the number of risk evaluations for chemicals evaluated under TSCA and the number of interviews and focus groups useful to gain information to evaluate these chemicals and develop regulatory actions to manage any unreasonable risk. The total estimated hourly burden imposed by this collection of information over the next three years for interviews and focus groups is approximately 950 hours or approximately 317 hours annually. There are about 283 respondents per year. This is derived by taking the approximate number of risk evaluations multiplied by the average number of interviews and focus groups per risk evaluation and again multiplying by the average number of participants per interview and focus group respectively. The total number of respondents for the 3-year collection would be about 850.

EPA assumes that the burden of focus groups and interviews is split evenly among technical and managerial personnel.

EPA is required to evaluate the risks of at least twenty existing chemicals starting in 2022, with a requirement to complete these risk evaluations within three and a half years of beginning the risk evaluation. Including manufacturer-requested evaluations, we assume that 25 risk evaluations will be completed over the next three years. To support this, EPA assumes that an average of twenty interviews and two focus groups with seven participants each will be needed per risk evaluation. EPA assumes that each interview would require an average of 0.5 hours and each focus group would require 2 hours. The average focus group size and duration is the same as that assumed for focus groups done through the Office of Policy in their generic ICR (EPA ICR No. 2205.21, OMB Control Number 2090-0028).

The total burden per year is valued at approximately $27,715.

Labor costs in this statement have been updated using the most recently available revised wage rates and information on benefits costs. These wage rates are taken from the Bureau of Labor Statistics (BLS) Employer Costs for Employee Compensation Supplemental Tables: December 2006-December 2020 (released in 2021) and are from private manufacturing industries. The clerical wages are taken from the BLS data for "office and administrative support." The technical wages are taken from the BLS data for "professional and related." The managerial wages are taken from the BLS data for "management, business and financial." Labor wage rates and hourly benefit costs taken from those sources have been used to calculate the labor cost to respondents, as shown below. The hourly overhead is calculated as 20% of total compensation. This approach is based on assumptions in Handbook on Valuing Changes in Time Use Induced by Regulatory Requirements and Other U.S. EPA Actions. (EPA 2020) The 2020 hourly industry wages used for this ICR are presented in the following table.

Table 1: Industry Hourly Labor Costs (2020$)

Wage Component	Professional/Technical	Managerial
Hourly Wage Rate	$44.63	$54.32
Benefit Costs	$22.45	$24.46

Fringe and Overhead Factor	1.20	1.20
Total Hourly Cost	$80.50	$94.54

These labor costs are multiplied by the estimated burden hours per activity and added to any non-labor costs to develop total unit costs per report.

Table 2: Estimated Respondent Burden and Cost

Type of Response	Approximate Number of Evaluations (Three Years)	Average Events per Evaluation	Average Respondents per Event	Average Hours of Duration for Each Event (includes screening)	Total Estimated Burden Over Next 3 Years (hours)	Estimated Annual Cost Burden
Interviews	25	20	1	0.5	250	$7,293
Focus Groups	25	2	7	2.0	700	$20,421
Total Respondent Burden					950	$27,715

EPA expects respondent hours to total 950 over the next 3 years or 317 each year. These hours will be spread over approximately 500 interviews and 50 focus groups over the next 3 yrs.

As indicated previously, since the information activities covered by this ICR do not involve recordkeeping or management and operations activities, there are no burden or costs associated with those activities.

13. Provide an estimate for the total annual cost burden to respondents or record keepers resulting from the collection of information. (Do not include the cost of any hour burden already reflected on the burden worksheet).

- **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.**
- **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.

- **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 capital costs or operating and maintenance costs associated with this collection.

14. Provide estimates of annualized costs 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.

Agency activities associated with this information collection will include:

- Deciding who the respondents will be;
- Drafting interview and focus group scripts and accompanying materials;
- Conducting interviews and observing and moderating focus group discussions;
- Summarizing focus group results and making changes to draft materials as appropriate;
- Analyzing claims of confidentiality and providing appropriate protections; and
- Summarizing, analyzing, and storing interview and focus group responses.

The Agency incurs costs to conduct interviews, develop focus group materials, and organize, conduct, and observe focus group discussions. These expenses will vary by specific project. The table below provides an estimate of costs per-year. EPA person-costs are estimated using an hourly rate for a GS-13 (step 5) based in Washington, DC in 2020. Time spent on each step may vary as well as the GS level of the employees involved. Contractor costs will also depend on the location of focus groups, degree of involvement in materials preparation, and whether written transcripts of each focus group are required. The estimates presented below assume that the Agency prepares all materials and that approximately 3 individuals observe each focus group. EPA assume that the contractor costs for each focus group would be half of the cost of the Office of Policy focus groups because the focus groups for TSCA existing chemicals would ask experts their observations about the chemical at issue rather than (as the Office of Policy does) asking broad questions regarding public opinion on economic subjects. The total agency burden and cost per year will be approximately $140,005.

Table 3: Estimated Average Annual Agency Burden and Costs for Focus Groups & Interviews

Task	Costs (and Person-hours) Per Focus Group or Interview Hour			Total Hours and Cost	
	EPA ($109.65/ Hour)	Estimated Contractor Costs[1]	O&M Cost	Number of Focus Group or Interview Hours/Year.	Total Cost/Year
Prepare Materials for Focus Group Discussion	$1,097 (10 hrs)	--	--	33.3	$36,567

Organize and Conduct Focus Group Discussion (Contractor)	--	$2,500	--	33.3	$83,333
Observe Focus Group Discussion	$329 (3 hrs)	--	--	33.3	$10,967
Interview	$110 (1 hrs)			83.3	$9,138
Total					$140,005

Notes: [1]includes recruiting respondents, meeting space, travel reimbursement for approximately 7 participants, and recording of discussion.

15. Explain the reasons for any program changes or adjustments reported on the burden worksheet (in hour or cost burden.)

This ICR will cover a new collection activity.

16. For collections of information whose results will be published, outline 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.

All information from these focus groups and interviews that is used in rulemaking will be summarized in the rulemaking docket. Interviews and focus groups will generate qualitative data and therefore no complex analytical techniques will be used. Time schedules for collections under this Generic ICR will vary according to the needs of the project and will be structured to conform to statutory schedules for risk evaluation and risk management.

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

Not applicable.

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.

Attachments

Attachments to the supporting statement are available in the public docket established for this ICR (Docket ID #: EPA-HQ-OPPT-2018-0611) at *http://www.regulations.gov.*

Attachment A Public Comments on Proposed ICR and EPA Responses to Public Comments

Attachment B E-mails Sent for Consultation and List of Organizations Consulted