

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

Part A

Section 1. Identification of the Information Collection

1(a) 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

1(b) 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.

Section 2. Need For and Use of the Collection

2(a) Need/Authority for the Collection

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.

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 the *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 collection² 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(b) Practical Utility/Users of the Data

EPA currently uses information on chemicals, including (but not limited to) information collected through the CDR, TRI, section 8, section 4, and section 11(c), to (1) characterize manufacture (including import), processing, distribution, use, and disposal of chemical substances and mixtures; (2) determine hazards to humans and the environment; (3) identify possible routes of human or environmental exposure; (4) prioritize chemicals as high priority for risk evaluation or low priority; (5) evaluate the risks to humans and the environment; (6) determine whether risks presented by chemicals are unreasonable; and (7) develop appropriate regulatory actions to address those risks,

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.

among other actions. In general, current information sources either provide basic exposure information about large numbers of chemicals (CDR and TRI), or anecdotal information about smaller numbers of chemicals (section 8(e)). Current information sources are important as a source of basic information to inform initial risk evaluation efforts once a chemical has been selected for risk evaluation. Once a chemical has been selected for evaluation under TSCA, EPA's Office of Pollution Prevention and Toxics (OPPT) proposes conducting surveys using this ICR to gain more detailed information about that chemical for risk evaluation, and if necessary, risk management. Information collected in surveys from this generic ICR will supplement current information from CDR and TRI and provide EPA with more granular, complete, and up-to-date information about chemicals and the chemical industry, allowing EPA to more precisely evaluate and manage the risks from chemicals evaluated under TSCA. Information from interviews and focus groups will be part of EPA's comprehensive efforts to obtain information necessary to meet its statutory obligations.

CDR collects basic exposure-related information on the types, quantities, and uses of chemical substances produced domestically and imported into the United States. It constitutes the most comprehensive source of basic screening-level, exposure-related information on chemicals available to EPA. CDR is collected every four years from manufacturers and importers of certain chemicals when production volumes are 25,000 pounds or greater at any single site for any year leading up to the reporting year (or 2,500 pounds if the chemical is subject to certain TSCA actions). While CDR provides valuable information on chemical manufacturing in the United States, EPA has found that the collection of additional information has been useful in understanding the details of the information submitted to CDR, as part of the characterization of the exposures expected from chemicals currently under risk evaluation. General use information is collected under CDR; however, in some instances, EPA might find that additional information is useful to conduct a detailed exposure assessment.

TRI tracks the management of a specific list of toxic chemicals that may pose a threat to human health and the environment. U.S. facilities in different industry sectors must report annually how much of each chemical is released to the environment and/or managed through recycling, energy recovery, and treatment. EPA often uses TRI information to characterize exposure as part of the TSCA risk evaluation process. In some instances, EPA might find additional information useful to characterize expected exposures to the general population, or to occupational, consumer, or ecological populations. EPA may also want to collect additional information to better understand how exposures are distributed throughout the year and how much of these TRI-reported releases might affect workers.

Section 4(a)(2)(A)(i) of TSCA allows EPA to require testing by rule, order, or consent agreement if, for example, EPA determines the information is necessary to perform a risk evaluation under section 6(b) of TSCA. Information collected through Section 4 will usually be that for which there is a standard test protocol. That information is likely to be different than the wide variety of types of information EPA would gather through surveys under this generic ICR. A survey under this generic ICR will usually include a variety of questions specific to a chemical and condition of use and will both be pre-tested with a small group of respondents and subject to public comment, which may be unlikely (and in some cases inappropriate) uses of Section 4. However, there may be cases where the Section 4 and this ICR could be used to gather similar information. Section 8(d) of TSCA allows EPA to promulgate rules to require chemical manufacturers, processors, and distributors to submit to EPA lists and copies of necessary health and safety studies to carry out the purposes of TSCA. This information may not be available for all chemicals under risk evaluation and is limited to completed health and safety studies.

Section 8(e) of TSCA requires chemical manufacturers, processors, and distributors to notify EPA if they obtain information which reasonably supports the conclusion that the chemical they manufacture, process, or distribute presents a substantial risk of injury to health or the environment. This information may not be available for all chemicals under risk evaluation.

Section 11(c) of TSCA allows EPA to require by subpoena the production of reports, papers, documents, answers to questions, and other information that EPA deems necessary. In some cases, this could be used to require that the type of information potentially subject to this ICR be provided to the Agency. However, this could be very time-consuming and expensive, since a subpoena would have to be enforced by a district court if the entity receiving the subpoena failed or refused to comply. EPA would also expect to engage in efforts to obtain information voluntarily before proceeding to the use of section 11(c) authority. Section 11(c) would also require a regular ICR if more than nine entities covered by the Paperwork Reduction Act received a subpoena. This ICR is a voluntary method to survey large numbers of entities.

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).

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.

Section 3. Non duplication, Consultations, and Other Collection Criteria

3(a) Non duplication

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.

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

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.

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 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.

3(d) Effects of Less Frequent Collection

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.

3(e) General Guidelines

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.

3(f) Confidentiality

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.

3(g) Sensitive Questions

No questions will be asked that are of a personal or sensitive nature.

Section 4. The Respondents and the Information Requested

4(a) Respondents/SIC Codes

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.

4(b) Information Requested

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.

Section 5. The Information Collected – Agency Activities, Collection Methodology, and Information Management

5(a) Agency Activities

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.

5(b) Collection Methodology and Management

Focus group studies are directed group discussions that do not produce statistically valid data, but which enable skilled observers to infer the underlying views and assumptions of the group that are expressed in the discussion. To facilitate interpretation, discussions are generally recorded and videotaped so that both a visual record and written transcript of the discussion are available for review. Participants are informed in advance that the sessions will be recorded. Transcripts and video tapes will be maintained in individual project files.

For interviews, notes will be taken and available for review.

Interview and focus group summaries may be used to inform risk evaluations, economic analyses, and other risk management activities, subject to relevant confidentiality protections.

5(c) Small Entity Flexibility

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.

5(d) Collection Schedule

Focus groups and interviews will be scheduled according to the needs of individual projects. No firm schedule for this collection can be established otherwise.

Section 6. Estimating the Burden and Cost of Collection

6(a) Estimating Respondent Burden and Costs

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 710 hours or approximately 237 hours annually. The total burden per year is valued at approximately \$18,296. There are no capital costs or operating and maintenance costs associated with this collection. There are about 238 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 714.

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 2017 (released in March 2018) 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 17 percent of the base wage. This approach is used for consistency with Office of Pollution Prevention and Toxics economics practices and is based on the analysis in *Wage Rates for Economic Analyses of the Toxics Release Inventory Program*, Cody Rice, U.S. EPA, Office of Pollution Prevention and Toxics, Economic and Policy Analysis Branch, June 10, 2002. The 2017 hourly industry wages used for this ICR are presented in the following table.

Wage Component	Technical	Managerial
Hourly Wage Rate	\$45.82	\$46.59
Benefit Costs	\$24.33	\$22.16
Fringe and Overhead Factor	1.70	1.65
Total Hourly Cost	\$77.94	\$76.67

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.

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 2019, with a requirement to complete these risk evaluations within three and a half years of beginning the risk evaluation. 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 1.7 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. 2205.04).

Type of	Approximate	Average	Average	Average	Total	Total
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Response	Number of Evaluations (Three Years)	Events per Evaluation	Respondents per Event	Hours of Duration for Each Event (includes screening)	Estimated Burden Over Next 3 Years (hours)	Estimated Burden per Year (\$)
Interviews	21	20	1	0.5	210	\$5,411
Focus Groups	21	2	7	1.7	500	\$12,884
Total Respondent Burden					710	\$18,296

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

6(b) Estimating Agency Burden and Costs

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 2017. 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 \$93,264.

Task	Costs (and Person-hours) Per Focus Group or Interview Hour			Total Hours and Cost	
	EPA (\$82.37/ 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	\$824 (10 hrs)	--	--	24	\$19,769
Organize and Conduct Focus Group Discussion (Contractor)	--	\$2,500	--	24	\$60,000
Observe Focus Group Discussion	\$247 (3 hrs)	--	--	24	\$1,977

Interview	\$82 (1 hrs)			140	\$11,518
Total					\$93,264

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

6(c) Bottom Line Burden Hours and Cost Tables

EPA expects respondent hours to total 710 over the next 3 years or 237 each year. These hours will be spread over approximately 420 interviews and 42 focus groups over the next 3 yrs.

Activity	Total Events Per Year	Respondent Burden		Respondent Costs		Agency Burden		Agency Costs	
		Per Event (Hrs)	Annual (Hrs)	Per Event (\$)	Annual (\$)	Per Event (Hrs)	Annual (Hrs)	Per Event (\$)	Annual (\$)
Interviews	140	0.5	70	\$39	\$5,411	1	140	\$82	\$11,518
Focus Groups	14	1.7	167	\$920	\$12,884	22	309	\$5,839	\$81,746
Totals	154		237		\$18,296				\$93,264

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.

6(f) Reasons for Change in Burden

This ICR will cover a new collection activity.

6(g) Burden Statement

The annual public reporting burden for this collection of information is estimated to average 0.99 hours per response. There are no recordkeeping burdens.

Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid

OMB control number. The OMB control numbers for EPA's regulations are listed in 40 CFR Part 9 and 48 CFR Chapter 15.

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