

**Supporting Statement Part B for Generic Information Collection Request under the
Paperwork Reduction Act**

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| ICR 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 |

Part B. STATISTICAL METHODS

1. Universe and Respondent Selection

Under this generic ICR, EPA will conduct focus groups and structured interviews with 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. Results will not be used to produce statistical descriptions (careful, repeatable measurements). The specific sample planned for each individual collection and the method for soliciting participation will be described fully in each collection request.

The data provided by interviews and focus groups under this generic ICR will be used to better understand conditions of use (such as manufacturing, import, and processing), consumption, market for, exposure to, and substitutes for each chemical evaluated and, if warranted, regulated. This data may also be used to pretest survey instruments used in risk evaluation or risk management under TSCA. The accuracy, reliability, and applicability of the results of these interviews and focus groups will be adequate for their purpose.

In general, for conditions of use and exposure EPA's primary objectives are to obtain information about:

1. production volume and process information;
2. conditions of use;
3. site release and transfer information (including disposal);
4. workplace exposure and practices in place to prevent or reduce worker exposure;
5. consumer exposure and practices in place to prevent or reduce consumer exposure (if applicable);
6. environmental exposure;
7. potentially exposed or susceptible populations;
8. chemical end uses, including products containing the chemical (if applicable); and
9. other information needed to identify conditions of use or exposures for the subject chemical or chemical category.

For substitutes, EPA's primary objectives are to obtain information about:

1. chemical and/or process substitutes for risk management of a given condition of use of a chemical;
2. efficacy and performance of substitutes;
3. experience and use practices with use of any substitutes;
4. advantages and disadvantages of any substitute; and
5. other information needed to calculate costs and benefits of various substitutes.

Participants will be recruited based on outreach to stakeholders and information gaps identified in risk evaluation or risk management. 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 industry and non-industry stakeholders (like unions) 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.

EPA determined the likely number of participants by extrapolating from likely information gaps in future risk evaluations. EPA believes that the projected burden is sufficient to fill information gaps, but there is significant uncertainty since this is a new information collection.

2. Procedures for Collecting Information

Data collection methods and procedures will vary and the specifics of these will be provided with each collection request.

3. Methods to Maximize Response

Information collected under this generic clearance will yield data about conditions of use, exposure, and alternatives to certain chemicals expected to require risk management. EPA will work with the universe of respondents to maximize response to gain valuable data.

4. Testing of Procedures

Pretesting may be done with internal staff, a limited number of external colleagues, and/or customers who are familiar with the chemicals, conditions of use, products and articles, as well with those familiar with the stakeholders.

5. Contacts for Statistical Aspects and Data Collection

The data collected under this generic clearance will be adequate for its purpose and will not be used to produce statistical descriptions. Instead, the data collected will be used to better understand the conditions of use evaluated, associated exposures, or the alternatives to chemicals that present unreasonable risks in a risk evaluation and are expected to be the subject of risk management action under TSCA. 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, and providing important context for publicly available information or other information already available to EPA.