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

EXECUTIVE SUMMARY

Identification of the Information Collection – Title and Numbers

Title: Procedures for Chemical Risk Evaluation under the Toxic Substances Control Act (TSCA) (Proposed Rule; RIN 2070-AL27)

EPA ICR No.: 2781.03

OMB Control No.: 2070-0231

Docket ID No.: EPA-HQ-OPPT-2025-0260

Abstract

This ICR is related to regulatory requirements that implement provisions outlined in the Frank R. Lautenberg Chemical Safety of the 21st Century Act which passed in June 2016 and amended the Toxic Substances Control Act (TSCA). The Environmental Protection Agency (EPA) is amending the process for conducting risk evaluations under the TSCA to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment under the known, intended, or reasonably foreseen conditions of use, without consideration of costs or other non-risk factors, including unreasonable risk to potentially exposed or susceptible subpopulations. EPA is reconsidering provisions of a 2024 amendment to the procedural framework rule for conducting such risk evaluations to determine whether they are consistent with the best reading of TSCA and whether they may impede the timely completion of risk evaluations and unnecessarily impair the effective and efficient protection of human health and the environment. Proposed revisions to the framework rule also include changes to the process by which a manufacture may request that EPA conduct a risk evaluation on a chemical for which they manufacture. This proposal would revise the criteria and information chemical manufacturers must provide for EPA to consider a chemical substance for risk evaluation, as well as the Agency's process and timing to review the request to determine whether to grant or deny. The information collection activities covered by this ICR are those carried out by a chemical manufacturer in requesting a specific chemical risk evaluation under TSCA be conducted by EPA.

Summary of Annual Burden and Costs

Activity	Number of Respondents	Average Annual Responses Per Respondent	Average Annual Burden Per Respondent	Average Annual Total Labor Burden	Average Annual Total Labor Costs	Average Annual Total Non-Labor Costs	Average Annual Total Costs
Agency Burden	-	-	-	5,920	$745,861	-	$745,861
Industry Burden and Cost							
CDX Registration	1	1	2.83	2.83	$287	-	$287

Rule Familiarization	1	1	3	3	$304	-	$304
Submission Package Burden	1	1	160	160	$16,239	$75,000	$91,239
All Industry Activities	**1**		**166**	**166**	**$16,831**	**$75,000**	**$91,831**

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 that choose to submit a request that EPA conduct a risk evaluation on a particular chemical.

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.
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Total Burden and Costs

Estimated total number of potential respondents: 1 annually.

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

Estimated total annual burden: 166 hours. Burden is defined at 5 CFR 1320.3(b).

Estimated total annual costs: $91,831.

Changes in the estimates: While the burden hours remaining the same, the average annual total non-labor costs per submission would decrease from $100,000 to $75,000 as a result of the proposed revisions to the information that must be submitted with a request that EPA conduct a risk evaluation.

SUPPORTING STATEMENT

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

Under section 6(b)(4)(B) 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). In selecting chemicals for risk evaluation EPA is required to, through the Prioritization process, identify high-priority chemical substances for risk evaluation. Additionally, as described in Section 6(b)(4)(C)(ii), TSCA allows manufacturers of a chemical substance to request that their substance be evaluated by the Agency. The statute requires the Agency to develop a form and manner and use the criteria prescribed by the Administrator in the rule promulgated under Section 6(b)(4)(B). As required by the statute, the Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act was finalized in June 2017 and amended in May 2024.

This proposal would amend the process by which the Agency would conduct risk evaluations on chemical substances under TSCA, including but not limited to targeted changes to certain definitions, clarifications regarding the required scope of risk evaluations, the approach for risk determinations on chemical substances and considerations related to unreasonable risk, the process for revisiting a completed risk evaluation, and the process and requirements for manufacturers making a discretionary request for an Agency-conducted risk evaluation on a particular chemical substance.

The purpose of the proposed revisions is to reconsider whether certain 2024 amendments to this rule are consistent with the best reading of TSCA and whether they may impede the timely completion of risk evaluations and unnecessarily impair the effective and efficient protection of human health and the environment.

More specifically with respect to this ICR, EPA is proposing to generally scale back the information collection obligations that the 2024 final rule imposed on requesting manufacturers, particularly with respect to conditions of use that neither the manufacturers nor their customers are engaged in. 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 under TSCA section 6(b)(4)(C)(ii). Without collecting the information outlined in this rule, there would not be a way for EPA to determine if enough data and information meeting the standards in section 26(h) is available to perform a risk evaluation on the requested chemical substance within the timeframe outlined in the law.

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.

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 this rule. A request meets EPA's criteria if it includes or references the information necessary for the Agency to conduct a risk evaluation addressing the circumstances identified by the manufacturer constituting condition(s) of use of the chemical substance within the meaning of TSCA section 3.

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

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.

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 the Central Data Exchange (CDX) system. 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.

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.

The EPA's collection pursuant to a manufacturer requested risk evaluation under TSCA Section 6(b)(4)(C)(ii) do not duplicate any other collection. There is no other Federal program that voluntarily allows the information collection activities related to the submission under the rule.

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

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.

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.

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.

7. Explain any special circumstances that require the collection to be conducted in a manner:

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

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

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

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

The proposed rulemaking will serve as the public notice for this ICR. Interested parties have the opportunity to submit comments to Docket ID No. EPA-HQ-OPPT-2025-0260 to the address listed at the end of this document. EPA's response to all comments received will be included in the docket for the final rule. EPA has also engaged in consultation and outreach with the regulated community and other affected entities during development of the proposed rulemaking.

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

This collection does not provide any payment or gift to respondents.

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

Some 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 information necessary for carrying out the analysis and determining whether or not the chemical presents 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 provided information, with any confidential information redacted, 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 some information provided in requests for risk evaluations notices will be CBI. EPA has developed a robust 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 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.

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.

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

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

- **a) Indicate the number of respondents, frequency of response, annual hour burden, and an explanation of how the burden was estimated. Unless directed to do so, agencies should not conduct special surveys to obtain information on which to base hour burden estimates. Consultation with a sample (fewer than 10) of potential respondents is desirable. If the hour burden on respondents is expected to vary widely because of differences in activity, size, or complexity, show the range of estimated hour burden, and explain the reasons for the variance. Generally, estimates should not include burden hours for customary and usual business practices.**
- **b) If this request for approval covers more than one form, provide separate hour burden estimates for each form and aggregate the hour burdens.**
- **c) Provide estimates of annualized cost to respondents for the hour burdens for collections of information, identifying and using appropriate wage rate categories. The cost of contracting out or paying outside parties for information collection activities should not be included here. Instead, this cost should be included under 'Annual Cost to Federal Government'.**

Manufacturer requested risk evaluation requests must include all of the following information:

(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.

(3) For requests pertaining to a category of chemical substances, an explanation of why the category is appropriate under 15 U.S.C. 2625(c). EPA will determine whether the category is appropriate for risk evaluation as part of reviewing the request in paragraph (e) of this section.

(4) A description of the circumstances for which the manufacturer is requesting that EPA conduct a risk evaluation, all information known to or reasonably ascertainable by the requesting manufacturer that supports the identification of the requested circumstances, and a rationale for why the requested circumstances constitute conditions of use under 40 CFR 702.33.

(5) All information known to or reasonably ascertainable by the requesting manufacturer on the health and environmental hazard(s) of the chemical substance, human and environmental exposure(s), and exposed population(s), including but not limited to:

(i) The chemical substance's exposure potential, including occupational, general population and consumer exposures, and facility release information;

(ii) The chemical substance's hazard potential, including all potential environmental and human health hazards;

(iii) The chemical substance's physical and chemical properties.

(iv) The chemical substance’s fate and transport properties including persistence and bioaccumulation;

(v) Industrial and commercial locations where the chemical is used or stored;

(vi) 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);

(vii) Consumer products containing the chemical;

(viii) The chemical substance's production volume or significant changes in production volume; and

(viii) Any other information relevant to the hazards, exposures and/or risks of the chemical substance.

(6) Where information described in paragraph (c)(4) or (5) of this section is unavailable, an explanation as to why, and the rationale for why, in the requester’s view, the provided information is nonetheless sufficient to allow EPA to complete a risk evaluation on the chemical substance.

(7) Copies of all information referenced in paragraph (c)(5) of this section, or citations if the information is readily available from public sources.

(8) A signed certification from the requesting manufacturer(s) that all information contained in the request is accurate and complete, as follows:

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

(A) The company named in this request manufactures the chemical substance identified for

risk evaluation.

(B) All information provided in the request is complete and accurate as of the date of the request.

(C) I have either identified or am submitting all information in my possession and control, and a description of all other data known to or reasonably ascertainable by me as required 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.*

(9) Where appropriate, 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).

Number of Entities Affected

EPA developed estimates for the number of manufacturers who are likely to elect to submit a chemical substance for risk evaluation. Submissions of this nature are still relatively new and EPA has only received few requests from manufacturers for risk evaluations. This proposed rule and ICR assumes 1 chemical manufacture may submit requests to the Agency in any given year which aligns with the assumptions in the current Fees Rule. The total number of entities affected by the recordkeeping and reporting requirements of the rule, therefore, is estimated to be 1 chemical manufacturer per year for a total of 3 respondents over the ICR reporting cycle.

Rule Familiarization Burden

EPA assumes that each manufacturer who elects to submit a chemical substance for risk evaluation consideration is assumed to spend 3 hours 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 (**Attachment 1**).

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 specified in 40 CFR 702.45(c), including but not limited to contact information of requesting entity(s), full chemical identity information, a description (with supporting information) of the circumstances for which the manufacturer is requesting that EPA conduct a risk evaluation and a rationale for why the requested circumstances constitute conditions of use, and all known or reasonably ascertainable information on the health and environmental hazard(s) of the chemical substance, human and environmental exposure(s), and exposed population(s), and a signed certification that all information in the submission is accurate and complete (**Attachment 1**).

While there have been a limited number of submissions to EPA under the previous Risk Evaluation Rule, the Agency has reviewed those activities and considered the additional requirements in this rule in determining the estimated burden and cost per submission. 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 $75,000 per chemical. In addition to the contractor cost, the manufacturer is expected to spend an average of 160 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 160 hours per respondent with an additional direct cost of $75,000 per submission package.

Costs

EPA assumes a direct cost of $75,000 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 $94.74 per hour. **Table 1** presents the labor rates used to estimate the costs of the labor burdens under the ICR.

Table 1.

Loaded Industry Wage Rates, December 2024								
Labor Category	**Data Source**	**Date (mm/yy)**	**Wage**	**Fringe Benefit**	**Total Comp.**	**Over-head % Total Comp.1**	**Over-head**	**Loaded Wages2**
			(a)	(b)	(c)= (a) +(b)	(d)	(e)=(c)* (d)	(f)=(c)+ (e)
Managerial	BLS *ECEC*, Private Manufacturing industries, "Mgt, Business, and Financial"[3]	12/24	$58.01	$26.57	$84.58	20%	$16.92	**$101.50**

Note(s):

[1] An overhead rate of 20% is used based on assumptions in Handbook on Valuing Changes in Time Use Induced by Regulatory Requirements and Other U.S. EPA Actions (U.S. Environmental Protection Agency (EPA) 2020a).

[2] Wage data are rounded to the closest penny; however, unrounded values were used in calculations.

[3] U.S. Bureau of Labor Statistics (BLS) 2024b

Table 2 presents the summary of the average annual burden hours and costs per respondent.

Table 2.

Summary of Annual Average Incremental Burden Hours and Costs for Primary Option

Activity	Number of Respondents	Average Annual Responses Per Respondent	Average Annual Burden Per Respondent	Average Annual Labor Cost Per Respondent	Average Annual Non-Labor Cost Per Respondent	Average Annual Total Labor Burden	Average Annual Total Labor Costs	Average Annual Total Non-Labor Costs
CDX Registration	1	1	2.83	$287	-	2.83	$287	-
Rule Familiarization	1	1	3	$304	-	3	$304	-
Submission Package Burden	1	1	160	$16,239	$75,000	160	$16,239	$75,000
All Activities	**1**	**1**	166	$16,831	$75,000	166	$16,831	$75,000

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

a) **The cost estimate should be split into two components: (a) a total capital and start-up cost component (annualized over its expected useful life) and b) a total operation and maintenance and purchase of services component. The estimates should take into account costs associated with generating, maintaining, and disclosing or providing the information. Include descriptions of methods used to estimate major cost factors including system and technology acquisition, expected useful life of capital equipment, the discount rate(s), and the time period over which costs will be incurred. Capital and start-up costs include, among other items, preparations for collecting information such as purchasing computers and software; monitoring, sampling, drilling and testing equipment; and record storage facilities.**

b) **If cost estimates are expected to vary widely, agencies should present ranges of cost burdens and explain the reasons for the variance. The cost of purchasing or contracting out information collections services should be a part of this cost burden estimate. In developing cost burden estimates, agencies may consult with a sample of respondents (fewer than 10), utilize the 60-day pre-OMB submission public comment process and use existing economic or regulatory impact analysis associated with the rulemaking containing the information collection, as appropriate.**

c) **Generally, estimates should not include purchases of equipment or services, or portions thereof, made: (1) prior to October 1, 1995, (2) to achieve regulatory compliance with requirements not associated with the information collection, (3) for reasons other than to provide information or keep records for the government, or (4) as part of customary and usual business or private practices.**

While there have been a limited number of submissions to EPA under the previous Risk Evaluation Rule, the Agency has reviewed those activities and considered the additional requirements in this rule in determining the estimated burden and cost per submission. 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 $75,000 per chemical.

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

EPA estimates costs of $2,237,582 to carry out the activities associated with the information collection activities covered over the ICR's three-year period, the costs for the Agency to review and determine completeness of 3 manufacturer requested risk evaluations. In order to determine the total cost for the Agency, an average number of labor hours per submission package were estimated. The labor rate was assumed to be a fully loaded GS-13, step 5 employee in the Washington D.C. area of $125.99 per hour. This cost includes an average labor time of 5,920 hours per chemical submitted by a manufacturer.

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

There is no change in the burden from what is currently approved by OMB, but the literature search that EPA expects manufacturers to perform as part of a request for a risk evaluation will be less extensive under the proposed rule than under the current rule. For this reason, EPA estimates that the costs associated with a manufacturer request will decrease. This is a program change.

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

The Agency does not intend to publish information gathered through this information collection.

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

The Agency plans to display the expiration date for OMB approval of the information collection on all instruments.

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

This information collection complies with all provisions of the Certification for Paperwork Reduction Act Submissions.

SUPPLEMENTAL INFORMATION

PRA Burden Statement

This collection of information is approved by OMB under the Paperwork Reduction Act, 44 U.S.C. 3501 et seq. (OMB Control No. 2070-0231). Responses to this collection of information are mandatory for certain persons, as specified at **40 CFR Part 702**. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The public reporting and recordkeeping burden for this collection of information is estimated to be **55 hour(s)** per response. Send comments on the Agency's need for this information, the accuracy of the provided burden estimates and any suggested methods for minimizing respondent burden to the Information Engagement Division Director, U.S. Environmental Protection Agency (2821T), 1200 Pennsylvania Ave., NW, Washington, D.C. 20460. Include the OMB control number in any correspondence. Do not send the completed form to this address.

To comment on the Agency's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden, including the use of automated collection techniques, EPA has established a public docket for this ICR under Docket ID Number EPA-HQ-OPPT-2023-0496, which is available at https://www.regulations.gov. This site can be used to submit or view public

comments, access the index listing of the contents of the public docket, and to access those documents in the public docket that are available electronically. When in the system, select “search,” then key in the Docket ID Number identified above.

LIST OF ATTACHMENTS

The attachments listed below can be found in the docket for this ICR or by using the hyperlink that is provided in the list below. The docket for this ICR is accessible electronically through http://www.regulations.gov using Docket ID Number: **EPA-HQ-OPPT-2025-0260**.

Ref.	**Title**
1.	Risk Evaluation CDX User Guide

REFERENCES

15 U.S.C. 2605 https://uscode.house.gov/view.xhtml?path=/prelim@title15/chapter53&edition=prelim