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

Title: Notification of Substantial Risk of Injury to Health and the Environment under TSCA Section 8(e)

EPA ICR No.: 0794.18

OMB Control No.: 2070-0046

Docket ID No.: EPA-HQ-OPPT-2015-0744

Abstract

Toxic Substances Control Act (TSCA) section 8(e) states, "any person who manufactures, [imports,] processes, or distributes in commerce a chemical substance or mixture and who obtains information which reasonably supports the conclusion that such substance or mixture presents a substantial risk of injury to health or the environment shall immediately inform the [EPA] Administrator of such information unless such person has actual knowledge that the Administrator has been adequately informed of such information." (15 U.S.C. 2607(e); see Ref.1.)

EPA receives and screens TSCA section 8(e) submissions including a wide range of chemical toxicity/exposure information on numerous chemical substances and mixtures. Although EPA's receipt of TSCA section 8(e) information does not necessarily trigger immediate regulatory action under TSCA or other authorities administered by EPA, all TSCA section 8(e) submissions receive screening level evaluations by EPA's Office of Pollution Prevention and Toxics (OPPT) to identify priorities for further Agency action and appropriate referrals to other programs.

EPA offers an electronic reporting option for those required to submit a notification of substantial risk under TSCA section 8(e) and those who wish to voluntarily submit "For Your Information" (FYI) notices by registering and submitting information electronically using the Agency's Central Data Exchange (CDX), as described below.

TSCA section 8(e) data on newly discovered chemical hazards/risks are available via EPA's ChemView website (https://chemview.epa.gov/chemview).

Information Collection Activity	Annual Number of Responses	Number of Respondents	Responses per Respondent	Annual Burden Hours	Annual Cost
TSCA section 8(e) submission	552	35	16	27,608	$2,802,212
FYI submission	5	5	1	251	$25,477
CDX Registration and e-Signature	37 [A]	37 [A]	1	24	$2,156
Respondent Total	**567**	**40**	**n/a**	**27,883**	**$2,829,844**
Agency Total	**-**	**-**	**-**	**3,963**	**$499,298**

[A]CDX registrations are counted as activities that some respondents undertake in service of making an 8(e) or FYI submission, but not as submissions on their own. Therefore, the respondent and response figures attributed to CDX Registration and e-Signature are not reflected in the overall totals.

SUPPORTING STATEMENT

1. NEED AND AUTHORITY FOR THE COLLECTION:

Explain the circumstances that make the collection of information necessary. Identify any legal or administrative requirements that necessitate the collection.

TSCA section 8(e) is an important and useful tool for early warning and identification of potential substantial risk situations allowing EPA and others to focus their limited resources on chemicals or mixtures of highest concern. The submission of TSCA section 8(e) information makes it possible for EPA and others to learn quickly about potential new chemical hazards/risks posed by exposure to chemical substances, to conduct more complete assessments, and to take effective action to eliminate or reduce such risks as needed.

The statutory authority for this information collection is TSCA section 8(e) (15 U.S.C. 2607(e)). No formal rulemaking by EPA was required to implement TSCA section 8(e), in that TSCA section 8(e) was a self-activating reporting provision of TSCA that became immediately effective on January 1, 1977 (TSCA's effective date). To facilitate compliance with TSCA section 8(e), however, EPA clarified the kinds of information that constitute substantial risk information, specified the types of information exempt from the reporting requirements, and outlined standard reporting procedures in published proposed guidance (42 FR 45362; September 9,

1977), followed by publication of a final "Statement of Interpretation and Enforcement Policy; Notification of Substantial Risk" (43 FR 11110) in March 1978. In June 1991, EPA further assisted the regulated community with publication of a "Section 8(e) Reporting Guide", offering examples and factors for determining reportability, especially concerning interpretation of acute lethality data. EPA also launched a voluntary Compliance Audit Program (CAP) in 1991 to ensure companies complied with reporting requirements, resulting in settlements with 123 participating companies by 1996.

In implementing the TSCA section 8(e) CAP, EPA identified a need to further refine reporting guidelines. EPA proposed a new guidance in 1993 and revised it in 1995 after receiving industry feedback. This led to the 2003 publication of the "TSCA Section 8(e); Notification of Substantial Risk; Policy Clarification and Reporting Guidance" (68 FR 33129), which extended the reporting deadline from 15 to 30 days and revised guidance on what information should be reported. Corrections and clarifications followed in 2005, alongside a question and answer (Q&A) document to assist with understanding reporting requirements.

Since the aforementioned Q&A and guidance documents have not been updated in more than 20 years, EPA is working on consolidating and updating these documents. A draft updated document will be opened for public comment in 2026.

2. PRACTICAL UTILITY/USERS OF THE DATA:

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.

Since 1977, EPA and members of the chemical industry have devoted significant efforts in fulfilling their respective responsibilities under TSCA section 8(e). Between January 1977 and mid-December 2025, EPA received and screened 25,222 initial TSCA section 8(e) notices (includes CAP and non-CAP submissions) covering a broad range of toxicity and exposure-related data on a wide range of chemicals and chemical mixtures. All incoming TSCA section 8(e) submissions are reviewed by EPA shortly after receipt. The initial processing of TSCA section 8(e) submissions includes a screening level evaluation of the submitted data. Such evaluations are not risk assessments, nor do they consider other available toxicity data on the chemical or exposure-related information on the chemical/mixture being reviewed. The results of screening level evaluations are used for priority-setting to select cases for more detailed assessment, as well as to identify referrals to other Offices and federal agencies.

EPA uses TSCA section 8(e) submission information for hazard/risk identification purposes in the initial stages of the TSCA chemical screening and review program. TSCA section 8(e) data are also used in ongoing EPA hazard and exposure assessments of both existing and new

chemicals, development of chemical testing rules under TSCA section 4, and regulation development under TSCA section 6 and other authorities administered by the Agency. In addition, TSCA section 8(e) submissions have been the basis for chemical advisories to communicate potential health risks and the need for exposure controls, as well as for chemical summaries to identify data availability for chemical hazard and exposure assessment.

Regardless of the type of TSCA section 8(e) follow-up action or activity taken, all reported information not claimed as TSCA Confidential Business Information (CBI) is made available to other EPA program and regional offices, other federal agencies and others (e.g., chemical industry, trade unions, environmental groups, the general public, and international community) who may be interested in the subject chemical or mixture. EPA offices and other federal agencies routinely utilize TSCA section 8(e) data in implementing their regulatory programs. The principal vehicle for making the information publicly available is ChemView.

EPA's implementation of TSCA section 8(e) has also resulted in heightened corporate awareness of the potential risk of injury posed by exposure to chemical substances. This increased corporate awareness has led to a variety of voluntary corporate actions designed to protect human health and/or the environment. Many companies have reported to EPA that the following types of measures were initiated in direct response to the submitted chemical toxicity and/or exposure data:

- Notification of workers, customers and others;
- Revision of product labels and Material Safety Data Sheets;
- Modification of manufacturing, processing, and/or handling;
- Ceasing production/use either temporarily or permanently;
- Initiation of additional toxicity or exposure studies to further define potential risks.

3. USE OF TECHNOLOGY:

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 developed the Chemical Information Submission System (CISS) reporting tool for use in submitting data electronically to the Agency. The tool is available for use with Windows, Macs, Linux, and UNIX based computers, using "Extensible Markup Language" (XML) specifications for efficient data transmission across the Internet. CISS provides user-friendly navigation, works with CDX to secure online communication, creates a completed Portable Document Format

(PDF) for review prior to submission, and enables data, reports, and other information to be submitted easily as PDF attachments (Attachment 1).

If submitters are claiming information as CBI, they must submit via EPA's electronic information reporting system per the Confidential Business Information Claims under the Toxic Substances Control Act (88 FR 37155, June 7, 2023) rule, finalized in 2023. Additionally, use of OECD Harmonized Templates (OHTs) is required for all TSCA submissions of health and safety studies under this rule when an appropriate template for the data type exists. This rule helps to ensure standardized and consistent data reporting, improving both compliance and data quality across various aspects of chemical regulation under TSCA. All information sent by submitters via CDX is transmitted securely to protect CBI. Furthermore, if anything in the submission is claimed as CBI a non-CBI copy of the submission must be provided by the submitter. The TSCA Section 8(e) Notice User Guide instructs users on how to submit and substantiate CBI information using CISS.

The Agency ensures secure transmission of the data, reports, and other documents sent from the user's desktop through the Internet via the Transport Layer Security (TLS) 1.2 protocol, with a planned update to TLS 1.3 in 2026. TLS 1.2 and subsequent versions updated as needed are widely used approaches for securing Internet transactions by the National Institute of Standards and Technology (NIST) as a means for protecting data sent over the Internet.

In addition, CISS enables submitters to electronically sign, encrypt, and transmit submissions, which EPA subsequently provides back to the submitter as an unaltered copy of record. This assures submitters that the Agency has received exactly what the submitter sent to EPA. The CISS reporting tool encrypts using a module based on SHA256 with RSA encryption. Details can be found in Federal Information Processing Standard (FIPS) 140-2 on the NIST website at http://csrc.nist.gov/publications/PubsFIPS.html. EPA may incorporate other encryption modules into future versions of the tool. Information submitted via CDX is processed within EPA by secure systems certified for compliance with FIPS.

To facilitate the efficiency in communications and cost savings in submissions and correspondence for both EPA and respondents, EPA has incorporated the following data elements into the TSCA section 8(e) reporting tool.

1. Submission Type	*Identifies the submission, including the type of submission and whether it is the initial submission, a follow-up or a final report.*
2. Summary of Attachment	*Allows the respondent to provide a summary or abstract of the attached study or report, any internal company tracking number, an EPA tracking number, and an indication of the number of studies submitted.*
3. Chemical Identification	*Identifies the chemical(s) addressed in the submission.*
4. Title of Attachment	*Identifies the title of the attached study or report.*
5. Indexing Terms	*Allows the respondent to identify the proper terms to use for indexing purposes, which facilitates the search and retrieval of the information.*
6. Submitter Information	*Identifies the submitter and/or technical contact, including name, title, company, mailing address, phone and e-mail address.*
7. Comments	*Allows the submitter to provide any additional comments, so as to avoid the need for or use of a separate cover letter.*

To further facilitate more efficient reporting and industry-EPA cooperation, TSCA section 8(e) indexing terms are now aligned with international standards developed by the Organisation of Economic Cooperation and Development (OECD) for reporting chemical test summaries known as the OECD Harmonized Templates (OHTs)[1]. Guidance is available at *https://www.oecd.org/en/topics/sub-issues/assessment-of-chemicals/harmonised-templates.html*.

EPA staff will be the primary users of the standardized metadata. EPA employees will use the metadata collected through CDX to identify submissions when they reach EPA without having to examine portions of a submission that may be very lengthy and complex, and to subsequently use the information to distribute, locate, and track submissions as they move through Agency reviews and decision points to index the data and to identify the data within EPA databases in making the data publicly available.

4. EFFORTS TO IDENTIFY DUPLICATION:

[1] https://www.oecd.org/en/topics/sub-issues/assessment-of-chemicals/harmonised-templates.html

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.

No other data source can be used in place of the data submitted to EPA under the TSCA section 8(e) statutory reporting requirement. The "substantial risk" information required to be reported to EPA is unpublished information not already known to the Agency. As discussed above, this information is used in a wide range of statutorily required activities within EPA and by external stakeholders. Importantly, information need not be submitted under TSCA section 8(e) if the information has been reported already to EPA pursuant to another TSCA mandatory information reporting requirement or another authority administered or delegated to the States by EPA. In its June 2003 Reporting Guidance, EPA clarified the circumstances under which certain information need not be reported to the Agency under TSCA section 8(e). This was expected to reduce some of the respondent reporting burden for TSCA section 8(e).

5. MINIMIZING BURDEN ON SMALL ENTITIES:

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

The statutory obligation to report information under TSCA section 8(e) applies to <u>all</u> manufacturers, importers, processors, and/or distributors of TSCA-covered chemical substances and mixtures. The statutory language of TSCA section 8(e) itself does not allow for any reporting exemption or burden minimization based on the size or earnings of a respondent. Nearly all reporting, however, is by large and medium size companies. This is primarily because larger companies tend to have the financial resources to conduct the toxicity testing that constitutes most TSCA section 8(e) reporting. Since TSCA section 8(e) imposes no routine reporting or recordkeeping provisions, the burden on most small entities is effectively zero.

6. EFFECTS OF LESS FREQUENT COLLECTION:

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.

TSCA section 8(e) reporting is self-implementing rather than cyclical. The statute states that persons covered under the TSCA section 8(e) reporting requirement shall immediately notify the EPA Administrator upon obtaining reportable information. As stated previously, TSCA section 8(e) continues to be an extremely important and useful EPA tool for early identification of potential substantial risk situations and allows the Agency as well as others to focus their resources on those chemicals or mixtures of highest concern. The consequences of EPA's not receiving TSCA section 8(e) data immediately following receipt by a respondent are serious. The Agency would be prevented from learning about and publicizing new information about

substantial risks to health or environmental injury posed by exposure to chemical substances and/or mixtures. Further, EPA would not be in a position to adequately assess and, if necessary, take action to effectively eliminate or reduce such risks in an expeditious manner.

Some respondents may be required to submit information to the agency more often than quarterly. According to the statutory text, individuals subject to TSCA section 8(e) must report the relevant information "immediately." EPA has interpreted this in its published guidance documents as occurring within 30 days. Since respondents are expected to provide substantial risk information on an ad hoc basis and within 30 days of receipt, this may occur more often than quarterly for some respondents, depending on the timing and amount of substantial risk information they have obtained.

7. GENERAL GUIDELINES:

Explain any special circumstances that require the collection to be conducted in a manner inconsistent with PRA Guidelines at 5 CFR 1320.5(d)(2).

As discussed in the second paragraph of Q6, under certain circumstances a respondent may be required to report multiple times within a three-month period. Otherwise, the proposed collection does not create special circumstances requiring justification under 5 CFR 1320.5(d)(2).

8. PUBLIC COMMENT PERIOD AND CONSULTATIONS:

8a. Public Comment

If applicable, provide a copy and identify the date and page number of publication(s) 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.

Pursuant to 5 CFR 1320.8(d), EPA published a notice in the Federal Register on July 2, 2025 (90 FR 29005 (FRL-12649-01-OCSPP), announcing the planned renewal of this information collection activity, soliciting public comment on specific aspects of the ICR and providing a 60-day public comment period.

During the public comment period, the American Chemistry Council (ACC) provided a comment encouraging the Agency to consult with stakeholders most likely to be impacted directly by the obligations imposed by TSCA section 8(e) to ensure the burden and cost estimates are reasonable and accurate. EPA fulfilled this obligation through the consultation process outlined below, during which nine stakeholders involved in TSCA section 8(e) reporting were selected and invited to provide feedback on the Agency's cost and burden estimates. As illustrated

above, this feedback has been taken into account for the purpose of cost and burden estimates, and additional comments provided by these stakeholders are being actively addressed. ACC also commented that the Agency should use data submitted under TSCA section 8(e) to evaluate risk management decisions for new chemicals. EPA historically conducted this type of analysis and plans to continue doing so in the near future.

8b. Consultations

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 report.

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 EPA also consulted nine stakeholders, specifically asking them for their assessment of the regulatory burden estimates expressed by the Agency in this ICR (Attachment 2). The stakeholders consulted were:

1) 3M
2) American Chemistry Council (ACC)
3) ReSyngenta Crop Protection, LLC
4) BASF Corporation
5) Corteva Agriscience, LLC
6) Momentive Performance Materials, Inc.
7) The Chemours Company FC, LLC
8) DuPont Specialty Products USA, LLC
9) The Dow Chemical Company

Of those consulted, EPA received comments from 3M and Syngenta (Attachment 3). The Agency received substantive comments during the consultations. The Agency's responses to those comments are summarized below. The Agency also received comments from the American Chemistry Council during the comment period, and the Agency's responses are summarized below (Attachment 4). EPA thanks the commenters for their comments and has considered them in developing this ICR.

In response to the consultation questions provided by the Agency, Syngenta Crop Protection, LLC commented that the Agency's transition to electronic submissions may increase cost and burden for submitters in the short-term, through a need for increased investments in IT infrastructure, including software development or procurement, system integration, and

security measures with implementation and operational costs. While Syngenta notes that these investments typically yield long-term benefits, the Agency must maintain a user-friendly electronic reporting system for electronic reporting to remain cost-effective. EPA believes a user-friendly electronic reporting system is imperative to maintain long-term savings in cost- and hour-burden associated with electronic reporting and continues to actively address issues and implement improvements with the existing electronic reporting system. Since EPA's transition to electronic reporting occurred more than a decade ago, and electronic submission via EPA's CDX platform is also required under other TSCA programs which 8(e)-reporters are also reporting under, EPA believes any burdens associated with this transition have already incurred or are attributable elsewhere.

3M also provided comments in response to the Agency's consultation questions, noting areas of confusion or outdated information in EPA's existing TSCA section 8(e) guidance documents, instability of the CDX electronic reporting platform, and insufficient guidance and clarity regarding expectations for submitting information using OECD harmonized templates (OHTs). EPA is aware that the currently published guidance documents available for TSCA section 8(e) reporting are out-of-date. A draft reporting guidance is in progress by EPA and will be made available for comment by industry stakeholders in 2026. In the updated reporting guidance, EPA plans to address areas of confusion highlighted by 3M and other stakeholders (namely, guidance on reporting results of New Approach Methodologies (NAMs) and hazard and exposure thresholds for reporting on non-emergency situations involving environmental contamination). As addressed above, EPA continues to upgrade its electronic reporting systems, including the CDX platform and is actively working on updating to the most up-to-date version of IUCLID to reduce submitter's burdens on providing electronic submissions in OHT format.

9. PAYMENTS OR GIFTS TO RESPONDENTS:

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

No payments or gifts are provided to respondents.

10. PROVISIONS FOR PROTECTION OF INFORMATION:

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 system of records notice (SORN) or privacy impact assessment (PIA), those should be cited and described here.

Any person submitting a notice to EPA under TSCA section 8(e) may assert a claim of business confidentiality covering information contained in the submission. Any information covered by a claim will be disclosed by EPA only to the extent and by means of the procedures set forth at 40 CFR Part 2. If no confidentiality claim accompanies a TSCA section 8(e) notice, the submission is

uploaded to ChemView and is available to the public without further notice to the submitting organization. The Agency has established and actively implements well-publicized standard procedures for the handling and safeguarding of information claimed as TSCA Confidential Business Information (TSCA CBI).

11. JUSTIFICATION FOR SENSITIVE QUESTIONS:

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. RESPONDENT BURDEN HOURS AND LABOUR COSTS:

Provide estimates of the hour burden of the collection of information.

- *Indicate the number of respondents, frequency of response, annual hour burden, and an explanation of how the burden was estimated.*
- *If this request for approval covers more than one form, provide separate hour burden estimates for each form and the 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 as O&M costs under non-labor costs covered under question 13.*

12a. RESPONDENTS/NAICS CODES

A statutory TSCA section 8(e) reporting obligation can be incurred by any person who manufactures, imports, processes, or distributes a TSCA-covered chemical substance or mixture. EPA's TSCA Section 8(e) Policy Statement defines the term "person" broadly to include "any natural person, corporation, firm, company, joint-venture, partnership, sole proprietorship, association, or any other business entity, any State or political subdivision thereof, any municipality, any interstate body and any department, agency, instrumentality of the Federal Government." Although this definition is quite broad in terms of subject persons, TSCA section 8(e) reporting obligations are most typically incurred by companies engaged in activities classified by the North American Industrial Classification System (NAICS) Codes 325 - Chemicals and Allied Products Manufacturers and 32411- Petroleum and Coal Products Manufacturing.

12b. INFORMATION REQUESTED

There is no required collection instrument or reporting form on which TSCA section 8(e) information must be submitted to EPA. The TSCA Section 8(e) Policy Statement requires all respondents to ensure that a written TSCA section 8(e) notice:

- is sent to EPA by a method verifying the Agency's receipt;
- states that it is being submitted under TSCA section 8(e);
- contains the name, address, job title, phone number and signature of the person reporting, and the name and address of the establishment with which the person is associated;
- identifies the chemical substance(s) or mixture including, if known, the Chemical Abstract Service (CAS) Registry Number(s);
- summarizes adverse health/environmental effects being reported including a description of the nature and extent of the risk; and
- contains the specific source/summary of the supporting data.

EPA is continuing its efforts to implement optional electronic reporting of TSCA section 8(e) submissions and FYIs to increase processing efficiency for both the Agency and the regulated community. With the TSCA e-reporting initiative in place for other information collections, submitters of TSCA section 8(e) information have taken advantage of the new reporting option with virtually all reports submitted via CDX. The option to submit TSCA section 8(e) notices and FYIs electronically using the CISS reporting tool and electronic submission via CDX changes the way that companies interact with EPA. Companies are registered with EPA to submit their data electronically to the Agency via CDX. The Agency in turn is able to communicate back electronically with submitters. This promotes efficiency in communications and cost savings in submissions and correspondence. EPA believes the adoption of electronic communications reduces the reporting burden on industry by reducing both the cost and the time required to review, edit and transmit data to the Agency. All information sent via CDX is transmitted securely to protect CBI. Furthermore, if anything in the submission has been claimed CBI, a sanitized copy of the notice must be provided by the submitter. The Agency also benefits from receiving electronic submissions. Data systems that previously were populated manually are now populated electronically, reducing the potential for human error that exists when data are entered by hand. EPA personnel are also able to communicate more efficiently with submitters electronically, compared to using U.S. mail.

The overall purpose of TSCA section 8(e) reporting is to ensure that new information that reasonably supports a conclusion that a chemical substance or mixture presents a "substantial risk" of injury to health or the environment is brought to EPA's attention immediately upon discovery. It should be noted again that TSCA section 8(e) applies to <u>all</u> chemical manufacturers, importers, processors, and distributors and applies also to information that a subject person possesses or about which that person has knowledge. Although compliance with TSCA section

8(e) does not require subject persons to search for information or to make extraordinary efforts to acquire information, TSCA section 8(e) does apply to information that is "obtained" (i.e., information that a person possesses or about which that person knows). Following a review of existing information and a decision that such information is of the type required under TSCA section 8(e), respondents must notify EPA in writing "immediately." EPA's June 2003 Reporting Guidance defines the term "immediately" in the context of written TSCA section 8(e) reports to mean within 30 calendar days of the date on which the information was obtained; the immediate reporting of an emergency incident of environmental contamination by a toxic substance is defined as a phone report to EPA or to the National Response Center as soon as a person knows about the incident.

Considering that TSCA section 8(e) submissions are received by the Agency on an ad hoc basis, there is no standard reporting cycle. Submitters are required to comply with TSCA section 8(e) immediately when they come into possession of or know about TSCA section 8(e)-reportable information. If TSCA section 8(e) information were not made available immediately to EPA, the Agency's ability to learn about, publicize, effectively assess, and respond appropriately to newly discovered chemical-related risks would be severely impeded, if not completely thwarted.

12c. RESPONDENT ACTIVITIES AND FREQUENCY

TSCA Section 8(e) Submissions

Pursuant to TSCA section 8(e)(15 U.S.C. 2607(e)), "Any person who manufactures, processes, or distributes in commerce a chemical substance or mixture and who obtains information which reasonably supports the conclusion that such substance or mixture presents a substantial risk of injury to health or the environment shall immediately inform the Administrator of such information unless such person has actual knowledge that the Administrator has been adequately informed of such information."

FYI Voluntary Submissions

EPA has received FYI submissions covering a wide variety of chemical substances and mixtures from chemical companies, trade associations, unions, public interest groups, civic associations, private citizens, academic institutions, state and other federal agencies, as well as similar organizations and agencies in foreign countries. These submissions contain information on human exposure, epidemiology, toxicity test results, monitoring studies, environmental fate, and other information that may be important to risk assessment.

FYI submissions are often submitted to EPA when a person or company that is not required to submit would like to bring information on a chemical to EPA's attention. Chemical companies, trade associations, public interest groups, and academic institutions are among those who

submit FYIs. These entities who wish to submit information to the Agency electronically will have to register with CDX or otherwise submit information by paper.

In addition, FYI submissions are submissions from a classification system that was established by EPA to distinguish voluntary submissions from "substantial risk" notices submitted formally to EPA under TSCA section 8(e), discussed above. EPA created the FYI classification to capture submissions by persons or organizations not subject to the reporting requirements, but who wish to inform EPA of a potential risk.

As stated earlier in this document, the majority of submissions are being received in electronic format. Therefore, estimates still account for some paper submission as described below

12d. RESPONDENT BURDEN HOURS AND LABOR COSTS

TSCA Section 8(e) Submissions

EPA estimates that it should take approximately 49 hours per submission to judge and concur on the TSCA section 8(e)-applicability of obtained information and to prepare and submit the necessary information. This figure is based on an average of 45 hours per submission of managerial staff time to review and evaluate data and an additional 4 hours for staff training on TSCA section 8(e) regulatory requirements. Additionally, the unit burden for recordkeeping is estimated at 1.06 hours of clerical staff time for electronic TSCA section 8(e) submissions and 2 hours for paper submissions.

To quantify the number of submissions for the current ICR renewal, EPA utilizes data on the number of TSCA section 8(e) submissions for calendar years 2022 through 2024. The average annual number of TSCA section 8(e) submissions is 552, constituted of 547 electronic and 5 paper submissions, as computed to provide the annual basis for this ICR renewal. Table 1 provides a summary of estimates for unit burden and the annual burden associated with the mandatory section 8(e) submissions.

Voluntary FYI Submissions

EPA believes that the burden associated with filing a voluntary FYI submission is on par with the burden related to filing a mandatory submission because the voluntary submissions usually contain information on human exposure, epidemiology, toxicity test results, monitoring studies, environmental fate, and other information that may be pertinent to risk assessment. Therefore, the burden associated with filing an FYI submission in paper is also estimated at an average of 45 hours per submission of managerial staff time to review and evaluate data plus an additional 4 hours for staff training on TSCA section 8(e) regulatory requirements. Additionally, the unit burden for recordkeeping is estimated at 1.06 hours of clerical staff time for FYI submissions and 2 hours for paper submissions.

To quantify the number of submissions for the current ICR renewal, EPA utilizes data on the number of FYI submissions for calendar years 2022 through 2024. The average annual number of initial FYI submissions is 5, constituted of 4 electronic and 1 paper submission, as computed to provide the annual basis for this ICR renewal. Table 1 provides a summary of estimates for unit burden and the annual burden associated with the voluntary FYI submissions.

Table 1: TSCA Section 8(e) and FYI Submission Unit and Total Burden

Activity	**Mode**	**Hours per Submission**			**Unit Burden (hrs)**	**# of Responses**	**# of Respondents**	**Total Annual Burden**
		Managerial	**Technical**	**Clerical**				
TSCA Section 8(e) submission	Electronic	49	0	1.06	50.06	547	32	27,383
	Paper	49	0	2	51	5	3	225
Subtotal TSCA Section 8(e)						**552**	**35**	**27,608**
FYI submission	Electronic	49	0	1.06	50.06	4	4	200
	Paper	49	0	2	51	1	1	51
Subtotal FYI						**5**	**5**	**251**
Overall TOTAL						**567**	**40**	**27,859**

CDX Registration Activities to Enable Electronic Reporting

To estimate the number of CDX registrants who will submit TSCA section 8(e) and voluntary FYI submissions, EPA averages the total number of distinct TSCA section 8(e) and FYI submitters from submissions for calendar years 2022, 2023, and 2024 to obtain an average of 37 annual registrations for the basis of this ICR renewal. Table 2 provides a summary of estimates for unit burden and the annual burden associated with CDX registrations.

Some TSCA section 8(e) and FYI submitters may already have registered to use the e-TSCA web reporting tool in CDX (and obtained an accompanying electronic signature) in order to comply with the mandatory electronic reporting requirements of EPA's e-PMN rule (EPA, 2022). Those submitters will not need to repeat the CDX registration and e-signature process in order to file TSCA section 8(e) and FYI notices. While there may be some overlap in the specific individuals that have already completed CDX activities, EPA is using a conservative assumption that most

submitters who file electronically will need to register with CDX and, thus, incur associated burdens. This assumption may overestimate the burdens and costs actually experienced by respondents. The one-time CDX burden includes the following:

CDX registration: Based on the TSCA section 5 ICR renewal (OMB Control No. 2070-0038), EPA assumed that companies would spend about 15 to 20 minutes per technical employee to register with CDX (EPA, 2021). This results in an average estimate of 17 minutes to complete registration.

CDX electronic signature (labor burden): Based on the TSCA section 5 ICR renewal, EPA assumed that companies' technical staff would spend 21 minutes preparing, submitting and filing an electronic signature agreement (Authentication of Identity) form to EPA, per employee (EPA, 2015).

Table 2: Estimated Annual Burden Associated with CDX Registration Activities

Activity	Estimated Hours per Response			Unit Burden (hours)	Number of Responses	Estimated Number of Annual Respondents	Annual Burden
	Managerial	Technical	Clerical				
CDX Registration	0	0.29	0	0.29	37	37	11
CDX E-Signature	0	0.35	0	0.35			13
TOTAL	**0**	**0.64**	**0**	**0.64**	**37**	**37**	**24**

Based on the figures presented in the preceding tables, the average annual estimated number of TSCA section 8(e) and FYI responses plus CDX registrations for the next 3 years is 594. The average annual industry reporting burden for the same period totals 27,883 hours (See also Table 4). Respondents continue to make paper submissions, which comprise roughly 1% of all submissions.

EPA estimates submitter costs using burden estimates above along with labor rates obtained from the Bureau of Labor Statistics (BLS). Table 3 presents the derivation of the loaded industry wage rates used in this analysis. The wages and fringe benefits for the Managerial, Technical, and Clerical labor categories are drawn from the BLS "Employer Costs for Employee Compensation Supplementary Tables Historical Data" for December 2024 (BLS, 2025). For each labor category, wages are loaded using fringe benefit rate from BLS plus a 20% overhead rate.

In Table 4, the unit burden estimates from the previous sections are combined with the wage rates in Table 3 to compute unit costs (per response) and total costs. Overall, the labor costs associated with 27,883 hours of burden total $2,829,705.

Table 3: Industry Wage Rates (2024$)

Labor Category	Data Sources [a]	Date	Wage	Fringe Benefit	Total Compensation	Overhead % of Total Compensation [b]	Overhead	Hourly Loaded Wages [c]
			(a)	*(b)*	*(c) =(a)+(b)*	*(d)*	*(e)=(c)*(d)*	*(f)=(c)+(e)*
Managerial	BLS ECEC, Private Manufacturing industries, "Mgt, Business, and Financial"	Dec-24	$58.01	$26.57	$84.58	20%	$16.92	$101.50
Professional / Technical	BLS ECEC, Private Manufacturing industries, "Professional and related"	Dec-24	$47.87	$23.11	$70.98	20%	$14.20	$85.18
Clerical	BLS ECEC, Private Manufacturing industries, "Office and Administrative Support"	Dec-24	$24.84	$11.34	$36.18	20%	$7.24	$43.42
Footnotes								
[a] Source: Employer Costs for Employee Compensation. Table 4. Private industry workers by occupational and industry group. December 2022. (U.S. Bureau of Labor Statistics 2023).								
[b] 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 (EPA 2020)								
[c] Wage data are rounded to the closest cent in this analysis.								

Table 4: Industry Annual Reporting Costs (2024$)

Activity	Unit Burden (hrs)	Weighted Average Wage Rate	Unit Cost (per response)	Number of Responses	Number of Respondents	Annual Burden Hours	Annual Cost
TSCA Section 8(e) Submission							
Electronic Submission	50.06	$101.50	$5,081	547	32	27,383	$2,779,374.50
Paper Submission	51	$101.50	$5,177	5	3	225	$22,837.50
Subtotal TSCA § 8(e)				**552**	**35**	**27,608**	**$2,802,212.00**
FYI Submission							
Electronic Submission	50.06	$101.50	$4,671	4	4	200	$20,300.00
Paper Submission	51	$101.50	$4,706	1	1	51	$5,176.50
Subtotal FYI				**5**	**5**	**251**	**$25,476.50**
CDX Activities							
CDX Registration	0.29	$85.18	$25	37	37	11	$913.98
CDX E-Signature	0.35	$85.18	$30			13	$1,103.08
CDX E-Signature non-labor	N/A	N/A	$3.75			N/A	$138.75
Subtotal CDX				**37**	**n/a**	**24**	**$2,155.81**
Overall Total				**567**[A]	**40**[A]	**27,883**	**$2,829,844**

[A]CDX registrations are counted as activities that some respondents undertake in service of making an 8(e) or FYI submission, but not as submissions on their own. Therefore, the respondent and response figures attributed to CDX Registration and e-Signature are not reflected in the overall totals.

13. RESPONDENT CAPITAL AND O&M COSTS:

Provide an estimate for the total annual cost burden to respondents or recordkeepers resulting from the collection of information.

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.

Non-labor costs include a $0.73 stamp and a $0.02 standard business envelope for each of five required electronic signature agreements (USPS, 2025). The total non-labor cost for electronic signature agreements equals $3.75. This amounts to $138.75 in non-labor costs per year and is shown in Table 4.

14. AGENCY COSTS:

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.

14a. AGENCY ACTIVITIES AND FREQUENCY

As explained in additional detail in the following sections, EPA's TSCA section 8(e) activities involve answering general and specific TSCA section 8(e)-related questions, development and maintenance of computerized information tracking (including data extraction, entry and quality

assurance/control), microfilming, confidential (restricted-access) and non-confidential (public-access) TSCA section 8(e) information filing, initial evaluation of all submitted TSCA section 8(e) information (including review of TSCA CBI substantiations), and the posting of TSCA section 8(e)-related information on the Internet for public access.

EPA will continue to use case numbers to identify TSCA section 8(e) submissions through the format: 8EHQ-YY-XXXX. Previously issued case numbers will remain the same, such as initial submissions were assigned as Sequence A; study amendments were assigned Sequence B, C, D, etc. Internal EPA tracking of TSCA section 8(e) submissions will still be handled via non-confidential and confidential computerized data bases.

In order to assure that the public is kept apprised of new adverse chemical-related toxicity and exposure information, the Agency provides public access to and actively disseminates non-confidential TSCA section 8(e) submission information in many ways. Examples of EPA's public access/outreach activities follow.

Non-confidential TSCA section 8(e) and FYI submissions, status reports, submission summaries, and EPA follow-up letters can be viewed/copied in EPA's Chemview database at https://chemview.epa.gov/chemview/

Under established Freedom of Information Act (FOIA) procedures, EPA responds to requests from industry, other stakeholders and the public.

14b. AGENCY BURDEN AND LABOR COST

For this ICR, EPA estimates that a GS-13, Step 5, staff member spends 7.1 hours to initially review, process, and/or answer questions on each electronic submission. EPA also estimates the time to process, copy, and file paper submissions in addition to the tasks described for electronic submissions results in an average of 8.5 hours. EPA's wage rate is presented in Table 5. Given 547 TSCA section 8(e) and 4 FYI electronic submissions, yielding 551 total electronic submissions, with each requiring 7.1 hours of EPA staff time, annual agency burden is 3,912 hours. In addition, given 5 TSCA section 8(e) and 1 FYI paper submissions, yielding 6 total paper submissions, with each requiring 8.5 hours of EPA staff time, annual agency burden is 51 hours. Total annual agency burden is 3,963 hours.

14c. Agency Non-Labor Costs

There are no anticipated non-labor costs for the Agency.

14d. Agency Total Costs

Applying the agency wage rate in Table 5 yields annual agency costs at $499,298 (see also Error: Reference source not found).

Table 5: Agency Wage Rate (2024$)

Labor Category	Data Source for Wage Information	Wage ($/hour)	Fringes as % wage[b]	Fringe Benefit	Total Compensation	Overhead as % total compensation[c]	Overhead	Loaded Wage ($/hr)
		(a)	(b)	(c) = (a)*(b)	(d) = (a)+(c)	(e)	(f) = (d)*(e)	(g) = (d)+(f)
EPA staff	Annual federal staff cost: OPM Washington-Baltimore-Northern Virginia, DC-MD-PA-VA-WV area, GS-13 Step 5 pay rates [a]	$64.06	63.90%	$40.93	$104.99	20%	$21.00	$125.99

Footnotes:

[a] Source: U.S. Office of Personnel Management. (2024). Salary Table 2024-DCB. Retrieved May 8, 2025 from Pay & Leave: Salaries & Wages: https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/24Tables/html/DCB_h.aspx.

[b] Source: Falk, J. 2012. "Comparing Benefits and Total Compensation in the Federal Government and the Private Sector." Congressional Budget Office Working Paper Series. https://www.cbo.gov/sites/default/files/112th-congress-2011-2012/workingpaper/2012-04fedbenefitswp0.pdf

[c] 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* (EPA 2020).

15. CHANGE IN BURDEN:

Explain the reasons for any program changes or adjustments reported on the burden worksheet.

There is an increase in industry reporting burden of 10,248 hours from that currently in the OMB inventory (from 17,635 to 27,883 hours). This reflects an overall increase in the number of TSCA section 8(e) submissions, which increased from 343 to 552. This change in an adjustment.

16. PUBLICATION OF DATA:

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 results of this information collection.

17. DISPLAY OF OMB CONTROL NUMBER AND EXPIRATION DATE ON INSTRUMENTS:

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. CERTIFICATION STATEMENT:

Explain each exception to the topics of 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.

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. 2070-0046). Responses to this collection of information are mandatory for certain persons, as specified at 15 USC 2607(e). 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 50 hours 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 Data & Enterprise Program Deputy 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.

You can also provide comments to the Office of Information and Regulatory Affairs, Office of Management and Budget via https://www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

All comments received by EPA will be included in the docket without change, including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI), or other information whose disclosure is restricted by statute. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

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-2015-0744.

Ref.	Title (hyperlink)
1.	EPA Form 9600-030 8e and FYI Submissions
2.	Consultation
3.	Consultation Responses
4.	Response to Comments
5	ACC Comments

LIST OF REFERENCES

15 U.S.C. 2607(e)

U.S. Bureau of Labor Statistics (BLS). 2021, Employer Costs for Employee Compensation Supplementary Tables: December 2006 – December 2020. Accessed March 18, 2021. Available at: https://www.bls.gov/web/ecec/ecsuphst.pdf.

U.S. EPA. (2023). Economic Analysis for the Final Rule: Procedures for Review of CBI Claims for the Identity of Chemicals on the TSCA Inventory (April 2, 2023).

U.S. EPA. 2015. Information Collection Request (ICR): Premanufacture Review Reporting and Exemption Requirements for New Chemical Substances and Significant New Use Reporting Requirements for Chemical Substances. EPA ICR No: 2702.010574.15. OMB Control No: 2070-0038. Available at https://www.regulations.gov/document/EPA-HQ-OPPT-2021-0660-0019

U.S. EPA 2013 CDX User Guide Section 8(e) Notice User Guide – Primary Authorized Official https://www.epa.gov/sites/default/files/2015-09/documents/section_8e_notice_user_guide-primary_authorized_official_v4.0p.pdf

U.S. EPA. 2021. About CDX System Information. Accessed December 27, 2021. Available at https://cdx.epa.gov/About/AboutSystemInformation#REG2.

U.S. Postal Service. 2020. U.S. Postal Service Announces New Prices for 2020. Accessed January 6, 2022. Available at https://about.usps.com/newsroom/national-releases/2019/1009-usps-announces-new-prices-for-2020.htm.