

## Attachment G

July 2, 2025

Carolyn Siu  
Mission Support Division (7602M)  
Office of Program Support  
Office of Chemical Safety and Pollution Prevention  
Environmental Protection Agency  
1220 Pennsylvania Ave. NW  
Washington, DC 20460

Submitted to [regulations.gov](https://www.regulations.gov) Docket ID EPA-HQ-OPPT-2021-0728

**Re: Agency Information Collection Activities; Proposed Renewal Collection and Request for Comment; Consolidation of Certain Reporting and Recordkeeping Under Section 8 of the Toxic Substances Control Act (TSCA).<sup>89</sup> Fed. Reg. 19715-16 (May 9, 2025). EPA ICR No. 2703.02, OMB Control No. 2070-0224.**

Dear Ms. Siu:

The American Chemistry Council (ACC)<sup>1</sup> appreciates the opportunity to submit the following comments to the U.S. Environmental Protection Agency (EPA or Agency) on the proposed renewal collection and request for comment; consolidation of certain reporting and recordkeeping under Section 8 of the Toxic Substances Control Act (TSCA) by EPA ICR No. 2703.02, OMB Control No. 2070-0224.

### Omission of Certain Section 8 Reporting Rules

This ICR renewal mentions TSCA Section 8(a) and 8(d) reporting but does not include the most recent TSCA Section 8 reporting rules: the December 2024 TSCA Section 8(d) Health and Safety Reporting Rule<sup>2</sup> and the October 2023 TSCA Section 8(a)(7) PFAS Reporting and Recordkeeping Rule.<sup>3</sup> It does, however, mention two TSCA Section 8(a) reporting rules<sup>4</sup> that are no longer active, and which had smaller reporting scopes. The cost estimates in this ICR renewal do not reflect the increased scope of the aforementioned TSCA Section 8 reporting rules, including a lack of de minimis threshold, waiving of impurity exemptions, OECD Harmonized

---

<sup>1</sup> The American Chemistry Council (ACC) represents the leading companies engaged in the multibillion-dollar business of chemistry. ACC members apply the science of chemistry to make innovative products, technologies and services that make people's lives better, healthier and safer. ACC is committed to improved environmental, health, safety and security performance through Responsible Care®; common sense advocacy addressing major public policy issues; and health and environmental research and product testing. ACC members and chemistry companies are among the largest investors in research and development, and are advancing products, processes and technologies to address climate change, enhance air and water quality, and progress toward a more sustainable, circular economy.

<sup>2</sup> Certain Existing Chemicals; Request To Submit Unpublished Health and Safety Data Under the Toxic Substances Control Act (TSCA); [89 Fed. Reg. 100756-63](#) (December 13, 2024).

<sup>3</sup> Toxic Substances Control Act Reporting and Recordkeeping Requirements for Perfluoroalkyl and Polyfluoroalkyl Substances; [88 Fed. Reg. 70516-59](#) (October 11, 2023).

<sup>4</sup> [“Chemical Substances When Manufactured or Processed as Nanoscale Materials; TSCA Reporting and Recordkeeping Requirements”](#) and [“Asbestos: Reporting and Recordkeeping Under the Toxic Substances Control Act \(TSCA\)”](#)

Template (OHT) requirements, and the requirement to report articles. Any ICR renewal request should include the most recent TSCA Section 8 reporting rules that dramatically increased the burden and cost to the regulated community.

The mandatory submission of OHTs substantially increases the burden of reporting. IUCLID is the most common software used to prepare OHTs, but use of this software often requires specialized training. According to EPA's economic analysis for its Confidential Business Information rulemaking, the creation of each OECD template document is estimated to take a significant amount of time<sup>5</sup> and require expert toxicologists who are able to interpret the results of each study. The ICR Supporting Statement provided in the docket<sup>6</sup> does mention OHTs but does not address the expanded use of OHTs required by the most recent TSCA Section 8 reporting rules. The increased burden associated with OHT requirements should be included in any ICR related cost estimates.

### Clarity of Instruction

There is a lack of guidance available on several TSCA Section 8 reporting activities on the EPA website. EPA does not have proper guidance on submitting OHTs, nor has it demonstrated how that information will be incorporated into its ongoing risk evaluations. The guidance for the TSCA Section 8(d) Rule promulgated in 2024 is a compilation of outdated Q&A's, some of which are not relevant to this reporting rule. The current guidance document on submitting via CDX<sup>7</sup> is dated October 2013, and the general TSCA Section 8(d) Guidance Document<sup>8</sup> is dated February 16, 1989. Both should be updated to include information relevant to the most recent TSCA Section 8(d) Reporting Rule and should be easily accessible on EPA's website. Agency guidance that is up to date will decrease reporting burden. EPA announced its intention to release additional guidance in a final rule<sup>9</sup> to extend the TSCA Section 8(d) due date, but without such guidance available at present, ACC is still concerned about the impact of the lack of guidance on reporting burden.

### IT Infrastructure

Even with proper guidance, the EPA's Central Data Exchange (CDX) is not equipped to handle the submission of OHTs and vast amounts of data associated with the TSCA Section 8 Rules. The start of reporting for the TSCA Section 8(a)(7) Rule has been delayed twice due to issues with the CDX. The due date for the 2024 TSCA Section 8(d) Rule has also been delayed twice due to issues with the reporting platform. Issues with the CDX platform increase the time associated with making TSCA Section 8 submissions, which was evident during the 2020 and 2024 Section 8 Chemical Data Reporting periods. Problems with CDX often lead to lost or double work, long wait times while loading pages, and difficulties that are not accounted for in the proposed ICR.

### Conclusion

ACC believes that the burden and scope associated with several provisions in TSCA Section 8 rules exceed what is necessary for proper data gathering. Revising and/or reconsidering TSCA Section 8 reporting rules to

---

<sup>5</sup> [EPA-HQ-OPPT-2021-0419-0020](https://www.regulations.gov/document/EPA-HQ-OPPT-2021-0419-0020)

<sup>6</sup> <https://www.regulations.gov/document/EPA-HQ-OPPT-2021-0728-0012>

<sup>7</sup> <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/section-8d-health-safety-data-reporting-user-guide-0>

<sup>8</sup> <https://www.epa.gov/system/files/documents/2021-09/1989-reporting-guide-for-tsca-8d.pdf>

<sup>9</sup> Certain Existing Chemicals; Request To Submit Unpublished Health and Safety Data Under the Toxic Substances Control Act (TSCA); Extension of Submission Deadline; [90 Fed. Reg. 24228-31](https://www.federalregister.gov/documents/2025/06/09/2025-11441-extension-of-submission-deadline) (June 9, 2025)

include de minimis thresholds, remove requirements to submit using OECD Harmonized Templates, and restore impurity exemptions could be considered “deregulatory action” under Executive Order 14192<sup>10</sup> with associated cost savings. This TSCA Section 8 ICR Renewal does not consider some of the most burdensome rules promulgated under TSCA Section 8 and is therefore an inaccurate representation of the costs associated with TSCA Section 8 reporting activities.

\* \* \*

Thank you for the opportunity to comment. Please feel free to contact me at [joseph\\_daniels@americanchemistry.com](mailto:joseph_daniels@americanchemistry.com) with any questions.

Sincerely,



Joseph Daniels  
Director, Chemicals Management  
American Chemistry Council (ACC)

---

<sup>10</sup> [Federal Register :: Unleashing Prosperity Through Deregulation](#)

## American Chemistry Council Responses

**Consultation Questions for the Information Collection Request (ICR) for Consolidation of Certain Reporting and Recordkeeping Under Section 8 of the Toxic Substances Control Act (TSCA)**

---

**(1) Publicly Available Data**

- A. Is the data that the Agency seeks available from any public source, or already collected by another office at EPA or by another agency?
- The data elements for the identified rules are typically not available through public documents unless reported via an EPA reporting rule or another agency.
  - Once reported to the EPA or another agency under a reporting requirement, public non-confidential data becomes accessible via a public database or report. The data reference in this ICR is not mandated to be reported under a single rule; consequently, the data is generally not available under one rule and instead can be found in various databases and/or under different EPA departments or agencies. Due to the data being dispersed across multiple databases, reports or different EPA departments or agencies, stakeholders seeking comprehensive information about a commercial site typically need to research several databases and publicly available reports to consolidate the necessary data.
- B. If yes, where can you find the data?  
(Does your answer indicate a true duplication, or does the input indicate that certain data elements are available, but that they do not meet our data needs very well?)
- The publicly available data is not duplicated; users must retrieve specific data from multiple sources like EPA SRS, ChemView, and 3E Ariel Insight.

---

**(2) Clarity of Instructions**

The ICR covers the requirement under several rules for respondents to maintain records.

- A. Based on the instructions (regulations, FR Notices, etc.), is it clear what you are required to do? If not, what suggestions do you have to clarify the instructions?
- The Federal Register notice does not clearly outline the requirements for stakeholders. A thorough review of the supporting statement for the Information Collection Request (ICR) provides stakeholders with a clearer understanding of its scope and their obligations
- B. Do you understand that you are required to maintain records?
- Yes. Recordkeeping obligations are identified as ICR reference guidelines (40 CFR citations), which enable us to pinpoint specific recordkeeping requirements. In cases where 40 CFR is not accessible, ICR will delineate the recordkeeping requirements.
-

### **(3) Electronic Reporting and Record keeping**

The Government Paperwork Elimination Act requires agencies make available to the public electronic reporting alternatives to paper-based submissions by 2003, unless there is a strong reason for not doing so. One such reason is that, at the present time, the Agency is unable to ensure the security of CBI that might be transmitted via email over the Internet. EPA is currently using Central Data Exchange (CDX) to securely upload CBI information, enabling electronic submissions.

A. What do you think about electronic alternatives to paper-based records and data submissions? Would you be interested in pursuing keeping records electronically?

- Records are maintained electronically within our internal systems, and we endorse this method of record-keeping. CDX is a secure application, and we support and comprehend the process of electronic submission.

B. Are you keeping your records electronically? If yes, in what format?

- We are currently managing records electronically using both a software application and a document repository.
- 

### **(4) Burden and Costs**

A. Are the labor rates accurate?

- The labor rates are below the industry average. The identified personnel and contributing hours may not be accurate. The supporting statement for this ICR includes clerical staff as part of the team for each Section 8 report covered in the ICR. These reports require a technical understanding of the regulation and the reporting companies' chemical manufacturing process; therefore, most of the reporting is completed by technical subject matter experts rather than clerical staff. In some instances, the breakdown of costs in the tables shows clerical personnel having equal or more hours than technical individuals; however, this is not typical industry practice, where clerical effort is usually minimal to non-existent.

B. The Agency assumes there is no capital cost associated with this activity. Is that correct?

- This activity does not entail the typical capital cost since purchasing software for report submission is unnecessary; CDX and IUCLID do not require license fees. However, IUCLID software is a cumbersome system, necessitating most companies to upgrade their servers to support its operation. Due to IUCLID's complexity, entering data from a study report into an OHT template demands technical expertise and training on the software's functionality.

C. Bearing in mind that the burden and cost estimates include only burden hours and costs associated with the paperwork involved with this ICR (*e.g.*, the ICR does not include estimated burden hours and costs for conducting studies) are the estimated burden hours and labor rates accurate? If you provide burden and cost estimates that are substantially different from EPA's, please provide an explanation of how you arrived at your estimates.

- Refer to our response to question A under this topic. Comparing the burden and cost outlined in the ICR with that for industry reporting under the TSCA CDR shows that the ICR estimate is significantly lower than the average hours and costs for the industry.
- D. Are there other costs that should be accounted for that may have been missed?
- Please refer to our response for Question B under this topic. The effort required for full study report entry into OHTs may not have been fully accounted for.

## Dupont Responses

### Consultation Questions for the Information Collection Request (ICR) for Consolidation of Certain Reporting and Recordkeeping Under Section 8 of the Toxic Substances Control Act (TSCA)

---

#### (1) Publicly Available Data

- A. Is the data that the Agency seeks available from any public source, or already collected by another office at EPA or by another agency?

The Company is not aware the data that they seek is available from any public source, already collected at another office at EPA or by another agency.

- B. If yes, where can you find the data?  
(Does your answer indicate a true duplication, or does the input indicate that certain data elements are available, but that they do not meet our data needs very well?)

---

#### (2) Clarity of Instructions

The ICR covers the requirement under several rules for respondents to maintain records.

- A. Based on the instructions (regulations, FR Notices, etc.), is it clear what you are required to do? If not, what suggestions do you have to clarify the instructions?

No, it is not always clear what is required and the guidance documents are quite old. We suggest updating the instructions and the guidance documents or reviewing available guidance marking it was reviewed by EPA and is still valid. Guidance should include fact sheets and Q&A information that has been collected.

- B. Do you understand that you are required to maintain records? Yes.

---

#### (3) Electronic Reporting and Record keeping

The Government Paperwork Elimination Act requires agencies make available to the public electronic reporting alternatives to paper-based submissions by 2003, unless there is a strong reason for not doing so. One such reason is that, at the present time, the Agency is unable to ensure the security of CBI that might be transmitted via email over the Internet. EPA is currently using Central Data Exchange (CDX) to securely upload CBI information, enabling electronic submissions.

- A. What do you think about electronic alternatives to paper-based records and data submissions? Would you be interested in pursuing keeping records electronically?

We support electronic alternatives to paper-based records and data submissions however electronic submissions through CDX are not always efficient due to CDX technical issues. CDX is in need of modernizing/updating.

- B. Are you keeping your records electronically? If yes, in what format? Yes. PDF files.

---

**(4) Burden and Costs**

- A. Are the labor rates accurate?

Unable to comment.

- B. The Agency assumes there is no capital cost associated with this activity. Is that correct?

We don't believe this is correct. Companies have invested capital on internal recordkeeping systems.

- C. Bearing in mind that the burden and cost estimates include only burden hours and costs associated with the paperwork involved with this ICR (e.g., the ICR does not include estimated burden hours and costs for conducting studies) are the estimated burden hours and labor rates accurate? If you provide burden and cost estimates that are substantially different from EPA's, please provide an explanation of how you arrived at your estimates.

Unable to comment.

- D. Are there other costs that should be accounted for that may have been missed?

Unable to comment.