

Response to Comment for TSCA Section 8(e) Information Collection Request (ICR) Renewal

EPA Docket Identification Number: EPA-HQ-OPPT-2015-0744-0023

No.	Topic	Author	Comment/Response
1	Consolidation and Update of Guidance	3M	<p>Comment: “3M is aware of EPA’s published guidance for TSCA Section 8(e). EPA has made this information available on its website; however, it is distributed over a series of Federal Register notices, a reporting guide, and frequently asked questions documents. Some of EPA’s guidance has been rescinded, reinstated, and modified over time. Many aspects of the guidance are ambiguous and engender confusion as to whether information (e.g., reports and studies) are required to be submitted. 3M recommends that, at a minimum, EPA consolidate all of its TSCA 8(e) guidance into a single, up-to-date reference for submitters to facilitate compliance. In addition, 3M believes that EPA should promulgate regulations to implement the TSCA 8(e) requirements in a clearer and more accessible manner.”</p> <p>Response: EPA acknowledges that the TSCA section 8(e) webpage and the 2003 TSCA Section 8(e) Policy and Reporting Guidance are due for an update. As part of an effort to modernize the TSCA section 8(e) program, EPA will update both the webpage and the reporting guidance, with a draft publication targeted for 2026. As part of this effort, EPA plans to consolidate all relevant guidance resources into one uniform source, remove references to outdated documents, and edit language to further enhance clarity and expectations for TSCA section 8(e) reporters. This year, stakeholders will receive an opportunity to review the draft guidance updates and provide feedback. Although EPA’s preferences regarding TSCA section 8(e) submissions could be codified in procedural rules under the Administrative Procedures Act (APA), 5 U.S.C. 551 <i>et seq</i>, EPA is not at this time adopting them as rules.</p>
2	Instability of CDX platform	3M, ACC	<p>Comment: “3M has experienced stability issues with the CDX platform. In several instances, information that 3M submitted via CDX has failed to migrate to the Agency. These failures are not always apparent to the submitter, and they require intervention by the CDX Help Desk to correct them. A stable and well-functioning CDX platform is essential to realizing the benefits of electronic submissions.”</p> <p>“The submission of TSCA 8(e) data is conducted through EPA’s Central Data Exchange (CDX). ACC has previously identified persistent technical issues with CDX and continues to encourage the Agency to completely overhaul the system. ACC commends the Trump Administration and Congress for allocating \$17 million in funding to improve EPA IT systems and is optimistic that the</p>

			<p>system will receive the necessary resources in the coming months and years.”</p> <p>Response: EPA acknowledges past challenges associated with using EPA’s CDX system. EPA actively addresses issues that are within its control and works to ensure submissions are accurate and submitted on schedule. Recent improvements to the CDX system include but are not limited to:</p> <ul style="list-style-type: none"> • Substantiation field sizes were increased. This will allow submitters to provide more detailed information and addresses issues when opting out of supplying substantiation, • Updates to the validations process were made on the submitter information screen to improve functionality, • Improving processes related to submission of large attachments to help eliminate submission time-outs, • Parsing of large submissions into smaller PDFs (i.e. CDR) to improve submission processes, • Updating of migration related software to improved and stabilize data movement between systems and, • Resolution of various submission-related issues as reported by users to improve system reliability. <p>EPA has received \$17M of funding from Congress for a modernized IT system, and addressing challenges associated with CDX is a priority with this funding. EPA will continue to engage with stakeholders and adopt solutions to minimize reporting delays during these ongoing IT modernization efforts.</p>
3	Inclusion of Guidance for NAMs	3M	<p>Comment: “New Approach Methodologies (NAMs): Much of EPA’s reporting guidance for toxicology studies is based on the TSCA Section 8(e) Reporting Guide published in 1991. Since that time, EPA and others have invested a significant amount of work in developing and validating NAMs to reduce animal testing. For example, EPA published a draft Science Policy to reduce animal testing for skin sensitization in 2018. Companies subject to Section 8(e) reporting requirements would benefit from updated guidance regarding whether and how information from these new types of studies should be evaluated for reporting.”</p> <p>Response: Pursuant to its statutory obligations as outlined in TSCA section 4(h), EPA recognizes the potential of NAMs to provide robust, efficient, and humane alternatives for chemical safety assessment and is committed to supporting the use of NAMs under TSCA as part of our ongoing</p>

			<p>efforts to advance scientific innovation and reduce reliance on animal testing. In alignment with this commitment, EPA developed a Strategic Plan to Promote the Development and Implementation of Alternative Test Methods Within the TSCA Program, which specifically references the TSCA section 8(e) program and “acknowledges that as NAMs are developed and used, there needs to be consideration of updating the TSCA Chemical Substantial Risk Notice guidance to reflect the potential role of NAMs in determination of risks.”</p> <p>In alignment with this statement, EPA will update the TSCA section 8(e) webpage and the 2003 TSCA Section 8(e) Policy Statement and Reporting Guidance. As part of this effort, existing EPA guidance on NAMs will be reviewed, and updated including the use of and the interpretation of NAMs for substantial risk reporting will be considered. A representative list of TSCA section 4(h) NAMs EPA will consider for inclusion in this guidance update can be found on EPA’s webpage at Strategic Plan to Reduce the Use of Vertebrate Animals in Chemical Testing US EPA.</p>
4	OHT Requirements	3M	<p>Comment: “3M and other companies have contributed to a request to EPA for additional guidance on the requirement to submit OECD Harmonized Templates (OHTs) under various TSCA requirements, including Section 8(e). 3M understands that EPA has been developing guidance for OHTs in response to this request. This guidance is expected to address important questions that have been raised by submitters, such as:</p> <ul style="list-style-type: none"> • The specific study types the Agency considers to have an “applicable” OHT. • How to develop and submit OHTs for studies that include more than one substance. • When to submit an OHT (i.e., only with a final report rather than with preliminary information). <p>3M encourages the Agency to complete and publish this guidance as soon as possible.”</p> <p>Response: The Agency is updating the electronic submission platform to accept OECD Harmonized Templates (OHTs) for all TSCA submissions of health and safety studies under the TSCA CBI Procedural Rule (40 CFR Part 703), 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.</p> <p>OHTs offer several key benefits, including standardization, which ensures consistency in international data submissions, making it easier to review and integrate data across jurisdictions.</p>

			<p>To advance its chemical data management efforts, EPA is committed to improving the quality, searchability, and functionality of information systems used to support implementation of TSCA. These improvements are intended to reduce burden for both the Agency and TSCA submitters. OECD Harmonized Templates (OHTs), which are developed by subject-matter experts with expertise in scientific disciplines, regulatory programs, and international test guidelines, provide a standardized structure for submitting test data on chemical substances and mixtures. The use of OHTs facilitates consistent data capture, supports quality assurance and quality control practices, and enables more efficient data review, comparison, and reuse. OHTs are non-proprietary, compatible with multiple file formats, and integrated into the free IUCLID software platform, which is supported by a help desk and widely used by industry and regulatory authorities. Broader adoption of OHTs and IUCLID in non-European jurisdictions is expected to further enhance international data interoperability and regulatory alignment.</p> <p>EPA acknowledges the need for clear TSCA guidelines on OECD formatting to ensure consistent submissions and to enable compliance with this requirement. While EPA has not developed a detailed TSCA-specific OHT guidance document at this time, EPA's website (Final Rule: Requirements for Confidential Business Information Claims under TSCA US EPA) offers information on OECD and International Uniform Chemical Information Database (IUCLID) formats, including details on implementation, requirements, and other resources to aid in understanding OECD/IUCLID formats. More information regarding the flexibilities of the OECD OHT formats can also be found at OECD's website (OECD Harmonised Templates). Further, IUCLID training materials, webinars, and video tutorials on data entry and software use are available at IUCLID 6 Website. EPA is coordinating with external stakeholders to support IUCLID efforts.</p> <p>Because EPA has not yet released a detailed, TSCA-specific instructions for choosing, populating, and submitting OHTs, EPA intends to be flexible in the initial implementation of this new requirement.</p>
5	Update to Guidance on Non-Emergency Situations Involving Environmental Contamination	3M	<p>Comment: "Non-emergency situations involving environmental contamination: EPA issued a Policy Clarification and Reporting Guidance in 2003 (68 FR 33129) that described criteria for reporting non-emergency situations of chemical contamination involving humans and/or the environment. These criteria are used to evaluate several different types of information, including environmental monitoring studies, epidemiology studies, exposure information, and biomonitoring information. EPA's reporting guidance includes several factors, including whether the contamination is widespread and previously unsuspected, the degree of hazard associated</p>

			<p>with the substance(s), and the degree of actual or likely exposure. Evaluation of these factors, separately and in combination, is subjective and requires the exercise of professional judgment upon which reasonable minds can differ. Companies subject to Section 8(e) reporting requirements would benefit from updated guidance/rule that establishes clearer thresholds for reporting based on EPA’s experience in receiving and evaluating this information in the twenty-two years since the 2003 Federal Register notice was published.”</p> <p>Response: EPA acknowledges that its 2003 Policy Clarification and Reporting Guidance needs an update. EPA is working on this update and will consider the feedback provided by stakeholders during this process, as well as information obtained from internal review of previously received TSCA section 8(e) submissions. EPA understands that enhanced clarity regarding TSCA section 8(e) reporting requirements is an important step in reducing industry and EPA burdens related to the submission and processing of TSCA section 8(e) data and therefore strives to provide clear guidance on reporting requirements and thresholds for interpreting hazard and exposure data for the purposes of TSCA section 8(e) reporting.</p> <p>EPA is targeting publication of a draft updated TSCA Section 8(e) Reporting Guidance in 2026. Upon publication of the draft reporting guidance, stakeholders will receive an opportunity to review and provide feedback.</p>
6	Outdated IUCLID Software	3M	<p>Comment: “EPA requires submission of OHTs for certain study reports. These files are typically prepared using IUCLID software developed and maintained by the European Chemicals Agency (ECHA). ECHA periodically updates IUCLID, and the new versions of the software have limited backwards compatibility.</p> <p>EPA has indicated in past discussions with the American Chemistry Council that it uses an older version of IUCLID and does not currently have plans to keep its version in sync with the latest version published by ECHA. This means that companies will need to maintain a separate instance of the older IUCLID software dedicated to generating OHTs for TSCA submissions. This represents additional costs and burdens in terms of time and IT support. This may involve capital costs for purchasing an additional server, or it could involve external service costs to backup information to a cloud-based server.</p> <p>These are unnecessary costs and burdens, in 3M’s view. 3M strongly recommends that EPA include IUCLID updates in its resource planning to avoid companies needing to maintain separate</p>

			<p>instances of IUCLID and OHTs for TSCA purposes compared to other global submissions.”</p> <p>Response: Maintaining updated IUCLID software is important for EPA to minimize the burden on submitters of providing OHTs for TSCA section 8(e). EPA has prioritized reducing industry burdens associated with TSCA section 8(e) and has recently updated its version of IUCLID to one version below the most recent version. This update resulted in technical issues that EPA is currently working to address before attempting further updates. As issues are addressed, EPA intends to continue performing regular updates to align with the latest versions of IUCLID published by ECHA . EPA will provide information to submitters on which versions of IUCLID are preferred/acceptable as these updates are completed.</p>
7	Data Utilization	ACC	<p>Comment: ACC encourages the Agency to use data submitted under TSCA 8(e) to evaluate whether risk management decisions for new chemicals were scientifically justified and aligned with actual exposure and hazard information. This approach strengthens EPA’s decision-making and helps ensure that regulatory actions on new chemicals remain appropriate and effective in protecting human health and the environment.</p> <p>ACC supports the annual review of submitted 8(e) data and recommends the following enhancements to the process:</p> <p>Benefits of Annual Reviews:</p> <ol style="list-style-type: none"> 1. Improve Regulatory Decision-Making: Identify patterns of overly conservative or insufficiently protective decisions and adjust future practices accordingly. 2. Promote Efficiency: Reassess whether existing restrictions remain scientifically justified based on new data. 3. Enhance Transparency and Accountability: Promote a data-driven approach for refining the New Chemicals review process. 4. Prevent Overregulation: Avoid unnecessary barriers to innovation by removing outdated or unsupported restrictions. 5. Support Science-Based Regulation: Integrate real-world exposure data into future risk assessments, reducing reliance on models and assumptions. <p>Recommendations:</p> <ul style="list-style-type: none"> • Establish an Annual Review Process: Systematically evaluate the previous year’s 8(e) submissions against past new chemical determinations.

			<ul style="list-style-type: none"> • Develop a Mechanism for Regulatory Adjustments: Create a streamlined process for industry to request modifications to SNURs or consent orders based on new data. • Increase Transparency: Publish annual summary reports detailing findings and any regulatory changes. • Stakeholder Engagement: Provide opportunities for submitters to offer input on the alignment of past decisions with current scientific evidence. <p>An annual review process will improve the scientific integrity and efficiency of EPA's New Chemicals Program and help ensure that regulatory decisions remain grounded in current data.</p> <p>Response: Between 2004-2016, EPA evaluated risk management decisions made through the New Chemicals Program using TSCA section 8(e) data annually. In these reports, EPA aligned incoming TSCA section 8(e) submissions with completed new chemical reviews that had been finalized before receipt of the TSCA section 8(e) submission. Matching records were then compared to determine if the new chemical review accurately identified the nature of the hazard apparent in the TSCA section 8(e) submission and the combined results were used to determine a performance measure success rate for the new chemicals program. The current 8(e) management team is aware of these historical reports and intends to implement a modernized process to continue developing them in collaboration with TSCA new chemicals staff. In the past, this report was for internal use only, but as EPA revitalizes this effort, additional options to provide CBI-protected summaries of this evaluation to the public will be considered. Opportunities to engage with stakeholders on this effort will also be explored. In the meantime, note that sanitized versions of all incoming TSCA section 8(e) submissions are available to the public at EPA's ChemView website for review and analysis.</p>
8	Burden and Cost Estimates	ACC	<p>Comment: EPA states its burden and cost estimates are robust, reasonable, and its practices have withstood reviews by the Office of Management and Budget (OMB) through ICR renewals. ACC believes that EPA should consult those stakeholders most likely to be impacted directly by the obligations imposed by TSCA Section 8(e) (i.e., chemical manufacturers and processors).</p> <p>Response: The Office of Management and Budget (OMB) requires federal agencies to consult with nine or fewer potential respondents prior to submitting the ICR renewal to OMB for review and approval. EPA specifically solicits feedback from the consulted stakeholders regarding burden and cost estimates as part of this process. In compliance with this requirement, EPA sent out consultation questions to nine TSCA section 8(e) stakeholders in July 2025. These stakeholders</p>

			<p>were selected as those most likely to be impacted as chemical manufacturers and reporters in the US. A subset of the questions included as part of this feedback solicitation specifically asked whether the burden and cost estimates present in the ICR renewal are accurate. Stakeholders who may not have received these consultation questions were also welcome to provide any concerns regarding burden and cost estimates via the normal public comment period, as announced in the Federal Register notice (90 FR 29005) for this ICR renewal.</p> <p>EPA received responses from two of the stakeholders that received the consultation questions. Both stakeholders expressed minor concerns regarding the burden and cost estimates which EPA has addressed in response to those comments. These comments and EPA's responses are publicly available in the docket. Based on the responses received, EPA maintains that its cost and burden estimates for this ICR renewal are reasonable and accurate.</p>
9	Increased Burden of Transition to Electronic Submissions	Syngenta	<p>Comment: We strongly support the transition to web-based forms and XML submissions as a modern, efficient alternative to paper-based processes. These digital platforms offer significant advantages in terms of speed, accessibility, and data consistency, and they align well with broader efforts to streamline regulatory reporting.</p> <p>It should be noted however that for electronic reporting to be widely adopted and successful, the user interface must be intuitive, responsive, and easy to navigate. If the system is overly complex, time-consuming, or prone to technical issues, it can discourage use and lead to incomplete or inconsistent submissions.</p> <p>The transition to electronic submissions may and likely will require substantial investments for organizations. Organizations must invest in IT infrastructure, including software development or procurement, system integration, and security measures. Additional expenses involve implementation costs such as validation, data migration, and comprehensive staff training programs. Ongoing operational costs encompass system maintenance, technical support, and continuous training needs. However, these investments typically yield long-term benefits through reduced manual processing, improved data quality, faster submission times, and better regulatory compliance</p> <p>Response: EPA transitioned to electronic submission more than a decade ago. As electronic submission via EPA's CDX platform is required by other TSCA programs under which TSCA section 8(e) reporters are reporting, EPA believes any burdens associated with this transition have already</p>

		<p>been incurred or are attributable elsewhere. EPA's intention in transitioning to electronic submissions was to decrease the burden on submitters of printing and mailing paper copies of submissions. EPA has historically received positive feedback from stakeholders regarding increased time savings and cost savings related to this transition.</p> <p>EPA acknowledges past challenges associated with using EPA's CDX system. EPA actively addresses issues as they arise and works to ensure submissions are accurate and submitted on schedule. Recent improvements to the CDX system include but are not limited to:</p> <ul style="list-style-type: none">• Substantiation field sizes were increased. This will allow submitters to provide more detailed information and addresses issues when opting out of supplying substantiation,• Updates on the validations process were made on the submitter information screen to improve functionality and,• Resolution of various submission-related issues to improve system reliability. <p>EPA has received \$17M of funding from Congress for a modernized IT system, and addressing challenges associated with CDX is a priority with this funding. EPA will continue to engage with stakeholders and adopt solutions to minimize reporting delays during these ongoing IT modernization efforts.</p>
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