

**Consultation Questions for “Notification of Substantial Risk of Injury to Health and the Environment under TSCA Section 8(e)”**

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**(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?

Under TSCA Section 8(e), persons do not have to disclose information if the ‘Administrator has been adequately informed of such information[.]’ In guidance, EPA purports to offer criteria to assist the regulated community in understanding what Congress meant by ‘adequately informed of such information.’ 3M applies these criteria when determining whether to submit information under TSCA Section 8(e).

- 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?)

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**(2) Frequency of Collection**

Can the Agency collect the information less frequently and still produce the same outcome?

TSCA Section 8(e) requires companies to “immediately inform the Administrator” of information that reasonably supports the conclusion that a substance or mixture presents a substantial risk of injury to health or the environment. 3M believes the reporting deadlines described in EPA’s current guidance (*i.e.*, immediately for emergency incidents of chemical contamination, within 90 calendar days of receipt for information regarding non-emergency incidents of environmental contamination that are subject to other statutory reporting requirements, and within 30 calendar days for other types of information) are appropriate.

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**(3) Clarity of Instructions**

- A. The ICR is intended to require that respondents provide certain data so that the Agency can utilize them.

- B. Based on the instructions (guidance documents, Federal Register Notices etc.), is it clear what you are required to do, and how to submit such data? If not, what suggestions do you have to clarify the instructions?

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 Some of EPA's guidance has been rescinded, reinstated, and modified over time.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.

Within the current guidance, EPA has established thresholds for reporting certain categories of information, such as acute toxicology studies in experimental animals. Guidance for other categories of information, such as exposure data and environmental monitoring data, is more subjective and subject to professional judgment. 3M recommends the following as areas that would benefit from further guidance and clarification:

- **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.
- **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 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.

In addition, 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:

- 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).

3M encourages the Agency to complete and publish this guidance as soon as possible.

EPA’s instructions for submitting information via CDX are clear.

C. Do you understand that you are required to maintain records?

Yes.

D. Considering that there is no required submission format, is it difficult to submit information in ways that are clear, logical, and easy to complete?

In general, no. The flexibility in submission format makes it easier to submit information that is clear and logical. As noted above, 3M believes there are opportunities for EPA to clarify requirements for OHTs (as stated above in response to Question 3B), which do have formatting requirements based on the software used to generate them.

E. Are there forms associated with this process? Do you use them? Are they clear, logical, and easy to complete?

3M utilizes the CDX submission forms for this process. In general, the forms are clear, logical, and easy to complete.

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#### **(4) 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 over the Internet.

- A. What do you think about electronic alternatives to paper-based records and data submissions? Current electronic reporting alternatives include the use of web forms/XML based submissions via the Agency's Internet site?

3M utilizes CDX for its TSCA 8(e) submissions and maintains electronic copies of the underlying studies and other information. 3M does not submit or maintain paper-based records for current information subject to TSCA Section 8(e).

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

Yes. Copies of records from CDX are in .pdf format. Other related records are in .pdf, .xlsx, .ppt, and .doc formats.

- C. What benefits would electronic submission bring you in terms of burden reduction or greater efficiency in compiling the information?

In general, electronic submission has been an efficient method of submitting TSCA 8(e) information to EPA. 3M has experienced time and cost savings compared to older submissions that had to be printed and mailed to the Agency.

However, 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.

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## (5) Burden and Costs

- A. Are the labor rates accurate? (Please see question 12 of the supporting statement)

3M salary ranges either meet or exceed each of the industry job categories based on overall compensation rate.

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

There are potential capital costs associated with this activity. Please see the response to D. below for additional information.

- 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.

The estimated burden hours are reasonable, in 3M's experience.

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

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.

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.

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 instances of IUCLID and OHTs for TSCA purposes compared to other global submissions.



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**Via Regulations.Gov and Email**

7 August 2025

Document Processing Desk  
Office of Chemical Safety and Pollution Prevention  
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1200 Pennsylvania Avenue, NW  
Washington, DC 20460-0001

Attention: Carolyn Hammack

**SUBJECT: Response to Information Collection Request (ICR) – TSCA Section 8(e)**

Dear Ms. Hammack

Thank you for the opportunity to participate in the consultation process for the renewal of the Information Collection Request (ICR) titled "Notification of Substantial Risk of Injury to Health and the Environment under TSCA Section 8(e)" (OMB Control No. 2070-0046).

We appreciate EPA's efforts to engage stakeholders in this important process and recognize the value of ensuring that the ICR reflects practical, efficient, and scientifically sound approaches to data collection and reporting.

Please find our responses to the consultation questions attached to this letter. We hope our input will be helpful in refining the ICR and supporting EPA's continued efforts to protect human health and the environment through effective implementation of TSCA Section 8(e).

Sincerely,

A handwritten signature in black ink that reads "Montague Dixon". The signature is written in a cursive, flowing style.

Montague Dixon  
US Regulatory Compliance Lead

Enclosure

Attachment 1

Syngenta Crop Protection Responses EPA ICR No. 0794.18

**Consultation Questions for “Notification of Substantial Risk of Injury to Health and the Environment under TSCA Section 8(e)”**

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**(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?

Syngenta Response

Yes (potentially)

- 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?)

Syngenta Response

There is potentially TSCA 8e relevant information available in other databases maintained by federal agencies and international organizations including:

- **National Technical Information Service (NTIS)**  
Repository of scientific, technical, engineering, and business-related information, including chemical safety data.
- **National Library of Medicine (NLM)**  
Hosts toxicological databases such as TOXNET and HSDB, offering peer-reviewed data on thousands of chemicals.
- **ECHA REACH Database**  
Comprehensive EU chemical registration data, including hazard, use, and safety information submitted under REACH.
- **OECD eChemPortal**  
Aggregates chemical hazard data from global regulatory bodies, including EPA, Health Canada, and Japan’s NITE.
- **Hazardous Substances Data Bank (HSDB)**  
Maintained by NLM, provides detailed toxicological profiles for over 5,000 substances.
- **International Chemical Safety Cards (ICSCs)**  
Concise workplace safety summaries developed by WHO and ILO for commonly used chemicals.

- **JMPR & JECFA Monographs**  
WHO/FAO toxicological evaluations of pesticides and food additives used in international food safety standards.

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**(2) Frequency of Collection**

Can the Agency collect the information less frequently and still produce the same outcome?

No response.

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**(3) Clarity of Instructions**

- A. The ICR is intended to require that respondents provide certain data so that the Agency can utilize them.
- B. Based on the instructions (guidance documents, Federal Register Notices etc.), is it clear what you are required to do, and how to submit such data? If not, what suggestions do you have to clarify the instructions?

Syngenta Response

Yes, the current guidance is generally clear and effective.

- The TSCA Section 8(e) submission portal is user-friendly and facilitates straightforward notification submissions.
  - Previously, we included a separate three-page justification statement with mailed submissions. Now, the portal integrates justification prompts directly into the submission workflow.
  - This built-in structure has improved the thoroughness and consistency of our responses, ensuring we meet the required standards without needing to reference external templates.
- C. Do you understand that you are required to maintain records?

Syngenta Response

Yes

- D. Considering that there is no required submission format, is it difficult to submit information in ways that are clear, logical, and easy to complete?

Syngenta Response

Submitting TSCA 8(e) reports is a straightforward process, with flexible formatting requirements that enable clear and concise submissions. We typically include detailed study summaries, and in most cases, can effectively convey all necessary information within a one-page format that meets reporting requirements without compromising clarity.

- E. Are there forms associated with this process? Do you use them? Are they clear, logical, and easy to complete?

Syngenta Response

We are not aware of specified forms to be used with this process.

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**(4) 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 over the Internet.

- A. What do you think about electronic alternatives to paper-based records and data submissions? Current electronic reporting alternatives include the use of web forms/XML based submissions via the Agency's Internet site?

Syngenta Response

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.

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.

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

Syngenta Response

We utilize a cloud-based content and data management platform as well shared drives and other platforms.

C. What benefits would electronic submission bring you in terms of burden reduction or greater efficiency in compiling the information?

Syngenta Response

The transition to electronic submissions, particularly through web-based forms and XML formats, has strong potential to enhance regulatory efficiency in several key ways:

- Streamlined Data Entry: Structured digital forms reduce ambiguity and standardize how information is submitted, making it easier to interpret and process.
- True Digital Submissions: Unlike PDF documents which are merely electronic versions of paper forms, structured data formats (XML, JSON) enable machine-readable submissions that can be automatically processed and validated. This distinction is crucial as PDFs still require manual review and data extraction.
- Automation of Reviews: XML-based submissions enable automated parsing and validation, allowing agencies to quickly flag incomplete or non-compliant entries and prioritize high-risk cases.
- Database Integration: Electronic formats facilitate direct integration into centralized databases, eliminating the need for manual data entry or "cut and paste" activities that are time-consuming and error-prone.
- Improved Searchability and Analytics: Digitally submitted data can be indexed, queried, and analyzed more effectively, supporting faster decision-making and better trend analysis."

However, for these benefits to be fully realized, the user interface must be intuitive and efficient. If the system is difficult to navigate or overly complex, it can hinder adoption and reduce the quality of submissions. A well-designed interface ensures that users can focus on the content of their reports rather than struggling with the mechanics of submission.

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**(5) Burden and Costs**

- A. Are the labor rates accurate? **(Please see question 12 of the supporting statement)**

No response

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

No response

- 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.

No response.

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

Syngenta Response

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.