Test Orders Under TSCA Section 4: Questions and Answers

Section 4 of the Toxic Substances Control Act (TSCA) allows the United States Environmental Protection Agency (EPA) to require chemical manufacturers (including importers) and processors to develop information on existing chemicals and submit such information to EPA.

Under Section 4(a) (15 U.S.C. 2603(a)), pursuant to specific statutory requirements, EPA may issue an order requiring the development of information on a chemical. This *Questions and Answers* document is intended to help clarify the requirements of such an Order.

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The contents of this document do not have the force and effect of law and are not meant to bind the public in any way. This document is intended only to provide clarity to the public regarding existing requirements under the law or agency policies. The statements in this document are intended solely as guidance to aid in complying with EPA regulation.

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These Questions and Answers (Q&As) are intended to clarify the testing requirements and notification process questions for individuals subject to Toxic Substances Control Act (TSCA) Section 4 Test Orders. Section 4 of TSCA allows EPA to require chemical manufacturers (including importers) and processors to develop information on chemical substances and submit such information to EPA.

These Q&As should be used for general information only and are not a substitute for the requirements in a specific TSCA Section 4 Test Order. Please carefully review the applicable Test Order for specific information on how to comply with its requirements.

For more help, visit EPA's Section 4 Test Order website, contact EPA's TSCA Hotline (tsca-hotline@epa.gov or 202-554-1404) or send an email to TSCATestOrders@epa.gov.

Document Overview:

1. General Questions Related to Test Orders

1.1 Does a company need to notify EPA that they have received the Order?

The Order provides the procedures on how a company needs to notify EPA, including a deadline by which they must provide an initial response to the Order. This initial response also serves to indicate that the company has received (and acknowledged) the Order. EPA encourages Order recipients to contact EPA should they have questions regarding the Order.

1.2 A company processes the chemical substance subject to the Test Order but does not manufacture or import it. Are processors of a chemical substance required to respond to an Order?

An Order may be issued to companies that manufacture (including import) and/or process the subject chemical substance(s). Review the Order to determine whether it applies to manufacturers, processors, or both manufacturers and processors. Additionally, in some orders the requirements for manufacturers and processors may differ.

Note that a company should consider its responsibilities relating to the Order separately from other TSCA activities. For example, manufacturing and/or processing activities involving a chemical substance subject to an Order may result in them being subject to the Order's requirements even though they may not have been included on the final list of manufacturers subject to fee payment obligations for chemical substances subject to EPA-initiated risk evaluations (see 40 CFR 700.45(b)).

Note that a company may claim that they are not subject to the Order if they do not manufacture or process the subject chemical substance or they believe the Order was otherwise sent to them in error. An explanation of the basis for the claim, along with appropriate supporting information to substantiate that claim, must be submitted using the Central Data Exchange (CDX) portal so that EPA can evaluate the claim. See the Order for details on this response option.

1.3 A Test Order has multiple tests. Does a company prepare one response that addresses all of the individual tests? Or does a company prepare an individual response for each of the tests?

Each Order specifies all of the tests required under the Order. If there are multiple tests that apply to a company, an option must be selected for each test and the options selected for all the tests are required to be included in the response.

1.4 If a company imports a finished product that includes the chemical substance subject to a Test Order, is the company still subject to a Test Order which identifies manufacturers as subject?

Import is a manufacturing activity under TSCA. Importers are therefore subject to the Test Order (and all corresponding fees) as manufacturers. A recipient of an Order who is an importer of record of a chemical substance identified by the Order is responsible for testing requirements of the Order, even if the recipient does not store, handle, use, or otherwise directly deal with the chemical. Test Orders issued to date have not made an exception for import as part of an article.

1.5 Why does EPA include processors in the scope of a particular test order?

Processors may be made subject to a Test Order where EPA identifies processing as a condition of use. These conditions of use are used to determine the pathways through which a person or the environment could be potentially exposed to this chemical.

2. Submission of Existing Data

2.1 Given that some of the chemicals receiving Test Orders are currently, or have been, evaluated by regulatory authorities in Europe and elsewhere, how much has the Agency considered whether the existing information for a chemical substance is sufficient? Is the Agency able to obtain any of that information on its own or is it reliant on companies to obtain the information for them?

Through the EPA's Systematic Review process, the Agency evaluates reasonably available information. However, note that the Agency may not be aware of all data that is available and/or may not be able to access all data that may have been provided to other entities. To this end, EPA encourages companies to submit existing information believed to be responsive to the Test Order as companies may be in possession of studies unknown or inaccessible to the Agency.

If the Agency finds sufficient information, it does not require testing for that information. Therefore, requiring a certain test signifies that the reasonably available information reviewed by the Agency was not sufficient for the needs of the risk evaluation.

3. Fees Associated with the Order

3.1 Does a company pay the fee associated with the Test Orders via the CDX website? How is this different than paying for the TSCA EPA-Initiated Risk Evaluation fees?

Fees for Test Orders under TSCA Section 4 will be invoiced electronically by EPA. Invoice notices will be populated into the specific user's "Copy of Record" screen in CDX and will contain a button that will initiate the payment process. When an invoice is generated, notification e-mails will be sent to the user's CDX inbox and the e-mail address associated with the relevant CDX account. Payment information will be collected in CDX and then submitted to Pay.gov for processing. Users should

not attempt to make payments directly to Pay.gov. For more information, please refer to TSCA Fees: Accessing and Submitting Payment for an Initial Response in CDX (note that this guidance refers specifically to fees for EPA-Initiated Risk Evaluations under TSCA rather than fees for Test Orders; however, the company follows the same process for paying a TSCA-related fee, selecting the Test Order fee rather than the Risk Evaluation fee).

Companies will be invoiced for their portion of the fee associated with the TSCA Section 4 Test Order. The fee applies to manufacturers (including importers) who develop information in compliance with the Order and will be evenly split across such companies (accounting for small business considerations) unless a consortium is formed to split the cost of the applicable fee, in which case the consortium, after first notifying EPA that a consortium has been formed, will determine how fees will be split among members of the consortium. See 40 CFR § 700.45 for information concerning the fees.

Note that there are a variety of fees associated with TSCA-related activities: https://www.epa.gov/tsca-fees/tsca-fees-table. For example, companies may have already received an invoice for the fee associated with the EPA-Initiated Risk Evaluation for the chemical substance. See this page for information on this fee: https://www.epa.gov/tsca-fees/final-list-fee-payers-next-20-risk-evaluations. As provided on this page, for EPA-initiated risk evaluations under TSCA Section 6, the total fee amount is $1,350,000. The total fee amount is shared amongst the manufacturers/importers identified on the final fees list for the risk evaluation. The amount each entity is responsible for varies depending on the total number of fee payers identified, and the number of entities identified as "small business concerns."

4. Company Ownership Scenarios

4.1 The Order lists two companies, one of which is the parent for the wholly owned subsidiary. One company received an email on behalf of both companies, but there is only one facility. Which must report to the Order?

The parent company will ultimately be responsible for the testing requirements of this Order. However, the wholly owned subsidiary must still complete a response to the Order.

The wholly owned subsidiary may respond to claim that they are not (separately) subject to this Order with the justification that they are a subsidiary of a company that is also a recipient of the Order and will be completing the required testing and therefore the testing would be duplicative. An explanation of the basis for the claim, along with appropriate supporting information to substantiate that claim, must accompany the response in the CDX portal so that EPA can evaluate the claim. This response must be submitted in the CDX portal by the deadline provided in this Order.

If EPA cannot verify the claim, the original requirements and deadlines in the Order remain. If the claim is approved, EPA will notify the company that they are not subject to this Order.

5. Consortia

5.1 What support is EPA providing to support consortia building?

EPA encourages consortia building. As a courtesy, the Agency is providing a way for companies to take the initial step of signaling to other companies their interest in forming consortia with those other companies. Should a company wish to join a consortium, they may contact the Toxic Substances Control Act (TSCA) Hotline. When a company contacts the Hotline, they can request to be added to a list of companies seeking to join a consortium for a given Test Order to signal the company's interest in forming a consortium for that Order and/or they can request to receive a current version of the list for a specified chemical substance. This list will be a living document and will continue to be updated indefinitely. A company can contact the TSCA Hotline by emailing tsca-hotline@epa.gov or calling (202) 554-1404. The TSCA hotline operates Monday through Friday, from 8:30 a.m. to 5:00 p.m. Eastern time.

5.2 Can a company do some of the studies themselves and join a consortium for other studies?

A company may choose a different response option for each of the tests required by the Order. A company claiming that it is Not Subject to the Order responds to the Order as a whole and thus would not select different response options for each testing requirement.

For companies that join a consortium for purposes of responding to the Order, the Consortium Lead's response must confirm the formation of the consortium, identify its member companies, and list the testing obligations that the consortium plans to fulfill on behalf of each company by indicating each specific test. Note that in order for a Consortium Leader to be able to identify its member companies by Test Order number, the consortium members must already have responded to the Order indicating that they will be joining a consortium for the relevant test(s).

5.3 How does a staff person for a trade organization representing companies subject to the Order build a Test Order Consortium in CDX?

Trade organization staff can create a consortium initial response by selecting 'Consortium Response to Order' from the Submission Type list in the Section 4 Order application. The organization representative will be prompted to provide a consortium name and enter in the Test Order number for each consortium member. Please be aware that each consortium member must have already submitted their own response indicating that they are joining a consortium for at least one test within the Order. Complete the remaining information and submit.

5.4 When companies individually provide a response, do they need to specify the name of the consortium they are joining or just that they are joining a consortium?

Consortium members will simply indicate that they are joining a consortium using the testing-specific drop-down menus within their individual response. Consortium leads will have to select the Consortium response to Order response type *and* provide the unique Test Order Numbers of the companies who will be joining their consortium. Because these Test Order Numbers are only provided to the companies to which they pertain, this will ensure that members and leads have coordinated with one another in the decision to form a consortium. Be sure to use the Test Order Number that matches the identifier that the consortium member used when it responded to the Order, for EPA issued two unique Test Order Numbers to each recipient, one for the recipient to use to

indicate its status as a manufacturer and the other to respond as a processor. The participation of consortium members in consortia will be confirmed based on the submission of the lead.

6. Fulfilling Test Order Requirements

6.1 Can EPA provide a list of laboratories and equipment suppliers that will conduct the testing on the chemical substance subject to the Order?

At this time, EPA is not able to provide a list of laboratories to a company. The Agency is looking into what resources it might be able to provide on this topic.

For more information, please refer to the Good Laboratory Practices Standards Compliance Monitoring Program.

6.2 How can a company be assured that the testing it is conducting will satisfy the Test Order requirement?

Companies are required to submit draft and final study plans for EPA to review before commencing testing. In developing the study plans, entities should review the required test protocol or guideline and ensure they are following or including all study plan parameters as required in the Order before submitting them to EPA. Study plan submissions should be robust and detailed, those that do not meet the basic criteria outlined in the Order will not qualify as meeting the study plan deadline and will not be considered an acceptable submission and will not be reviewed by EPA.

Once a study plan is approved by EPA, the testing should strictly align with the EPA-approved study plan. If any technical difficulties are experienced during testing that would cause deviation from the approved study plan, EPA should be informed immediately, otherwise, the entity risks ultimately not complying with the testing requirement. After EPA receives final reports of required tests, the Agency will review them and inform the entity if they have fulfilled their testing requirement. This process is necessary to produce high quality data to inform the TSCA section 6 risk evaluation.

6.3 Can recipients of an Order modify their study plans in any way?

Recipients may modify their study plans and submit modified study plans through CDX for approval in the draft study plan phase. If the modified study plans are found to have acceptable modifications, EPA will approve such study plans for use by companies. If EPA finds the modifications unacceptable, the Agency will provide comments. In that case, the company should submit a new study plan that addresses EPA's comments for the Agency to review and determine if acceptable. Testing should not be commenced until EPA approves the company's study plan.

7. Submission of Tests

7.1 What file formats are acceptable for test data submission in CDX?

EPA will accept study reports in the file types: i5z, i6z, Word, Excel, and PDF. Where appropriate, the report must use the OECD Harmonized Template reporting format, and the underlying data should be submitted for a required test. Consult the Order to determine whether the OECD Harmonized Template is required for a given submission.

Please note, there is no limit on the number of documents that may be submitted, however, the maximum capacity per submission is 600MB. Should you experience technical difficulties when submitting your information, please visit the CDX Help Desk at: https://cdx.epa.gov/Help.