TSCA Section 4 Test Orders

Information for entities subject to Orders under
EPA's TSCA Section 4(a) authority

December 2021

Agenda

- Test Order Authority under the Toxic Substances Control Act (TSCA)
- Understanding Test Orders, Issuance, and Recipient Responsibilities
- Responding to a Test Order (4 options)
- Building Consortia
- TSCA User Fee
- Additional Test Order Resources

TSCA Section 4 Test Order Background

- **Authority**: Under **TSCA Section 4**, EPA has authority to require the generation of new information by chemical manufacturers (including importers) and processors:
  - TSCA Section 4(a)(1), where insufficient information exists, testing is necessary to get that information, and:
    - (i) the chemical substance may present unreasonable risk, or
    - (ii) the chemical substance is produced in substantial quantities and may cause substantial or significant exposures to the environment or humans
  - TSCA Section 4(a)(2), supports certain activities undertaken to specific provisions of TSCA and other federal law

Why are Test Orders Important?

- Under TSCA Section 4(a), Test Orders are important because they provide a means for EPA to secure the information needed (i.e., chemical testing data) to make decisions and/or conduct certain activities that support EPA's mission (e.g., conducting a risk evaluation)

How Are Test Order Recipients Identified?

- EPA assesses publicly available data and data collected via its various authorities to identify entities/recipients. Examples include:
  - **Chemical Data Reporting (CDR):** manufacturers (including importers) provide EPA with information on the production and use of chemicals in commerce. The information is collected every four years on certain chemicals in commerce.
  - **Toxics Release Inventory (TRI)**: an inventory of toxic chemical releases and pollution prevention activities are reported to EPA by industrial and federal facilities.
  - **TSCA 8(e) Notices:** EPA is immediately notified when substances or mixtures present a substantial risk of injury to health or the environment.

What is Required to be Compliant with the Order and Avoid an Enforcement Action?

STEP 1: Identify as a Manufacturer, Processor, or both - You must identify as a manufacturer, processor, or both via EPA's CDX portal. Deadline is within 30 days of the effective date of the Order

- EPA's CDX Portal: https://cdx.epa.gov. New CDX Users must register via EPA's CDX Portal. Instructions are provided in the CDX User Guide
- Effective date of the Order is five calendar days after the Order's signature

What is Required to be Compliant with the Order and Avoid an Enforcement Action?

STEP 2: Responding to the Order - You must respond to the Order via EPA's CDX portal. Deadlines vary per response option, and are measured in calendar days:

- Option 1 – Develop the Testing Information **(respond within 65 days)**
- Option 2 – Submit Existing Information **(respond within 30 days)**
- Option 3 – Request an Exemption & Provide Rationale **(respond within 65 days)**
- Option 4 – Claim Not Subject to the Order **(respond within 45 days)**

Option 1 – Develop the Information

Respond to indicate intent to:

- **Develop the Information**
- **Join consortium for a specific test or tests**

Option 1 – Develop the Information (continued)

Examples of Required Testing include:

- Physical/Chemical Properties
- Fate Properties
- Health Effects
- Environmental Hazard
- Occupational Exposure
- Consumer Exposure

Option 2: Submit Existing Information

- Submit an existing study and/or other relevant information that you believe EPA has not considered
  - Include supporting rationale
- **EPA Review of Submissions of Existing Information**:
  - Based on the weight of the scientific evidence using all relevant information reasonably available to the Agency (40 CFR 702.33)
  - If submitted information is deemed **acceptable,** EPA will repeal all obligations of the Order that the submitted study and/or relevant information fulfills
  - If EPA determines that the submitted information is **not acceptable**, another response option must be submitted 10 days within EPA's rejection of the submitted existing information

Option 3: Request an Exemption & Provide Rationale

- Apply for an exemption from a requirement (TSCA Section 4(c)(1))
- An application for an exemption must:
  - Provide/indicate that information on an equivalent chemical has been submitted or is being developed in accordance with an action under TSCA section 4(a) and that submission of information by the exemption applicant would be duplicative of information which has been submitted or is being developed in accordance with such an action
  - Identify who has submitted or is developing the information
  - Include a sworn statement to pay fair and equitable reimbursement to the person(s) who incurred or shared in costs to submit information
- EPA may terminate the exemption if it determines that none of the companies identified in the exemption request have complied with the Order (i.e., submitted or developed information the Order required)

Option 4: Claim that you Are Not Subject to the Order

- Claim that you are not subject to the Order by attesting that your company has not manufactured (including imported) and/or processed the chemical identified by the Order within the period of time provided by the Order and does not intend to manufacturer or process this chemical
  - Attach supporting attestation on company letterhead signed by an appropriate company official
- If your claim is approved, EPA will notify you of its determination (i.e., whether or not you are subject to the Order)

Once I Submit a Response in CDX, What Should I Expect Next?

- You will receive an automated validation email from EPA's CDX system. Save this email for your records!
- Once EPA has reviewed your response, expect to receive a response from TSCATestOrders@epa.gov, either:
  - Requesting additional information to substantiate and/or clarify your response; or
  - Confirming receipt of a well substantiated response, requiring no further action under the Test Order
- Deadlines for submitting to EPA will be automatically extended should EPA fail to respond within the timeframe provided in the Test Order

EPA Encourages Consortia Building

Why?

- Avoid unnecessary duplication of tests
- Opportunity for facility-specific or product-specific data to be used efficiently (e.g. a single dataset may be amenable to “read-across” to multiple facilities provided similarity can be demonstrated)
- Consolidate testing costs
- Minimize competition for laboratory services
- More efficient correspondence with EPA

How to Signal Interest in Starting or Joining a Test Order Consortium to other Companies?

- Contact the TSCA Hotline at: tsca-hotline@epa.gov or (202) 554-1404

Once Your Consortium is Formed, Inform EPA that You will be Responding via Consortium

- Order recipients that join/form testing consortia must **each individually** inform the EPA (via CDX):
  - for each specific chemical; and
  - for each specific test
- The designated lead for the consortium must also submit to EPA (via CDX):
  - a **consortium initial response**
  - study plans and final study reports in accordance with the requirements of the Order
- All members of the consortium are liable in the event of any failure of the consortium to comply with the Order

TSCA Fees for Orders

- **Who Pays?** Manufacturers subject to a TSCA Section 4 Order
- **Fee Amount:** $11,650 split amongst all manufacturers subject to each Order
- **Deadline for Fee Payments:** Within 120 days of issuance of Order (invoice will provide the deadline)
- **How to Pay Fees:** By responding to the invoice that will be sent by EPA via CDX
  - **Note:** Companies may form consortia to pay this fee that are distinct from consortia used for fulfilling Order requirements

Additional Resources

- TSCA Webpage
- How EPA Evaluates the Safety of Existing Chemicals Webpage
- TSCA Section 4 Test Orders Webpage
- TSCA Fees for Test Orders and Enforceable Consent Agreements
- Quality Data: An Essential Element of Chemical Safety
- U.S. Code Version of TSCA
- Test Order Q & As
- CDX User Guide

Appendix

Please note that EPA has modified aspects of Test Orders as compared with Test Orders issued in January 2021

- EPA removed the cease manufacturing and/or processing response option
- Each recipient must identify, in CDX, as a manufacturer and/or processor
- Deadlines for response options have changed
- EPA will only provide automatic extensions to deadlines for submissions received by specified deadlines should EPA fail to respond within 15 days of the deadline
- Requirement to use OECD harmonized template, if available, when submitting developed data