

Overview on Activities Involved in Issuing a TSCA Section 4 Order

The 2016 amendments to section 4 of TSCA provided EPA with the authority to issue test orders (Orders), in addition to rules. Prior to issuing an order, the law requires that EPA make certain findings and determine the appropriate testing to require, which is a complex and months-long process involving many scientific and regulatory considerations. While issuing an Order is a more efficient process than a multi-year notice and comment rulemaking, issuing an Order is a significant undertaking for the Agency.

EPA must ensure that the required determinations are made. Additionally, the Order must be developed in a manner that identifies what information is required, what analyses were conducted that indicate the need for the information, what testing will provide such information, and what methodologies or other documents—such as [OECD](#) and/or [OCSPP test guidelines](#)—can inform the generation of such information. Standard, globally-recognized test guidelines are often appropriate to inform certain data needs, whereas other times, EPA may need to look elsewhere such as at New Approach Methods or even develop new protocols that will enable the development of the needed data. Multiple technical considerations go into determining testing requirements. Ultimately, EPA seeks to ensure that the testing generates useful, high-quality data.

This document describes the steps EPA takes in preparing and issuing a TSCA section 4 Order. EPA expects to expand and update this document as it gains experience in developing and issuing Orders. This document does not cover the work entailed in administering Orders once they are issued (e.g., addressing questions from and meeting with Order recipients, providing technical clarifications, reviewing study plan submissions, etc.).

Statutory Requirements and Determinations

TSCA section 4 authorizes EPA to order manufacturers and/or processors to conduct testing on identified chemical substances (or mixtures). The findings EPA must make before it can exercise this authority vary depending on which specific section 4 testing authority EPA is using, but the general theme across these authorities is that EPA must determine with specificity what information it needs for its decision-making, and must also meet certain statutory criteria as it requires the development of this information:

- TSCA section 4(a)(1) authorizes an Order where EPA finds that (1) the chemical substance may present unreasonable risk or is produced in substantial quantities and may cause substantial or significant exposures to the environment or humans, (2) there is insufficient information to predict the effects of the chemical substance, and (3) testing is necessary to develop this information.
- TSCA section 4(a)(2) authorizes an Order to support certain activities undertaken pursuant to specific provisions of TSCA and other federal laws. For example, EPA may issue an Order to address a data need to support a risk evaluation undertaken pursuant to TSCA section 6. When requiring the development of information pursuant to this provision, TSCA section 4(a)(3) requires EPA to provide a “statement of need” that identifies, among other things, the need for the new information and how information reasonably available to the Agency was used to inform the decision to require new information.

- TSCA section 4(a)(4) states that EPA, “shall employ a tiered screening and testing process, under which the results of screening-level tests or assessments of available information inform the decision as to whether 1 or more additional tests are necessary.” When EPA requires the development of information under section 4, EPA must design a tiered-testing strategy (e.g., determine which screening-level tests would inform additional testing), unless EPA identifies information that suggests advanced testing should be required. It typically takes EPA weeks to months to complete these tasks, depending on the complexity of the tiered testing being considered.
- TSCA section 4(h), which is entitled “Reduction of testing on vertebrates”, requires that EPA reduce or replace the use of vertebrate animals to the extent practicable and scientifically justified. EPA must not only consider reasonably available existing information prior to requiring vertebrate testing, but must also encourage the use of scientifically valid test methods that reduce or replace the use of vertebrate animals (provided that those methods will provide information of equivalent or better scientific quality and relevance). If EPA requires vertebrate testing in an Order issued under 4(a)(2), the Agency must explain why such testing is needed. EPA is also encouraged under section 4(h)(2) to group chemicals into “scientifically appropriate categories” to reduce testing on the substances within the category. These considerations typically also take EPA weeks to months to address depending on the complexity of the methods being considered.

In addition to the statutory requirements and determinations, before an Order can be issued, EPA must also estimate the burden of an Order on the recipient(s). This step requires EPA to estimate the time required for and cost of the testing it is ordering as well as the number of recipients subject to such testing requirements. EPA may need to consult with testing laboratories to estimate the costs of specific tests. This is because in addition to TSCA, EPA must also comply with the Paperwork Reduction Act (PRA) by providing an Information Collection (IC), which summarizes the estimated burden for clearance of each Order, to the Office of Management and Budget (OMB). Developing burden information can take anywhere from weeks to months, and the OMB review process can also take a month or more, which includes time for the internal processing steps required to submit an IC to OMB.

Addressing the statutory requirements typically takes at least several months. When added to the time it typically takes to estimate the burden, identify Order recipients, and prepare for OMB review and issuance of the Order, it is not uncommon for the entire process to require 6 months or longer. Many of the statutory requirements interrelate in that EPA can work on them concurrently, and a high-level description of such activities is described below in the Determining Testing Needs and Requirements and Order Development Process sections of this document. Certain activities, such as estimating burden and developing ICs, require EPA to first determine what testing is appropriate. EPA anticipates that it will become more efficient in making findings to support Orders as it gains experience in using its Order authority.

Determining Testing Needs and Requirements

To issue a TSCA section 4 Order, EPA must determine what information is needed as well as adhere to the statutory requirements summarized above. The available information and understanding of chemical substances varies. For instance, for some chemical substances (e.g., those that may have been recently reviewed as new chemical pre-manufacture notices, or substances that have already been

designated as high-priority substances for risk evaluation) EPA will already know a fair extent of what hazard and exposure data are reasonably available, as well as how the chemical substance is used and what exposure concerns might exist. However, for other chemical substances (e.g., most PFAS, the thousands of chemical substances grandfathered onto the 1976 TSCA inventory that have not subsequently undergone review, etc.), EPA will need to spend more time and resources determining what information on the substance is reasonably available, which may include reviewing multiple internal and external data resources. This work typically takes weeks to months depending on the chemical. Ultimately, the consideration of reasonably available hazard and exposure data is a fundamental process EPA undertakes prior to issuing an Order.

Once EPA has determined what information is required, it must consider what testing would produce such information (see TSCA section 4(a)(1) and 4(a)(3)). EPA reviews whether available testing methods and guidance—including OECD, OCSPP, or other standardized test guidelines—would produce the needed information. If available testing methods to produce the needed information do not exist, test protocols may need to be developed by EPA *de novo*. This review includes ensuring that testing pursuant to an identified method or methods would produce consistent and scientifically relevant results for the chemical substance. EPA staff working on the Order consult with experts throughout the Agency and, as applicable, with experts outside EPA (e.g., the Occupational Safety and Health Administration). This work often takes several months to complete. EPA anticipates that these consultations will decrease in frequency and scope as it gains experience in identifying and assembling a library of applicable test guidelines.

While standardized test methods typically provide general protocols to follow to ensure that the conduct of the testing and reporting are appropriate, EPA may need to require additional metadata and parameters that are essential to yield data that will ultimately be fit for its intended purpose. Collaborating with technical experts inside and outside of EPA to define these metadata and parameters may add weeks to months to Order development.

Order Development Process

EPA developed the procedures and infrastructure for developing TSCA Orders *de novo* since the law was amended in 2016. The Agency is learning from and refining this process with feedback from internal reviews and Order recipients. EPA expects that additional experience and feedback will continue to lead to efficiencies and other improvements. With time, these steps should become more systematized, and therefore quicker to complete.

Once EPA determines its specific testing needs, as described above, drafting the Order and determining the burden associated with the Order can take an additional several months. EPA anticipates it will complete the steps described below more quickly as it gains experience in using its Order authority.

One Order is often issued to multiple companies that manufacture and/or process the chemical substance. EPA must identify these companies and their associated points of contacts. To do this, EPA reviews EPA databases (e.g., the Chemical Information System (CIS) that stores TSCA data and the Toxics Release Inventory (TRI), among other sources) and external sources (e.g., Safety Data Sheets) to identify such manufacturers and/or processors. To improve the transparency of the process, EPA also tries to address confidential business information (CBI) claims that prevent EPA from publicly connecting a company to the chemical substance prior to issuing Orders. Based on EPA's experience to date, this

process can take anywhere from a week to a month (or more) depending on how many companies are identified and whether CBI claims that associate the company(ies) with the substance exist.

Once EPA identifies the recipients of the Order, the Agency uses EPA data, company websites, and other resources to determine a Point of Contact (POC) for each company, who is authorized to receive service on the company's behalf. The Agency then contacts the POCs to request that they confirm they are able to represent their company for purposes of an Order or to help identify a different POC, as appropriate. EPA also uses this communication to answer advance questions companies might have and help prepare the companies ahead of the Order's issuance. This pre-issuance outreach the Agency now conducts as a matter of course generally takes up to a few weeks to complete, depending on how many entities may be subject to the Order.

EPA has recently developed TSCA section 4 Order templates. There is a template that details the process for responding to the Order and other overarching topics related to the Order. EPA has been continually refining this template as the Agency learns from past Orders, as well as in response to feedback provided by stakeholders. EPA maintains additional templates that are used by the technical staff to describe the testing needs and specify particular requirements for each identified testing need (e.g., compositions of chemical substance to test, test species, conditions of testing, etc.). These various templates are then merged to create each specific Order. Because TSCA Section 4 provides unique statutory requirements for issuing an Order depending on which specific basis for the Order is being relied upon, EPA has developed unique template text associated with each of the TSCA section 4 provisions when using a given provision for the first time (see TSCA sections 4(a)(1)(A)(i), 4(a)(1)(A)(ii), 4(a)(2)(A), and 4(a)(2)(B)).

EPA's issuance of Orders has also necessitated improvements to its IT infrastructure to manage the Orders and the information they generate. The Central Data Exchange (CDX) reporting application and backend tools used to access information submitted via the CDX application are continuously refined to support the receipt and management of information from hundreds of entities and facilitate transferring the information into a workflow that is being developed and refined as it is simultaneously implemented. Once an Order is signed, EPA enters the Order information into the reporting application that recipients will use to respond to the Order, which generates a unique identifier that the recipient will use when logging into the reporting application. EPA notifies each recipient's POC of the issued Order, providing the unique identifier. Whenever EPA updates the template and/or response process recipients will follow for a given Order, the Agency must make conforming edits to the CDX reporting application before issuing the Order. Support for the IT infrastructure work currently relies on mostly the same staff that develop and administer the Orders, given existing resources.

Finalizing an Order for Issuance

Once an Order is drafted, it undergoes a thorough review process that includes a legal review to ensure that the Order meets applicable requirements, programmatic review to ensure that the Order provides sufficient information for recipients to understand and respond to the Order, a technical review to ensure that the requirements were incorporated correctly via the templating process and finally, management review. These review processes often prompt additions or improvements to the Orders (e.g., further clarifications to testing requirements), and can take a few weeks.

As described herein, creating an Order, starting with the templating process, determining and adding the testing requirements and conducting all appropriate reviews takes at least six months, depending on

how complicated the testing being required is as well as how unique the testing is (e.g., the extent to which EPA needs to add information specific to the substance being tested to what a study protocol requires in terms of the testing process or the test report that such testing will produce). As EPA accrues experience in developing and issuing TSCA section 4 Orders, it is expected that development of future Orders will become more efficient. Further, EPA expects to continue to learn from recipients of Orders as to what could be improved in the template to help convey requirements of the Order and thereby continue to improve and refine Order templates and the Order development process.