UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND
POLLUTION PREVENTION

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**Policies Regarding Manufacturers and Processors Subject to TSCA Section 4(a) Testing**

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 new information on chemical substances and submit such information to EPA.

Under Section 4(a) (15 U.S.C. 2603(a)), pursuant to specific statutory requirements, EPA may issue a rule, order, or consent agreement requiring the development of new information about a chemical substance. This document describes certain EPA policies on the Agency's use of this authority that pertain to the Agency's identification of persons required to conduct testing pursuant to Section 4(a) (i.e., under a rule, consent agreement, or order).

The policies discussed here apply equally to manufacturers and processors. For readability's sake the remainder of this policy document refers to manufacturers (except for quotations that mention processors), but the policy document should be understood as also applying to processors.

Additionally, for readability's sake, this document will use the term "company" or "companies" rather than "person," which is the term used in TSCA to describe who may be subject to a testing requirement pursuant to Section 4.

**Policies Provided in this Document:**

- **Policy 1:** Companies engaged in manufacturing activities for a chemical substance during the five years prior to the projected signature date or effective date of a Section 4(a) action (i.e., a rule, consent agreement, or order) will generally be included in the scope of the action. However, EPA may apply a longer or shorter period of time when appropriate in specific cases.
- **Policy 2:** Section 4 actions will not include an option to cease manufacturing as a means to satisfy the requirements of the action. Test orders issued in January 2021 included this option.

This policy document is not intended to bind EPA or members of the public. The Agency may revisit and depart from these policies based on reasoned consideration as it deems appropriate in the future.

**Description of Policies**

1. **Policy 1:** Companies engaged in manufacturing activities for a chemical substance during the five years prior to the projected signature date or effective date of a Section 4(a) action (i.e., a rule, consent agreement, or order) will generally be included in the scope of the action. However, EPA may apply a longer or shorter period of time when appropriate in specific cases.

Under a TSCA Section 4(a) action, EPA may require the development of information by any company who manufactures or processes or intends to manufacture or process a chemical substance or mixture subject to the action. See TSCA Sections 4(b)(3)(B) and 4(b)(3)(C).

The phrase "who manufactures or processes or intends to manufacture or process" a chemical substance or mixture clearly encompasses companies that have recently manufactured the chemical substance even if they are not actively manufacturing at the precise moment a Section 4 action is issued. For example, chemical producers may pause manufacturing for a variety of reasons, such as market fluctuations or supply chain considerations, and may reinitiate manufacture months or even years later. The same company might put its production in an indeterminate pause, subject to future conditions. EPA generally believes it is appropriate to account for variability in manufacturing activities by considering recent manufacturers to be subject to TSCA Section 4(a) testing responsibilities even if those companies are not actively engaged in manufacturing at the moment the action is issued or during the period of time in which testing obligations must be fulfilled.

Additionally, Section 2(b)(1) of TSCA provides that "It is the policy of the United States that […] (1) adequate information should be developed with respect to the effect of chemical substances and mixtures on health and the environment and that the development of such information should be the responsibility of those who manufacture and those who process such chemical substances and mixtures." Congressional policy provided by Section 2(b)(1) and the data needs driving testing requirements may in some cases dictate that the Agency use a longer time horizon for considering a company to be a person who manufactures the chemical substance or mixture.

Generally, EPA's default approach will be to look to manufacturing for the chemical substance that has occurred within the past five years. However, on a case-by-case basis, the Agency may consider a longer or shorter period of time as further described below.

The five-year period generally aligns with Chemical Data Reporting (CDR) pursuant to Section 8(a)(1) of TSCA (which also applies to a person "who manufactures or processes" a chemical substance or mixture), where reporting occurs every four years. Depending on when the most recent CDR reporting occurred, EPA may use information from up to five years earlier to help identify manufacturers of a chemical substance for purposes of Section 4 testing obligations.

EPA's ability to use recent CDR data to identify companies who have manufactured within the past five-year period simplifies the process and analysis EPA uses for identifying entities subject to a Section 4(a) action. For example, CDR submissions provide EPA with centralized, easily-accessible, and timely information that can be used to inform Section 4 actions. Further, having a default period of time helps clarify expectations prior to the issuance of Section 4 testing requirements for companies who may be subject to such testing requirements.

Where (1) a five-year period fails to identify a sufficient number of manufacturers, (2) fairness reasons warrant inclusion of a manufacturer, especially a high-volume manufacturer, of the chemical substance with less recent manufacturing, (3) a chemical substance has persistence and/or bioaccumulative properties that warrant inclusion of companies that contributed to potential exposures associated with such substance, or (4) where warranted for other reasons, which the Agency would explain as part of the Section 4(a) action, EPA will consider a longer manufacturing period than five years for the identification of companies as manufacturers subject to TSCA Section 4 testing obligations for a given chemical substance.

Additionally, based on case-specific facts, EPA may not include a company which has manufactured in the past 5 years as a manufacturer subject to testing requirements in a specific Section 4(a) action. Similarly, certain companies may have unique case-specific situations that present a compelling case that they are not "manufacturers" of the chemical substance that is subject to the action and may submit such information for EPA's consideration. For example, a company may have gone into bankruptcy and be in the hands of receivers who do not seek to continue the company's manufacturing activities involving the chemical substance subject to the testing requirements. Such situations are anticipated to be uncommon and will be highly fact-determinant; decisions for such situations will be made on a case-by-case basis.

2. **Policy 2:** Section 4 actions will not include an option to cease manufacture as a means to satisfy the requirements of the action. Test orders issued in January 2021 included this option.

In TSCA section 4 Orders issued in January 2021, EPA provided a "cease manufacture" response option when issuing its first Section 4 test Orders, allowing a company to excuse itself from the testing requirements provided it ceased manufacturing of the chemical substance within 90 days of the Order and certified that it would not resume its manufacturing during the life of the Order. This response option had been provided to encourage the lowering of overall production and processing of a potentially risky substance. Additionally, the option had been provided to align with the TSCA Fees rule, 40 CFR 700.45, which exempted manufacturers from the risk evaluation fee obligation if they ceased manufacture of the chemical substance by a certain date and certified that they would not manufacture the substance again in the successive five years.

Upon further consideration of the implications of this response option to the ability of EPA to obtain needed testing, the Agency removed this response option from Orders issued in 2022 to ensure that a sufficient number of entities remained subject to an Order (e.g., for one 2021 Order, no manufacturers identified by the Order remained available to conduct the testing due to their use of the cease manufacture response option). Further, EPA's position, which aligns with the policy of TSCA, as provided by sections 2(b)(1) and 4(a)-(b), is that a company manufacturing the chemical substance should contribute to the generation of needed data being collected pursuant to Section 4(a).

Entities that manufacture a chemical substance for which testing is required should contribute to the generation of such information. A company should not be able to forgo needed testing by ceasing such production. Not providing a "cease manufacture" option ensures that recent manufacturers of a

chemical substance appropriately contribute to the generation of required data. Were all entities subject to the testing requirements able to exit the market to forgo producing the required data, EPA would be unable to seek and obtain data under Section 4(a) to better support Agency assessments and action. Further, where EPA is conducting a risk evaluation on chemical substances that have conditions of use which are not currently ongoing but are reasonably foreseen to reoccur or for which the effects and exposures are ongoing, EPA generally believes it is appropriate to include companies responsible for those activities in testing obligations. Ultimately, the policy to not provide a cease manufacture response option ensures that companies responsible for such chemical substances support the generation of the required data.

Note that even without the cease manufacture response option, a company may decide to cease its dealings with a chemical subject to a testing requirement. A company who ceases manufacture in response to an Section 4 Order or rule might apply for an exemption under the terms of the TSCA Section 4 action, if applicable (e.g., a company may forgo conducting the required testing upon having identified another entity that is conducting the required testing, contingent on EPA approval and the satisfactory completion of testing requirements), and work out an appropriate compensation arrangement with those companies that perform the testing, or work out such an arrangement as part of a consortium.

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