



## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 700

[EPA-HQ-OPPT-2024-0501; FRL-12463-01-OCSPP]

## **Preliminary Lists Identifying Manufacturers Subject to Fee Obligations for Five Chemical Substances Undergoing EPA-Initiated Risk Evaluations Under the Toxic Substances Control Act (TSCA); Notice of Availability and Request for Comment**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Determination; request for comments.

**SUMMARY:** The Environmental Protection Agency (EPA or Agency) is announcing the availability of and soliciting comment on the preliminary lists of manufacturers (including importers) of five chemical substances that have been designated as High-Priority Substances for risk evaluation under the Toxic Substances Control Act (TSCA) and for which fees will be charged. As required by TSCA, EPA established fees to defray a portion of the costs associated with administering certain provisions of TSCA. The comment period provides an opportunity for the public to provide comments, self-identify, or correct errors on the preliminary lists. In addition, manufacturers (including importers) are required to self-identify as a manufacturer (or importer) of one or more the five identified High-Priority Substances irrespective of whether they are included on the preliminary lists, and may use this period to do so. Where appropriate, entities may also avoid or reduce fee obligations by making certain certifications consistent with the TSCA Fees Rule. EPA expects to publish final lists of manufacturers (including importers) subject to fees no later than concurrently with the publication of the final scope documents for risk evaluations of these five High-Priority Substances. Manufacturers (including importers) identified on the final lists will be subject to the applicable fees.

**DATES:** Comments must be received on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

**ADDRESSES:** Submit your comments, identified by docket identification (ID) number EPA-HQ-OPPT-2024-0501, online at <https://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <https://www.epa.gov/dockets>.

**FOR FURTHER INFORMATION CONTACT:**

*For technical information:* Kathleen Ferry, Existing Chemicals Risk Management Division (7404M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460-0001; telephone number: (202) 564-2214; email address: [ferry.kathleen@epa.gov](mailto:ferry.kathleen@epa.gov).

*For general information:* The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554-1404; email address: [TSCA-Hotline@epa.gov](mailto:TSCA-Hotline@epa.gov).

**SUPPLEMENTARY INFORMATION:**

**I. Executive Summary**

*A. Does this action apply to me?*

This action applies to entities that manufacture (including import) a chemical substance undergoing a risk evaluation under TSCA section 6(b) (*e.g.*, entities identified under North American Industrial Classification System (NAICS) codes 325 and 324110). The action may also be of interest to chemical processors, distributors in commerce, and users; non-governmental organizations in the environmental and public health sectors; state and local government agencies; and members of the public. Since other entities may also be interested, the Agency has not attempted to describe all the specific entities and corresponding NAICS codes for entities that may be interested in or affected by this action. If you have questions regarding the applicability of this action, please consult the technical person listed under **FOR FURTHER**

## INFORMATION CONTACT.

### B. *What is the Agency's authority for taking this action?*

TSCA section 26(b), 15 U.S.C. 2625(b), provides EPA with authority to establish fees to defray a portion of the costs associated with administering EPA-initiated TSCA section 6 risk evaluations. The implementing fee regulations, which are codified in 40 CFR part 700, subpart C, imposes a fee for any person who manufactures (including imports) a chemical substance that is the subject of an EPA-initiated risk evaluation under TSCA section 6 (Ref. 1). The requirements for those fee payments are codified in 40 CFR 700.45. See also <https://www.epa.gov/tsca-fees>.

### C. *What action is the Agency taking?*

EPA is publishing preliminary lists identifying manufacturers (including importers) that may be subject to fee obligations under 40 CFR 700.45, associated with each EPA-initiated risk evaluation of the following five High-Priority Substances under TSCA section 6 (Refs. 2):

- Acetaldehyde (CASRN 75-07-0);
- Acrylonitrile (CASRN 107-13-1);
- Benzenamine (CASRN 62-53-3);
- Vinyl chloride (CASRN 75-01-4); and
- 4,4'-Methylene bis(2-chloroaniline) (CASRN 101-14-4).

EPA is also providing an opportunity for public comment during which manufacturers (including importers) are required to self-identify as a manufacturer (including importer) of a High-Priority Substance, irrespective of whether they are listed on the preliminary list, unless they meet one or more of the exemptions listed in 40 CFR 700.45(a)(3)(i) through (iii) (*i.e.*, importing articles, producing as a byproduct that is not later used or distributed for commercial purposes, and manufacturing as an impurity). During this comment period, manufacturers and importers may make certain certifications to EPA to avoid or reduce fee obligations. The public will also have the opportunity to correct errors or provide comments on the preliminary lists.

EPA is providing a 60-day comment period, which exceeds the minimum 30-day comment period established in 40 CFR 700.45(b)(4), to maximize public participation during the comment period for the preliminary lists. EPA expects to publish final lists of manufacturers (including importers) subject to fees no later than concurrently with the publication of the final scope document for risk evaluations of these five High-Priority Substances. Manufacturers (including importers) identified on the final lists will be subject to applicable fees under 40 CFR 700.45.

*D. Why is the Agency taking this action?*

TSCA section 26 authorizes EPA to establish, by rule, a fee structure to defray some of the costs of administering certain provisions of TSCA. Established in 2018 and amended in 2024, pursuant to the TSCA Fee Rule EPA will collect payment from manufacturers (including importers) who manufacture (including import) a chemical substance that is the subject of a risk evaluation under TSCA section 6(b). As intended by Congress, these fees are a sustainable source of funds for EPA to fulfill its legal obligations such as conducting risk evaluations to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, as required under TSCA section 6.

Pursuant to TSCA section 6(b) and its implementing regulations, EPA designated the five chemical substances listed in Unit I.C. as High-Priority Substances for risk evaluation (EPA-HQ-OPPT-2018-0464-0002). EPA is now preliminarily identifying the manufacturers (including importers) that may be subject to fee obligations associated with the risk evaluations of the five High-Priority Substances.

*E. What should I consider as I prepare my comments for EPA?*

*1. Submitting Confidential Business Information (CBI).*

Do not submit CBI to EPA through <https://www.regulations.gov> or email. If you wish to include CBI in your comment, please follow the applicable instructions at <https://www.epa.gov/dockets/commenting-epa-dockets#rules> and clearly mark the part or all of the information that you claim to be CBI. In addition to one complete version of the comment that includes

information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR parts 2 and 703.

*2. Tips for preparing your comments.*

When preparing and submitting your comments, see the commenting tips at <https://www.epa.gov/dockets/comments.html>.

## **II. Background**

TSCA section 6(b)(3)(C) requires EPA to designate at least one new High-Priority Substance for risk evaluation upon completion of each risk evaluation for a High-Priority Substance. Because EPA generally expects to complete five risk evaluations per year over the next several years, in December 2024, EPA designated the five chemical substances listed in Unit I.C. as High-Priority Substances for risk evaluation. Under TSCA section 6(b)(1)(B) and its implementing regulations (40 CFR 702.3), a High-Priority Substance is defined as a chemical substance that EPA determines, without consideration of costs or other non-risk factors, may present an unreasonable risk of injury to health or the environment because of a potential hazard and a potential route of exposure under the conditions of use, including an unreasonable risk to potentially exposed or susceptible subpopulations identified as relevant by EPA. EPA is now announcing the availability of the preliminary lists of fee payers for the risk evaluations for these five High-Priority Substances.

In addition, in February 2024, EPA amended the 2018 TSCA Fees Rule to revise the fee amounts, which entities are obligated to pay fees, and the requirements for self-identification (Ref. 1 and 3). Specifically, EPA 2024 final rule established fee amounts based on EPA's total costs for administering TSCA; provided six exemptions for entities subject to the EPA-initiated risk evaluation fees; modified the self-identification and reporting requirements; established a production-volume-based fee allocation for EPA-initiated risk evaluations; and extended timeframes for certain fee payments and notices, among other changes. The TSCA Fee Rule is

codified in 40 CFR part 700, subpart C.

### **III. Preliminary Lists and Requirements for Self-Identification**

#### *A. The Preliminary Lists*

This document announces the availability of EPA's preliminary lists of manufacturers (including importers) associated with each TSCA section 6 risk evaluation for the five High-Priority Substances who are potentially responsible for payment of fees, as required by 40 CFR 700.45. The preliminary lists are available at in the docket (Ref. 4, 5, 6, 7, and 8). EPA developed the preliminary lists using the most up-to-date information available, including information submitted to the Agency (*e.g.*, information submitted under TSCA section 8(a) (including the Chemical Data Reporting (CDR) Rule), TSCA section 8(b), and to the Toxics Release Inventory (TRI)).

This documents initiates a 60-day comment period during which manufacturers (including importers) of the chemical substance must self-identify as a manufacturer (or importer) to EPA (40 CFR 700.45(b)(5)). Where appropriate, entities may also certify as to “no manufacture”, “cessation” of manufacture or to meeting an exemption, in accordance with 40 CFR 700.45(b)(5)(ii)-(iv). Manufacturers (including importers) are required to provide EPA with the contact information as described in 40 CFR 700.45(b)(5)(i). The public will also have the opportunity to correct errors in the preliminary lists during the comment period. EPA expects to publish a final list of manufacturers subject to fees for each chemical substance following the comment period and no later than the date EPA issues the final scope document for these five High-Priority Substances. Manufacturers listed on the final lists will be subject to applicable fees under 40 CFR 700.45.

EPA is soliciting public comments that would inform the final lists by defining the universe of manufacturers (including importers) obligated to pay fees associated with each TSCA section 6 EPA-initiated risk evaluation for the five chemical substances identified in Unit I.C.

## *B. Self-Identifying as a Manufacturer or Importer*

In accordance with 40 CFR 700.45(b)(5), all persons who have manufactured or imported any of the five chemical substances designated as High-Priority Substances in the five years preceding publication of this preliminary list, other than those meeting the article, byproduct, and impurity exemptions listed in 40 CFR 700.45(a)(3)(i) through (iii), must submit notice to EPA, irrespective of whether they are included in the preliminary list specified in paragraph (b)(3) of this section. The manufacturers (including importers) of a chemical substance as a non-isolated intermediate as defined in 40 CFR 704.3, for research and development described under 40 CFR 700.45(a)(3)(v), and those who manufacture (including import) quantities below a 2,500 lbs annual production volume described under 40 CFR 700.45(a)(3)(vi) must still self-identify even though they meet an exemption. In addition, as discussed in more detail in Unit III.B.4., certain manufacturers (including importers) must submit their production volume for the applicable substance for the calendar years 2022, 2023 and 2024.

The notice must be submitted electronically via EPA's Central Data Exchange (CDX), the Agency's electronic reporting portal, using the Chemical Information Submission System (CISS) reporting tool, and must contain the following information: Name and address of the submitting company, the name and address of the authorized official for the submitting company, and the name and telephone number of a person who will serve as technical contact for the submitting company and who will be able to answer questions about the information submitted by the company to EPA.

Manufacturers (including importers) on the preliminary lists have an opportunity to certify through CDX that: (1) they have already ceased manufacturing prior to the defined cutoff dates and will not manufacture (including import) in the successive five years; (2) they have not manufactured the chemical substance in the five-year period preceding publication of the preliminary lists; or (3) they meet one of the six exemptions at 40 CFR 700.45(a)(3)(i) through (vi). If EPA receives such a certification statement from a manufacturer, then the manufacturer

will not be obligated to pay the fee, unless all manufacturers of a chemical substance manufacture the chemical in quantities below a 2,500 lbs annual production volume, in which case the exemption is not applicable, and those manufacturers are obligated to pay the fee. Manufacturers (including importers) who are not listed on the preliminary lists and otherwise believe they can certify that they are not subject to fee obligations as described in this Unit and in 40 CFR 700.45(b)(5) may choose to attest to these facts to EPA. In addition, entities will have the opportunity to certify as to whether they meet the definition of a “small business concern” as defined in 40 CFR 700.43 and qualify for a reduced fee amount.

*1. Certifying an exit from the market.*

Manufacturers (including importers) certifying an exit from the market (*i.e.*, cessation of manufacture and import) of any of the five High-Priority substances must have ceased manufacture prior to the certification cutoff date of December 18, 2023, and are prohibited from manufacturing the substance again in the successive five years. If EPA receives a certification attesting to these facts, the manufacturer will not be included in the final list of manufacturers and will not be obligated to pay the fee under this section. Manufacturers (including importers) planning to cease manufacture (including import) in the future (but have not yet done so), or those which have already ceased but may re-enter the market within the next five years, would not be permitted to certify out of the fee obligation. Manufacturers (including importers) which certify cessation are not required to provide production volume as discussed in B.4. of this Unit.

*2. Certification of no manufacture.*

Manufacturers (including importers) identified on the preliminary list but have not manufactured the chemical in the five-year period preceding publication of this preliminary list, should submit a certification statement attesting to these facts. If EPA receives such a certification statement from a manufacturer, the manufacturer will not be included in the final list of manufacturers and will not be obligated to pay the fee under this section.

*3. Certification of meeting exemptions.*

Manufacturers (including importers) of a chemical substance which exclusively qualify for one or more of the following exemptions will not be obligated to pay fees: (i) import of articles containing the chemical substance; (ii) produce the chemical substance as a byproduct that is not later used for commercial purposes or distributed for commercial use; (iii) manufacture the chemical substance as an impurity as defined in 40 CFR 704.3; (iv) manufacture the chemical substance as a non-isolated intermediate as defined in 40 CFR 704.3; (v) manufacture small quantities of the chemical substance solely for research and development, as defined in 40 CFR 700.43; or (vi) manufacture the chemical substance in quantities below a 2,500 lbs annual production volume as described in 40 CFR 700.43, unless all manufacturers of a chemical substance manufacture the chemical in quantities below a 2,500 lbs annual production volume in which case the exemption is not applicable and those manufacturers are obligated to pay the fee.

In order to avoid fee payment based on an exemption for all but the production volume exemption under 40 CFR 700.45(a)(3)(vi), the manufacturer must meet one or more exemptions, and not conduct manufacturing outside of those exemptions, on or after the certification cutoff date of December 18, 2023, and meet one or more of the exemptions in the successive five years. To meet the requirements for the production volume exemption under 40 CFR 700.45(a)(3)(vi), the manufacturer must meet that exemption for the five-year period preceding publication of the preliminary list (*i.e.*, have had a production volume below 2,500 lbs annually for the previous five years), does not conduct manufacturing of that chemical substance outside of the exemption, and will meet the exemption in the successive five years.

If a manufacturer is identified on the preliminary list and exclusively meets one or more of these exemptions, the manufacturer must submit a certification statement attesting to these facts in order to not be included in the final list of manufacturers. Regardless of whether they are included on the preliminary list or not, manufacturers (including importers) of a chemical substance as a non-isolated intermediate (*i.e.*, the exemption under 40 CFR 700.45(a)(3)(iv)), for

research and development (*i.e.*, the exemption under 40 CFR 700.45(a)(3)(v)), and manufacturers (including importers) of a chemical substance in quantities below a 2,500 lbs annual production volume (*i.e.*, the exemption under 40 CFR 700.45(a)(3)(vi)), must self-identify to EPA. Requiring self-identification of manufacturers that qualify for the production volume-based exemption allows EPA to allocate fees based on production volume and collect fees in a timely manner in situations in which all fee payers have met that exemption criteria. In addition, those manufacturers (including importers) meeting the production volume exemption under 40 CFR 700.45(a)(3)(vi) must report their production volume for the three calendar years prior to publication of the preliminary list.

#### 4. *Reporting production volume.*

Manufacturers (including importers) that do not submit a certification of cessation, a certification of no manufacture, or does not meet one or more of the exemptions, other than the production volume exemption in 40 CFR 700.45(a)(3)(vi), must submit their production volume for the applicable substance for the three calendar years prior to publication of the preliminary list (40 CFR 700.45(b)(5)(v)). Similar to the requirements in the CDR rule, two significant figures should be used when calculating production volume. Companies with multiple facilities producing the same chemical substance should include the total aggregated production volume from all facilities when calculating the average production volume. Such companies should also not double count distribution of the same chemical substance within one company when that chemical mixture is “manufactured” more than once (*e.g.*, a company that manufactures a chemical, then exports for further processing, then imports the chemical mixture would not need to double count its production volume). Note, this does not apply if multiple companies are involved (*e.g.*, a company manufactures a chemical, then exports it for additional processing, then a separate company imports the mixture). EPA will assess a fee for each of those manufacturers based on the production volume that they separately manufacture or import. EPA does not require the inclusion of non-TSCA chemicals in production volume calculations.

### *C. Failure to Self-Identify*

Manufacturers (including importers) who fail to self-identify as manufacturers subject to fee obligations, as required by the Fees Rule (Ref. 1), may be subject to a penalty under TSCA section 16. Each day of failed self-identification by a manufacturer (including importer) past the publication of the final list is a separate TSCA violation subject to penalty. Likewise, manufacturers (including importers) who falsely certify to having ceased manufacture (including import) or not re-initiating manufacture (including import) within five years will also be subject to penalty, as described in Unit III.H. of the 2018 Fees Rule (Ref. 3).

### *D. Fee Obligations*

Fee obligations are set forth in 40 CFR 700.45 and include a total fee of \$4,287,000 for each chemical substance undergoing EPA-initiated risk evaluation, with a reduced fee amount for small business concerns (Ref. 1). The total fee is shared amongst all identified manufacturers (including importers). The Fees Rule provides more detailed information on how EPA determined the fee amounts (Ref. 1). As required by 40 CFR 700.45(g)(3)(iv)(A), fees will be paid in two installments, with the first payment of 50% due 180 days after publishing the final scope of a risk evaluation and the second payment for the remainder of the fee due after 545 days after publishing the final scope of a risk evaluation. Manufacturers may also form a consortium to pay fees in accordance with 40 CFR 700.45(f)(3). The consortium must notify EPA that a consortium has formed within 90 days of the publication of the final scope of a risk evaluation (40 CFR 700.45(f)(3)(i)). Once established, the consortium would determine how the fee would be split among the members, and ultimately paid to EPA. For the consortium to qualify for the reduced small business fee, each person in the consortium must qualify as a small business concern under 40 CFR 700.43.

### *E. Providing Public Comments*

With publication of the preliminary lists, EPA is providing a 60-day comment period for manufacturers (including importers) and the public to correct errors, self-identify as a

manufacturer, or certify that they have already exited the market and that they will not resume manufacture (including import) for a period of five years. After the comment period for the preliminary lists of entities subject to a fee obligation, EPA expects to make any necessary updates or corrections before publishing final lists of manufacturers for each of the five High-Priority Substances. If information received during the public comment period would prompt the addition of manufacturers (including importers) to the final lists, then EPA plans to first notify those manufacturers (including importers).

EPA expects the final lists will indicate whether any manufacturers were identified in error, any additional manufacturers that were identified through the comment period or self-identification process, and whether any manufacturers have certified that they have already ceased manufacture (including import) prior to the cutoff date of December 18, 2023, and will not manufacture the subject chemical substance for five years. The final list will be published no later than concurrently with the final scope document for each risk evaluation initiated by EPA under TSCA section 6 for these five High-Priority Substances.

#### **IV. References**

The following is a listing of the documents that are specifically referenced in this notice. The docket includes these documents and other information considered by EPA, including documents that are referenced within the documents that are included in the docket, even if the referenced document is not physically located in the docket. For assistance in locating these other documents, please consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

1. EPA. Final Rule: Fees for Administration of Toxic Substances Control Act; Final Rule. *Federal Register*. 89 FR 12961, February 21, 2024 (FRL-7911-05-OCSP).

2. EPA. Notice: High-Priority Substance Designations Under the Toxic Substances Control Act (TSCA) and Initiation of Risk Evaluation on High-Priority Substances; Notice of Availability. *Federal Register*. 89 FR 102903, December 18, 2024 (FRL-11581-07-OCSP)

(Docket ID No. EPA-HQ-OPPT-2023-0601).

3. EPA. Final Rule: Fees for Administration of Toxic Substances Control Act. *Federal Register*. 83 FR 52694, October 17, 2018 (FRL-9984-41).

4. EPA. Preliminary List Identifying Manufacturers Subject to Fee Obligations for EPA-Initiated Risk Evaluations of Chemical, Acetaldehyde, CASRN 75-07-0. December 2024.

5. EPA. Preliminary List Identifying Manufacturers Subject to Fee Obligations for EPA-Initiated Risk Evaluations of Chemical, Acrylonitrile, CASRN 107-13-1. December 2024.

6. EPA. Preliminary List Identifying Manufacturers Subject to Fee Obligations for EPA-Initiated Risk Evaluations of Chemical, Benzenamine, CASRN 62-53-3. December 2024.

7. EPA. Preliminary List Identifying Manufacturers Subject to Fee Obligations for EPA-Initiated Risk Evaluations of Chemical, Vinyl Chloride, CASRN 75-01-4. December 2024.

8. EPA. Preliminary List Identifying Manufacturers Subject to Fee Obligations for EPA-Initiated Risk Evaluations of Chemical, 4,4'-Methylene bis(2-chloroaniline) (MBOCA), CASRN 101-14-4. December 2024.

**Authority:** 15 U.S.C. 2601 *et seq.*

**Michael S. Regan,**

*Administrator.*

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