EPA Public Webinar on the Preliminary List of Fee Payers for Five High Priority Substances

January 14, 2025, at 1PM ET



Webinar Logistics

- Format
 - Presentation only
 - Slides will be available on the EPA website: www.epa.gov/tsca-fees/outreach-tsca-administration-fees-rule.epa.gov/tsca-fees
 - Send follow up questions to <u>TSCAFees@epa.gov</u>
- Audio and Technical Information
 - All attendees are muted
 - Disconnect from VPN for optimal audio/video quality
 - To enable closed captioning, click "CC" on Zoom toolbar
 - For technical support, email <u>Durand.Chole@epa.gov</u>



Agenda

- Overview of TSCA Fees
- Steps for Self-Identification
 - What is self-identification?
 - How do I self-identify?
 - Who qualifies as a small business?
 - Who should certify no manufacturer?
 - Who should certify cessation?
 - Who should certify as meeting an exemption?
 - How do I report my production volume?
- Methodology for how EPA will allocate fees
- Recordkeeping Requirements
- Key Dates
- Additional Resources



Overview of TSCA Fees under TSCA Section 26(b)

- TSCA provides EPA with authority to establish fees to defray a portion of the costs associated with administering TSCA sections 4, 5, and 6, and with respect to information management under TSCA section 14.
- For EPA-initiated risk evaluations, EPA collects one fee amount (i.e., \$4,287,000) that is shared by manufacturers (including importers) of that chemical substance.
- EPA affords small businesses an approximately 80% discount.
- In February 2024, EPA finalized changes to the fee requirements, modifying who is obligated to pay fees and who is exempted and changing the self-identification and recordkeeping requirements.

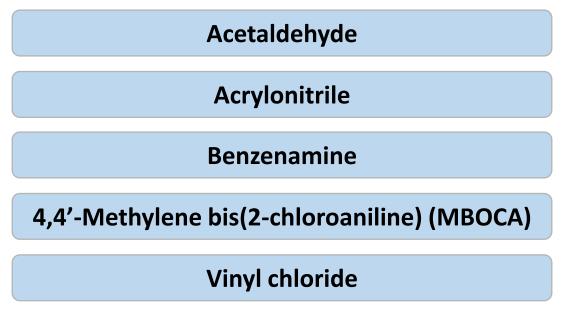
40 CFR Part 700 Subpart C: https://www.ecfr.gov/current/title-40/chapter-l/subchapter-R/part-700/subpart-C

2024 Final Rule: https://www.federalregister.gov/documents/2024/02/21/2024-02735/fees-for-the-administration-of-the-toxic-substances-control-act-tsca



Overview of TSCA Fees under TSCA Section 26(b) (Cont.)

• On December 18th, 2024, EPA designated five High-Priority Substances (HPS) that will undergo a risk evaluation:



• Manufacturers (including importers) of these chemicals have to self-identify and, if applicable, certify cessation, no manufacture, or meeting an exemption.

Steps for Self-Identification



What is Self-Identification?

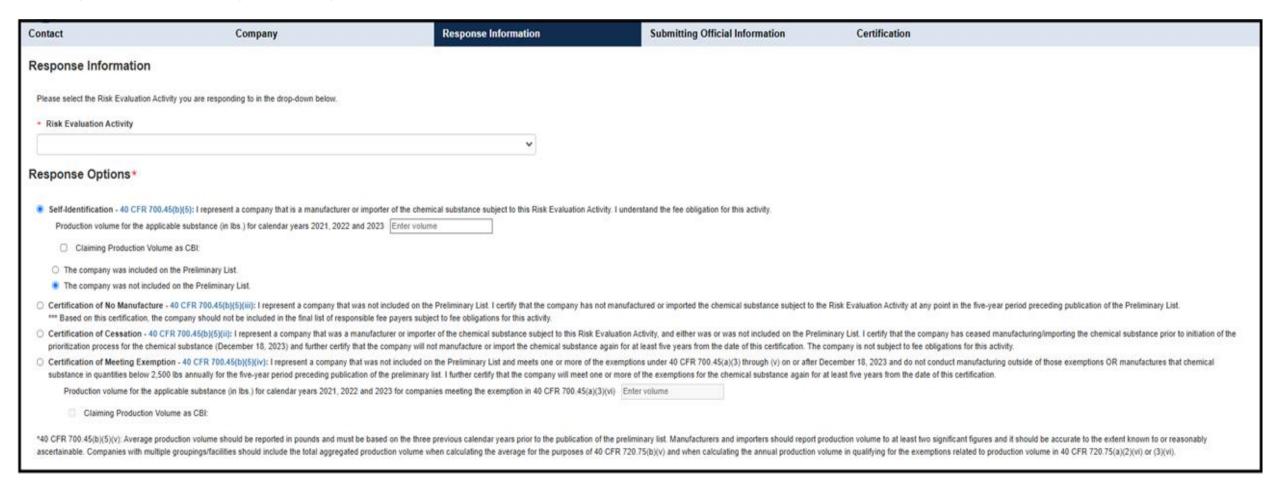
- The self-identification process identifies fee payers and involves publication of a preliminary list, a
 public comment and self-identification period, and publication of a final list identifying
 manufacturers (including importers) responsible for payment.
- Manufacturers (including importers) who have manufactured (including imported) the chemical substance in the previous five years must submit notice to EPA, irrespective of whether they are included in the preliminary list.
- 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.
- During self-identification, manufacturers (including importers) can correct errors and make certain certifications to alleviate fee payment obligations.
- EPA uses the information gathered during the self-identification process to generate the final list of manufacturers (including importers) responsible for payment.

How do I self-identify?

- EPA provides instructions for self-identification and other certifications in CDX, including how to register for CDX.
 - Fees website: https://www.epa.gov/tsca-fees/tsca-fees-epa-initiated-risk-evaluations
 - CDX Help Desk: 888-890-1995 | (970) 494-5500 for International callers
- Manufacturers (including importers) are required to provide:
 - The name and address of the submitting company;
 - The name and address of the authorized official for the submitting company;
 - 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.
 - Average annual production volume for calendar years 2021, 2022 and 2023.
 - Production volume is not required for those that submit a certification of cessation, a certification of no manufacture, or meet one or more of the exemptions, other than the production volume exemption in 40 CFR 700.45(a)(3)(vi).

How do I self-identify?

Example of CDX Response Options





Who qualifies as a small business?

- Manufacturers (including importers) can identify as a small business and qualify for a reduced fee. They must meet the size standards identified in the table in the fee regulations.
 - https://www.ecfr.gov/current/title-40/part-700/subpart-C#p-700.43(Small%20business%20concern)
- If the North American Industry Classification System (NAICS) code of a manufacturer is not represented in the table, it will be considered small if it has 500 or fewer employees.
- When calculating the number of employees, a manufacturer or processor must include the employees of all of its "parent companies" (if any) and all companies it "owns or controls."
- The number of employees are calculated as the average number of people employed for each pay period of the business' latest 12 calendar months, regardless of hours worked or temporary status.

Who should certify "no manufacturer"?

- TSCA section 3(9) defines manufacturer as follows:
 - The term "manufacture" means to import into the customs territory of the United States (as defined in general note 2 of the Harmonized Tariff Schedule of the United States), produce, or 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 risk evaluation fee.

Who should certify cessation?

- You can certify to having exited the market (i.e., cessation of manufacture and import) if you have ceased manufacture (and import) prior to the certification cutoff date of December 18, 2023, and will not be manufacturing (or importing) the substance again in the successive five years.
- If EPA receives this certification, you will not be included in the final list of manufacturers and will not be obligated to pay the risk evaluation fee.
- Note: Manufacturers planning to cease manufacturing in the future (but have not yet done so), or those who have already ceased but may re-enter the market within the next five years, are not permitted to certify out of the fee obligation.
- If you are certifying cessation, you are not required to provide production volume information.

Who should certify as meeting an exemption?

- Manufacturers (including importers) of a chemical substance who exclusively qualify for one
 or more of the exemptions will not be obligated to pay fees.
- If you were identified on the preliminary list and feel you should be exempted, you must submit a certification statement attesting to these facts in order to not be included in the final list.

Six Exemptions for Fees:

- Import of articles containing the chemical substance;
- ii. Produce as a byproduct that is not later used for commercial purposes or distributed for commercial use;
- iii. Manufacture as an impurity as defined in 40 CFR 704.3;
- iv. *Manufacture 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; or
- vi. *Manufacture in quantities below a 2,500 lbs <u>annual</u> production volume, unless all manufacture is below 2,500 lbs, in which case the exemption is not applicable and manufacturers are obligated to pay the fee.
- * Manufacturers (including importers) in these categories must self-identify to EPA, regardless of whether they are included on the preliminary list or not.



Who should certify as meeting an exemption?

Exemption Qualifications:

- For all exemption categories except the production volume exemption:
 - You 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):
 - You 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), you must not conduct manufacturing of that chemical substance outside of the exemption, and certify that you will meet the exemption in the successive five years.

How do I report production volume?

Production Volume Rationale:

- Manufacturers (including importers) that do not submit a certification of cessation, a certification of no manufacture, or do 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 information.
- Important Note: Those manufacturers (including importers) meeting the production volume exemption under 40 CFR 700.45(a)(3)(vi) must also report their production volume.
- Fees are not allocated based on production volume for small businesses who are either not associated with a consortium or associated with an all-small business consortium.

How do I report production volume?

Calculating Production Volume

- Submit your average production volume for the three calendar years prior to publication of the preliminary list.
- Report your average production volume for calendar years 2021, 2022 and 2023.
- Report production volume to at least two significant figures; it should be accurate to the extent known or reasonably ascertainable.
- 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.
- You should also not double-count distribution of the same chemical 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); 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).

Methodology for how EPA will allocate fees



Methodology for How EPA Will Allocate Fees

- The \$4,287,000 fee amount for EPA-initiated risk evaluations will be shared by all manufacturers (including importers) for that chemical substance listed on the final list.
- The fee amount obligated to each will depend on several factors (e.g., the number of manufacturers sharing the fee, their small business status, reported production volumes).
- Manufacturers (including importers) can form a consortium to split the applicable fee and they must notify EPA that the consortium has been formed within 90 days of the publication of the final scope. It is up to the consortium to determine how fees will be split among the consortium members.
- Consortia are strongly encouraged to set lower fees for small businesses participating in the consortium.
- EPA provides all small businesses who are either (a) not associated with a consortium, or (b) associated with an all-small business consortium, with an 80 percent discount from the base fee.
- For a consortium to qualify for the reduced fee, each person in the consortium must qualify as a small business under § 700.43.



Methodology for How EPA Will Allocate Fees

- To calculate fees, EPA will rank the fee-payers that do not qualify as a small business concern by their reported production volume, then assign fees based on where the manufacturer (including importers) falls within those rankings.
- The non-small business manufacturers (including importers) in the top 20th percentile ranking will pay 80 percent of the total fee, distributed evenly among those manufacturers, counting each manufacturer in a consortium as one entity.
- The remaining fee will be distributed evenly across the remaining manufacturers, counting each manufacturer in a consortium as one entity.
- Note that EPA will send invoices through CDX and payments must be made within CDX.

Methodology for How EPA Will Allocate Fees

After the small business fees have been allocated, providing an 80% discount...

Rank based on production volume:

Rank the remaining manufacturers that do not qualify as a small business in ascending order based on reported production volume.

EXAMPLE

Manufacturer(s)	Assigned number	Fee
With the highest	5	\$1,714,800
With the 2 nd highest	4	\$1,714,800
With the 3 rd highest	3	\$285,800
Manufacturer with the 2 nd to last lowest	2	\$285,800
Manufacturer with lowest production volume	1	\$285,800

Total fee collected per substance: \$4,287,000

Determine the top 20th percentile:

Determine the manufacturers in the top 20th percentile by multiplying the total number of manufacturers by 0.8. Then compare the manufacturers with the assigned numbers that are equal to or larger than that.



So... the 4th and 5th manufacture in our table are in the top 20th percentile.

Assign fees:

Manufacturers in the top 20th percentile will share 80% of the fee (i.e., \$3,429,600) equally. The other 20% of the fee (i.e., \$857,400) is allocated evenly amongst the other manufacturers. In both cases, each manufacturer in a consortium is counted as one person.

In the example provided, manufacturers 4 and 5 would equally pay 80% of the fee (i.e., \$1,714,800 each) while manufactures 1, 2, and 3 would equally pay the remaining 20% (i.e., \$285,800 each).

Recordkeeping Requirements



Recordkeeping Requirements

- All manufacturers other than those qualifying for the exemptions related to articles, byproducts, impurities, non-isolated intermediates, and/or research and development must maintain production volume records related to their production volume submission. These records must be maintained for a period of five years from the date the notice is submitted to EPA.
- Manufacturers that manufacture (including import) a chemical substance in quantities below a 2,500 lbs annual production volume (i.e., those meeting the exemption criteria in 40 CFR 700.45(a)(3)(v)) must maintain production volume records related to compliance with the exemption criteria. These records must be maintained for a period of five years from the date notice is submitted to EPA.
- Manufacturers of a chemical substance as a non-isolated intermediate (i.e., those meeting the exemption criteria in 40 CFR 700.45(a)(3)(iv)) must maintain manufacturing and other business records related to compliance with that exemption criteria.
- Manufacturers of small quantities (as defined in 40 CFR 700.43) of a chemical substance solely for research and development (i.e., the exemption criteria in 40 CFR 700.45(a)(3)(v)) must also maintain manufacturing and other business records related to compliance with that exemption, such as production volume, plans of study, information from research and development notebooks, study reports, or notice solely for research and development use. These records must be maintained for a period of five years from the date notice is submitted to EPA.

Key Dates



Key Dates

- Certification Cut-off date: December 18, 2023
 - 88 FR 87423
- Designation of five High-Priority Substances: December 18, 2024
 - 89 FR 102900
- Fee Preliminary List Publication: December 31, 2024
 - 89 FR 107099
- All manufacturers (including importers) identified on the preliminary list need to submit a notice self-identifying as a manufacturer, certifying cessation, certifying no manufacture (e.g., they were identified in error), or certifying that they meet an exemption
- Public Comment period ends March 3, 2025
 - 89 FR 107099
- 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
- Consortium Formation Notification: 90 days from the publication of the final scope of the risk evaluation
- Fee Payment: Payment of 50% due 180 days after publishing the final scope of the EPA-initiated risk evaluation and the second payment for the remainder of the fee due 545 days after publication of the final scope

Additional Resources

- 2024 Final Rule: https://www.federalregister.gov/documents/2024/02/21/2024-02735/fees-for-the-administration-of-the-toxic-substances-control-act-tsca
- The TSCA fee regulations can be found on the Government Printing Office website at: https://www.ecfr.gov/cgi-bin/text-idx?SID=9eda67a7aca9587005971816bc1885a7&mc=true&node=sp40.33.700.c&rgn=div6
- Press Release for next 5 High Priority Substances: https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/prioritization-actions-under-tsca
- Information on TSCA risk evaluation fees can be found on EPA's website at: https://www.epa.gov/tsca-fees/tsca-fees-epa-initiated-risk-evaluations
- Instructions on reporting in CDX can be found on EPA's website at: https://www.epa.gov/sites/production/files/2020-03/documents/tsca fees instructions for reporting in cdx.pdf
- For questions, email EPA at <u>TSCAFees@epa.gov</u>
- For help with CDX, email: helpdesk@epacdx.net



Thank You!

