



BILLING CODE 6560-50-P

## **ENVIRONMENTAL PROTECTION AGENCY**

**[EPA-HQ-OPPT-2019-0677; FRL-10014-28]**

### **Final Lists Identifying Manufacturers Subject to Fee Obligations for EPA-Initiated Risk Evaluations under Section 6 of the Toxic Substances Control Act (TSCA); Notice of Availability**

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

**ACTION:** Notice.

**SUMMARY:** As required by the final rule on fees for the administration of the Toxic Substances Control Act (TSCA) (the Fees Rule), in which the Environmental Protection Agency (EPA) established fees to defray some of the costs of administering certain provisions of TSCA, EPA this document announces the availability of the final lists identifying the manufacturers (including importers) of the 20 chemical substances that have been designated as a High-Priority Substance for risk evaluation and for which fees will be charged. In January 2020, EPA announced the availability of and solicited public comment on the preliminary lists identifying manufacturers subject to fee obligations for EPA-initiated risk evaluations under TSCA. During the comment period, which closed on June 15, 2020, manufacturers (including importers) were also required to self-identify as a manufacturer of one of the 20 High-Priority Substances irrespective of whether they are included on the preliminary lists. Where appropriate, entities had the opportunity to avoid or reduce fee obligations by making certain certifications consistent with the Fees Rule. The public had the opportunity to correct errors or provide comments on the preliminary lists. Manufacturers (including importers) identified on the final list will be subject to applicable fees.

**DATES:** Effective on August 27, 2020.

**FOR FURTHER INFORMATION CONTACT:** *For technical information contact:* Benjamin Dyson, Environmental Assistance Division (7408M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW, Washington, DC 20460-0001; telephone number: (202) 774-8976; email address: *dyson.benjamin@epa.gov*.

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

**SUPPLEMENTARY INFORMATION:**

**I. General Information**

*A. Does this action apply to me?*

This action applies to entities that manufacture (including import) one or more of the High-Priority Substances currently undergoing a risk evaluation under TSCA section 6(b). 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. 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.

*B. What action is the Agency taking?*

EPA is announcing the availability of the final lists identifying manufacturers (including importers) that are subject to fee obligations under 40 CFR 700.45. These entities manufacture or import one or more of the 20 High-Priority Substances subject to EPA-initiated risk evaluations under TSCA section 6.

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

As amended by the Frank R. Lautenberg Chemical Safety for the 21<sup>st</sup> Century Act of 2016 (Pub. L. 114-182, see also <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/frank-r-lautenberg-chemical-safety-21st-century-act>), TSCA authorizes EPA to establish, by rule, a fee structure to defray some of the costs of administering certain provisions of TSCA. Pursuant to the Fees Rule, the Agency will collect payment from identified manufacturers (including importers) who manufacture (including import) a chemical substance that is the subject of a risk evaluation under TSCA section 6(b) (Ref. 1). As intended by Congress, these fees are a sustainable source of funds for EPA to fulfill its legal obligation to conduct 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 has designated 20 chemical substances as High-Priority Substances for risk evaluation (Ref. 2) (84 FR 71924, December 30, 2019) (FRL-10003-15); those substances are listed in Unit III. EPA is now identifying the manufacturers (including importers) that are subject to fee obligations associated with the risk evaluations of these High-Priority Substances.

*D. What is the Agency's authority for this action?*

TSCA provides EPA with authority to establish fees to defray a portion of the costs associated with administering EPA-initiated TSCA section 6 risk evaluations. On September 27, 2018, EPA finalized a rule imposing a fee for persons who manufacture (including import) 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.

**II. Background**

*A. How was the final list developed?*

TSCA section 6(b)(1) requires EPA to prioritize chemical substances as High-Priority Substances for risk evaluation. In accordance with TSCA section 6(b) and 40 CFR 702.7, on March 21, 2019, EPA initiated the prioritization process for 20 chemical substances identified as candidates for High-Priority Substance designation (Ref. 3). On August 23, 2019, EPA proposed to designate the same 20 chemical substances as High-Priority Substances for risk evaluation (Ref. 4). EPA finalized the High-Priority Substance designations of the same 20 chemical substance proposed for High-Priority Substance designations (Ref. 2) and announced on January 27, 2020 the availability of the preliminary lists for the 20 High-Priority Substances designated (Ref. 5) (see docket EPA-HQ-OPPT-2019-0677). EPA provided a 60-day comment period, with two additional extensions closing the second comment period on June 15, 2020 (Ref. 6 and Ref. 7) (March 13 (<https://www.regulations.gov/document?D=EPA-HQ-OPPT-2019-0677-0058>) and May 28 (<https://www.regulations.gov/document?D=EPA-HQ-OPPT-2019-0677-0087>)).

EPA developed each preliminary list using the most up-to-date information available, from information submitted to the Agency (*i.e.*, information submitted under TSCA section 8(a) (including the Chemical Data Reporting (CDR) Rule) and TSCA section 8(b), and the Toxics Release Inventory (TRI)). To include the two most recent CDR reporting cycle data (collected every four years) and to account for annual or other typical fluctuations in manufacturing (including import), EPA used six years of data submitted or available to the Agency under CDR and TRI to create the preliminary lists (2012 – 2018). EPA considered using other sources of information available to the Agency, such as publicly available information (*e.g.*, Panjiva, Datamyne) or information submitted to other agencies to which EPA has access (*e.g.*, U.S. Customs and Border Protection data) but concluded that data quality limitations would create

more false positives than appropriate additions to the lists. Following publication of the preliminary lists, manufacturers of the 20 High-Priority Substances who had manufactured or imported the chemical substance in the previous five years were required to self-identify to EPA, irrespective of whether they were included in the preliminary lists. See 40 CFR 700.45(b)(5).

EPA is now announcing the final list of manufacturers (including importers) for the 20 High-Priority Substances who are responsible for fee payments (Ref. 8). EPA is also providing the list of companies that certified to ceasing manufacture for each of the 20 High-Priority Substances (Ref. 9).

EPA believes the requirement to self-identify, established by 40 CFR 700.45(b)(5), was sufficient to identify additional manufacturers (including importers). Manufacturers (including importers) on the preliminary lists had an opportunity to certify through CDX that: (1) they had already ceased manufacturing prior to the defined cutoff dates and will not manufacture (including import) for five years; or (2) they have not manufactured the chemical substance in the five-year period preceding publication of the preliminary lists. For this group of 20 chemicals, the cutoff date for ceasing manufacture or import of a chemical substance was March 20, 2019, which is the day prior to initiation of the prioritization process for the applicable designated High-Priority Substance. If EPA received such a certification statement from a manufacturer, then the manufacturer was not identified on the final list and will not be obligated to pay the fee. Additionally, EPA found that the broad scope of the current Fees Rule unintentionally imposes potentially significant burdens on importers of chemical substances in articles, and manufacturers of byproducts and impurities, and that certain stakeholders would be obligated to undertake significant and burdensome efforts to attempt to determine the presence of the 20 High-Priority Substances in their products and processes. EPA announced the Agency's

intention to immediately begin the rulemaking process to amend the Fees Rule to propose exemptions to the self-identification requirements in the Fees Rule associated with EPA-initiated risk evaluations for three categories of manufacturers of chemical substances subject to such risk evaluations: 1) importers of articles containing the chemical substances; 2) producers of the chemical substances as a byproduct; and 3) producers or importers of the chemical substances as an impurity. As a bridge to the final revised rule EPA provided a “No Action Assurance” on March 24, 2020 (Ref. 10).

Additionally, the Agency was asked whether a manufacturer that has ceased manufacture of one of the 20 High-Priority Substances prior to the cutoff date for ceasing manufacture or import of a chemical substance (March 2019) other than manufacture in the three categories impacted by the planned regulatory change, and that also commits to not manufacturing the chemical in the future five years, other than in those same three categories should be subject to fee obligations. The Agency responded that in light of the rulemaking announcement, EPA does not expect to identify entities who otherwise meet the criteria for “cessation” except for manufacture or potential manufacture in one of the three categories - and who certify as such in the “Additional Information” field in CDX - on the final lists of responsible fee payers. Finally, entities had the opportunity to certify as to whether they meet the definition of a “small business concern” as defined in the Fees Rule and qualify for an 80% reduced fee amount.

*B. What are the final lists and fee obligations of manufacturers (including importers)?*

This Notice announces the availability of EPA’s final list of manufacturers (including importers) of the 20 High-Priority Substances subject to risk evaluation who are responsible for payment of fees, as required by 40 CFR 700.45 (Ref. 2). The final lists are available at docket number EPA-HQ-OPPT-2019-0677 at <http://www.regulations.gov> and on EPA’s website at

<http://www.epa.gov/TSCA-fees>. Also included in the docket are the list of companies that certified to having ceased manufacturing by March 20, 2019 and have no plans to restart manufacturing in the next five years (Ref. 9) as well as those that certified to not manufacturing the chemical substance in the five-year period preceding publication of the preliminary lists (Ref. 11). The “Certification of Cessation” list also includes those manufacturers who ceased manufacturing by March 20, 2019 except for manufacture of a byproduct, or impurity or in an article. The final list of manufacturers differs from the preliminary lists (see docket number EPA-HQ-OPPT-2019-0677) for several reasons. For example, many CDR/TRI manufacturers that were identified on the preliminary list had either ceased manufacturing prior to the cutoff dates were not manufacturers (or importers) of the chemical substances. Such entities were not included on the final lists. Other entities from the preliminary lists, in accordance with the planned regulatory change, that only manufactured (or imported) chemicals as a byproduct, impurity, or in an article and certified as such, were not included in the final list. The only company that self-identified for TCEP imported a very small quantity in 2019 for R&D use only. The Agency used the discretion offered by the TSCA Fees Rule to not collect a fee from this one company. As a result, there are no fees associated with the risk evaluation for tris (2-chloroethyl) phosphate (115-96-8). The TSCA Fees Rule provides EPA flexibility to refine the final list of manufacturers in a manner that is reasonable and prudent, in light of statutory and regulatory obligations related to TSCA risk evaluations and associated fee payment obligations. As such, the Agency decided to not charge a fee to those importers who were only importing small quantities of the 20 HPS for research and development purposes only.

This document announces the availability of EPA’s final list of manufacturers (including importers) of the 20 High-Priority Substances subject to risk evaluation who are responsible for

payment of fees, as required by 40 CFR 700.45 (Ref. 2). The final lists are available at docket number EPA-HQ-OPPT-2019-0677 at <http://www.regulations.gov> and on EPA's website at <http://www.epa.gov/TSCA-fees>. Also included in the docket are the list of companies that certified to having ceased manufacturing by March 20, 2019 and have no plans to restart manufacturing in the next five years (Ref. 9) as well as those that certified to not manufacturing the chemical substance in the five-year period preceding publication of the preliminary lists (Ref. 11). The "Certification of Cessation" list also includes those manufacturers who ceased manufacturing by March 20, 2019 except for manufacture of a byproduct, or impurity or in an article. The final list of manufacturers differs from the preliminary lists (see docket number EPA-HQ-OPPT-2019-0677) for several reasons. For example, many CDR/TRI manufacturers that were identified on the preliminary list had either ceased manufacturing prior to the cutoff dates were not manufacturers (or importers) of the chemical substances. Such entities were not included on the final lists. Other entities from the preliminary lists, in accordance with the planned regulatory change, that only manufactured (or imported) chemicals as a byproduct, impurity, or in an article and certified as such, were not included in the final list. Other entities that were not included on a preliminary list, such as importers of chemical substances for laboratory or R&D use that imported volumes below the CDR 25,000 lb threshold, self-identified as a manufacturer (including importer) during the reporting period and were therefore included on a final list. There are no fees associated with the risk evaluation for tris (2-chloroethyl) phosphate (115-96-8).

Fee obligations are set forth in 40 CFR 700.45 and include a total fee of \$1,350,000 for EPA-initiated risk evaluations, 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 established the fee for EPA-initiated risk evaluations (Ref. 1).

In recognition of the unprecedented and unforeseen challenges to the economy as a result of public health emergency, the Agency is exploring options for payment flexibilities, including payment plans and extended due dates for fees. 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 60 days of the publication of the final scope of a risk evaluation. Once established, the consortium would determine how the fee would be split among the members, and ultimately paid to EPA. For additional information on the possible division of costs amongst consortia and individual manufacturers, please see the Fees Rule Unit III.J, Multiple Parties Subject to Fee Obligation (Ref. 1).

### *C. How can I access the final list?*

The final list of manufacturers that will be subject to the Fees Rule for EPA-initiated risk evaluations under section 6 of TSCA can be found at docket number EPA-HQ-OPPT-2019-0677 at <http://www.regulations.gov> and on EPA's website at <http://www.epa.gov/TSCA-fees>.

## **III. Public Comments on Preliminary Lists and EPA Responses**

EPA received public comments from 78 entities on the preliminary lists. As a general matter, many of the comments raised questions asking further clarification of what constitutes a byproduct or article; requesting a de minimis exemption; etc. The Agency responded to the questions by communicating directly with individual stakeholders, hosting conference calls with stakeholders, participating in webinars for stakeholders, improving web content, and adding Frequently Asked Questions to the EPA web page at <https://www.epa.gov/tsca-fees/frequently-questions-about-tsca-fees-epa-initiated-risk-evaluations>.

#### **IV. References**

The following is a listing of the documents that are specifically referenced in this document. 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. Fees for the Administration of the Toxic Substances Control Act. *Federal Register*. (83 FR 52694, October 17, 2018) (FRL-9984-41).
2. EPA. High-Priority Substance Designations Under the Toxic Substances Control Act (TSCA); Notice of Availability. *Federal Register*. (84 FR 71924, December 30, 2019) (FRL-10003-15).
3. EPA. Initiation of Prioritization Under the Toxic Substances Control Act (TSCA); Notice. *Federal Register*. (84 FR 10491, March 21, 2019) (FRL-9991-06).
4. EPA. Proposed High-Priority Substance Designations Under the Toxic Substances Control Act (TSCA); Notice of Availability and Request for Comment. *Federal Register*. (84 FR 44300, August 23, 2019) (FRL-9998-29).
5. EPA. Preliminary Lists Identifying Manufacturers Subject to Fee Obligations for EPA-Initiated Risk Evaluations Under Section 6 of the Toxic Substances Control Act (TSCA): Notice of Availability and Request for Comment. *Federal Register*. (85 FR 4661, January 27, 2020) (FRL-10003-14).
6. EPA. Preliminary Lists Identifying Manufacturers Subject to Fee Obligations for EPA-Initiated Risk Evaluations Under Section 6 of the Toxic Substances Control Act (TSCA): Notice

of Availability and Request for Comment; Extension of Comment Period. *Federal Register*. (85 FR 14677, March 13, 2020) (FRL-10006-03).

7. EPA. Preliminary Lists Identifying Manufacturers Subject to Fee Obligations for EPA-Initiated Risk Evaluations Under Section 6 of the Toxic Substances Control Act (TSCA): Notice of Availability and Request for Comment; Extension of Comment Period. *Federal Register*. (85 FR 32036, May 28, 2020) (FRL-10010-37).

8. EPA. List of Final Manufacturers for all 20 High Priority Substances. August 2020

9. EPA. List of Manufacturers Who Certified as Ceasing Manufacture. August 2020.

10. EPA. “No Action Assurance Letter” of March 24, 2020.

11. EPA. List of Manufactures Who Self-Identified as “No Manufacture”. August 2020.

**Authority:** 15 U.S.C. 2625

**Andrew Wheeler,**

*Administrator.*

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