ENvironMentAL PROTECTION AGENCY

[EPA-HQ-OPPT-2019-0677; FRL-10003-14]

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

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: As required by EPA’s Final Rule on Fees for the Administration of TSCA (the Fees Rule), in which EPA established fees to defray some of the costs of administering certain provisions of the Toxic Substances Control Act (TSCA), this Notice identifies the preliminary lists of manufacturers (including importers) of 20 chemical substances that have been designated as a High-Priority Substance for risk evaluation and for which fees will be charged. EPA is providing a 60-day comment period during which manufacturers (including importers) are required to self-identify as a manufacturer of a High-Priority Substance irrespective of whether they are included on the preliminary lists. Where appropriate, entities may also avoid or reduce fee obligations by making certain certifications consistent with the Fees Rule. During this 60-day comment period, the public will have the opportunity to correct errors or provide comments on 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 20 High-Priority Substances. Manufacturers (including importers) identified on the final lists will be subject to 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-2019-0677, by one of the following methods:

- *Federal eRulemaking Portal: http://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.


- *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at http://www.epa.gov/dockets/contacts.html.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at http://www.epa.gov/dockets.

**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 a chemical substance (including import of the chemical substance or import of an article containing the 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.

B. 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 20 High-Priority Substances under TSCA section 6. 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. 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’s 60-day comment period exceeds the minimum 30-day comment period established in the Fees Rule codified at 40 CFR 700.45(b)(4) to maximize public participation during the first comment period for an initial lists of manufacturers (including importers) subject to fee obligations for EPA-initiated risk evaluations under TSCA section 6. 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 20 High-Priority
Substances. Manufacturers (including importers) identified on the final lists will be subject to
applicable fees under 40 CFR 700.45.

C. Why is the Agency taking this action?

As amended in by the Frank R. Launtenberg Chemical Safety for the 21st Century Act of
2016 (Pub. L. 114-182), TSCA authorized EPA to establish, by rule, a fee structure to defray
some of the costs of administering certain provisions of TSCA. Pursuant to Fees Rule, the
Agency 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 section 6(b) of TSCA and its implementing regulations, EPA has
designated 20 chemical substances as High-Priority Substances for risk evaluation (84 FR 71924,
December 30, 2019) (FRL-10003-15); those substances are also listed in Unit III. EPA is now
preliminarily identifying the manufacturers (including importers) that may be 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 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.

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

1. Submitting Confidential Business Information (CBI). Do not submit this information to EPA through regulations.gov or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI in a disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed as 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 part 2.

2. Tips for preparing your comments. When preparing and submitting your comments, see the commenting tips at http://www.epa.gov/dockets/comments.html.

II. Background

TSCA section 6(b)(1) requires EPA to prioritize 20 chemical substances as High-Priority Substances. 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. 2). On August 23, 2019, EPA proposed to designate the same 20 chemical substances as High-Priority Substances for risk evaluation (Ref. 3). After considering additional information collected during the comment periods following initiation of prioritization and the proposed designation, EPA finalized, in a separate action, the High-Priority Substance designations of the same 20 chemical substance proposed for High-Priority Substance designations (Ref. 4). EPA is now announcing the availability of the preliminary lists for the 20 High-Priority Substances designated (Refs. 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20,
A. Preliminary Lists, Final Lists, and Fee Obligations of Manufacturers/Importers

This Notice describes EPA’s preliminary lists of manufacturers (including importers) who are potentially responsible for payment of fees, as required by 40 CFR 700.45, and associated with each TSCA section 6 risk evaluation that EPA will initiate for 20 High-Priority Substances (Ref. 1). The preliminary 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. As described in Unit III.C. of the preamble to the Fees Rule (Ref. 2), EPA developed each preliminary list 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) and section 8(b), and to the Toxics Release Inventory (TRI)). 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. Custom and Border Patrol data) but concluded that data quality limitations would create more false positives than appropriate additions to the lists. Additionally, EPA believes the Self-Identification process, established by 40 CFR 700.45(b)(5), will be sufficient to identify additional manufacturers (including importers), as appropriate. 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).

This Notice initiates a 60-day comment period during which manufacturers (including importers) of the chemical substance must self-identify to EPA irrespective of whether they are included on a preliminary list. Where appropriate, entities may also certify as to no manufacture
or cessation of manufacture in accordance with 40 CFR 700.45(b)(5). Manufacturers (including importers) are required to provide EPA with the contact information as described in 40 CFR 700.45(b)(5)(i). Other stakeholders also have the opportunity to correct errors in the preliminary lists. This process is explained further in Unit II.B.

Following the comment period and no later than the date EPA issues the final scope document as part of the risk evaluations for these 20 High-Chemical Substances, EPA expects to publish a final list of manufacturers subject to fees for each chemical substance. Manufacturers listed on the final lists will be subject to applicable fees under 40 CFR 700.45.

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. 2). 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. 2). The fees established in 2018 are fees for the 2019, 2020, and 2021 fiscal years. Fees for the 2022 and later fiscal years may be adjusted on a three-year cycle as described in the final Fees Rule (Ref. 2).

As required by 40 CFR 700.45(g)(3)(iv)(A), payment of fees are due within 120 days following the publication of the final scope of a chemical 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 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).

B. Self-identification Requirement
In accordance with 40 CFR 700.45(b)(5), all manufacturers who have manufactured or imported any of the 20 chemical substances designated as High-Priority Substances (Ref. 5) in the previous five years, must submit notice to EPA, irrespective of whether they are included in the preliminary lists. The notice must be submitted electronically via EPA’s Central Data Exchange (CDX), the Agency’s electronic reporting portal, 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. EPA has also made the Chemical Information Submission System (CISS) reporting tool available for this electronic reporting.

All manufacturers (including importers) of these chemical substances, including those who import the chemical as part of an article, or manufacture (including import) chemical substances that are considered an impurity or byproduct, or in small amounts are subject to the Fees Rule requirements. TSCA requires EPA to evaluate chemicals under their conditions of use, and conditions of use evaluated may involve import of articles containing the chemical, the manufacture of the chemical as an impurity or byproduct, or in small amounts. As described in Unit III.E. of the Fees Rule, EPA does not exempt these manufacturers from fee obligations for TSCA section 6 activities.

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) 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 is March 20, 2019, which is the day prior to initiation of the prioritization process for the applicable designated High-Priority Substance. If EPA receives such a certification statement from a manufacturer, then the manufacturer will not be obligated to pay the fee. Manufacturers who are not listed on the preliminary lists and otherwise believe they can “certify out” 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 the Fees Rule and qualify for a reduced fee amount.

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). Manufacturers (including importers) who plan to cease manufacture (including import) 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, would not be permitted to “certify out”, and would still be subject to the fee obligation.

C. Failure to Self-Identify

Manufacturers (including importers) who fail to identify themselves 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 payment due date 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.C.7. of the Fees Rule.
III. Request for Comments and Manufacturer Information

With publication of the preliminary lists, EPA is providing a 60-day comment period for manufacturers 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.

A. The Preliminary Lists

The preliminary lists of manufacturers (including importers) that may be subject to fee obligations under 40 CFR 700.45 associated with EPA-initiated risk evaluations of 20 High-Priority Substances are in this docket; there is a separate preliminary list for each substance (Refs. 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, and 24). Each list is provided in two formats: a searchable Excel file and in two PDF files - the first file presenting manufacturers in parent company name order and the second file presenting manufacturers in parent company Dun & Bradstreet Number order. Instructions for using the searchable Excel file are presented in the READ ME FIRST tab. Instructions for accessing the TSCA section 6 User Fees application through CDX are also provided in the READ ME FIRST tab and at the top of the PDF files.

EPA is soliciting public comments that would inform the final lists defining the universe of manufacturers (including importers) obligated to pay fees associated with each TSCA section 6 EPA-initiated risk evaluation for the 20 following chemicals, which separately have been designated as High Priority Substances for risk evaluation (Ref. 4):

1. 1,3-Butadiene, CASRN 106-99-0.

2. Butyl benzyl phthalate (BBP) (1,2-Benzenedicarboxylic acid, 1-butyl 2-(phenylmethyl)ester), CASRN 85-68-7.
3. Dibutyl phthalate (DBP) (1,2-Benzenedicarboxylic acid, 1,2-dibutyl ester), CASRN 84-74-2.

4. o-Dichlorobenzene (Benzene, 1,2-dichloro-), CASRN 95-50-1.

5. p-Dichlorobenzene (Benzene, 1,4-dichloro-), CASRN 106-46-7.

6. 1,1-Dichloroethane, CASRN 75-34-3.

7. 1,2-Dichloroethane, CASRN 107-06-2.

8. trans-1,2-Dichloroethylene (Ethene, 1,2-dichloro-, (1E)-), CASRN 156-60-5.

9. 1,2-Dichloropropane, CASRN 78-87-5.

10. Dicyclohexyl phthalate (1,2-Benzenedicarboxylic acid, 1,2-dicyclohexyl ester), CASRN 84-61-7.

11. Di-ethylhexyl phthalate (DEHP) (1,2-Benzenedicarboxylic acid, 1,2-bis(2-ethylhexyl) ester), CASRN 117-81-7.

12. Di-isobutyl phthalate (DIBP) (1,2-Benzenedicarboxylic acid, 1,2-bis(2-methylpropyl) ester), CASRN 84-69-5.

13. Ethylene dibromide (Ethane, 1,2-dibromo-), CASRN 106-93-4.

14. Formaldehyde, CASRN 50-00-0.

15. 1,3,4,6,7,8-Hexahydro-4,6,6,7,8,8-hexamethylcyclopenta [g]-2-benzopyran (HHCB), CASRN 1222-05-5.


17. Phosphoric acid, triphenyl ester (TPP) CASRN 115-86-6.

18. Phthalic anhydride (1,3-Isobenzofurandione), CASRN 85-44-9.

19. 1,1,2-Trichloroethane, CASRN 79-00-5.

20. Tris(2-chloroethyl) phosphate (TCEP) (Ethanol, 2-chloro-, 1,1′,1″-phosphate),
B. Self-Identifying as a Manufacturer or Importer

Instructions for self-identifying as a manufacturer (including importer) of any of the 20 High Priority Substances are in each preliminary list Excel and PDF files in the docket (Refs. 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, and 24).

C. Certifying an Exit from the Market (i.e., Cessation) or No Manufacture

Instructions for certifying an exit from the market (i.e., cessation of manufacture and import), and for certifying no manufacture (including import) of any of the 20 High Priority substances are in each preliminary list Excel and PDF files in the docket (Refs. 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, and 24).

D. Providing public comments

Please see Unit I.E for more information on how to submit comments to EPA. 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 20 High-Priority Substances. EPA expects that these final lists will indicate if any manufacturers were identified in error, any additional manufacturers that were identified through the comment period or self-identification process, and if any manufacturers have certified that they have already ceased manufacture (including import) prior to the cutoff date of March 20, 2019 and will not manufacture the subject chemical substance for five years. Each final list will be published concurrently with the final scope document for each risk evaluation initiated by EPA under TSCA section 6 for these 20 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.


5. EPA. Preliminary List Identifying Manufacturers Subject to Fee Obligations for EPA-Initiated Risk Evaluations of 1,3-Butadiene, CASRN 106-99-0. December 2019.


7. EPA. Preliminary List Identifying Manufacturers Subject to Fee Obligations for EPA-Initiated Risk Evaluations of Dibutyl phthalate (DBP) (1,2-Benzenedicarboxylic acid, 1,2-dibutyl ester), CASRN 84-74-2. December 2019.

8. EPA. Preliminary List Identifying Manufacturers Subject to Fee Obligations for EPA-Initiated Risk Evaluations of o-Dichlorobenzene (Benzene, 1,2-dichloro-), CASRN 95-50-1.


11. EPA. Preliminary List Identifying Manufacturers Subject to Fee Obligations for EPA-Initiated Risk Evaluations of 1,2-Dichloroethane, CASRN 107-06-2. December 2019.

12. EPA. Preliminary List Identifying Manufacturers Subject to Fee Obligations for EPA-Initiated Risk Evaluations of trans-1,2-Dichloroethylene (Ethene, 1,2-dichloro-, (1E)-), CASRN 156-60-5. December 2019.

13. EPA. Preliminary List Identifying Manufacturers Subject to Fee Obligations for EPA-Initiated Risk Evaluations of 1,2-Dichloropropane, CASRN 78-87-5. December 2019.

14. EPA. Preliminary List Identifying Manufacturers Subject to Fee Obligations for EPA-Initiated Risk Evaluations of Dicyclohexyl phthalate (1,2-Benzenedicarboxylic acid, 1,2-dicyclohexyl ester), CASRN 84-61-7. December 2019.

15. EPA. Preliminary List Identifying Manufacturers Subject to Fee Obligations for EPA-Initiated Risk Evaluations of Di-ethylhexyl phthalate (DEHP) (1,2-Benzenedicarboxylic acid, 1,2-bis(2-ethylhexyl) ester), CASRN 117-81-7. December 2019.

16. EPA. Preliminary List Identifying Manufacturers Subject to Fee Obligations for EPA-Initiated Risk Evaluations of Di-isobutyl phthalate (DIBP) (1,2-Benzenedicarboxylic acid, 1,2-bis(2-methylpropyl) ester), CASRN 84-69-5. December 2019.

17. EPA. Preliminary List Identifying Manufacturers Subject to Fee Obligations for EPA-

18. EPA. Preliminary List Identifying Manufacturers Subject to Fee Obligations for EPA-Initiated Risk Evaluations of Formaldehyde, CASRN 50-00-0. December 2019.

19. EPA. Preliminary List Identifying Manufacturers Subject to Fee Obligations for EPA-Initiated Risk Evaluations of 1,3,4,6,7,8-Hexahydro-4,6,6,7,8,8-hexamethylcyclopenta [g]-2-benzopyran (HHCB), CASRN 1222-05-5. December 2019.


23. EPA. Preliminary List Identifying Manufacturers Subject to Fee Obligations for EPA-Initiated Risk Evaluations of 1,1,2-Trichloroethane, CASRN 79-00-5. December 2019.

24. EPA. Preliminary List Identifying Manufacturers Subject to Fee Obligations for EPA-Initiated Risk Evaluations of Tris(2-chloroethyl) phosphate (TCEP) (Ethanol, 2-chloro-, 1,1',1”-phosphate), CASRN 115-96-8. December 2019.
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**Authority:** 15 U.S.C. 2625


**Andrew R. Wheeler,**

*Administrator.*

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