

Regulatory Alert

Preliminary Lists Identifying Manufacturers and Importers 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

EXECUTIVE SUMMARY

Background on Regulation:

The Toxic Substances Control Act (TSCA), as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act of 2016, provides the United States Environmental Protection Agency (EPA) with authority “to establish fees to defray a portion of the costs associated with administering TSCA sections 4, 5, and 6, as amended, as well as the costs of collecting, processing, reviewing, and providing access to and protecting information about chemical substances from disclosure as appropriate under TSCA section 14.”

As authorized by TSCA, EPA is instituting fees for certain activities including manufacturing/importing chemical substances that are the subject of EPA’s risk evaluation process. On September 27, 2018, EPA finalized a rule that included imposing a fee for any person who manufactures/imports a chemical substance that is the subject of an EPA-initiated risk evaluation under TSCA section 6. The requirement for the fee payments is codified in 40 CFR 700.45, and the total fee amount per substance is \$1,350,000. The total fee per substance is shared among all self-identified manufacturers/importers, and there is a reduced fee for small businesses.

Link to regulation: <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0401-0072>

Regulatory Update:

On January 27, 2020, EPA published preliminary lists identifying U.S.-based manufacturers/importers that may be subject to fee obligations under 40 CFR 700.45 associated with the designated 20 High-Priority Substances subject to EPA-initiated risk evaluations. The 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>. EPA developed these preliminary lists using information previously submitted to the Agency (e.g., Chemical Data Reporting (CDR) Rule), Toxics Release Inventory (TRI)). Any US-based legal entity that has manufactured/imported 1 or more of the 20 High-Priority Substances in the previous 5 years must self-identify to EPA, regardless of whether it is on the preliminary list. This requirement also covers the *import of articles* containing any of the 20 High-Priority Substances. There is no de minimus concentration or volume threshold.

Manufacturers/importers that are on final lists to be published by EPA will be required to share a portion of the total \$1,350,000 fee for each related substance risk evaluation. Payments will be due 120 days after the final scoping documents for the risk evaluations are published. Companies may choose to participate in a consortium to share in the cost associated with risk evaluation fees. If forming a consortium, a notification must be submitted via EPA’s Central Data Exchange (CDX) within 60 days of the publication of the final scope of a chemical risk evaluation. The consortium determines how the fee will be distributed. If a decision cannot be made by the consortium, they must notify EPA prior to the notification deadline and EPA will then use its published fee structure to distribute the fees.

EPA is providing an opportunity for public comment by March 27, 2020 during which time manufacturers/importers (M/I) are also required to self-identify as a M/I of a High-Priority Substance. During this comment period, M/I may also make certifications to EPA to avoid or reduce fee obligations (see page 3). The public can also correct errors or provide comments on the preliminary lists. Final lists of M/I subject to fees should be published by EPA no later than concurrently with the publication of the final scope document for risk evaluations of these 20 High-Priority Substances.

Link to Federal Register notice Jan 27, 2020: <https://thefederalregister.org/2020-01-27/2020-01320>

APPLICABILITY

Applies to M/I of the following 20 substances, including importers of these substances in articles:

Chemical Substance	CAS #
1,3-Butadiene	106-99-0
Butyl benzyl phthalate (BBP) (1,2-Benzenedicarboxylic acid, 1-butyl 2-(phenylmethyl) ester)	85-68-7
Dibutyl phthalate (DBP) (1,2-Benzenedicarboxylic acid, 1,2-dibutyl ester)	84-74-2
o-Dichlorobenzene (Benzene, 1,2-dichloro-)	95-50-1
p-Dichlorobenzene (Benzene, 1,4-dichloro-)	106-46-7
1,1-Dichloroethane	75-34-3
1,2-Dichloroethane	107-06-2
trans-1,2-Dichloroethylene (Ethene, 1,2-dichloro-, (1E)-)	156-60-5
1,2-Dichloropropane	78-87-5
Dicyclohexyl phthalate (1,2-Benzenedicarboxylic acid, 1,2-dicyclohexyl ester)	84-61-7
Di-ethylhexyl phthalate (DEHP) (1,2-Benzenedicarboxylic acid, 1,2-bis(2-ethylhexyl) ester),	117-81-7
Di-isobutyl phthalate (DIBP) (1,2-Benzenedicarboxylic acid, 1,2-bis(2-methylpropyl) ester)	84-69-5
Ethylene dibromide (Ethane, 1,2-dibromo-)	106-93-4
Formaldehyde	50-00-0
1,3,4,6,7,8-Hexahydro-4,6,6,7,8,8-hexamethylcyclopenta [g]-2-benzopyran (HHCB)	1222-05-5
4,4'-(1-Methylethylidene)bis[2, 6-dibromophenol] (TBBPA)	79-94-7
. Phosphoric acid, triphenyl ester (TPP)	115-86-6
Phthalic anhydride (1,3-Isobenzofurandione)	85-44-9
1,1,2-Trichloroethane	79-00-5
Tris(2-chloroethyl) phosphate (TCEP) (Ethanol, 2-chloro-, 1,1',1-phosphate)	115-96-8

RESTRICTIONS/REPORTING/RECORDKEEPING

EPA is providing a 60-day comment period for manufacturers and the public to:

- Correct errors
- Self-identify as a M/I, or
- Certify that they have exited the market and will not resume manufacture/import for a period of five years.

M/I of any of the 20 High Priority Substances in the previous five years must notify EPA electronically via EPA's Central Data Exchange (CDX), even if the M/I was not included in the preliminary lists. Report:

- Name and address of the submitting company
- Name and address of the authorized official for the submitting company, and
- 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

Certification Type	Condition	BUT	THEN
Certification of cessation	M/I in 5-year period prior to preliminary list publication	Ceased M/I prior to March 20, 2019 and will not manufacture/import substance again in the successive 5 years	M/I may submit a certification statement and will not have to pay the fee
Certification of no manufacture	M/I identified on the preliminary list	Has not manufactured the chemical in the five-year period preceding publication of the preliminary list	M/I may submit a certification statement and will not have to pay the fee

RELEVANT DATES

- ❖ **Effective date: January 21, 2020**
- ❖ **Comments to EPA must be received on or before March 27, 2020**
 - Reference docket identification (ID) number EPA-HQ-OPPT-2019-0677
 - Submit 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.
 - Mail: Document Control Office (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460-0001.
 - 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>.
- ❖ **Payment of fees are due within 120 days following the publication of the final scope of a chemical risk evaluation. This is expected to occur approximately October 2020.**
- ❖ **Notification to EPA of the intent to form a consortium must be made within 60 days of the publication of the final scope of a chemical risk evaluation.**

RISKS TO AEROSPACE AND DEFENSE

- M/I who fail to identify themselves as M/I subject to fee obligations may be subject to a penalty under TSCA section 16
- Each day of failed self-identification by a M/I past the payment due date is a separate TSCA violation subject to penalty.
- M/I who falsely certify to having ceased manufacture/import or not re-initiating manufacture (including import) within five years will also be subject to penalty
- If part of a consortium, failure to provide notice or submit fee payments constitutes a violation by each consortium member.
- If a U.S. based supplier of a High Priority substance to an aerospace and defense company is a M/I and does not comply with this regulation, there is potential risk of supply chain disruption.

Risk mitigation actions for IAEG members, in summary:

- 1) Review the preliminary EPA lists to see if their legal entity is identified. There is one list of legal entities per substance, and each list is provided in 2 formats: pdf and Excel.
- 2) Determine if they must self-identify, correct EPA information, or certify cessation/no manufacture. Take action accordingly, **before March 27, 2020**.
- 3) If self-identification is required, consider whether forming a consortium with other affected companies may be beneficial and make financial plans for payment of fees.

Note: Some industry groups have expressed their concern to EPA about the fees applying to importers of articles containing the targeted substances. Follow EPA communications on the TSCA fee rule, in case further information on this topic becomes available.

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