

ALERT

EPA's Preliminary Lists of Manufacturers Subject to Fee Obligations for TSCA Risk Evaluations: What You Need to Know

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This week, the U.S. Environmental Protection Agency (EPA) released its preliminary lists of manufacturers that are subject to the fee obligations for EPA-initiated risk evaluations under section 6 of the Toxic Substances Control Act (TSCA). Manufacturers of the 20 high-priority chemicals undergoing risk evaluations – including companies that import these chemicals in mixtures and articles or manufacture/import them as an impurity or a byproduct – are required to pay these fees. The failure to self-identify as a manufacturer of these chemicals and make timely payments exposes companies to enforcement actions and penalties. Now that EPA has published these lists, a sixty-day comment period is underway through **March 27, 2020**.

EPA anticipates that companies will voluntarily form consortia to fairly and appropriately allocate the fees among the obligated companies. The agency's regulations create a process to identify affected manufacturers and importers and allow them to form consortia for payment of the required fees in a timely manner, which we discuss below. Downstream processors and users are not subject to EPA's fees for a section 6(b) risk evaluation as long as they do not also import these high priority chemicals.

We invite manufacturers and importers of the chemicals under evaluation to take advantage of Wiley's unparalleled TSCA expertise and experience establishing successful consortia to help you allocate these fees and engage EPA as it analyzes the hazards and exposures related to the chemicals under evaluation. Approaching these risk

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evaluations with a coordinated strategy benefits all involved.

TSCA Risk Evaluations

As readers are likely aware, the Frank R. Lautenberg Chemical Safety for the 21st Century Act significantly amended EPA's responsibilities under TSCA. The law established a risk evaluation process for the agency to review and analyze chemicals currently in commerce to determine whether they present unreasonable risks to health or the environment. Under this framework, EPA is initially required to conduct and complete risk evaluations on the first ten chemical substances by this June.

The TSCA amendments also direct EPA to initiate risk evaluations for the twenty "high-priority" chemical substances immediately upon finalizing these designations, which occurred on December 20, 2019. EPA must now complete these evaluations within three years. TSCA allows the agency, however, to extend the deadline by an additional six months. EPA has started its evaluations for the following twenty chemicals that include solvents, flame retardants, phthalates, and several high-profile chemicals that have particularly broad use patterns:

- p-Dichlorobenzene;
- 1,2-Dichloroethane;
- trans-1,2-Dichloroethylene;
- o-Dichlorobenzene;
- 1,1,2-Trichloroethane;
- 1,2-Dichloropropane;
- 1,1-Dichloroethane;
- Dibutyl phthalate (DBP) (1,2-Benzene-dicarboxylic acid, 1,2-dibutyl ester);
- Butyl benzyl phthalate (BBP) (1,2-Benzene-dicarboxylic acid, 1-butyl 2(phenylmethyl) ester);
- Di-ethylhexyl phthalate (DEHP) (1,2-Benzene-dicarboxylic acid, 1,2-bis(2-ethylhexyl) ester);
- Di-isobutyl phthalate (DIBP) (1,2-Benzene-dicarboxylic acid, 1,2-bis-(2methylpropyl) ester);
- Dicyclohexyl phthalate;
- 4,4'-(1-Methylethylidene)bis[2, 6-dibromophenol] (TBBPA);
- Tris(2-chloroethyl) phosphate (TCEP);
- Phosphoric acid, triphenyl ester (TPP);
- Ethylene dibromide;
- 1,3-Butadiene;
- 1,3,4,6,7,8-Hexahydro-4,6,6,7,8,8-hexamethylcyclopenta [g]-2-benzopyran (HHCB);

- Formaldehyde; and
- Phthalic anhydride.

You may access the agency's dockets for these chemicals here: <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/chemical-substances-undergoing-prioritization-high>. "Manufacturers" of these chemicals, as discussed below, must pay fees in the near future to help cover the costs of EPA's risk evaluations.

EPA's Fees Rule

Section 26(b) of TSCA authorized EPA to require manufacturers and processors to pay fees to defray the cost related to section 6(b) risk evaluations, among other statutory duties. Pursuant to this authority, EPA issued its final rule, "Fees for the Administration of the Toxic Substances Control Act" (Fees Rule), on October 17, 2018 (83 Fed. Reg. 52694). This rule set forth the process for identifying manufacturers subject to TSCA fees for risk evaluations, the requirements for submitting payments to the agency, and the consequences if the fees are not paid.

It is crucial to know that, for purposes of TSCA fees, EPA considers "manufacturers" to include (1) manufacturers of the chemical substances being evaluated, (2) those who import the chemicals alone, as part of a mixture, or as part of an article, and (3) companies that manufacture (including import) the chemicals as impurities or byproducts, or in small amounts.

As noted above, EPA decided not to subject processors to fees for the risk evaluations because it represented an appropriate balance of fee allocation and "trying to identify relevant processors for all fee-triggering actions would be overly burdensome" for the agency. Processors may voluntarily join a consortium, however, and agree to pay a portion of the fee as a prerequisite to joining the consortium. Processors are still responsible for fees related to certain TSCA actions under sections 4 and 5.

The Fees Rule requires EPA to publish preliminary lists that identify manufacturers of each chemical undergoing evaluation, based on information available to the agency through Chemical Data Rule reporting, the Toxics Release Inventory, and other sources. Although the Fees Rule committed EPA to publishing the preliminary lists concurrently with the final list of high-priority chemicals to be evaluated, EPA needed an additional month to publish these preliminary lists in this case. It is important to note that EPA acknowledges that these lists are incomplete. EPA compiled these lists largely based on reports the agency receives for high volumes of these chemicals under Chemical Data Reporting and the Toxic Release Inventory. Therefore, it is reasonable to anticipate that many small-quantity manufacturers and certain importers will not find themselves on EPA's preliminary lists. Nevertheless, such companies must still self-identify.

During the sixty-day comment period currently underway, manufacturers and the public may take any of the three actions below.

First, the public may identify additional manufacturers that are not on the preliminary lists. If the public comments would cause EPA to add a manufacturer to a final fee list, the agency will contact that manufacturer prior to publication of the final list and provide the manufacturer with the opportunity to confirm or disprove the basis for adding it to the final list. EPA's Fees Rule requires the agency to issue the final list concurrently with the publication of the final scope documents for the risk evaluations. TSCA section 6(b)(3)(D) directs EPA to publish the scope documents no later than six months after initiation the risk evaluations for the high-priority chemicals, which is June 20, 2020.

Second, if manufacturers of the twenty chemicals (including importers of these chemicals, importers of articles that contain these chemicals, and manufacturers/importers of these chemicals as impurities or byproducts) are not identified on the preliminary lists, they must self-identify as a manufacturer before the end of the comment period and submit a notice to EPA with certain information via the agency's Central Data Exchange (CDX). We strongly believe that EPA needs to extend the comment period for at least sixty days after the agency issues the draft scopes of the risk evaluations because EPA's scope documents will provide better clarity about which manufacturers (especially importers of articles) will be subject to the risk evaluation fees.¹

Third, manufacturers on the preliminary lists will have the opportunity to certify via CDX that either (1) they have already ceased manufacturing prior to December 20, 2019, and will not manufacture for five years into the future, or (2) they have never manufactured the chemical substance. Upon timely and proper notice, the agency will not require that manufacturer to pay the fee. Even if manufacturers do not appear on the preliminary lists, they may use this comment opportunity to submit a certification that they are not manufacturers subject to fees, as long as they meet one of the two criteria above.

Payment of Risk Evaluation Fees

Pursuant to the Fees Rule, the fee for each TSCA section 6(b) risk evaluation will be \$1,350,000. EPA requires all manufacturers subject to the risk evaluation fees to make a complete payment no later than 120 days after publication of the final scope documents. Assuming EPA meets its statutory deadlines, the payment due date should be no later than October 18, 2020. Where consortia are not formed or cannot agree on a cost-sharing mechanism themselves, EPA's rules call for apportioning fees equally. The agency will not use other common fee sharing mechanisms, such as market share.

EPA strongly encourages manufacturers to form consortia to pay for the risk evaluation fees. In the consortia context, alternative fee-setting mechanisms are possible. Manufacturers will have 60 days from the day the agency publishes final scope documents to identify a principal sponsor and notify EPA they have formed a consortium. If the manufacturers within a consortium fail to agree on how fees will be allocated, the principal sponsor of the consortium must notify EPA in writing during the 60-day window from the date of the final scope documents. In other words, within this 60-day window, the principal sponsor of the consortium must notify EPA that (1) the manufacturers have formed a consortium and, where applicable, (2) they have failed to reach agreement within the consortium on the allocation of fees.

Of course, EPA's "ideal scenario is that a single consortium forms and independently agrees upon allocation of payment amongst its members." In this ideal scenario, EPA would send a single invoice to the consortium for payment of the risk evaluation fee. Manufacturers within a consortium are free to agree on how to allocate the fee among its members. EPA has explained how it will apportion fees in the event that that multiple consortia form or there is a combination of consortia and individual manufacturers. This allocation becomes even more complicated when taking into account the discounts for small business concerns under TSCA.

If a single consortium does not represent all manufacturers subject to the pertinent risk evaluation fee and/or manufacturers fail to agree on splitting the fees within a consortium, then EPA will calculate and allocate the fee according to the following formula:

- Count the total number of manufacturers (including importers and manufacturers within any consortium);
- Divide the total fee amount (\$1,350,000) by the total number of manufacturers;
- Allocate equally on a "per capita" basis to generate a "base fee";
- Provide all small businesses with an 80% discount from the base fee as long as those small businesses are not associated with a consortium (other than an all-small business consortium);
- Recalculate the total remaining fee and total number of remaining manufacturers by subtracting the discounted fees and the number of small businesses; and
- Reallocate the remaining fee across those remaining manufacturers in equal amounts (each manufacturer within a consortium represents one manufacturer).

Below, we provide three basic scenarios to illustrate how EPA could allocate the \$1,350,00 risk evaluation fee:

- There are 10 manufacturers subject to the risk evaluation fee. They are all members of the same consortium. EPA will invoice the consortium for \$1,350,000. The manufacturers will reach an agreement on how to allocate the fee within the consortium.
- There are 10 manufacturers subject to the risk evaluation fee. Only five of the manufacturers are members of a consortium. EPA will charge the five individual manufacturers \$135,000 each and send an invoice to the consortium for \$675,000.
- There are 10 manufacturers subject to the risk evaluation fee. Five are members of a consortium, two are small businesses, and the remaining three are neither. EPA will calculate a base fee of \$135,000 (\$1,350,000 divided by 10). The two small businesses would receive their 80% discount and be required to pay \$27,000 each (\$135,000 multiplied by 0.2). EPA would then recalculate the remaining fee to be \$162,000 for each remaining manufacturer (\$27,000 multiplied by 2, then subtracted from \$1,350,000, and finally divided by 8). The agency would invoice the consortium for \$810,000 (\$162,000 multiplied by 5), while the three remaining individual manufacturers would each be responsible for paying \$162,000.

Again, EPA requires manufacturers to pay these fees 120 days after EPA issues the final scope document for a particular risk evaluation. Given that these payments will be due no later than October 2020, your company may need to set aside funds from its 2020 fiscal-year budget to pay for one or more risk evaluations.

Civil Enforcement Actions and Penalties

EPA's Federal Register notice for the preliminary lists reminds companies that manufacturers (including importers) that fail to identify themselves as subject to fee obligations may be subject to a penalty under section 16 of TSCA. 85 Fed. Reg. 4661, 4663 (Jan. 27, 2020). EPA's Fees Rule establishes that failure to timely remit the appropriate fees "is a violation of TSCA and enforceable under section 15 of the Act." 40 C.F.R. § 700.49(b). Specifically, "[f]ailure to pay the appropriate fee at the required time would subject each manufacturer . . . who is subject to the fee payment to penalties regardless of whether they intend to pay independently . . . or through a consortium." 83 Fed. Reg. 53694, 52710 (Oct. 17, 2018). Until the fee is paid, any non-compliant manufacturer (or importer) faces a potential penalty up to the maximum allowed by statute, including an inflation adjustment, of \$40,576/day for each day the manufacturer (or importer) has failed to make a payment past the payment due date. Likewise, companies that falsely certify to having ceased manufacture (including import) or not re-initiating manufacture (including import) within five years will also be subject to penalties. Companies should anticipate that EPA is set to impose substantial penalties for noncompliance to strongly disincentivize companies from trying to avoid risk evaluation fee payments. Indeed, a manufacturer's share of the fee could prove to be much lower than the penalty that the agency would seek to impose on a free-rider who violated the law. There is no provision in TSCA or the Fees Rule that authorizes companies that have paid risk evaluation fees to seek compensation from free-riders on their own.

The Need for Consortia

Manufacturers and importers should come together to form consortia because EPA's default allocation methodology fails to reflect any market-share realities. To wit, in the absence of a consortia, manufacturers and importers of significantly different sizes would be required to pay the same portion of the risk evaluation fee. Because the outcome of the risk evaluations may have a greater impact on those companies that use and rely on the chemicals under evaluation, processors and other downstream users are allowed to voluntarily join consortia and contribute towards the risk evaluation fee. Creating a consortium of manufacturers, importers (including those that import the chemical within an article), processors, and downstream users will be beneficial to all the parties involved.

Nevertheless, forming consortia and fairly allocating fees for a risk evaluation is a complex endeavor. Wiley has decades of experience in forming and managing consortia of chemical manufacturers under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) to pay for high-value studies that generate data needed for EPA's review and approval of pesticides. In managing these consortia, we have successfully worked through data compensation issues to ensure that the cost of generating data is fairly apportioned among consortia members. Specifically, we know how to work with consortia members to determine a fair allocation of costs among the members. Finally, we are skilled at mediating potential disputes among consortia

members, thus preventing dissolution of the consortia. Failure to form a consortium could have significant, costly consequences for manufacturers.

Consortia also serve a vital role in coordinating the generation and submission of data needed to inform agency action. Another unique dynamic emerging in TSCA stems from the lack of provisions authorizing companies to seek data compensation for data which are voluntarily submitted to EPA. Our consortia will work closely with agency staff to ensure that EPA truly understands how our chemicals are manufactured, processed, and used, in addition to understanding the agency's data needs. When engaging EPA, it is important for the affected industries - through the consortia - to speak with a unified voice and have a consistent message. A consortium would also allow manufacturers, processors, and downstream users to exchange ideas and strategies on what studies to conduct, what information to submit to the agency, and which arguments will persuade the key decisionmakers within EPA.

Conclusion

The publication of EPA's preliminary lists of manufacturers subject to the risk evaluation fees represents a significant action by the agency that warrants close attention by your company. Failure to self-identify or correct the agency's record could result in potential EPA enforcement actions and related penalties.

We strongly believe that EPA needs to extend the comment period for at least sixty days after the agency issues the draft scopes of the risk evaluations because EPA's scope documents will provide better clarity about which manufacturers (especially importers of articles) will be subject to the risk evaluation fees. Moreover, we encourage companies to comment on fee fairness issues, such as by encouraging EPA to establish *de minimis* fee cut-offs, during the comment period.

If you would like to discuss what EPA's preliminary lists mean for your company or how you can join one of our consortia, please contact Martha Marrapese (mmarapese@wiley.law or 202.719.7156).

[1] For an additional discussion on why EPA must extend the comment period, please read this article from The Wiley Environmental Law Line: <https://www.thewell.law/blogposts/will-importers-of-articles-be-forced-to-pay-costly-fees-for-tsca-risk-evaluations-or-face-potentially-draconian-penalties>.