WASHINGTON WATCH

EPA-Initiated TSCA Risk Evaluations: Who Is on the Hook for Fees Has Changed

By Lynn L. Bergeson

Under the amended Toxic Substances Control Act (TSCA), the U.S. Environmental Protection Agency (EPA) has authority to collect fees from chemical manufacturers and importers to defray a portion of the EPA costs associated with risk evaluation efforts. The fees are quite substantial and who pays them has been the subject of considerable debate and uncertainty. This column addresses issues that have caused confusion and anxiety for industry stakeholders regarding the self-identification criteria, time lines, and procedures, and seeks to add much needed clarity to this chaotic issue.

Background

The EPA fees rule became effective on October 18, 2018. It requires payment of fees for eight categories of fee-triggering events under TSCA, including EPA-initiated risk evaluations under TSCA Section 6. As part of the final fees rule, EPA is required to prepare a preliminary list of manufacturers subject to fee obligations for EPA-initiated Section 6 risk assessments.

On January 27, 2020, EPA published a *Federal Register* notice identifying the preliminary lists of manufacturers (including importers) of the 20 high-priority chemical substances for risk evaluation for which fees will be charged. The notice included information on the circumstances and processes for which manufacturers (including importers) are required to self-identify as manufacturers of a high-priority substance irrespective of whether they are included on the preliminary lists identified by EPA.

Under the rule, any company that has manufactured or imported any of the 20 high-priority chemicals since January 27, 2015, must respond, whether they are listed on the preliminary manufacturers list or not. A company that is listed on the preliminary list but has not manufactured or imported the

subject chemical since January 27, 2015, must also respond, otherwise, under the rule, it will be assessed a share of the fees. A company that processes or uses a subject chemical or incorporates it into a product, but does not manufacture or import the subject chemical, is not required to respond.

If a company has manufactured or imported since January 27, 2015, but can certify that it has not manufactured or imported the subject chemical since March 20, 2019 (the day before the publication of the proposed high-priority chemical list on March 21, 2019), and the company will certify that it will not manufacture or import the subject chemical in any amount for five years, or until January 27, 2025, the company is not subject to the fee obligation. If a company is included on a subject chemical preliminary list, but has not manufactured or imported the subject chemical in any amount since January 27, 2015, it can certify this to EPA and be relieved from the fee obligations.

Responses to the EPA preliminary list, including required self-identification and/or certifications on time lines for manufacture or imports, were due by May 27, 2020. Responses were to be submitted to EPA via the Central Data Exchange (CDX). General comments on the EPA notice were also due by May 27, 2020.

Open Issues that Are Being Resolved

Since the rules were issued, several issues have arisen and for the most part have been resolved over the past nine months. Each is discussed below.

No Action Assurance: The 2018 final fees rule offers no explicit exemptions for chemicals manufactured or imported as an impurity, byproduct, in an article, or in trace amounts. This represents a stark departure from other obligations under TSCA that historically have exempted from certain TSCA obligations chemicals found to be byproducts, impurities, and included in articles. In response to widespread confusion and concern, EPA issued a press release on March 25, 2020, announcing that it intends to consider a proposed rule that would provide exemptions to the October 2018 TSCA fees rule. Specifically, EPA indicates that it plans to initiate a rulemaking to exempt manufacturers that (1) import the chemical

substance in an article, (2) produce the chemical substance as a byproduct, and (3) produce or import the chemical substance as an impurity. Because it will not be possible for EPA to promulgate such a rulemaking prior to when reporting is needed for the 20 high-priority chemicals later this year, EPA also states in the press release that it issued a "no action assurance" for the three categories. Importantly, this means that EPA will exercise its enforcement discretion if a company fits within these three categories that will be exempted but does not self-identify. This is very good news for industry stakeholders. An EPA FAQ on the March 2020 rulemaking announcement and no action assurance is available.

Contrary to some speculation, there is no *de minimis* exemption under the fees rule. If a listed chemical was manufactured or imported at any volume and does not meet the proposed exemptions noted above, it would still trigger the need to self-identify as a manufacturer. Similarly, there is no exemption for subject chemicals manufactured or imported for research and development (R&D) within the time lines specified.

Import Brokers May Be Required to Respond: Questions have arisen regarding the obligations of import brokers under the fees rule. Typically, the company that is the importer of record is the party that is obligated to comply with TSCA regulations. EPA is currently working on additional guidance on this issue specific to the fees rule based on feedback during an April 16, 2020, EPA-sponsored webinar. Based on this, EPA is expected to follow its Chemical Data Reporting (CDR) rule guidance related to importer responsibilities. That CDR guidance indicates that provided one of the parties to the import transaction satisfies the TSCA obligation, EPA is satisfied. If none of the parties to the import transaction satisfies the obligation, EPA will consider all parties in violation. In this case, as long as one of the parties involved in the import transaction properly self-identifies and pays its share of the fee, presumably, EPA will be satisfied. If none of the import transaction parties self-identifies or pays the share of the fee, then EPA may consider all parties in violation.

Failure to Self-Identify: Some have questioned whether EPA will pursue entities that should have self-identified but did not, for one reason or another. EPA has stated that once it issues the final list of companies subject to the fees rule, it would not be revisiting that list. EPA has indicated that there could be enforcement actions and assessment of

potential penalties if a company was aware of a chemical's potential liability for a fee but did not self-identify. Now EPA's positon is that once the initial fee payment is made, there is no requirement for others to contribute, even if they were nominally out of compliance. EPA can and may well seek penalty fees if EPA becomes aware of instances of non-compliance, but this would be separate and apart from seeking to collect the TSCA manufacturer fees.

Whether to Join a Consortium: There is no requirement to join a consortium. Companies are, however, urged to consider doing so. Forming a consortium has the benefit of the consortium determining how the fees to EPA should be divided among its members. Perhaps as important, a consortium provides members a means of engaging effectively in advocacy in the risk evaluation process for substances of interest. This engagement includes developing and submitting comments during the scoping phase, ensuring that EPA is using the best available data and science to conduct the risk evaluation, and providing to EPA data on conditions of use that reflect realistic exposure scenarios and workplace controls. EPA has stated its preference for working with consortia as they create efficiencies for EPA and the member companies. EPA should be notified of consortium formation, including the names of its members, within 60 days of EPA's publication of the final scope of the risk evaluation for the subject chemical.

The 20-High Priority Chemicals: A commonly asked question is what are the high-priority chemicals. As reference, provided below is the list of the 20 high-priority chemicals:

Chemical Name	**CAS**
p-Dichlorobenzene	106-46-7
1,2-Dichloroethane	107-06-2
trans-1,2-Dichloroethylene	156-60-5
o-Dichlorobenzene	95-50-1

1,1,2-Trichloroethane	79-00-5
1,2-Dichloropropane	78-87-5
1,1-Dichloroethane	75-34-3
Dibutyl phthalate (DBP) (1,2-Benzene-dicarboxylic acid, 1,2-dibutyl ester)	84-74-2
Butyl benzyl phthalate (BBP) (1,2-Benzene-dicarboxylic acid, 1-butyl 2-(phenylmethyl) ester)	85-68-7
Di-ethylhexyl phthalate (DEHP) (1,2-Benzene-dicarboxylic acid, 1,2-bis(2-ethylhexyl) ester)	117-81-7
Di-isobutyl phthalate (DIBP) (1,2-Benzene-dicarboxylic acid, 1,2-bis(2-methylpropyl) ester)	84-69-5
Dicyclohexyl phthalate	84-61-7
4,4'-(1-Methylethylidene)bis[2,6-dibromophenol] (TBBPA)	79-94-7
Tris(2-chloroethyl) phosphate (TCEP)	115-96-8
Phosphoric acid, triphenyl ester (TPP)	115-86-6
Ethylene dibromide	106-93-4
1,3-Butadiene	106-99-0
1,3,4,6,7,8-Hexahydro-4,6,6,7,8,8-hexamethylcyclopenta[g]-2-benzopyran (HHCB)	1222-05-5

Formaldehyde	50-00-0
Phthalic anhydride	85-44-9

Conclusion

Despite the considerable confusion occasioned by EPA's implementation of the 2018 fees rule, there are several positive take-a ways. First, the rule has expanded considerably the relevance of TSCA to a broad spectrum of downstream chemical stakeholders. For those of the view that TSCA is relevant to many more entities beyond industrial chemical manufacturers and importers, the fees rule has really given expression to the new reality. That TSCA authorizes the payment of fees for risk revaluations by entities far down the chemical value chain was revelatory to many and helps demonstrate TSCA's broad reach.

Second, the experience demonstrates EPA's willingness to listen to stakeholders and make accommodations based on comments. That EPA is prepared to consider issuing no action assurance letters is both comforting and quite significant given EPA's historic reluctance to issue such letters.

Third, EPA's decision to amend the fees rule based on comments it received in response to its solicitation is another indication of EPA's desire to get it right. Arguably, the rule should never have applied to article manufacturers and listed chemicals considered byproducts or impurities. But the final rule, for whatever reason, did not exempt these categories and a new rulemaking is needed. EPA's commitment to devote the resources to address the situation is commendable.