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Importer Beware: You Might Be Asked to Pay EPA to Evaluate a Chemical You Don't Manufacture

Advisory

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Someday very soon, the US Environmental Protection Agency (EPA or the Agency) will publish a preliminary list of companies that it considers to be "manufacturers" of certain chemicals designated as High Priority Substances pursuant to the Toxic Substances Control Act (TSCA). The Agency recently announced its plans to undertake risk evaluations for 20 High Priority Substances.[1] In accordance with EPA's new procedures to implement the 2016 amendments to TSCA, the Agency plans to assess a separate $1.35 million fee for each risk evaluation it conducts. If your company's name shows up on EPA's preliminary list of manufacturers or importers of any one of those chemicals, you may be asked to pay a portion of as much as $25 million in fees EPA might assess to partially offset its costs for conducting 20 risk evaluations.

You might think that sounds fair for businesses that are in the business of manufacturing or importing chemicals in bulk for use and distribution in the US. However, even if you read the Agency's prioritizing and fee-setting regulations, you might be surprised to learn EPA also plans to impose that fee-sharing obligation on companies that import any "article" (i.e., manufactured components and finished goods such as cars, clothing and even toys) that might contain those chemicals. The problem is, importers of such commodities are very unlikely to have any idea if the goods they import contain a High Priority Substance; yet they will find themselves in violation of TSCA if they fail to "self-identify" as an importer of such substances in "articles."

This Advisory discusses the statutory and regulatory background for risk evaluation fees and suggests some strategies for dealing with the issue of whether a company is or should be subject to the fee obligation.

Background

A regulation the Agency promulgated in October 2018 specifies that certain "user fees" would be paid by "[m]anufacturers of a chemical substance that is subject to a risk evaluation."[2] In most cases, "manufacturers" and "importers" of chemical substances are well aware they are subject to TSCA and likely have a growing awareness that they could become one of the parties required to contribute their share of a $1.35 million fee for a risk evaluation fee EPA initiates. However, for persons who import commodity products that are formulations (think of a detergent or cleaning product imported from Mexico to the US) or manufactured items (imagine a camisole or a maple desk chair imported from Canada), there may be surprises in store. In somewhat obscure preamble language in the final rule, EPA indicated that it interprets the risk evaluation fees obligation to extend to importers of High Priority Substances that are present in formulations only as byproducts or impurities. In an even more remote location found only in the annals of the on-line docket for the rulemaking, EPA noted that importers of manufactured articles that contain High Priority Substances are also considered to be subject to the final fees rule.

2016 Amendments to TSCA Authorized Fees for Risk Evaluations

Prior to the enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act in 2016,[3] TSCA did not provide for fees for Section 6 activities.[4] The pre-2016 TSCA only authorized fee assessments on parties submitting data pursuant to Sections 4 or 5 and capped those fees at very low levels. Moreover, EPA's pre-2016 implementation of fee rules only imposed user fees for applicants submitting Section 5 new chemical notifications. The 2016 amendments increased and enhanced EPA's responsibilities under Section 6 to evaluate and regulate existing chemicals, including by prioritizing

chemical substances and conducting risk evaluations to determine whether a substance presents an unreasonable risk under its conditions of use. The amended TSCA also authorized the collection of a fee from "any person . . . who manufactures or processes a chemical substance that is the subject of a risk evaluation under section 6(b)."[5] The TSCA amendments specified that EPA could collect fees to "provide a sustainable source of funds to annually defray" up to the lower of $25 million or 25 percent of EPA's costs of administering Sections 4, 5, 6, and 14.[6]

2018 Rule Established the Fees Process

A final fees rule published in October 2018 set the fee for an EPA-initiated risk evaluation at $1.35 million for the fiscal years 2019 through 2021.[7] This fee is due 120 days after the publication of a "final scope" document outlining EPA's detailed plan for a risk evaluation.[8]

The final fees rule also established the process for identifying the parties who must pay the fee for a risk evaluation.[9] First, EPA will use various data sources to identify manufacturers of the High-Priority Substances. Data sources include information submitted to (i) EPA under Sections 5(a), 8(a) (including information submitted through the Chemical Data Reporting (CDR) program) and 8(b); (ii) the Toxics Release Inventory; (iii) other publicly available information (think internet searches); and (iv) other agencies such as the US Custom and Border Patrol.[10] EPA will rely on the five most recent years of data to determine which companies to include on a preliminary list of manufacturers subject to the fee.[11]

After publication of the preliminary list, there will be an opportunity for: (i) public comment, (ii) "self-identification" by manufacturers and importers of the substance, (iii) "certifications of no manufacture" (if a manufacturer is listed but has not manufactured the substance in the past five years), and (iv)"certifications of cessation" (if a manufacturer has ceased manufacture of the substance prior to initiation of the prioritization process for the applicable chemical substance and will not manufacture the substance again in the successive five years).[12] EPA will publish a final list of manufacturers subject to fee obligation no later than it publishes the final scope for the risk evaluation.[13]

Within 60 days of publication of the final scope document, manufacturers have to notify EPA of any intent to form a consortium with other companies that are subject to the fee.[14] The consortium members then decide among themselves how to allocate the fee.

Although the fee rule provides that EPA will publish the preliminary list of companies required to contribute to the fee at the time of the final designation of a High-Priority Substance,[15] as of this writing, EPA has not yet released the preliminary lists for the 20 initial High-Priority substances it designated in December 2019.

Who Will Have to Pay Fees? A Possibly Surprising Twist—With Significant Consequences

As those familiar with TSCA well know, the statute makes clear that the term "manufacturers" includes importers of chemical substances,[16] but EPA has indicated that it is construing the term more broadly in the risk evaluation fee context than some regulated entities may have anticipated. For example, EPA explicitly stated in the preamble to the final fees rule that it did not think it was appropriate to exclude manufacturers of a chemical as an impurity or byproduct from the fee obligation.[17] This is generally consistent with EPA's interpretation of obligations that may be imposed for test rules, for example. In addition, although the final rule and the preamble are completely silent on the imposition of fees on importers of manufactured articles that contain a High-Priority Substance, EPA's online list of frequently asked questions currently indicates that the fee obligation will extend to such parties.[18] Although providing an exemption from fees for importers of articles was a frequent request among those submitting public comments, this topic was not addressed in the discourse included in the preamble to the final rule; and EPA's decision not to grant the request is noted only in the somewhat difficult to find "responses to comment" document tucked away in the rulemaking docket.[19]

EPA's current interpretation creates considerable risks for importers of articles who either (a) are not aware of EPA's interpretation or (b) are not aware that articles they import or manufacture contain a High-Priority Substance. The same risks are experienced by importers of finished consumer and commercial products (e.g., cleaning product, detergent, air freshener) that are formulations that could contain a High Priority Substance as a manufacturing byproduct or impurity.

The Agency's broad interpretation, and the lack of awareness of EPA's very broad interpretation, creates considerable compliance risks for such importers who might have no awareness they are expected to "self-identify" under the current regulations even if their names do not appear on EPA's preliminary list of persons who are manufacturers or importers of a High Priority Substance. EPA specifically stated in the preamble to the final fees rule that

> manufacturers who fail to identify themselves as required by this are committing "a

> prohibited act under TSCA section 15(1) and[are] therefore subject to a penalty under TSCA section 16. [Moreover,] EPA views each day of failed identification by a manufacturer past the payment due date as a separate event subject to penalty.[20]

EPA may impose penalties under TSCA which currently exceed $30,000 dollars per day per violation.

Among the 20 High Priority Substances recently designated is Formaldehyde. It is easy to imagine that an importer/distributer of finished consumer or commercial products that are supplied by another entity might not have any awareness of the potential presence of Formaldehyde as a minor manufacturing byproduct or impurity in the finished product. Easier still to conceive of is the automotive manufacturer or appliance maker who imports cars or washing machines that might bear a paint or coating applied overseas but which might contain a High Priority Substance in the cured finish. Formulation or other downstream users would not know the chemical content of an article due, for example, to suppliers withholding such information either intentionally or unintentionally. Is it reasonable for EPA to expect such importers to know the chemical content of every coating and on-board component in their imported articles for purposes of "self-identifying" as a "manufacturer" of every chemical substance that comprises a component?

It is also highly unlikely that the data sources EPA is relying on to draw up the preliminary lists will identify importers of articles as manufacturers since, for example, the CDR rule exempts from reporting persons who import chemical substances as part of an article.[21] Companies should not breathe a sigh of relief, however, if they are not listed on the preliminary lists that EPA releases. As mentioned above, the comment period that follows the publication of these lists is intended to provide an opportunity for companies to "self-identify" as manufacturers or importers of the High Priority Substance, and the failure to step up (even as an importer of articles) creates the threat of sanctions. Even more concerning is this opportunity also might encourage listed manufacturers to report to EPA the names of *other* entities who the listed manufacturer thinks should share the burden of EPA-imposed fees. It follows that EPA might have created an opportunity for public interest organizations that currently sample everyday products in California for Proposition 65 purposes to apply their sampling technologies in the TSCA fees rule context to stalk importers of consumer products and finished articles.

How Can Importers and Distributers of Formulated Products or Articles Prepare?

As ingredient disclosure and labeling and warning requirements in the US have grown, businesses at all levels of the supply chain have increased their expectations for transparency on the part of their suppliers. International treaties and common market-level restrictions on the presence of certain chemicals of concern in products have amplified such expectations. EPA's interpretation of its TSCA risk evaluation fees rule, and the compliance implications for importers of finished products that are consumer- and commercial-use formulations and manufactured goods, serves to underscore the need for importers of such products to increase their diligence with respect to transparency concerning product-content. This requires commercial enterprises at all points in the value chain to maintain a keen awareness of the substances EPA considers to be High Priority, as well as those which it might select for subsequent prioritization efforts under TSCA in the coming months and years.

**Margaret Barry contributed to this Advisory.*

[1] 84 Fed. Reg. 71924 (Dec. 30, 2019). The 20 substances are listed on page 71934 of the *Federal Register* notice.

[2] 40 CFR § 700.45(a)(3).

[3] Frank R. Lautenberg Chemical Safety for the 21st Century Act, Pub. L. No. 114-182, 130 Stat. 448 (2016).

[4] *See* 15 USC § 2625(b).

[5] 5 USC § 2625(b)(1). The amendments also authorized collection of fees for a broader array of activities under Sections 4, 5 and 14.

[6] 15 USC § 2625(b)(4)(B)(i). TSCA separately provides for recovery of costs associated with risk evaluations conducted at manufacturers' request. *See* 15 USC § 2625(b)(4)(D).

[7] 40 CFR § 700.45(c)(2)(ix); 83 Fed. Reg. 52694 (Oct. 17, 2018).

[8] 40 CFR § 700.45(g)(3)(iv).

[9] 40 CFR § 700.45(b). This process also will be used to determine who is subject to fees for Section 4 test rules.

[10] 40 CFR § 700.45(b)(2); 83 Fed. Reg. at 52696.

[11] 40 CFR § 700.45(b)(2).

[12] 40 CFR § 700.45(b)(4), (5).

[13] 40 CFR § 700.45(b)(7).

[14] 40 CFR § 700.45(f)(3).

[15] 40 CFR § 700.45(b)(3)(i).

[16] *See* 40 CFR § 2602(9).

[17] 83 Fed. Reg. at 52699. EPA also said it would not be appropriate to exclude those who manufacture chemicals for small, niche markets. *Id*.

[18] *Frequent Questions about TSCA Administration Fees*, EPA, (last updated Dec. 19, 2019).

[19] EPA, Response to Public Comments on the Proposed Rule: Fees for the Administration of the Toxic Substances Control Act (not dated).

[20] 83 Fed. Reg. 52694 at p 52697. *See* 15 USC §§ 2614, 2615.

[21] 40 CFR § 711.10(b).