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EPA Releases Final Rule on TSCA User Fees

Article By:

Thomas C. Berger

Herbert Estreicher, Ph.D.

James G. Votaw

On September 27, 2018, EPA (the Agency) released a pre-publication copy of the final rule establishing "user fees" for the administration of the Toxic Substances Control Act (TSCA) (15 U.S.C. § 2601 *et seq*.). This rulemaking is one of the four "framework" rules promulgated by EPA as part of the implementation of the Frank R. Lautenberg Chemical Safety for the 21st Century Act (LCSA). The rule became effective October 1, 2018.

Purpose of User Fees

Section 26(b) of TSCA authorizes EPA to collect fees for certain TSCA activities from chemical manufacturers, importers, and processors, and establishes provisions for auditing, fee adjustments and refunds, and considerations for fee allocation and small businesses. The purpose of such fees is to defray a portion of the costs associated with:

- The Agency's administration of sections 4, 5, and 6;
- The Agency's collection, processing, review, and protection of confidential business information (CBI) claims under section 14.

These fees defray both intramural (EPA staff) and extramural costs (*i.e*., contractor costs). In the rule, EPA established user fees for manufacturers and importers that:

- Submit information to EPA under section 4 (testing);
- Submit a notice, exemption application, or other information under section 5 (new chemicals);
- Manufacture or import a chemical subject to a risk evaluation or request a risk evaluation under section 6(b).

The rule allows EPA to collect fees from processors in limited scenarios, such as when a processor submits a significant new use notice (SNUN), when a fee-triggering section 4 activity is tied to a SNUN submission by a processor, or when a processor joins a consortium.

As EPA indicated in the proposed rule, EPA expects to collect approximately $20 million in average annual fees (excluding fees for manufacturer-requested risk evaluation). For manufacturer-initiated risk evaluations, EPA expects to collect $1.3 million annually for chemicals in the TSCA Work Plan, and $3.9 million for chemicals not included in the Work Plan.

Summary of Fees

In the final rule, apart from manufacturer-initiated risk evaluations, EPA established the same fee amounts as originally proposed:

FEE CATEGORY	FEE AMOUNT (NOT APPLICABLE TO SMALL BUSINESSES)	FEE AMOUNT (SMALL BUSINESSES)	Timing of Pa
TSCA Section 4			
Test order	$9,800	$1,950	Within 120 issuance of te
Test rule	$29,500	$5,900	Within 120 publication of rule.
Enforceable consent agreement (ECA)	$22,800	$4,600	Within 120 signing E
TSCA Section 5			
PMN and consolidated PMN	$16,000	$2,800	Upfro
SNUN			
MCAN and consolidated MCAN			
*LoREX	$4,700 (fee for each exemption request and modifications to previous exemption requests)	$940	Upfro
LVE			
*TME			
Tier II exemption			
TERA			
Film Articles			
TSCA Section 6			
EPA-initiated risk evaluation	$1,350,000	$270,000	Within 120 publishing the of risk eval
Manufacturer-initiated risk evaluation on a chemical included in the TSCA Work Plan	Initial payment of $1.25M, with final invoice to recover 50% of actual costs	Initial payment of $1.25M, with final invoice to recover $50% of actual costs	Initial payment days of EPA request, follo final invoice at the risk eva
Manufacturer-initiated risk evaluation on a chemical not included in the TSCA Work Plan	Initial payment of $2.5M, with final invoice to recover 100% of actual costs	Initial payment of $2.5M, with final invoice to recover 100% of actual costs	Initial payment days of EPA request, follo final invoice at

			the risk eva

***** EPA will waive the TME fee for submissions from companies that have graduated from EPA's Sustainable Futures program.

*EPA is imposing fees for all exemption submissions except Tier 1 exemption submissions and polymer exemption reports. There is also no fee for bona fide submissions.

EPA had proposed a fee of $1.3M for a manufacturer-requested risk evaluation of a chemical included in the Work Plan, and $2.6M for a manufacturer-requested risk evaluation of a chemical not included in the Work Plan. However, in the final rule, EPA decided to structure the payments so that the manufacturer makes an initial payment ($1.25M for Work Plan Chemicals and $2.5M for non-Work Plan chemicals) and then EPA submits an invoice to the manufacturer once the risk evaluation is completed to defray the costs (50% of actual costs for Work Plan chemicals and 100% of the actual costs for non-Work Plan chemicals).

For submissions under section 5, EPA retained its proposal to assess the same fee for individual pre-manufacture notices (PMNs) as consolidated PMNs to keep a "practical, implementable TSCA fee structure", and for simplicity. However, consolidated PMNs are still limited to up to six chemical substances.

Refunds

The Agency also finalized its proposed provisions for refunds and stated that it plans to issue *full* refunds for:

- PMN submissions for substances that are determined not to be "new chemical substances,"
- MCAN submissions when the microorganism is determined not to be a new microorganism or significant new use,
- SNUN submissions if the use is determined not to be a "significant new use,"
- The Agency's failure to make a determination on a notice by the end of the applicable notice review period, unless the submitter unduly delayed the process (note that a voluntary suspension simply "pauses" the review period), and
- The Agency's failure to approve or deny an exemption within the applicable review period, unless the submitter unduly delayed the process. EPA clarified that "undue delay" by the submitter "might occur" if the submitter submits an amended submission or new information late in the review process and that in this case, the Agency will not suspend the review period.

EPA will issue *partial* refunds, or 75% of the fee amount, if a TSCA section 5 submission is withdrawn during the first 10 business days after the beginning of the applicable review period.

Identifying Manufacturers Subject to Fees for Test Rules and EPA-Initiated Risk Evaluations

EPA finalized several provisions from the proposed rule, including the methodology for calculating fees (other than manufacturer-requested risk evaluations), program cost estimates, fee categories, payment through consortia, small business provisions, and the provision for refunds. However, EPA also made some changes from the proposed rule. One of the major changes is that EPA established a new process for identifying manufacturers subject to fee rules under TSCA section 4 (test rules), as well as EPA-initiated risk evaluations under section 6. EPA originally proposed to rely on Chemical Data Reporting (CDR) information and self-identification from manufacturers not subject to CDR reporting. However, in the final Fee Rule, EPA establishes a new process for identifying the universe of manufacturers, which includes:

- Publication of a preliminary list (based on CDR reporting, information submitted under TSCA section 5, Toxic Release Inventory data, U.S. Customs and Border Patrol data, and other publicly available sources like Panjiva);
- A public comment period to allow for self-identification and correction of errors, and/or certification of no manufacture for the next five years; and
- Publication of final list defining the universe of manufacturers obligated to pay.

If EPA receives a certification statement that a manufacturer has ceased manufacturing the substance in question, prior to the date the prioritization process is initiated for the chemical, and will not manufacture for 5 years into the future, or they have not manufactured the chemical in the five years preceding publication of the preliminary list, then the manufacturer will not be obligated to pay the fee.

Importantly, the obligation to pay for EPA-initiated risk evaluations attaches to manufacturers and importers when EPA initiates prioritization (i.e., before publication of the preliminary list), which means that companies cannot avoid paying for a risk evaluation by dropping out of the market after prioritization is underway. Rather, companies must cease manufacture or import before prioritization begins. Thus, companies that manufacture or import a substance that was on the TSCA Work Plan should be prepared to cease manufacture and import before the first round of substances are identified for prioritization (which may be as early as December 2018), if they wish to avoid fees for risk evaluation.

Industry Consortia and Allocation of Fees

EPA also provided additional guidance on the allocation of fees for industry consortia. The Agency explained that manufacturers subject to test orders, test rules, enforceable consent agreements, and EPA-initiated risk evaluations can form a consortium and work out the allocation of fees within the consortium. Manufacturers will have 60 days to notify EPA of their intent to form a consortium (rather than only 30 days as proposed) and 120 days from the triggering event for payment. As for the allocation of fees, EPA explains in the final rule that the “ideal scenario” is that a single consortium forms and agrees on the allocation of fees, and EPA would send a single invoice to the consortium. However, if multiple consortia form, EPA will allocate fees by:

- Counting the total number of manufacturers, including the number of manufacturers within any consortia.
- Dividing the total fee amount by the total number of manufacturers and allocating equally on a

per capita basis to generate a base fee.

- Providing all small businesses that are either (a) not associated with a consortium, or (b) associated with an all-small business consortium with an 80% discount from the base fee.
- Calculating the remaining fee and number of remaining manufacturers by subtracting out the discounted fees and the number of small businesses identified.
- Reallocating the remaining fee across those remaining individuals and groups in equal amounts, counting each manufacturer in a consortium as one person.

It is critical for companies impacted by this Fee Rule—including manufacturers, importers and processors—to carefully review the new fee requirements, as they apply to activities and submissions on or after Oct. 1, 2018.

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