



# WASHINGTON WATCH

## EPA Proposes TSCA User Fees

By Lynn L. Bergeson

We all knew it was coming, and the proposal has finally arrived. On February 8, 2018, the U.S. Environmental Protection Agency (EPA) announced that EPA Administrator Scott Pruitt signed a proposed rule regarding user fees for the administration of the Toxic Substances Control Act (TSCA). As amended by the Frank Lautenberg Chemical Safety for the 21st Century Act, TSCA provides EPA the authority to levy fees on certain chemical manufacturers, including importers and processors, to “provide a sustainable source of funding to defray resources that are available for implementation of new responsibilities under the amended law” (EPA, 2018a, p. 1). EPA states in its press release that these fees:

would go toward developing risk evaluations for existing chemicals; collecting and reviewing toxicity and exposure data and other information; reviewing Confidential Business Information (CBI); and, making determinations in a timely and transparent manner with respect to the safety of new chemicals before they enter the marketplace. (EPA, 2018a. p. 1).

This column summarizes the proposal and explains why it is significant.

### Overview

Under the amendments to TSCA, EPA has authority to require payment from manufacturers and processors who:

- Are required to submit information by test rule, test order, or enforceable consent agreement (ECA) (TSCA Section 4);

- Submit notification of or information related to intent to manufacture a new chemical or significant new use of a chemical (TSCA Section 5); or
- Manufacture or process a chemical substance that is subject to a risk evaluation, including a risk evaluation conducted at the request of a manufacturer (TSCA Section 6(b)).

Beginning in fiscal year (FY) 2019, EPA is required to adjust fees, as necessary, every three years to reflect inflation and ensure that fees are sufficient to collect 25% of the costs to EPA in administering TSCA Sections 4, 5, 6, and 14. Before establishing new fees or revising any existing fees, EPA is required to consult with manufacturers and processors, or their representatives.

The proposed rule provides a description of proposed TSCA fees and fee categories for FYs 2019, 2020, and 2021, and explains the methodology by which the proposed TSCA user fees were determined and would be determined for subsequent FYs. In proposing the new TSCA user fees, EPA also proposes amending long-standing user fee regulations governing the review of premanufacture notices (PMN), exemption applications and notices, and significant new use notices (SNUN). After implementation of final TSCA user fees regulations, certain manufacturers and processors would be required to pay a prescribed fee for each notice, exemption application, and data set submitted or chemical substance subject to a risk evaluation for EPA to recover certain costs associated with carrying out certain work under TSCA. EPA requests comment on the proposed user fees and the methodology used for determining the amounts. EPA is also proposing and taking comment on standards for determining which persons qualify as small business concerns, and thus, would be subject to lower fee payments.

### **Who Will Be Charged Fees**

EPA notes that although it has the authority to collect fees from both manufacturers and processors, it is proposing to focus fee collection on manufacturers. EPA proposes to collect fees from processors only when processors submit a SNUN under Section 5 or when a Section 4 activity is tied to a SNUN submission by a processor. According to the proposed rule,

the agency believes that “the effort of trying to identify a representative group of processors for the other three fee-triggering actions would be overly burdensome and expects many processors would be missed” (EPA, 2018b, p. 8216). Furthermore, the EPA states that it expects that manufacturers required to pay user fees will have a better sense of the universe of processors and will pass some of the costs on to them. EPA seeks public comment on this approach.

While fee payers will self-identify for certain actions, such as making a Section 5 new chemical submission to EPA, for other actions, such as TSCA Section 6 risk evaluations, EPA proposes to use Chemical Data Reporting (CDR) data to identify a preliminary list of companies. EPA seeks comment on whether to adopt a process that would allow time for public input for adding to that preliminary list before it is issued in final. EPA states that it is also interested in comments on using other sources to identify those subject to payment of fees. These sources include information reported to the Toxics Release Inventory (TRI), notice of commencement (NOC) submissions under EPA’s TSCA New Chemicals Review Program, and information reported under the TSCA Inventory active/inactive notification rule.

### **How EPA Calculated the Proposed User Fees**

EPA states that it believes that assigning fees across TSCA Sections 4, 5, and 6 is the most equitable and efficient approach for allocating costs. EPA intends its proposed fee methodology to recover fully the amount specified in the statute per TSCA Section 26(b)(4)(F). According to EPA, the estimated annual costs of carrying out TSCA Sections 4, 5, 6, and 14, without including the costs associated with manufacturer-requested chemical risk evaluations, are approximately \$80.2 million. Based on these cost estimates, EPA anticipates collecting approximately \$20.05 million in fees each year. In addition, EPA intends to collect fees from manufacturers to recover a portion of costs incurred by the agency in conducting chemical risk evaluations requested by manufacturers. EPA expects this fee amount will be \$1.3 million per chemical for chemicals on the Work Plan and \$2.6 million per chemical for chemicals not on the Work Plan.

EPA states that it determined the anticipated costs associated with TSCA Sections 4, 5, 6, and 14 activities, including both program costs and indirect

costs. For FYs 2019 through 2021, EPA estimated these costs to be approximately \$80.2 million per year, as detailed in the table below:

### **Estimated Annual Costs to EPA (FYs 2019 through 2021)**

	<b>Direct Program Costs</b>	<b>Indirect Costs</b>	<b>Annual Costs</b>
<b>TSCA Section 4</b>	\$2,765,000	\$778,000	\$3,543,000
<b>TSCA Section 5</b>	\$22,375,000	\$6,296,000	\$28,672,000
<b>TSCA Section 6</b>	\$34,073,000	\$9,545,000	\$43,618,000
<b>TSCA Section 14</b>	\$3,531,000	\$814,000	\$4,345,000
<b>Total</b>	<b>\$62,744,000</b>	<b>\$17,425,000</b>	<b>\$80,178,000</b>

Notes: Numbers may not add due to rounding. The indirect cost rate for Office of Chemical Safety and Pollution Prevention is estimated at 28.14% for the purposes of this analysis. (EPA, 2018b, p. 8217).

After EPA estimated the annual costs of administering TSCA Sections 4, 5, 6, and 14, the agency had to determine how the costs would be allocated over the narrower set of activities under TSCA Sections 4, 5, and 6 that trigger a fee. EPA states that it took an approach to determining user fees that parsed the fees based on the type of submission or fee triggering event, allowing costs to be more equitably allocated among the submissions and their related costs.

Under the proposed rule, EPA would require payment of fees for most types of fee triggering events under TSCA Sections 4, 5, and 6. This includes the requirement to submit information to comply with a test order, test rule, or ECA under TSCA Section 4. EPA would also require payment for the following TSCA Section 5 notices and exemptions: PMNs and consolidated PMNs, SNUNs, microbial commercial activity notices (MCAN) and consolidated MCANs, test marketing exemptions (TME), low releases and low exposures (LoREX), low volume exemptions (LVE), Tier II, film article exemptions, and TSCA experimental release applications (TERA). Payment would also be required for chemicals undergoing both EPA-initiated and manufacturer-requested risk evaluations under TSCA Section 6.

For TSCA Section 4 activities for existing chemicals, EPA is proposing three fee categories. The proposed fee associated with a test order is \$10,000. The proposed fee associated with a test rule is \$32,000, and the fee proposed for an ECA is \$25,000. The agency states that it expects these fees will be paid by consortia, assuming that multiple companies manufacture the same chemical, and is requesting that consortia assign comparatively lower fees for small businesses than for large businesses in the consortia. Consistent with comments previously received, EPA is proposing to provide flexibility to manufacturers to form consortia to allocate these fees amongst those members involved in each submission activity.

EPA proposes two categories of fees, with different fee amounts, for TSCA Section 5 submissions. According to the proposed rule, EPA “chose to lump activities with similar Agency costs together” (EPA. 2018b, p.8220) to develop a simple fee structure. The fee proposed for each PMN, SNUN, and MCAN is \$16,000. The fee proposed for each LoREX, LVE, TME, Tier II, film article, and TERA is \$4,700. EPA proposes to continue the practice of allowing consolidation of PMNs, consolidation of MCANs, and in some cases, consolidation of a synthetic sequence, for up to six closely similar chemical substances with similar use, structure, and probable toxicology at the same time and for the same fee as a single chemical substance. According to EPA, consolidated PMNs (and MCANs) benefit submitters by reducing the administrative burden of developing multiple Section 5 submission forms for manufacture of two or more structurally related new chemical substances that have similar use, exposure, environmental release, and test data. EPA notes that its review process is also better facilitated by reviewing similar substances simultaneously.

The fee amounts being proposed are summarized in the following table:

### Proposed TSCA User Fees

PROPOSED FEE CATEGORY	PROPOSED FEE
<b>TSCA Section 4</b>	
Test order	\$9,800
Test rule	\$29,500
Enforceable consent agreement	\$22,800
<b>TSCA Section 5</b>	

PMN and consolidated PMN	\$16,000
SNUN	
MCAN and consolidated MCAN	
LoREX	\$4,700
LVE	
TME*	
Tier II exemption	
TERA	
Film Articles	
<b>TSCA Section 6</b>	
EPA-initiated risk evaluation	\$1,350,000
Manufacturer-requested risk evaluation on a chemical included in the Work Plan	\$1,300,000
Manufacturer-requested risk evaluation on a chemical <u>not</u> included in the Work Plan	\$2,600,000

\*EPA is proposing to waive the TME fee for submissions from companies that have graduated from EPA's Sustainable Futures program. (EPA, 2018b, p. 8222).

### Small Business Concerns

EPA proposes reduced fees for small businesses, as summarized in the following table:

#### Proposed TSCA User Fees for Small Businesses

PROPOSED FEE CATEGORY	PROPOSED FEE
<b>TSCA Section 4</b>	
Test order	\$1,950
Test rule	\$5,900
Enforceable consent agreement	\$4,600
<b>TSCA Section 5</b>	
PMN and consolidated PMN	\$2,800
SNUN	
MCAN and consolidated MCAN	

LoREX	\$940
LVE	
TME	
Tier II exemption	
TERA	
<b>TSCA Section 6</b>	
EPA-initiated risk evaluation	\$270,000
Manufacturer-requested risk evaluation on a chemical included in the Work Plan	\$1,300,000
Manufacturer-requested risk evaluation on a chemical <u>not</u> included in the Work Plan	\$2,600,000

(EPA, 2018b, p. 8224.)

EPA set the proposed small business fees at an 80% reduction compared to the proposed base fee for each category. EPA notes that in one case, for PMN and related actions, the proposed small business fee reduction is 82.5%. According to the agency, this slightly higher percentage reduction is due to the concern for the potential impact on small businesses of higher fee levels. The proposed small business fees for each category fee is triggered only when there is one entity subject to the fee, and that entity is a small business, or if there is a consortium paying the fee, and all members of that consortium are small businesses.

EPA proposes to revise the size standard used to identify businesses that can qualify as a “small business concern” (EPA, 2018b, p. 8224) under TSCA for the purposes of fee collection. In 1988, EPA promulgated a regulatory definition for a small business that makes a submission under TSCA Section 5, based on the annual sales value of the business’ parent company. EPA states that the definition provided in 40 C.F.R. Section 700.43 currently states: Small business concern means any person whose total annual sales in the person’s fiscal year preceding the date of the submission of the applicable section 5 notice, when combined with those of the parent company (if any), are less than \$40 million” (EPA, 2018b, p. 8224).

The agency proposes several changes to this definition. Consistent with the definition of small manufacturer or importer at 40 C.F.R. Section 704.3, EPA proposes to increase the current revenue threshold of \$40 million using the

Producer Price Index (PPI) for Chemicals and Allied Products, as compiled by the U.S. Bureau of Labor Statistics. Using a base year of 1988 and inflating to 2015 dollars results in a value of approximately \$91 million.

Pursuant to 13 C.F.R. Section 121.903(a)(1)(ii), EPA also proposes to change the time frame over which annual sales values are used when accounting for a business's revenue. Instead of using just one year preceding the date of submission, EPA proposes to average annual sales values over the three years preceding the submission. EPA proposes to apply this updated definition -- adjusted for inflation and averaging sales revenue over three years -- to not only TSCA Section 5 submissions, but also to TSCA Section 4 and 6 submissions, as well.

### **Timing of Fee Payment**

EPA proposes to collect lump sum payment of the entire user fee for Section 5 notices prior to reviewing each submission or undertaking the activity associated with the fee. EPA proposes to require fee payment at the time a TSCA Section 5 notice (including an exemption) is submitted.

EPA proposes to allow fee submitters for test orders, test rules, ECAs, and EPA-initiated chemical risk evaluations time to associate with a consortium and work out fee payments within that consortium. Payment for fee categories under TSCA Section 4 (*i.e.*, test orders, test rules, and ECAs) is due within 60 days of the effective date of the order or rule, or 60 days upon the signing of an ECA. For EPA-initiated risk evaluations, full payment is due within 60 days of EPA publishing the final scope of a chemical risk evaluation. EPA states that it believes this provides sufficient time for manufacturers to associate as a consortium, if they so choose, and to decide on the partial fee payments each member of the consortium will be responsible for. The agency notes that manufacturers will have ample warning that a risk evaluation is underway, well before the final scope is published in the *Federal Register*.

For manufacturer-requested risk evaluations, EPA proposes to collect a fee when it grants the request to conduct the evaluation. Payment will be required within 30 days of EPA providing such notice.

EPA proposes that user fees will begin to be incurred starting **on October 1, 2018**. The agency states that it will not, however, collect any fees until the final user fee rule is effective. Instead, EPA intends to record actions that would be expected to trigger payment of fees, and once the rule is final, send invoices to the affected parties. The invoices would reflect timing for payments and amounts based on the final rule.

### **Consequences of Failing to Pay a Fee**

The proposed rule states that failure to comply with any requirement of a rule promulgated under TSCA is a prohibited act under TSCA Section 15 and is subject to penalties under TSCA Section 16. When the final rule is promulgated, failure to pay the appropriate fee at the required time would subject each manufacturer and processor who is subject to the fee payment to penalties of as much as the maximum statutory amount per day (\$38,114 as of January 2017) until the required fee is paid. Each person subject to fees would be subject to such penalties regardless of whether they intend to pay independently, as a joint submitter, or through consortia. Specifically, each member of a consortium, and each joint submitter, is individually responsible for payment of the fee, and is subject to penalties for non-payment, until the fee is actually paid.

### **Compliance Date**

EPA proposes to start collecting fees the day after the final TSCA user fees rule is published in the *Federal Register*.

### **Discussion**

The proposal is substantial and important, and not all aspects are addressed here. EPA seeks comment on many issues. It is important because the financial integrity of the TSCA program is essential, and this revenue stream is critical. The proposal represents an excellent basis upon which to engage stakeholders on this important issue. EPA urgently needs a reliable revenue stream to support the implementation of TSCA to ensure Congress' goals are fulfilled. Industry seeks timely, professional, and expert review of industrial chemicals to ensure new chemicals are commercialized as quickly as possible and all industrial chemicals are evaluated accurately and thoroughly. This

takes resources; and the proposed approach strikes the right balance addressing competing interests. Stakeholders are urged to comment and ensure the new fee structure is fair and adequate to fulfill all stakeholder expectations.

## References

EPA (2018a). EPA meets important milestone: Proposes fees rule, the final of four framework rules for EPA chemical safety evaluations under TSCA.

EPA Press Office, February 8, 2018. Available at:

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EPA (2018b). User fees for the administration of the Toxic Substances Control Act. Proposed Rule. Federal Register, February 26, 2018, 83(38), 8212-8235. Available at:

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