

EPA Releases Final TSCA Fees Rule

Article By:

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On February 8, 2024, the Environmental Protection Agency (EPA) [announced](#) its final amendments to the 2018 final rule that established fees for the administration of the Toxic Substances Control Act (TSCA). The final rule includes changes to the fee amounts and EPA's total costs for administering TSCA; exemptions for entities subject to the EPA-initiated risk evaluation fees; exemptions for test rule fee activities; modifications to the self-identification and reporting requirements of EPA-initiated risk evaluation and test rule fees; modifications to EPA's proposed methodology for the production-volume-based fee allocation for EPA-initiated risk evaluation fees in any scenario in which a consortium is not formed; expanded fee requirements to companies required to submit information for test orders; modifications to the fee payment obligations of processors subject to test orders and enforceable consent agreements (ECA); and extended timeframes for certain fee payments and notices. The final rule will be effective 60 days after publication in the *Federal Register*. EPA has posted a [pre-publication version](#) of the rule.

Program Cost Estimates and Activity Assumptions

In the final rule, EPA states that as discussed in its November 16, 2022, supplemental notice (2022 Supplemental Notice) to its January 11, 2021, proposed rule (2021 Proposal), the October 18, 2018, fee rule (2018 Fee Rule) "has resulted in collection of roughly half of the (artificially low) baseline costs EPA has the authority to collect, resulting in additional TSCA implementation challenges due to insufficient resources." EPA notes that in addition, the baseline cost estimates in the 2018 Fee Rule were based on what EPA spent on implementing TSCA before it was amended in 2016, rather than what it would cost to implement the revised law. According to EPA, in the first four years following the 2016 law's enactment, it did not conduct a comprehensive budget analysis designed to estimate the costs of implementing the amended law, and it did not conduct such an analysis until spring 2021. The 2022 Supplemental Notice included a program cost estimate based on the 2021 analysis that more adequately accounted for the anticipated costs of meeting its statutory mandates. In reviewing comments on the proposals for this rulemaking, EPA has revisited its budget analysis and the program cost estimates, and its final estimates differ from the 2022 Supplemental Notice. Specifically, EPA has reduced the total program cost estimate by over 19 percent, and it is now approximately \$146.8 million (compared to approximately \$181.9 million in the 2022 Supplemental Notice). EPA has also included a more granular breakdown of the costs, as requested by stakeholders, in a separate technical support document (TSD) for the final rule. EPA recognizes that the costs associated with implementing TSCA may be re-evaluated and can change over time (e.g., due to changes in

administrative priorities or insights and changes in practice gained through experience implementing the law). The cost estimates discussed in the TSD and the final rule are based on EPA's estimates at the time the rulemaking and support materials were developed.

Program Costs

The final rule summarizes the total cost estimates for TSCA Section 4, 5, 6, and 14 activities. EPA states that it evaluated its costs from fiscal year (FY) 2023, and then, after considering the assumptions and activities discussed in more detail in the TSD, evaluated the projected increase or decrease of those activities for contract dollars and full-time equivalents (FTE). According to EPA, “[a]nnually, from FY 2024 through FY 2026, the Agency anticipates a direct need of 383.67 FTE and \$55,415,307 in contract (i.e., non-pay) dollars.” The total estimated program costs, including personnel compensation and benefits (PC&B) applied to each FTE directly involved in TSCA Section 4, 5, 6 (excluding manufacturer-requested risk evaluations (MRRE)), and 14 activities and the indirect cost, is \$146,754,074. Table 1 in the final rule provides the following estimated annual costs to EPA (FY 2024 through FY 2026):

Annual Costs	
TSCA Section 4	\$7,678,352
TSCA Section 5	\$40,219,461
TSCA Section 6 (excluding MRREs)	\$70,486,244
TSCA Section 14	\$7,823,436
Agency Indirect Costs	\$20,546,580
Total	\$146,754,074

Indirect Costs

EPA states that it calculated the indirect costs included in the estimates for TSCA Sections 4, 5, and 6, and for collecting, processing, reviewing, and providing access to and protecting confidential business information (CBI) from disclosure as appropriate under TSCA Section 14, by multiplying the appropriate indirect cost rates for FY 2024 and beyond by the estimated direct costs. The Office of the Controller calculates indirect cost rates each year, using EPA's current indirect methodology. On an annual basis, each program office is provided with an independent rate, expressed as a percentage, for use in calculating indirect costs.

According to EPA, for direct TSCA Section 4, 5, 6, and 14 costs, an indirect cost rate of 16.28 percent was applied. Table 6 in the final rule includes the following total indirect costs included in the overall TSCA Section 4, 5, 6, and 14 cost estimates:

Direct Costs	Indirect Costs	
TSCA Section 4	\$7,678,352	\$1,250,036
TSCA Section 5	\$40,219,461	\$6,547,728

TSCA Section 6	\$70,486,244	\$11,475,161
TSCA Section 14	\$7,823,436	\$1,273,655
Total	\$126,207,494	\$20,546,580

Total Collections for Fee-Triggering Events

EPA states that it estimated a total program cost of implementing TSCA Sections 4, 5, 6 (excluding MRREs), and 14 to be \$146,754,074. Based on its assumptions and the final fee amounts, the total estimated fees collected for all fee categories, excluding the MRRE is \$36,687,346 plus a collection of \$5,671,013 from MRREs totaling \$42,358,359. EPA notes that it also accounted for refunds for certain TSCA Section 5 activities as seen in Table 7 of the final rule:

Fee Category	Estimated Activity Levels –Non-Small Business	Estimated Activity Levels — Small Business	Fee — Non-Small Business	Fee — Small Business	Total Annual Collections
Test Order	14.0	n/a	\$25,000	\$5,000	\$350,000
Test Rule	0.33	n/a	\$50,000	\$10,000	\$16,500
ECA	0.33	n/a	\$50,000	\$10,000	\$16,500
Total Estimated Annual Fees Collected for Section 4 Activities					\$383,000
PMN (including intermediate)/MCAN/SNUN	151.0	65.0	\$37,000	\$6,480	\$6,014,304
LoREX, LVE, TME, Tier II exemption, TERA, Film Articles	178.0	88.0	\$10,870	\$2,180	\$2,128,612
Full (100%) refund — Notices	8.0	3.0	(\$37,000)	(\$6,480)	(\$315,440)
Full (100%) refund — Exemptions	10.0	4.0	(\$10,870)	(\$2,180)	(\$117,420)
75% refund — Notices	0	0	(0)	(0)	(0)
Total Estimated Fees Collected for Section 5 Activities					\$7,710,056
EPA-Initiated Risk	6.67	n/a	\$4,287,000	\$857,400	\$28,594,290

Evaluation					
MRRE (work plan chemical)	0.67	n/a	\$4,244,771	n/a	\$2,843,996
MRRE (non-work plan chemical)	0.333	n/a	\$8,489,541	n/a	\$2,827,017
Total Estimated Fees Collected for Section 6 Activities					\$34,265,303
Total Estimated Fees Collected for All Sections after Refunds (including MRREs)					\$42,358,359

Fee Amounts

EPA states that it calculated fees by estimating the total annual costs of carrying out relevant activities under TSCA Sections 4, 5, and 6 (excluding the costs of MRRE) and conducting relevant information management activities under TSCA Section 14; identifying the full cost amount to be defrayed by fees under TSCA Section 26(b) (*i.e.*, 25 percent of those annual costs); and allocating that amount across the fee-triggering events in TSCA Sections 4, 5, and 6. EPA notes that in addition, it affords small businesses an approximately 80 percent discount, in accordance with TSCA Section 26(b)(4)(A).

According to EPA, while TSCA allows it to collect approximately but not more than 25 percent of its costs for eligible TSCA activities via fees, to date, EPA has collected roughly half of that amount due to the insufficiencies of the current fees rule. EPA states that the final fee amounts are designed to ensure fee amounts capture approximately but not more than 25 percent of the costs of TSCA activities, fees are distributed equitably, and fee payers are identified via a transparent process. In addition, although TSCA allows EPA to recover approximately but not more than 25 percent of its costs of implementing certain provisions of TSCA, EPA notes that “the percentage applies to the total aggregate cost and does not preclude EPA from recovering an amount above or below 25 percent of the costs for each section of TSCA. Therefore, some fee-triggering activities account for a larger proportion of the total fee collections than others.”

EPA states that it considered several factors, including comments from stakeholders, in determining the final fee amounts that would result in EPA collecting 25 percent of those estimated costs, while also setting lower fees for small businesses. These factors include activity cost and numbers associated with the individual fee-triggering events, including fee refunds; proportion of small businesses; the cost to industry to implement the activity (*e.g.*, test order fees are not as high due to reduced burden to industries that are already paying for testing); and the potential burden of the fee to industry (*e.g.*, whether a fee is shared by multiple manufacturers). Table 8 of the final rule compares the current fees to the final fee amounts:

Fee Category	Current Fees ¹	Final Fees
Test Order	\$11,650	\$25,000
Test Rule	\$35,080	\$50,000
ECA	\$27,110	\$50,000

PMN and consolidated PMN, SNUN, MCAN, and consolidated MCAN	\$19,020	\$37,000
LoREX, LVE, TME, Tier II exemption, TERA, Film Articles	\$5,590	\$10,870
EPA-Initiated Risk Evaluation	Two payments resulting in \$2,560,000	Two payments resulting in \$4,287,000
MRRE on a Chemical Included in the TSCA Work Plan	Two payments of \$945,000, with final invoice to recover 50% of actual costs	Two payments of \$1,414,924, with final invoice to recover 50% of actual costs
MRRE on a Chemical <i>Not</i> Included in the TSCA Work Plan	Two payments of \$1.89M, with final invoice to recover 100% of actual costs	Two payments of \$2,829,847, with final invoice to recover 100% of actual costs

¹The current fees reflect an adjustment for inflation as required by TSCA. The adjustment went into effect on January 1, 2022.

Fee Amounts for TSCA Section 4 Activities

EPA is promulgating the fee amounts proposed in the 2022 Supplemental Notice for TSCA Section 4 activities: \$25,000 for test orders; \$50,000 for test rules; and \$50,000 for ECAs. EPA states that it is adopting fees that, based on the expected activity levels of the three fee categories for TSCA Section 4 activities, will result in a collection of \$383,000.

Fee Amounts for TSCA Section 5 Activities

EPA sets two fee amounts for TSCA Section 5 activities — one for notices (premanufacture notices (PMN), significant new use notices (SNUN), and microbial commercial activity notices (MCAN)) and one for exemptions (including low exposure/low release exemptions (LoREX), low volume exemptions (LVE), test marketing exemptions (TME), certain microorganism Tier II exemptions (Tier II), and TSCA experimental release applications (TERA)). In response to comments and the overall reduction in EPA's program cost estimates, the final fee amounts are lower than those proposed in the 2022 Supplemental Notice (*i.e.*, \$45,000 for notices and \$13,200 for exemptions). EPA set final fees of \$37,000 for notices and \$10,870 for exemptions. Entities that qualify as a small business concern receive an approximately 80 percent discount. EPA states:

Additional funding collected through TSCA section 5 fees will help EPA reduce the backlog of delayed reviews and support additional work for new cases. As previously noted in the 2022 Supplemental Notice, these delays result from a years-long absence of the additional resources required to implement the 2016 amendments, which shifted the Agency's past practice of making risk determinations on about 20 percent of the new chemical submittals it received to a requirement to make such determinations on 100 percent of submittals. These final fee amounts will result in an annual collection of approximately \$7.7 million from TSCA section 5 activities.

Fee Amounts for TSCA Section 6 Activities

EPA collects one fee amount for EPA-initiated risk evaluations that is shared by manufacturers of that chemical substance. In response to comments on the amount proposed in the 2022 Supplemental Notice (*i.e.*, \$5,081,000), as well as an overall reduction in the total program cost estimate due to found efficiencies, EPA lowered the final fee amount for EPA-initiated risk evaluations. EPA states that it set a fee of \$4,287,000 paid over two installments that, based on the expected activity levels of this fee category, would result in EPA collecting approximately \$29.9 million from TSCA Section 6 EPA-initiated risk evaluations.

EPA takes an actual cost approach for MRREs, whereby the requesting manufacturer or consortium of manufacturers is obligated to pay either 50 percent or 100 percent of the actual costs of the activity, depending on whether the chemical was listed on the TSCA Work Plan. Based on the installment plan and the estimated costs of these risk evaluations, EPA will require manufacturers to make two payments of \$1,414,924 for a TSCA Work Plan chemical, or two payments of \$2,829,847 for a non-TSCA Work Plan chemical. EPA will then invoice the requestor for the remainder.

Fee Amounts for Small Businesses

The final fee amounts for small businesses represent an approximate 80 percent reduction compared to the proposed base fee for each category. EPA states that for TSCA Section 5 notices (*i.e.*, PMNs, MCANs, and SNUNs), the small business reduction is 82.5 percent. For all fee categories, the reduced fee is available only when the only entity or entities that owe that particular fee are small businesses, including when a consortium is paying the fee and all members of that consortium are small businesses. According to EPA, “[r]educed fees are not available for small businesses that request MRREs, as TSCA requires those fees to be set at a specific percentage of the actual costs of the activity.” Table 9 summarizes the fees for small businesses:

Fee Category	Final Fees
Test Order	\$5,000
Test Rule	\$10,000
ECA	\$10,000
PMN and consolidated PMN, SNUN, MCAN, and consolidated MCAN	\$6,480
LoREX, LVE, TME, Tier II exemption, TERA, Film Articles	\$2,180
EPA-Initiated Risk Evaluation	\$857,400

Fee Categories

The 2018 Fee Rule has eight distinct fee categories: (1) test orders; (2) test rules; (3) ECAs, all under TSCA Section 4; (4) notices; (5) exemptions, both under TSCA Section 5; (6) EPA-initiated risk evaluations; (7) MRREs for chemicals on the TSCA Work Plan; and (8) MRREs for chemicals not on the TSCA Work Plan, all under TSCA Section 6. The activities in these categories (other than the first ten risk evaluations) are fee-triggering events that result in obligations to pay fees under the 2018 Fee Rule.

In the 2021 Proposal, EPA proposed two additional fee categories under TSCA Section 5, Bona Fide Intent Notices (BFI) and Notices of Commencement of Manufacture or Import (NOC), and one additional fee category for TSCA Section 4, for amended test orders. After considering public comments received on the 2021 Proposal and the 2022 Supplemental Proposal, and to keep the fee structure simple by reducing the number of fee categories, EPA states that it is not implementing new fee categories for BFIs, NOCs, and amended test orders as proposed in the 2021 Proposal. According to EPA, in this final rule, the cost associated with NOCs will continue to be captured with those of PMNs, MCANs, and SNUNs, as they were under the 2018 Fee Rule. In addition, while EPA “envisioned the additional fee for amended test orders to create an incentive for manufacturers to submit facially complete data outlined under TSCA section 4,” to simplify the TSCA Section 4 fee structure, the final rule does not include the amended test order fee category proposed in the 2021 Proposal. EPA notes that because the costs incurred by EPA to review resubmitted data are included in EPA’s total program cost estimate, these costs will be captured under other fees.

Refund for Withdrawal during Review

The final rule does not include the refund proposed in the 2022 Supplemental Notice for 20 percent of the user fee to the submitter if a PMN is withdrawn ten or more business days after the beginning of the applicable review period, but prior to EPA initiating risk management on the chemical substance. According to EPA, the steps required to initiate a refund and to provide notice that the risk assessment on the chemical substance has concluded would impose additional burden on EPA. To make an informed decision on whether to withdraw their notice, EPA states that it would need to send submitters details about the risk findings, complete risk assessments, and/or potential risk management being considered by EPA. Providing these details or sending final risk assessment documents requires review and redaction prior to transmission and development of draft risk mitigation terms, and these steps “would further consume limited resources and impose an additional burden on staff and run contrary to the idea that EPA would not have spent the final 20% of the fee on risk management.”

Methodology for Calculating Fees for EPA-Initiated Risk Evaluations

The approach in the final rule includes ranking the fee payers that do not qualify as a small business concern by their reported production volume, then assigning fees based on those rankings. The non-small business manufacturers in the top 20th percentile ranking would pay 80 percent of the total fee, distributed evenly among those manufacturers. EPA states that it “believes this methodology is equitable, accounts for various fee payer scenarios, protects CBI, and ensures EPA is collecting approximately but not more than 25 percent of applicable program costs.” According to EPA, these changes ensure that the manufacturers of the largest quantity of production volume for a chemical undergoing risk evaluation pay the majority of the obligated fee. In any scenario in which all manufacturers of the chemical substance undergoing the EPA-initiated risk evaluation do not form a single consortium, EPA will take the following steps to allocate fees:

- Step 1: Count the total number of manufacturers, including the number of manufacturers within any consortia;
- Step 2: Divide the total fee amount by the total number of manufacturers to generate a base fee;
- Step 3: Provide all small businesses who are either (a) not associated with a consortium, or (b) associated with an all-small business consortium, with an 80 percent discount from the base fee;
- Step 4: Calculate the total remaining fee amount and the total number of remaining

manufacturers that will share the fee by subtracting out the discounted fees and the number of small businesses identified;

- Step 5: Place remaining manufacturers in ascending order (from lowest to highest production volume based on their average annual production volume from the three calendar years prior to the publication of the preliminary list);
- Step 6: Assign each remaining manufacturer a number with 1 for lowest production volume, 2 for second lowest production volume, etc.;
- Step 7: Multiply the total number of remaining manufacturers by 0.8;
- Step 8: Determine the manufacturer(s) in the top 20th percentile spot by comparing the number derived from Step 7 to the manufacturer(s) with the assigned number derived in Step 5. Manufacturers with an assigned number under Step 6 that is equal to or larger than the number in Step 7 are in the top 20th percentile;
- Step 9: Reallocate 80 percent of the remaining fee evenly across manufacturers in the top 20th percentile determined in Step 8, counting each manufacturer in a consortium as one entity; and
- Step 10: Reallocate the remaining fee evenly across the remaining manufacturers, counting each manufacturer in a consortium as one entity.

In the event that three or fewer manufacturers are identified for a chemical substance, EPA states that it will distribute the fee evenly among those three or fewer fee payers, regardless of production volume. In the event the number assigned to the top 20th percentile is not an integer, EPA will round to the nearest integer to determine the manufacturer(s) with the reported production volume greater than or equal to the top 20th percentile. In the event multiple manufacturers report the same production volume and are greater than or equal to the top 20th percentile, EPA will include all manufacturers with that same production volume in the fee calculation for the top 20th percentile group.

Export-Only Manufacturers

In the 2021 Proposal, EPA proposed to require manufacturers that exclusively export chemicals subject to EPA-initiated risk evaluations to pay fees to defray the costs of the risk evaluations. EPA notes that it acknowledged the ambiguity of TSCA Section 12(a) in that rulemaking. After further review, EPA states that it has decided not to exercise any discretion it may have under TSCA Sections 12(a) and 26 to require export-only manufacturers to make payments to defray the costs of risk evaluations.

Exemptions for Certain Fee-Triggering Activities

The final rule includes the six exemptions as proposed in the 2021 Proposal and further amended in the 2022 Supplemental Notice. These exemptions apply to EPA-initiated risk evaluations and/or test rules for: (1) importers of articles containing a chemical substance; (2) producers of a chemical substance as a byproduct that is not later used for commercial purposes or distributed for commercial use; (3) manufacturers of a chemical substance as an impurity as defined in 40 C.F.R. Section 704.3; (4) producers of a chemical as a non-isolated intermediate as defined in 40 C.F.R. Section 704.3; (5) manufacturers of small quantities of a chemical substance used solely for research and development (R&D) as defined in 40 C.F.R. Section 700.43; or (6) manufacturers of chemical substances with production volume less than 2,500 pounds (lb) for TSCA Section 6 activities and 1,100 lbs for TSCA Section 4 test rules. EPA states that for clarification, “manufacture for commercial purposes” is defined in 40 C.F.R. Section 704.3 as “to import, produce, or manufacture with the purpose of obtaining an immediate or eventual commercial advantage for the manufacturer, and includes among

other things, such “manufacture” of any amount of a chemical substance or mixture.”

According to EPA, by narrowing the byproduct exemption to include only manufacturers of byproducts that are not later used for commercial purposes or distributed for commercial use, EPA will still collect fees from producers of chemicals that are then sold or used for commercial purposes. EPA states that in addition, it “has confidence that producers of byproducts that are later sold or used for commercial purposes will not encounter the same issues and self-identification requirements described in EPA’s memorandum from March 18, 2020, since those producers knowingly produce the byproduct before it is introduced into the market (86 FR 1899).” The final byproduct exemption addresses commenters’ concerns with challenges with self-identification as related to identifying and tracking byproducts that are unintentionally or coincidentally produced (40 C.F.R. Section 700.45(b)(5)).

Self-Identification and Certification Requirements

EPA states that it has weighed the various approaches to establishing a final list of fee payers for the EPA-initiated risk evaluations and TSCA Section 4 test rules, including eliminating steps in the self-identification process. EPA “has confidence that the self-identification process (i.e., publication of a preliminary list that identifies manufacturers, a public comment period, and publication of a final list defining the universe of manufacturers responsible for payment), including changes discussed in the 2021 Proposal and 2022 Supplemental Notice, best ensures that all obligated fee payers are identified, thereby reducing the burden of the shared fees on manufacturers.” EPA notes that the process also allows for correction of errors and certification of no-manufacture or meeting an exemption to alleviate certain manufacturers of fee payment obligations. EPA is amending 40 C.F.R. Section 700.45(b) by modifying who is obligated to pay fees and self-identify through exemptions, requiring certification of meeting exemption for certain manufacturers, requiring submission of production for certain manufacturers, and allowing for changes to the final list if necessary.

According to EPA, due to significant industry stakeholder feedback, it proposed exemptions for EPA-initiated risk evaluations and proposed changes to the submission of self-identification information in 40 C.F.R. Section 700.45 to accompany those changes. EPA expanded those proposed exemptions in the 2022 Supplemental Notice to apply to test rules under TSCA Section 4 and provided additional context around certain exemptions by cross-referencing and narrowing the byproduct exemption. The final rule includes these exemptions as proposed in 2021 and amended in 2022 and is not requiring manufacturers that meet the criteria of three of the exemptions (*i.e.*, importers of articles containing the chemical substance, manufacturers of the substance that is produced as a byproduct, and manufacturers of the substance that is produced or imported as an impurity) from self-identification. Manufacturers of small quantities solely for R&D, those that manufacture in quantities not to exceed 1,100 lbs or 2,500 lbs depending on whether it is a test rule or EPA-initiated risk evaluation, and manufacturers of chemical substances produced as a non-isolated intermediate are required to certify that they meet those exemption criteria. In addition, if a manufacturer is identified on the preliminary list and exclusively meets one or more of the exemptions, that manufacturer must submit a certification statement attesting to these facts to not be included in the final list of manufacturers.

Companies Required to Submit Information under TSCA Section 4

EPA states that regardless of whether a manufacturer conducts testing to comply with a test order, EPA incurs costs for developing the test order and administering the test order after it has been issued, including reviewing data submitted by test order recipients. To ensure that a portion of these costs will be recovered, EPA is promulgating as proposed in the 2022 Supplemental Notice revisions

to 40 C.F.R. Section 700.45(a)(2) to refer to manufacturers required to submit information rather than manufacturers “required to test.” According to EPA, this change “includes all manufacturers required to submit information regardless of when data or other information was procured and creates a more equitable fee allocation.”

Payment by Processors Subject to Test Orders and ECAs

The 2018 Fee Rule established that only manufacturers are required to pay fees for TSCA Section 4 test orders and ECAs. EPA notes that as a result, when no manufacturers are identified as recipients, EPA would be required to absorb the entire cost of administering TSCA Section 4 test orders and ECAs. EPA is modifying the fee payment obligations in 40 C.F.R. Section 700.45(a) to require payment by processors identified in the TSCA Section 4 test orders and ECAs who submit information. When no manufacturers receive a test order or ECA, requiring fee payments by processors would allow EPA to recoup the costs of administering such test orders and ECAs.

Timeframe for Fee Payments and Notifications

After the effective date of the final rule, manufacturers will have 90 days from the fee-triggering event (in comparison to the 60 days established in the 2018 Fee Rule) to notify EPA of their intent to form a consortium. EPA states that this revision will allow manufacturers subject to test orders, test rules, ECAs, and EPA-initiated risk evaluations additional time to associate with a consortium and establish fee payments within that consortium. EPA “believes this additional time will be useful for businesses to plan for the fee expense.”

Under the 2018 Fee Rule, full payment for EPA-initiated risk evaluations was due within 120 days of EPA publishing the final scope of a chemical risk evaluation. EPA is extending that first payment timeline to 180 days and requiring payments to be made in two installments instead of one, with the first payment of 50 percent due 180 days after EPA publishes the final scope of a risk evaluation and the second payment for the remainder of the fee due 18 months (*i.e.*, 545 days) after EPA publishes the final scope of a risk evaluation. For MRREs, EPA is extending the initial payment timeframe to within 180 days of when EPA grants the request to conduct the evaluation, with the total amount to be paid over a series of three installments.

The final rule extends the timeframe for test order and test rule payments from 120 days to 180 days after the effective date of the order or rule. EPA notes that this timeframe aligns with the proposed timeframe for the initial fee payment associated with EPA-initiated risk evaluations under TSCA Section 6. According to EPA, the change would provide it with sufficient time to review fee payments, identify and allocate fees across several different entities, and issue invoices.

Recordkeeping

EPA is amending the recordkeeping requirements related to the exemptions and production volume-based fee methodology for EPA-initiated risk evaluations, as discussed in the 2022 Supplemental Notice, with slight modifications. These requirements can be found in 40 C.F.R. Section 700.45(b)(10).

Under the final rule, all manufacturers other than those listed in 40 C.F.R. Section 700.45(a)(2)(i) through (v) or (a)(3)(i) through (v) (*i.e.*, all manufacturers other than those that qualify for the exemptions related to articles, byproducts, impurities, non-isolated intermediates, and/or R&D) must

maintain production volume records related to their production volume submission. These records must be maintained for a period of five years from the date the notice is submitted to EPA.

Manufacturers that manufacture or import a chemical substance in quantities below a 1,100 lbs annual production volume for test rules or 2,500 lbs annual production volume for EPA-initiated risk evaluations (*i.e.*, those meeting the exemption criteria in 40 C.F.R. Section 700.45(a)(2)(v) or (a)(3)(v)) must maintain production volume records related to compliance with the exemption criteria. These records must be maintained for a period of five years from the date notice is submitted to EPA.

Manufacturers of a chemical substance as a non-isolated intermediate (*i.e.*, those meeting the exemption criteria in 40 C.F.R. Section 700.45(a)(2)(iv) or (a)(3)(iv)) must maintain manufacturing and other business records related to compliance with those exemption criteria. Manufacturers of small quantities of a chemical substance solely for R&D (*i.e.*, the exemption criteria in 40 C.F.R. Section 700.45(a)(2)(v) or (a)(3)(v)) must also maintain manufacturing and other business records related to compliance with that exemption, such as production volume; plans of study; information from R&D notebooks; study reports; or notice solely for R&D use. These records must be maintained for a period of five years from the date notice is submitted to EPA.

Commentary

Bergeson & Campbell, P.C. (B&C[®]) is pleased to see that EPA issued the long-awaited fees rule as stakeholders have been anxious to know how much EPA intended to increase TSCA fees, especially after EPA issued its 2022 Supplemental Notice. Readers may recall that Dr. Michal Freedhoff, the current Assistant Administrator of EPA's Office of Chemical Safety and Pollution Prevention (OCSP) [cautioned](#) regulated entities to prepare for "sticker shock" prior to the release of the 2022 Supplemental Notice. For discussion on the 2022 Supplemental Notice, see our [memorandum](#) dated November 18, 2022. Dr. Freedhoff prepared us well, as regulated entities will still feel a sense of sticker shock from the costs in the final rule, despite EPA reducing the overall program cost estimate by 19% from the proposal in the 2022 Supplemental Notice. B&C notes that our commentary is written in advance of EPA posting its Response to Comments on the 2022 supplemental notice of proposed rulemaking (SNPRM) in the rulemaking [docket](#). Before delving into the final rule, we wish to raise some interesting points about the 2022 SNPRM that readers may find helpful for understanding EPA's fee categories in the final rule.

As an example, EPA [provided](#) the following justification for its initial cost increases in the 2022 Supplemental Notice:

[T]he 2018 Fee Rule has resulted in collection of roughly half of the (artificially low) baseline costs EPA has the authority to collect, resulting in additional TSCA implementation challenges due to insufficient resources.

We note this because EPA's Office of Inspector General (OIG) issued a report on October 12, 2023, titled "[Audit of the EPA's Fiscal Years 2021 and 2020 Toxic Substances Control Act Service Fee Fund Financial Statements.](#)" OIG stated on page 8 of the report that it "found that the TSCA fee structure in the fees rule from FYs 2019 through 2021 appeared reasonable based on the data available when the EPA developed the fees rule." OIG further stated on page 8 of the report that:

The fees collected in FYs 2019–2021 met the intent of TSCA to defray 25 percent of the specified costs of carrying out sections 4 and 5, parts of section 6, and section 14. During the

three-year period, relevant TSCA expenses were \$135.3 million, and the EPA collected approximately \$33.1 million of relevant TSCA service fees, which defrayed 24.47 percent of costs.

It is not clear how EPA reconciles the OIG's report with its now-final fee increase, given that EPA collected about 25% of its TSCA costs in fees during FYs 2019-2021 or through its FY 2023 appropriations. Despite the OIG's findings, EPA stated in its February 8, 2024, [press release](#) that it "based its November 2022 proposed rule on its comprehensive 2021 analysis that more adequately accounted for the anticipated costs of implementing the amended law based on data from the first several years of implementation." It appears to us that EPA is taking the position that the new fees reflect costs EPA expects it will need at some point in the future, as opposed to EPA's costs for implementing TSCA now. EPA has the authority to collect fees up to 25% of its actual costs or \$25 million, whichever is less. In Table 6 of the final rule, EPA estimates \$146,700,000 for direct and indirect costs. This means that the most EPA can collect in fees is \$25 million ($\$146,700,000 \times 0.25 = \$36,675,000$ which is more than \$25 million). EPA's estimate of fees to be collected is over \$42 million (or about \$38 million excluding MRRE fees). The answers to these discrepancies will, however, remain unknown until EPA posts its Response to Comments.

EPA made some sensible changes to who is subject to fees. EPA retained the proposed exemptions for R&D, manufacturers of low volumes, non-isolated intermediates, substances imported as part of an article, byproducts, or impurities. Some of EPA's early experience with risk evaluation fees led to anomalous circumstances, including one manufacturer that imported, one time, a small R&D sample of one substance, leading EPA to impose hundreds of thousands of dollars of risk evaluation fees.

EPA also retained its proposal to spread risk evaluation fees over multiple years — needed relief for fee payers who may be hit with high fees at an unpredictable time in their budget cycles. Invoicing fees over multiple years also aligns better with the timeframe for the risk evaluation. We were disappointed that EPA punted on the free-rider problem, but we acknowledge that it is complicated and may, in the end, be more of a theoretical problem rather than an actual one.

Time will tell if EPA's new fees will take effect prior to a lawsuit being filed challenging EPA's fees.

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