

PRE-PUBLICATION NOTICE

On February 5, 2024, Michael S. Regan, the EPA Administrator, signed the following document:

Action: **Final Rule**
Title: **Fees for the Administration of the Toxic Substances Control Act (TSCA)**
FRL #: **7911-05-OCSP**
Docket ID #: **EPA-HQ-OPPT-2020-0493**

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 700

[EPA-HQ-OPPT-2020-0493; FRL-7911-05-OCSP]

RIN 2070-AK64

Fees for the Administration of the Toxic Substances Control Act (TSCA)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is finalizing amendments to the 2018 final rule that established fees for the administration of the Toxic Substances Control Act (TSCA). Specifically, EPA is finalizing 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.

DATES: This rule is effective on **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2020-0493, is available online at <https://www.regulations.gov>. Additional instructions on visiting the docket, along with more information about dockets generally, is available at

<https://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: *For technical information contact:* Marc Edmonds, Existing Chemicals Risk Management Division (7404M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; telephone number: (202) 566-0758; email address: edmonds.marc@epa.gov.

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I. Executive Summary

A. Does this action apply to me?

You may be affected by this action if you manufacture (including import), process, or distribute in commerce a chemical substance (or any combination of such activities) and are required to submit information to EPA under TSCA sections 4 or 5, or if you manufacture a chemical substance that is the subject of a risk evaluation under TSCA section 6(b). The following list of North American Industry Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include companies found in major NAICS groups:

- Chemical Manufacturers (NAICS code 325).
- Petroleum and Coal Products (NAICS code 324).
- Chemical, Petroleum and Merchant Wholesalers (NAICS code 424).

If you have any questions regarding the applicability of this action, please consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

B. What is the Agency's authority for taking this action?

TSCA, 15 U.S.C. 2601 *et seq.*, as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act of 2016 (Pub. L. 114–182) (Ref. 1), provides EPA with authority to establish fees to defray, or provide payment for, a portion of the costs associated with administering TSCA sections 4, 5, and 6, as amended, as well as the costs of collecting, processing, reviewing, and providing access to and protecting from disclosure as appropriate under TSCA section 14 information on chemical substances under TSCA. EPA is required in TSCA section 26(b)(4)(F) to review and, if necessary, adjust the fees every three years after consultation with parties potentially subject to fees, to ensure that funds are sufficient to defray part of the cost of administering TSCA. EPA is issuing this final rule under TSCA section 26(b), 15 U.S.C. 2625(b).

C. What action is the Agency taking?

After establishing fees under TSCA section 26(b), TSCA requires EPA to review and, if necessary, adjust the fees every three years, after consultation with parties potentially subject to fees. This document describes the final changes to 40 CFR part 700, Subpart C as promulgated in the final rule entitled “Fees for the Administration of the Toxic Substances Control Act (TSCA)” (2018 Fee Rule) (83 FR 52694) (Ref. 2) and explains the methodology by which these changes to TSCA fees were determined.

D. Why is the Agency taking this action?

The fees collected under TSCA are intended to achieve the goals articulated by Congress by providing a sustainable source of funds for EPA to fulfill its legal obligations under TSCA sections 4, 5, and 6 and with respect to information management under TSCA section 14. Information management includes “collecting, processing, reviewing, and providing access to and protecting from disclosure as appropriate under [section 14] information on

chemical substances under [TSCA]” (15 U.S.C. 2625(b)(1)). In 2021, EPA proposed changes to the TSCA fee requirements established in the 2018 Fee Rule (2021 Proposal) (Ref. 3) based upon TSCA implementation experience. In the 2021 Proposal, EPA proposed to adjust the fee amounts based on changes to program costs and inflation and to address certain issues related to implementation of the fee requirements (Ref. 3). EPA consulted and met with stakeholders that were potentially subject to fees, including several meetings with individual stakeholders and public webinars in February 2021 and December 2022. Additional information on the stakeholder engagement can be found in the 2021 Proposal, Unit III.A.1. (Ref. 3) and in Unit II.B. of this final rule.

This final rule takes into consideration comments received in response to the 2021 Proposal and a 2022 Supplemental Notice of Proposed Rulemaking (2022 Supplemental Notice) (87 FR 68647) (Ref. 4). A summary of those comments and the responses can be found in the Response to Comments (RtC) document for this rulemaking (Ref. 5). Based on the comments received, EPA experience implementing TSCA, adjustments to EPA’s cost estimates, and experience implementing the 2018 Fee Rule, EPA is issuing this final rule to amend the 2018 Fee Rule.

E. What are the estimated incremental impacts of this action?

EPA has evaluated the potential incremental economic impacts of the 2021 Proposal, as modified by the 2022 Supplemental Notice for FY 2023 through FY 2025, and the economic analysis for this final rule, entitled “Economic Analysis of the Final Rule; Fees for the Administration of the Toxic Substances Control Act (TSCA)” (Economic Analysis) (Ref. 6) is available in the docket and is briefly summarized here.

1. *Benefits.* The principal benefit of the 2021 Proposal, as modified by the 2022 Supplemental Notice, is to provide EPA with a sustainable source of funding necessary to

administer certain provisions of TSCA.

2. *Cost.* The annualized fees collected from industry under the proposed cost estimate described in this final rule are approximately \$36.69 million (after refunds) at both 3 percent and 7 percent discount rates (the annualized fee collection is independent of the discount rate), excluding fees collected for manufacturer-requested risk evaluations. Total annualized fee collection was calculated by multiplying the estimated number of fee-triggering events anticipated each year by the corresponding fees (Refs. 6 and 7). Total annual fee collection for manufacturer-requested risk evaluations (MRREs) is estimated to be \$2.84 million for chemicals included in the 2014 TSCA Work Plan (TSCA Work Plan) (Ref. 7) (based on the assumed potential for two requests over the three-year period) and approximately \$2.83 million for chemicals not included in the TSCA Work Plan (based on the assumed potential for one request over the three-year period) (Ref. 7). EPA analyzed a three-year period because the statute requires EPA to reevaluate and adjust the fees, as necessary, every three years.

3. *Small entity impact.* EPA estimates that 31.7 percent of TSCA section 5 submissions will be from small businesses in the 33 industries anticipated to be affected by this rulemaking (from the petroleum manufacturing, chemical manufacturing, and merchant wholesalers, and nondurable goods sectors with three-digit NAICS codes 324, 325, and 424) that are eligible to pay the TSCA section 5 small business fee because they meet the definition of “small business concern” as defined in 40 CFR 700.43. Total annualized fee collection from small businesses submitting notices under TSCA section 5 is estimated to be \$583,104 (Ref. 6). For TSCA sections 4 and 6, reduced fees paid by eligible small businesses and fees paid by non-small businesses may differ because the fee paid by each entity would be dependent on the number of entities required to share the total fee per fee-triggering event and

production volume of that chemical substance. EPA estimates that average annual fee collection from small businesses for fee-triggering events under TSCA sections 4 and 6 would be approximately \$20,427 and \$1,827,483, respectively (Ref. 6). For each of the three years covered by this final rule, EPA estimates that total fee revenue collected from small businesses will account for about 6 percent of the approximately \$36.69 million total fee collection, for an annual average total of approximately \$2.4 million.

4. *Environmental justice.* Although not directly impacting environmental justice-related concerns, the fees will enable the Agency to better protect human health and the environment. EPA identifies and addresses environmental justice concerns by providing for fair treatment and meaningful involvement in the implementation of the TSCA program and addressing unreasonable risks from chemical substances.

5. *Effects on State, local, or Tribal governments.* The final rule will not have any significant or unique effects on small governments, or federalism or tribal implications.

II. Background

A. Rule History

TSCA authorizes EPA to establish, by rule, fees for certain fee-triggering activities under TSCA sections 4, 5, and 6. In so doing, the Agency must set lower fees for small business concerns and establish the fees at a level such that they will offset approximately but not more than 25 percent of the Agency's costs to carry out a broader set of activities under TSCA sections 4, 5, and 6, and relevant information management activities under TSCA section 14. In addition, in the case of MRREs, the Agency is directed to establish fees sufficient to defray 50 percent of the costs associated with conducting the MRRE on a chemical substance included in the TSCA Work Plan and 100 percent of the costs of conducting the MRRE for all other chemicals. EPA is also required in TSCA section 26(b)(4)(F) to review and adjust, as necessary, the fees every

three years.

1. *2021 Proposal*. On January 11, 2021 (Ref. 3), EPA proposed updates and adjustments to the 2018 Fee Rule (Ref. 2). This included proposed modifications to the TSCA fees and fee categories for fiscal years (FY) 2023, 2024, and 2025 and explained the methodology by which these TSCA fees were determined. EPA proposed to add three new fee categories: a Bona Fide Intent to Manufacture or Import Notice (Bona Fide Notice), a Notice of Commencement of Manufacture or Import (NOC), and an additional fee associated with test orders. In addition, EPA proposed exemptions for entities subject to certain fee triggering activities, including: (1) An exemption for research and development activities; (2) An exemption for entities manufacturing less than 2,500 pounds (lbs) of a chemical subject to an EPA-initiated risk evaluation; (3) An exemption for manufacturers of chemical substances produced as non-isolated intermediates; and (4) Exemptions for manufacturers of a chemical substance subject to an EPA-initiated risk evaluation if the chemical substance is imported in an article, produced as a byproduct, or produced or imported as an impurity. EPA proposed to update its cost estimates for administering TSCA and individual fee calculation methodologies. EPA proposed a production volume-based fee allocation for EPA-initiated risk evaluation fees in any scenario in which a consortium is not formed and proposed to require export-only manufacturers to pay fees for EPA-initiated risk evaluations. EPA also proposed various changes to the timing of certain activities required throughout the fee payment process.

EPA requested public comments on its proposal through February 25, 2021, and later extended the comment period through March 27, 2021 (86 FR 10918, February 23, 2021 (FRL-10020-69)). EPA received a total of 43 comments. Of the 43 submissions, two written comment submissions and five oral comments were associated with a public webinar hosted on February 18, 2021 (Ref. 5), and three were requests for a comment period extension.

2. *2022 Supplemental Notice.* Based on comments received on the proposed rule, stakeholder engagement, experience implementing TSCA, and EPA's continued experience in implementing the 2018 Fee Rule (e.g., through collection of fees associated with EPA-initiated risk evaluations for the 20 High Priority Substances (<https://www.epa.gov/tsca-fees/tsca-fees-epa-initiated-risk-evaluations>)), EPA supplemented its January 2021 Proposal in November 2022 with the publication of a Supplemental Notice (Ref. 4).

EPA published the 2022 Supplemental Notice to ensure that the fees charged accurately reflect the level of effort and resources needed to implement TSCA in the manner envisioned by Congress when it amended the law, as well as subsequent appropriations bills and associated explanatory statements. Additionally, the purposes of the Supplemental Notice were: To propose changes to the fee amounts and EPA's total costs for administering TSCA; to narrow certain proposed exemptions for entities subject to the EPA-initiated risk evaluation fees and propose exemptions for the test rule fee activities; to propose modifications to the self-identification and reporting requirements for EPA-initiated risk evaluation and test rule fees; to propose a partial refund of fees for premanufacture notices withdrawn at any time after the first 10 business days during the assessment period of the chemical; to propose 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; to propose expanding the fee requirements to companies required to submit information for test orders; to propose modifying the fee payment obligations to require payment by processors subject to test orders and enforceable consent agreements (ECA); and to propose extending the timeframe for test order and test rule payments.

EPA requested public comments on its 2022 Supplemental Notice through January 17, 2023. EPA received a total of 32 comments. Among the 32 comments, two were written

comments and five were oral comments associated with a public webinar hosted on December 6, 2022 (Ref. 5). Three were requests for a comment period extension. The comments and EPA responses, as well as a more thorough summary of the comments received, are presented in the Response to Public Comments document (Ref. 5) available in the docket for this rulemaking. After considering the public comments, EPA made changes to the EA and rulemaking as discussed in Unit III.

B. Stakeholder Engagement

Under TSCA section 26(b)(4)(E), EPA is required to consult and meet with parties potentially subject to the fees or their representatives prior to establishment or amendment of TSCA fees. Similarly, under TSCA section 26(b)(4)(F), EPA is required to adjust the fees as necessary every three years after consulting with parties potentially subject to the fees and their representatives. Since the 2018 Fee Rule, EPA has held several outreach meetings with industry stakeholders on implementation issues. These outreach meetings are summarized at:

<https://www.epa.gov/tsca-fees/outreach-materials-tsca-administration-fees-rule>.

In fall and winter of 2019, EPA held a series of webinars with industry to explain changes to EPA's Central Data Exchange (CDX) and how to pay fees through the system. In December 2019, EPA hosted a conference call to give a brief overview of the fees associated with an EPA-initiated risk evaluation, the creation of the preliminary list that identifies manufacturers and importers subject to fees, and how fees would be divided among the identified businesses. On February 24, 2020, EPA hosted a conference call to review certain provisions of the 2018 Fee Rule. On April 16, 2020, EPA hosted a call to discuss a decision to reduce burden for certain stakeholders subject to TSCA Fee Rule requirements for EPA-initiated risk evaluations via a No Action Assurance for enforcement of certain provisions of the 2018 Fee Rule. On February 18, 2021, EPA hosted a webinar to provide an overview of the 2021 Proposed

Fee Rule to stakeholders. On December 6, 2022, EPA hosted a public webinar to provide an overview to stakeholders about the 2022 Supplemental Notice. These webinars gave the public an opportunity to provide comment to EPA on the proposed changes.

EPA is committed to stakeholder outreach and will continue to meet with federal partners, companies, trade associations and consortia that represent affected manufacturers and processors, as appropriate. EPA will consult with the Small Business Administration as needed regarding engagement with small businesses.

III. Provisions of this Final Rule

A. Program Cost Estimates and Activity Assumptions

As discussed in the 2022 Supplemental Notice, the 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. 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 the Agency to implement the revised law in the manner envisioned and directed by Congress. In the first four years following the 2016 law's enactment, EPA did not conduct a comprehensive budget analysis designed to estimate the costs of implementing the amended law. EPA did not conduct such an analysis until spring 2021. EPA's 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 is finalizing estimates that differ from the 2022 Supplemental Notice. Specifically, the total program cost estimate has been reduced by over 19 percent and 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 this final rule (Ref. 7). EPA recognizes that the costs associated with implementing TSCA may be re-evaluated and can change over time (e.g., due changes in administrative priorities or insights and changes in practice gained through experience implementing the law). The cost estimates discussed in the technical support document and this unit are based on EPA’s estimates at the time the rulemaking and support materials were developed.

1. *Program costs.* This unit summarizes the total cost estimates for TSCA sections 4, 5, 6, and 14 activities. EPA evaluated its costs from FY 2023, and then, after consideration of 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). Annually, 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 sections 4, 5, 6 (excluding MRREs) and 14 activities and the indirect cost, is \$146,754,074.

Table 1—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

Table Note: The indirect cost rate is estimated at 16.28 percent for the purposes of this analysis.

a. *TSCA section 4 program costs.* TSCA, as amended, permits the Agency to undertake test rules, test orders and enforceable consent agreements (ECA). The Agency believes it is reasonable to assume that approximately 14 test orders per year will be

initiated between FY 2024 and FY 2026. Approximately 10 of these test orders are expected to be associated with the Agency’s actions on per- and polyfluoroalkyl substances (PFAS) per EPA’s implementation of the National PFAS Testing Strategy. In addition, the Agency assumed one test rule and one ECA between FY 2024 and FY 2026. EPA decreased its estimate of the number of issued test orders from the 2022 Supplemental Notice. For this final rule, EPA is finalizing an estimated annual cost to EPA of administering relevant activities under TSCA section 4 of \$7,678,352. Additional information about actions included in this cost estimate can be found in the TSD for this final rule (Ref. 7).

Table 2 – TSCA Section 4 Annual Cost Estimates for FY 2024 – FY 2026

	Non-Pay	Pay	FTE	Total
Test Orders – Risk Evaluation	\$331,577	\$1,177,705	7.00	\$1,510,800
Test Orders – PFAS	\$124,841	\$1,445,882	7.50	\$1,571,300
Test Rules	\$88,870	\$780,684	4.00	\$870,000
ECA Issuance	\$14,755	\$195,171	1.00	\$210,000
Project Management and Operations	\$0	\$312,757	1.64	\$295,200
IT/IM	\$3,159,555	\$46,555	0.25	\$3,221,052
Total	\$3,719,598	\$3,958,754	21.39	\$7,678,352

b. *TSCA section 5 program costs.* Under TSCA section 5, EPA conducts risk assessments and risk management activities for approximately 482 submissions per year to ensure safety of new chemicals before they enter commerce. EPA estimates it will receive 216 premanufacture notices (PMNs), significant new use notices (SNUNs), and microbial commercial activity notices (MCANs) per year, and another 266 exemption applications, which include low exposure/low release exemptions (LoREXs), low volume exemptions (LVEs), test-marketing exemptions (TMEs), certain microorganism Tier II exemptions (Tier II), and TSCA experimental release applications (TERAs) per year. EPA's cost estimates for administering TSCA section 5 include costs associated with processing and retaining records related to a Notice of Commencement of Manufacture or Import (NOC) submission, as well as the costs of pre-notice consultations, processing and reviewing applications,

retaining records, and related activities. EPA is finalizing an estimated annual cost to EPA of administering relevant activities under TSCA section 5 of \$40,219,461. Additional information about actions included in this cost estimate can be found in the TSD for this final rule (Ref. 7).

Table 3 – TSCA Section 5 Annual Cost Estimates for FY 2024 – FY 2026

	Non-Pay	Pay	FTE	Total
Risk Assessment	\$5,586,677	\$11,662,890	63.00	\$17,252,116
Risk Management	\$1,180,463	\$5,909,657	32.00	\$7,091,190
Project Management and Operations	\$0	\$358,282	1.89	\$340,200
IT/IM	\$5,747,093	\$45,564	0.25	\$5,797,480
Other	\$6,801,271	\$2,927,565	15.00	\$9,738,475
Total	\$19,351,668	\$20,903,957	112.14	\$40,219,461

c. *TSCA section 6 program costs.* EPA has the authority under TSCA section 26(b) to collect fees to recover a portion of the costs for TSCA section 6 activities including prioritization, risk evaluations, and risk management. TSCA requires that the EPA have at least 20 High-Priority chemical risk evaluations underway by December 2019, and that a new chemical risk evaluation be initiated each time another concludes. Based on these parameters, the Agency has assumed that EPA will be undertaking at least 20 EPA-initiated chemical risk evaluations at all times, and that each risk evaluation will take three and a half years to complete. In the case of MRREs, the Agency is directed to establish fees sufficient to defray 50 percent of the costs associated with conducting a MRRE on a chemical included in the *TSCA Work Plan for Chemical Assessments: 2014 Update* (Ref. 8), and 100 percent of the costs of conducting a MRRE for all other chemicals.

Based on an overall reduction in the total program cost estimate as a result of found efficiencies (discussed in more detail in the TSD (Ref. 7)), the estimated annual cost to EPA of administering relevant activities under TSCA section 6 is \$70,486,244 per year not including the cost of MRREs. Individual risk evaluations, including MRREs, are estimated to cost \$8,489,541 to complete (including indirect costs). Additional information about

actions included in this cost estimate can be found in the TSD for this final rule (Ref. 7).

Table 4 – TSCA Section 6 Annual Cost Estimates for FY 2024 – FY 2026

	Non-Pay	Pay	FTE	Total
Annual Prioritization Process	\$2,737,635	\$2,905,161	15.25	\$5,645,500
TSCA Section 6 Risk Evaluation	\$14,782,167	\$28,517,222	152.00	\$43,320,378
TSCA Section 6 Risk Management	\$4,106,513	\$11,367,735	61.60	\$15,477,675
Project Management and Operations	\$0	\$687,878	3.64	\$655,200
IT/IM	\$5,197,532	\$184,401	1.00	\$5,387,491
Total	\$26,823,847	\$43,662,397	233.49	\$70,486,244

d. *Costs of collecting, processing, reviewing, and providing access to and protecting from disclosure as appropriate under TSCA section 14, information on chemical substances.* EPA's cost estimates include the costs of information management for TSCA sections 4, 5, 6 and 14, but do not include the costs of administering other authorities for collection such as those in TSCA sections 8 and 11. Activities considered when developing this estimate for activities under TSCA section 14 include: Prescreening/initial review; substantive review and making final determinations; documents review and sanitization; regulation development; IT systems development; and transparency/communications. Estimates also include Office of General Counsel (OGC) costs associated with coordinating, reviewing, issuing, and defending TSCA Confidential Business Information (CBI) claim final determinations, and supporting guidance, policy, and regulation development for TSCA section 14 activities. The annual cost estimate of collecting, processing, reviewing, and providing access to and protecting from disclosure as appropriate information on chemical substances under TSCA section 14, including FTE and extramural costs, from FY 2024 through FY 2026 is \$7,823,436. Additional information about actions included in this cost estimate can be found in the TSD for this final rule (Ref.7).

Table 5 – TSCA Section 14 Annual Cost Estimates for FY 2024 – FY 2026

	Non-Pay	Pay	FTE	Total
CBI Reviews	\$714,288	\$2,237,712	16.40	\$2,952,000
IT/IM	\$4,842,070	\$29,366	0.25	\$4,871,436
Total	\$5,556,358	\$2,267,079	16.65	\$7,823,436

2. *Indirect costs.* 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 CBI from disclosure as appropriate under TSCA section 14, were calculated by multiplying the appropriate indirect cost rates for FY 2024 and beyond by the estimated direct costs. Indirect cost rates are calculated each year by the Office of the Controller, using the 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.

For direct TSCA section 4, 5, 6 and 14 costs, an indirect cost rate of 16.28 percent was applied. Total indirect costs included in the overall TSCA sections 4, 5, 6 and 14 cost estimates total approximately \$20,546,580 (Table 6).

Table 6 – Total Indirect Cost Estimates for TSCA Sections 4, 5, 6 and 14

	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

3. *Total collections for fee-triggering events.* EPA estimated a total program cost of implementing TSCA sections 4, 5, 6 (excluding MRREs) and 14 to be \$146,754,074. Based on the assumptions previously discussed and the final fee amounts addressed in Unit III.B, 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 also accounted for refunds for certain TSCA section 5 activities as seen in Table 7.

Table 7 – Summary of Total Estimated Annual Fee Collections and Refunds for FY 2024 - 2026

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 Evaluation	6.67	n/a	\$4,287,000	\$857,400	\$28,594,290
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

Table Note: The “n/a” under small business activity levels are a reflection that total annual collections do not depend on the breakdown of small and non-small businesses because total fee is split between the two groups.

B. Fee Amounts

EPA 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. In addition, EPA affords small businesses an approximately 80 percent discount, in accordance with TSCA section 26(b)(4)(A).

While TSCA allows the Agency 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. These 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, 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 considers several factors, including comments from stakeholders, to finalize 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 reduce burden to industry which are already paying for testing); and the potential burden of the fee to industry (e.g., whether a fee is shared by multiple manufacturers).

The final fee amounts as compared to the current fees are provided in Table 8.

Table 8 – Final TSCA 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	Two payments of \$1,414,924, with final invoice to recover 50% of

	actual costs.	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.

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

1. *Fee amounts for TSCA section 4 activities.* EPA is finalizing the fee amounts proposed in the 2022 Supplemental Notice for TSCA section 4 activities. Specifically, EPA is finalizing \$25,000 for test orders, \$50,000 for test rules, and \$50,000 for ECAs. EPA is finalizing 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.

2. *Fee amounts for TSCA section 5 activities.* EPA sets two fee amounts for TSCA section 5 activities—one for notices (PMNs, SNUNs, and MCANs) and one for exemptions (including LoREXs, LVEs, TMEs, Tier II, and TERAs). EPA received comments on the fee amounts for TSCA section 5 activities. In response to those comments and the overall reduction in EPA’s program cost estimates, EPA is finalizing fee amounts lower than those proposed in the 2022 Supplemental Notice (i.e., \$45,000 for notices and \$13,200 for exemptions). EPA is finalizing \$37,000 for notices and \$10,870 for exemptions. Entities that qualify as a small business concern receive an approximately 80 percent discount as discussed in Unit III.B.4. 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.

3. *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. EPA received numerous comments on the fee amount proposed in the 2022 Supplemental Notice (i.e., \$5,081,000). In response to those comments, as well as an overall reduction in the total program cost estimate due to found efficiencies (discussed in more detail in the TSD (Ref.7)), EPA is finalizing a lower fee amount for EPA-initiated risk evaluations. EPA is finalizing a fee of \$4,287,000 paid over two installments which, 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 requesting consortia 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 or not, respectively. Based on the installment plan and the estimated costs of these risk evaluations, manufacturers are required 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 and are then invoiced for the remainder.

4. *Fee amounts for small businesses.* The final fee amounts for small businesses summarized in Table 9 represent an approximate 80 percent reduction compared to the proposed base fee for each category. 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.

Reduced 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 – 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

C. Fee Categories

Under the 2018 Fee Rule, EPA 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 10 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 Notices and NOCs, and one additional fee category for TSCA section 4, i.e., for amended test orders. EPA received several comments supporting the removal of the fee categories for Bona Fide Notices, NOCs, and amended test orders. A few commenters stated that these additional fee categories should remain to help recover the costs of reviewing and responding to these submissions. 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 is not finalizing the new fee categories for Bona Fide Notices, NOCs, and amended test orders as proposed in the 2021 Proposal.

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. EPA believes these fees are better captured under the fee increase for existing TSCA section 5 categories. 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, EPA is not finalizing the amended test order fee category proposed in the 2021 Proposal. Because the costs incurred by EPA to review resubmitted data are included in the Agency's total program cost estimate, these costs will be captured under other fees.

D. Refund for Withdrawal During Review

EPA received several comments expressing opposition of the refund for 20 percent of the user fee to the submitter if a premanufacture notice is withdrawn 10 or more business days after the beginning of the applicable review period, but prior to EPA initiating risk management on the chemical substance as proposed in the 2022 Supplemental Notice. Some commenters stated that EPA should not dedicate additional resources to providing this refund and that this refund would drain resources. EPA agrees with these commenters and is not finalizing the proposed refund. The steps required to initiate a refund and to provide notice that the risk assessment on the chemical substance has concluded, as outlined in the 2022 Supplemental Notice, would impose additional burden on EPA. To make an informed decision on whether to withdraw their notice, EPA 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 require review and redaction prior to transmission and development of draft risk mitigation terms. To protect CBI, EPA must review and redact what is known as third-party CBI information from each risk assessment report. Third-party CBI information is CBI information submitted to EPA by another submitter as part of a separate notice which may then be used in the assessment of another chemical (e.g., an analogue). 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.

E. Methodology for Calculating Fees for EPA-initiated Risk Evaluations

EPA received multiple industry comments supporting the use of production volume to determine fee obligations for EPA initiated risk evaluations, stating that this approach would allocate fees more equitably and minimize burdens to smaller manufacturers. One commenter recommended a tiered band approach supported by a few other industry commenters. This commenter recommended that EPA establish “four bands of set fees” based on the EU REACH metric tonnage bands and estimate the number of manufacturers in each band EPA would expect for future risk evaluations using historical data. EPA determined this approach would likely result in EPA not collecting 25 percent of program costs due to difficulties in estimating future numbers of manufacturers. Therefore, EPA rejected this alternative method proposed and is finalizing the approach outlined in the 2022 Supplemental Notice.

The finalized approach 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 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. 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 would 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.

Step 10: Reallocate the remaining fee evenly across the remaining manufacturers, counting each manufacturer in a consortium as one entity.

As stated in the 2022 Supplemental Notice, in the event that three or fewer manufacturers are identified for a chemical substance, EPA 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.

In addition, EPA is finalizing as proposed in the 2022 Supplemental Notice the requirement of reporting average production volume based on the three previous calendar years prior to the publication of the preliminary list. This change will alleviate additional concerns over potential CBI disclosure by further separating the production volume submissions under this rule from other potentially public production volume reporting (e.g., CDR) that could be used in conjunction with data reported under this proposal to estimate a manufacturer's production volume.

EPA is also providing additional clarification on production volume calculations as it applies to certification, meeting exemptions, recordkeeping, etc. For example, EPA clarifies that two significant figures should be used when calculating production volume as required by the CDR rule. Companies with multiple groupings/facilities should include the total aggregated production volume when calculating the average for the purposes of 40 CFR 720.75(b)(v) and when calculating the annual production volume in qualifying for the exemptions related to production volume in 40 CFR 720.75(a)(2)(vi) or (3)(vi). Production volume calculations would not require companies to double count distribution of the same chemical substance within one company when that chemical mixture is "manufactured" more than once (e.g., a company that manufactures a chemical, then exports for further processing, then imports the chemical mixture would not need to double count their production volume). This does not apply if multiple

companies are involved (e.g., a company manufactures a chemical, then exports it for additional processing, then separate company imports the mixture). EPA will assess a fee for each of those “manufacturers” based on the production volume that they separately manufacture or import. Regarding “non-TSCA uses,” chemicals may be manufactured for uses that do not fall under TSCA. EPA does not require the inclusion of non-TSCA chemicals in production volume calculations.

These changes are expected to eliminate all potential disclosure of production volume that may be claimed as CBI. In the rare event of multiple fee payers submitting under the same parent company and asserting a CBI claim for production volume and/or multiple companies reporting the exact same amount as a competitor, EPA would mask the company names on the final list for that chemical to protect disclosure.

As described in steps one through three previously in this unit, EPA is not finalizing the production volume-based methodology for manufacturers of a chemical substance undergoing an EPA-initiated risk evaluation that qualify as a small business concern. These entities would be provided an 80 percent discount from the “base fee” calculated as described in the 2018 Fee Rule (40 CFR 700.45(f)).

F. Export-Only Manufacturers

In EPA’s 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 also acknowledged the ambiguity of TSCA section 12(a) in that rulemaking. After further review, EPA is not finalizing the proposed provision in this final rule. EPA agrees with numerous commenters that this is inconsistent with other TSCA programs. Further, some commenters viewed EPA’s proposed interpretation of section 12(a) as inconsistent with prior regulatory interpretations. EPA 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 and is declining to finalize it in the proposal.

G. Exemptions for Certain Fee-Triggering Activities

EPA is finalizing 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 CFR 704.3; (4) producers of a chemical as a non-isolated intermediate as defined in 40 CFR 704.3; (5) manufacturers of small quantities of a chemical substance used solely for research and development as defined in 40 CFR 700.43; or (6) manufacturers of chemical substances with production volume less than 2,500 lbs for TSCA section 6 activities and 1,100 lbs for TSCA section 4 test rules. For clarification, “manufacture for commercial purposes” is defined in 40 CFR 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.”

Based on consideration of public comments to the 2021 Proposal, in the 2022 Supplemental Notice EPA proposed narrowing the exemption on byproducts by limiting it to “producers of a chemical substance as a byproduct that is not later used for commercial purposes or distributed for commercial use.” In this final rule, EPA is finalizing that exemption as proposed in the 2022 Supplemental Notice. Although numerous industry trade and advocacy organizations supported the limited exemption, some commenters expressed opposition to it, stating that creators of a byproduct should not be subject to TSCA fees (e.g., for risk assessment), as the byproducts are not created with separate commercial intent, and that EPA

should revise the exemption to apply as long as there is no *intent* for the byproduct to be imparted as useful property. 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. In addition, EPA 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 finalized byproduct exemption addresses commenter's concerns with challenges with self-identification as related to identifying and tracking byproducts that are unintentionally or coincidentally produced (40 CFR 700.45(b)(5)).

In response to commenters' concerns with the previously proposed five year look back period associated with the exemptions criteria, EPA has aligned the requirements for five of the six exemptions (i.e., all except the exemptions associated with low production volume as described in 40 CFR 700.45 (a)(2)(vi) and (3)(vi)) with the certification of cessation timeline. A manufacturer is not required to make or contribute to a fee payment if it meets one or more of the five exemptions on or after the applicable certification cutoff date identified in 40 CFR 700.45 (b)(6) and will not conduct manufacturing outside of those exemptions at any point in time within five years after the certification cutoff dates. EPA agrees with commenters that this change will help facilitate the self-identification and certification of cessation process.

EPA is finalizing the five-year timeline detailed in the 2021 Proposal for the production volume exemptions in this rule, stating that manufacturers of a chemical substance subject to risk evaluation are exempt from fee payment requirements if they meet the low production volume exemptions for the five-year period preceding publication of the preliminary list and will also

need to meet one or more of the exemptions in the successive five years and not conduct manufacturing outside of those exemptions in the successive five years. EPA has confidence that this five-year look back period is necessary for the exemptions based on production volume (manufactured quantities below a 1,100 lbs annual production volume subject to a test rule under TSCA section 4(a) and manufactured quantities below a 2,500 lbs annual production volume that is subject to a risk evaluation under TSCA section 6(b)) to account for fluctuations in annual production volume and to better align with the reporting and recordkeeping requirements associated with this exemption. EPA's intent is to provide this exemption for manufacturers who produce small amounts of the chemical and to direct fee obligations to those companies that produce most of the chemical substance. The five-year look back period helps ensure the subject manufacturer meets that intent.

Outside of these six exemptions, several commenters proposed additional exemptions including a concentration-based exemption and a re-imported substances exemption. EPA has confidence that the final rule covers the necessary exemptions excluding byproducts, impurities, small quantities for research and development, low-production volumes, and imported articles. EPA agrees with commenters that most of the incidental chemical scenarios in the suggested additional exemptions would fall under the production volume exemptions. Regarding the suggested re-imported substances exemption, EPA has clarified in the preamble of the final rulemaking how companies should calculate production volume in situations such as these, but EPA is not finalizing a separate exemption covering the distribution of a chemical across multiple companies and re-imports.

Overall, several advocacy organizations opposed the proposed exemptions, stating that EPA's rationales for the exemptions were unsupported and not allowed as a justification for exempting fees under TSCA. TSCA does not preclude EPA from exempting certain

manufacturers from fee-paying activities, states that manufacturers “may” be required to pay (TSCA section 26(b)(1)) and provides EPA the authority to “take into account the ability to pay of the person required to pay such fee and the cost of the Administrator of carrying out the activities described in this paragraph (TSCA section 26(b)).” The six proposed exemptions do not reduce how much EPA collects for each risk evaluation. Rather, they simply reduce how many participating manufactures split the fee. Other commenters claimed that the exemptions outlined in the 2021 Proposal were too broad and lacked details on how the fee applies to chemical manufacturers. Following the 2021 Proposal, EPA narrowed the exemptions in the 2022 Supplemental Notice and in this final rule. Finally, a few industry trade organizations expressed opposition to requiring manufacturers to split the fee payment when each entity produces less than 2,500 lbs annually, claiming that splitting the payment would increase the unpredictability of TSCA fees and penalize low volume producers. This condition applies because EPA must ensure it receives compensation to carry out a risk evaluation and meet TSCA requirements.

H. Self-Identification and Certification Requirements

EPA 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. 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 finalizing changes to 40 CFR 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.

Due to significant industry stakeholder feedback as discussed in more detail in the 2021 Proposal, EPA proposed exemptions for EPA-initiated risk evaluations and proposed changes to the submission of self-identification information in 40 CFR 700.45 to accompany those changes. The 2022 Supplemental Notice expanded those exemptions to apply to test rules under TSCA section 4 and provided additional context around certain exemptions by cross referencing (i.e., defining impurities by referencing 40 CFR 704.3) and narrowing the byproduct exemption. EPA is finalizing 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 research and development, 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 (i.e., those that meet the exemption in 40 CFR 700.45(a)(2)(iv-vi) and (a)(3)(iv-vi)) 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.

To accompany the production volume-based fee allocation methodology changes discussed in Unit III.E., EPA is also requiring certain manufacturers to provide the volume

produced by that manufacturer for the subject chemical undergoing an EPA-initiated risk evaluation. Applicable manufacturers are required to report their average production volume using the past three calendar years' worth of production volume data. Unit III.E. and the RtC (Ref. 5) include additional discussion on how to calculate production volume for this provision as well as the exemptions for low producing manufacturers (40 CFR 700.45(a)(2)(vi) and (3)(vi)). As clarified and proposed in the 2022 Supplemental Notice, manufacturers that qualify for the 1,100 lbs or 2,500 lbs exemption are also required to report the average annual production volume from the three calendar years prior to the publication of the preliminary list. Requiring self-identification of those manufacturers that qualify for the production volume-based exemptions would allow EPA to allocate fees based on production volume and collect fees in a timely manner in situations in which all fee payers have met that exemption criteria.

EPA received comments regarding the 2021 Proposal allowing additional changes to the final list after it is published. EPA's intent is to publish the final list no later than concurrently with the final scope document for risk evaluations initiated by EPA under TSCA section 6 and with the final rule for test rules under TSCA section 4 with no further modifications. EPA is finalizing changes to 40 CFR 700.45(b)(7) to also state, "EPA may modify the list after the publication of the final list" because this flexibility is needed to allow for potential modifications of the list upon receipt of information indicating that a change is warranted. Examples of potential changes to the final list of fee payers include addressing potential errors (e.g., self-identification as a manufacturer rather than meeting an exemption, not registering as a "small business concern" when a company qualifies) and when a manufacturer has not self-identified as required and is obligated to pay fees.

Lastly, EPA received numerous comments from industry trade organizations, a chemical manufacturer, advocacy organizations, and others requesting that EPA revise the requirements to

address new market entrants that enter the market after fee payment for a risk evaluation has been finalized. Commenters have referred to manufacturers which fall under this category as “new entrants” or “free riders.” Commenters have requested EPA address these manufacturers to prevent a competitive disadvantage for those companies that have paid a risk evaluation fee and have spent time and resources supporting those same substances through the risk evaluations. Many of the commenters also requested that EPA allow manufacturers that had previously certified cessation to be allowed to begin manufacturing or importing the substances within the successive five-year period, or “re-enter” the market and pay their portion of the fee after initial invoicing. An advocacy organization expressed strong opposition to such approaches, reasoning that they would result in an unnecessary increased burden to EPA and could create inequities between manufacturers paying the fees up front relative to those opting back in.

EPA has considered these comments and provided additional responses, including to an industry trade organization’s alternative approach, in the RtC (Ref. 5). Generally, EPA concludes that allowing continued changes to those entities responsible for paying the EPA-initiated risk evaluation fees after the initial invoicing period would result in a substantial increase in burden to EPA. The additional burden to EPA would depend on the approach taken but could include the need to continue to track manufacturers for years, need to recalculate invoices and issue multiple refunds, and could have potential CBI implications. Therefore, EPA is not finalizing changes to the self-identification requirements to address late entrants or re-entrants. EPA believes the self-identification process and ability to certify cessation addresses majority of the concerns raised by commenters. EPA recognizes that these comments have been raised in past TSCA fee rulemakings and that the matter is a concern to multiple commenters. To understand the potential scope of this issue, EPA plans to track manufacturers that might fall under one of these categories to inform the need for a provision to address this in future TSCA fee

rulemakings.

I. Companies Required to Submit Information under TSCA Section 4

As discussed in the 2022 Supplemental Notice, the 2018 Fee Rule does not reflect all circumstances in which a manufacturer subject to a TSCA section 4 test order could be required to pay fees. Specifically, fees are required for manufacturers that conduct testing. TSCA section 26(b)(1) provides for the collection of fees “from any person required to submit information” under TSCA section 4. In some circumstances, a manufacturer subject to the information development or submission requirements under TSCA section 4 may not need to conduct testing. For instance, a manufacturer may have already conducted the testing prior to the issuance of a TSCA section 4 test order, in which case the manufacturer may submit the information they have already produced if it meets the issued requirements. Under TSCA, EPA must establish what information is required, what testing will provide such information, and what test protocols can inform the generation of such information.

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 finalizing as proposed in the 2022 Supplemental Notice, revisions to 40 CFR 700.45(a)(2) to refer to manufacturers required to submit information rather than manufacturers “required to test.” 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.

J. 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. 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 finalizing its proposal in the 2022 Supplemental Notice and modifying the fee payment obligations in 40 CFR 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.

K. Timeframe for Fee Payments and Notifications

The 2018 Fee Rule generally required up-front payment of fees (i.e., payment due prior to EPA reviewing a TSCA section 5 notice, within 120 days of publication of final test rule, within 120 days of issuance of a test order, within 120 days of signing an ECA, within 30 days of granting a MRRE, and within 120 days of publishing the final scope for an EPA-initiated risk evaluation). For MRREs, payment is collected in two installments over the course of the activity. In response to stakeholder engagements, EPA is finalizing several changes to the timing of specific stages within this fees process. These are summarized in Table 10 and discussed in more detail throughout this unit.

After the effective date of this final rule, manufacturers 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. 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.

As previously mentioned, 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 the 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.

Similarly, the 2018 Fee Rule established a 120-day timeline for TSCA section 4 test order and test rule payments. This timeline has been found to be too short for creating invoice payments and other Agency work related to allocating such payments before fees are assessed for entities submitting data. EPA has extended the timeframe for test order and test rule payments to 180 days after the effective date of the order or rule. This timeframe aligns with the proposed timeframe for the initial fee payment associated with EPA-initiated risk evaluations under TSCA section 6. The change would provide EPA with sufficient time to review fee payments, identify and allocate fees across several different entities, and issue invoices.

Table 10 – Changes to Timing Within the Fee Rule

Stage in the Fees Process	Timing Under 2018 Fee Rule	Final Timing Changes
Payment of fees for EPA-initiated risk evaluations.	Payment is collected in one installment 120 days after EPA publishes the final scope of a chemical risk evaluation.	Payment is collected over two installments, the first payment of 50 percent is due 180 days after EPA publishes the final scope of a chemical risk evaluation and the second payment is due not later than 545 days after EPA publishes the final scope of a chemical risk evaluation.
Payment of fees for manufacturer-requested risk assessments.	Initial payment is due within 30 days of EPA providing notice of granting a MRRE. Payment is collected in two installments over the course of the activity.	Initial payment is due within 180 days of EPA providing notice of granting a MRRE. Payments are collected over three installments.
Payment of fees for test rules and test orders.	Payment is collected in one installment 120 days after the effective date of a test rule or test order	Payment is collected in one installment 180 days after the effective date of a test rule or test order

Intent to form a consortia.	Must notify EPA within 60 days of the triggering event.	Must notify EPA within 90 days of the triggering event.
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L. Recordkeeping

EPA is finalizing 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 CFR 700.45(b)(10).

Under this final rule, all manufacturers other than those listed in 40 CFR 700.45(a)(2)(i) through (v) or (a)(3)(i) through (v) (i.e., all manufacturers other than those which qualify for the exemptions related to articles, byproducts, impurities, non-isolated intermediates, and/or research and development) must maintain production volume records related to their production volume submission (discussed in Unit III.H.). 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 CFR 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.

Manufactures of a chemical substance as a non-isolated intermediate (i.e., those meeting the exemption criteria in 40 CFR 700.45(a)(2)(iv) or (a)(3)(iv)) must maintain manufacturing and other business records related to compliance with that exemption criteria.

Manufacturers of small quantities of a chemical substance solely for research and development (i.e., the exemption criteria in 40 CFR 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 research and development notebooks, study reports, or notice solely for research and development use. These records must be maintained for a period of five years from the date notice is submitted to EPA.

IV. References

The following is a listing of the documents specifically referenced in this document. The docket includes these documents and other information considered by EPA, including documents that are referenced within the documents that are included in the docket, even if the referenced document is not physically located in the docket. For assistance in locating these other documents, please consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

1. The Frank R. Lautenberg Chemical Safety for the 21st Century Act. June 22, 2016. Pub. L. 114–182.
2. U.S. EPA. Final Rule; Fees for the Administration of the Toxic Substances Control Act. *Federal Register*. 83 FR 52694, October 17, 2018 (FRL-9984-41).
3. U.S. EPA. Proposed Rule; Fees for the Administration of the Toxic Substances Control Act. *Federal Register*. 86 FR 1890, January 11, 2021 (FRL-10018-40).
4. U.S. EPA. Supplemental Notice of Proposed Rulemaking; Fees for the Administration of the Toxic Substances Control Act. *Federal Register*. 86 FR 1890, November 16, 2022 (FRL-10018-40).
5. U.S. EPA. Response to Public Comments on the 2021 Proposed Rule and 2022 Supplemental Proposed Rule Addressing Fees for the Administration of the Toxic Substances Control Act (RIN 2070-AK64). January 23, 2024.
6. U.S. EPA. Economic Analysis of the Final Rule; Fees for the Administration of the Toxic Substances Control Act (TSCA); RIN 2070-AK46. January 23, 2024.

7. EPA. Technical Support Document: Final Rulemaking; Fees for the Administration of the Toxic Substances Control Act (TSCA); RIN 2070-AK64. January 23, 2024.

8. EPA. TSCA Work Plan Chemicals: Methods Document. February 2012.

https://www.epa.gov/sites/production/files/2014-03/documents/work_plan_methods_document_web_final.pdf

9. EPA. Supporting Statement for an Information Collection Request (ICR) under the Paperwork Reduction Act (PRA): Fees for the Administration of the Toxic Substances Control Act (TSCA); Final Rule (RIN 2070-AK64). EPA ICR No. 2569.06; OMB Control No. 2070-0208. January 23, 2024.

10. EPA. Supporting Statement for an Information Collection Request (ICR) under the Paperwork Reduction Act (PRA): User Fees for the Administration of the Toxic Substances Control Act (TSCA); Proposed Rule (RIN 2070-AK64). EPA ICR No. 2569.03; OMB Control No. 2070-0208. January 31, 2021.

11. EPA. Supporting Statement for an Information Collection Request (ICR) under the Paperwork Reduction Act (PRA): “Reporting Requirements Associated with the Payment of Fees under Section 26(b) of the Toxic Substances Control Act (TSCA); Supplemental Proposed Rule (RIN 2070-AK64).” EPA ICR No. 2569.05; OMB Control No. 2070-0208. September 2022.

12. OMB. Notice of Office of Management and Budget Action under the Paperwork Reduction Act on the ICR entitled: “User Fees for the Administration of the Toxic Substances Control Act (TSCA) (Proposed Rule).” EPA ICR No. 2569.03; OMB Control No. 2070-0208; OMB ICR Reference No. 202101-2070-002. April 5, 2021.

https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202101-2070-002#

13. OMB. Notice of Office of Management and Budget Action under the Paperwork

Reduction Act on the ICR entitled: “User Fees for the Administration of the Toxic Substances Control Act (TSCA) (Supplemental Proposed Rule).” EPA ICR No. 2569.05; OMB Control No. 2070-0208; OMB ICR Reference No. 202211-2070-001. January 11, 2023. https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202211-2070-001#.

V. Statutory and Executive Order Reviews

Additional information about these statutes and Executive Orders can be found at <https://www.epa.gov/laws-regulations/laws-and-executive-orders>.

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 14094: Modernizing Regulatory Review

This action is a “significant regulatory action” as defined in Executive Order 12866 (58 FR 51735, October 4, 1993), as amended by Executive Order 14094 (88 FR 21879, April 11, 2023). Accordingly, EPA, submitted this action to the Office of Management and Budget (OMB) for Executive Order 12866 Review. Documentation of any changes made in response to the Executive Order 12866 Review is available in the docket.

EPA prepared an economic analysis of the potential impacts associated with this action (Ref. 6), which is available in the docket and is summarized in Unit I.E.

B. Paperwork Reduction Act (PRA)

The information collection activities in this rule have been submitted to OMB for approval under the PRA, 44 U.S.C. 3501 *et seq.* The Information Collection Request (ICR) document that EPA prepared has been assigned EPA ICR No. 2569.06 (Ref. 9). EPA previously prepared and submitted ICRs for the 2021 Proposed Rule (Ref. 10) and the 2022 Supplemental Notice (Ref. 11), and in both cases, the Notice of OMB Action that was issued identified the OIRA Conclusion Action as “Comment filed on proposed rule and continue” (Refs. 12 and 13). EPA intends for the final rule ICR to amend and replace the

existing ICR that is currently approved under OMB Control No. 2070-0208 through February 28, 2025. You can find a copy of the ICR (Ref. 9) in the docket for this rule, and it is briefly summarized in this unit.

The information collection activities associated with this final rule include familiarization with the revised regulation; reduced fee eligibility determination; CDX registration (for new entrants); formation, management and notification to EPA of participation in consortia; self-identification and certification; and electronic payment of fees through *Pay.gov*.

Respondents/affected entities: Persons who manufacture or process a chemical substance (or any combination of such activities) and are required to submit information to EPA under TSCA sections 4 or 5 or manufacture a chemical substance that is the subject of a risk evaluation under TSCA section 6. See also Unit I.A.

Respondent's obligation to respond: Mandatory under TSCA section 26(b).

Total estimated number of respondents: 802.

Frequency of response: On occasion.

Total estimated number of responses: 502.

Total estimated burden: 383 hours (per year). Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: \$ 555,663 (per year), includes \$0 annualized capital or operation and maintenance costs.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA regulations in title 40 of the CFR are listed in 40 CFR part 9. When OMB approves this ICR, the Agency will announce that approval in the *Federal Register* and publish a technical amendment to 40 CFR part 9 to display the OMB control number for the

approved information collection activities contained in this final rule.

C. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA, 5 U.S.C. 601 *et seq.* The small entities expected to be subject to the requirements of this action are small chemical manufacturers and processors, small petroleum refineries, and small chemical and petroleum wholesalers. There may be some potentially affected firms within other sectors, but not all firms within those sectors will be potentially affected firms. The Agency has determined that 58 small businesses, including 12 processors and 47 manufacturers, may be affected annually by TSCA section 4 actions; 153 small businesses may be affected by TSCA section 5 actions; and 31 small businesses may be affected by TSCA section 6 actions. EPA estimates the annual revenue distribution using U.S. Census data for small businesses likely to be affected by TSCA sections 4, 5, and 6 actions, and compares it to incremental fee amounts to estimate the economic impact. For example, EPA expects 88 small businesses to pay incremental TSCA section 5 Exemption fees of \$1,062. According to the estimated revenue distribution, 96 percent of parent firms have an annual revenue greater than \$106,200, 4 percent have an annual revenue between \$106,200 and \$35,400, and no firms have revenues less than \$35,400. Accordingly, of the 88 small businesses affected, 96 percent will have an impact under 1 percent, 4 percent will have an impact between 1 percent and 3 percent, and none will have an impact greater than 3 percent. Estimates for each fee category are available in section 6.3 of the economic analysis. The average annual incremental cost per affected small business is expected to be about \$336 for TSCA section 4; \$1,748 for TSCA section 5, and \$35,665 for TSCA section 6. As a result, EPA estimates that, of the 242 small businesses paying fees every year, 217 will have impacts under 1 percent, 15 will have impacts between 1 percent and

3 percent, and 10 will have impacts greater than 3 percent. Details of this analysis are presented in the economic analysis (Ref. 6), which is available in the docket.

D. Unfunded Mandates Reform Act (UMRA)

This action does not contain an unfunded mandate of \$100 million or more as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. This action imposes no enforceable duty on any state, local or tribal governments.

E. Executive Order 13132: Federalism

This action does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999), because it will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government.

F. Executive Order 13175: Consultation and Coordination with Indian Tribal Governments

This action does not have Tribal implications as specified in Executive Order 13175 (65 FR 67249, November 9, 2000), because it will not have substantial direct effects on Tribal governments, on the relationship between the Federal government and the Indian Tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes. Thus, Executive Order 13175 does not apply to this action.

G. Executive Order 13045: Protection of Children from Environmental Health and Safety Risks

This action is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997), because it does not concern an environmental health or safety risk. Since this action does not concern human health, EPA's 2021 Policy on Children's Health also does not apply.

Although this action does not concern human health or environmental conditions, EPA identifies and addresses children’s environmental health concerns in the risk evaluations conducted under TSCA section 6(b).

H. Executive Order 13211: Actions Concerning Regulations that Significantly Affect Energy Supply, Distribution, or Use

This action is not a “significant energy action” as defined in Executive Order 13211 (66 FR 28355, May 22, 2001), because it is not likely to have a significant adverse effect on the supply, distribution or use of energy.

I. National Technology Transfer and Advancement Act (NTTAA)

This action does not involve technical standards under NTTAA section 12(d), 15 U.S.C. 272.

J. Executive Order 12898: Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations and Executive Order 14096: Revitalizing Our Nation’s Commitment to Environmental Justice for All

This action does not concern human health or environmental conditions and therefore cannot be evaluated with respect to the potential for disproportionate and adverse effects on communities with environmental justice concerns in accordance with Executive Order 12898 (59 FR 7629, February 16, 1994) and Executive Order 14096 (88 FR 25251, April 26, 2023).

Although this action does not concern human health or environmental conditions, EPA identifies and addresses environmental justice concerns in the risk evaluations conducted under TSCA section 6(b).

K. Congressional Review Act (CRA)

This action is subject to the CRA, 5 U.S.C. 801 *et seq.*, and the EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United

States. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects 40 CFR Part 700

Chemicals, Environmental protection, Hazardous substances, Reporting and recordkeeping requirements, User fees.

Michael S. Regan,

Administrator.

Therefore, for the reasons stated in the preamble, 40 CFR part 700 is amended as follows:

PART 700— GENERAL

1. The authority citation for part 700 continues to read as follows:

Authority: 15 U.S.C. 2625 and 2665, 44 U.S.C. 3504.

2. Amend § 700.43 by adding in alphabetical order a definition for “Production volume” and “Small quantities solely for research and development.”

The additions read as follows:

§ 700.43 Definitions applicable to this subpart.

* * * * *

Production volume means manufactured (including imported) amount in pounds.

* * * * *

Small quantities solely for research and development (or “small quantities solely for purposes of scientific experimentation or analysis or chemical research on, or analysis of, such substance or another substance, including such research or analysis for the development of a product”) means quantities of a chemical substance manufactured (including imported), or processed or proposed to be manufactured (including imported), or processed solely for research and development that are not greater than reasonably necessary for such purposes.

* * * * *

3. Amend § 700.45 by revising paragraphs (a)(2) and (3), (b)(5), (7) and (10), (c)(1)(i) through (viii) and (2)(i) through (xi), (d)(1) through (3), (f)(2)(i), (3)(i), (4) through (6), and (g)(3)(i) and (iv), (5) and (6). The revisions read as follows:

§ 700.45 Fee payments.

(a) * * *

(2) Manufacturers and processors of chemical substances and mixtures required to submit information for these chemical substances and mixtures under a TSCA section 4(a) test order or enforceable consent agreement, or manufacturers of chemical substances and mixtures required to submit information for these chemical substance and mixtures under a TSCA section 4(a) test rule, shall remit for each such test rule, order, or enforceable consent agreement the applicable fee identified in paragraph (c) of this section in accordance with the procedures in paragraphs (f) and (g) of this section. Manufacturers of a chemical substance subject to a test rule under TSCA section 4(a) are exempted from fee payment requirements in this section, if they meet one or more of the exemptions under this paragraph (a)(2)(i) through (v) on or after the certification cutoff date identified in 40 CFR 700.45 (b)(6) and do not conduct manufacturing outside of those exemptions after the certification cutoff dates or if they meet the exemptions under this paragraph (a)(2)(vi) for the five-year period preceding publication of the preliminary list and do not conduct manufacturing outside of that exemption during the five-year period preceding publication of the preliminary list; and the exemptions are only available if the manufacturer will meet one or more of the exemptions in this paragraph (a)(2)(i) through (vi) in the successive five years; and will not conduct manufacturing outside of the exemptions in paragraph (a)(2)(i) through (v) in the successive five years or will meet the exemption in paragraph (a)(2)(vi) in the successive five years:

- (i) import articles containing that chemical substance;
- (ii) produce that chemical substance as a byproduct that is not later used for commercial purposes or distributed for commercial use;
- (iii) manufacture that chemical substance as an impurity as defined in 40 CFR 704.3;
- (iv) manufacture that chemical substance as a non-isolated intermediate as defined in 40 CFR 704.3;

(v) manufacture small quantities of that chemical substance solely for research and development, as defined in 40 CFR 700.43; or

(vi) manufacture that chemical substance in quantities below a 1,100 lbs annual production volume as described in § 700.43, unless all manufacturers of that chemical substance manufacture that chemical in quantities below a 1,100 lbs annual production volume as defined in § 700.43, in which case this exemption is not applicable.

(3) Manufacturers of a chemical substance that is subject to a risk evaluation under section 6(b) of the Act, shall remit for each such chemical risk evaluation the applicable fee identified in paragraph (c) of this section in accordance with the procedures in paragraphs (f) and (g) of this section. Manufacturers of a chemical substance subject to risk evaluation under section 6(b) of the Act are exempted from fee payment requirements in this section, if they meet one or more of the exemptions under this paragraph (a)(3)(i) through (v) on or after the certification cutoff date identified in 40 CFR 700.45(b)(6)(i) and do not conduct manufacturing outside of those exemptions after the certification cutoff dates or if they meet the exemptions under this paragraph (a)(3)(vi) for the five-year period preceding publication of the preliminary list and do not conduct manufacturing outside of that exemption during the five-year period preceding publication of the preliminary list; and the exemptions are only available if the manufacturer will meet one or more of the exemptions in paragraph (a)(3)(i) through (vi) in the successive five years and will not conduct manufacturing outside of the exemptions in paragraph (a)(3)(i) through (v) in the successive five years or will meet the exemption in paragraph (a)(3)(vi) in the successive five years:

(i) import articles containing that chemical substance;

(ii) produce that chemical substance as a byproduct that is not later used for commercial purposes or distributed for commercial use;

(iii) manufacture that chemical substance as an impurity as defined in 40 CFR 704.3;

(iv) manufacture that chemical substance as a non-isolated intermediate as defined in 40 CFR 704.3;

(v) manufacture small quantities of that chemical substance solely for research and development, as defined in 40 CFR 700.43; or

(vi) manufacture that chemical substance in quantities below a 2,500 lbs annual production volume as described in § 700.43, unless all manufacturers of that chemical substance manufacture that chemical in quantities below a 2,500 lbs annual production volume as defined in § 700.43, in which case this exemption is not applicable.

* * * * *

(b) *Identifying manufacturers subject to fees.*

* * * * *

(5) *Self-identification.* All manufacturers other than those listed in paragraph (a)(2)(i) through (iii) and (a)(3)(i) through (iii) of this section who have manufactured (including imported) the chemical substance in the previous five years must submit notice to EPA, irrespective of whether they are included in the preliminary list specified in paragraph (b)(3) of this section. The notice must be submitted electronically via EPA's Central Data Exchange (CDX), the Agency's electronic reporting portal, using the Chemical Information Submission System (CISS) reporting tool, and must contain the following information:

(i) * * *

(ii) *Certification of cessation.* If a manufacturer has manufactured in the five-year period preceding publication of the preliminary list but has ceased manufacture prior to the certification cutoff dates identified in paragraph (b)(6) of this section and will not manufacture the substance again in the successive five years, the manufacturer may submit a certification statement

attesting to these facts. If EPA receives such a certification statement from a manufacturer, the manufacturer will not be included in the final list of manufacturers described in paragraph (b)(7) of this section and will not be obligated to pay the fee under this section.

(iii) *Certification of no manufacture.* If a manufacturer is identified on the preliminary list but has not manufactured the chemical in the five-year period preceding publication of the preliminary list, the manufacturer may submit a certification statement attesting to these facts. If EPA receives such a certification statement from a manufacturer, the manufacturer will not be included in the final list of manufacturers described in paragraph (b)(7) of this section and will not be obligated to pay the fee under this section.

(iv) *Certification of meeting exemption.* If a manufacturer is identified on the preliminary list and exclusively meets one or more of the exemptions as described in paragraph (a)(2) or (a)(3) of this section, the manufacturer must submit a certification statement attesting to these facts in order to not be included in the final list of manufacturers described in paragraph (b)(7) of this section. If a manufacturer is not on a preliminary list and exclusively meets one or more of the exemptions as described in paragraph (a)(2) or (a)(3) of this section, the manufacturer may submit a certification statement attesting to these facts. If EPA receives such a certification statement from a manufacturer, the manufacturer will not be included in the final list of manufacturers described in paragraph (b)(7) of this section and will not be obligated to pay the fee under this section, unless all manufacturers of that chemical substance meet the exemption as described in (a)(2)(vi) or (a)(3)(vi) of this section.

(v) *Production volume.* If a manufacturer has not submitted certification of cessation, as described in paragraph (b)(5)(ii) of this section, or certification of no manufacture, as described in paragraph (b)(5)(iii) of this section, for purposes of identifying manufacturers subject to fees for TSCA section 6 EPA-initiated risk evaluations and does not meet one or more of the

exemptions in paragraph (a)(3)(i) through (v) of this section, the manufacturer must submit their production volume as defined in 40 CFR 700.43 for the applicable substance for the three calendar years prior to publication of the preliminary list. Only production volume reported to EPA prior to the final list being published will be used in determining fees described in § 700.45(f).

* * * * *

(7) *Publication of final list.* EPA expects to publish a final list of manufacturers to identify the specific manufacturers subject to the applicable fee. This list will indicate if additional manufacturers self-identified pursuant to paragraph (b)(5) of this section, if other manufacturers were identified through credible public comment, and if manufacturers submitted certification of cessation, no manufacture, or meeting exemption pursuant to paragraph (b)(5)(ii), (iii), or (iv) of this section. The final list will be published no later than concurrently with the final scope document for risk evaluations initiated by EPA under TSCA section 6, and with the final test rule for test rules under TSCA section 4. EPA may modify the list after the publication of the final list.

* * * * *

(10) *Recordkeeping.* After **[INSERT DATE 60 DAYS AFTER THE DATE OF PUBLICATION IN THE *Federal Register*]**:

(i) All manufacturers other than those listed in paragraph (a)(2)(i) through (v) or (a)(3)(i) through (v) of this section must maintain production volume records related to compliance with paragraph (b)(5)(v) of this section. These records must be maintained for a period of five years from the date notice is submitted pursuant to paragraph (b)(5) of this section.

(ii) Those manufacturers that are exempt from fee payment requirements pursuant to paragraph (a)(2)(iv) or (a)(3)(iv) of this section must maintain manufacturing and other business

records related to compliance with the exemption criteria described in paragraph (a)(2)(iv) or (a)(3)(iv) of this section, respectively. These records must be maintained for a period of five years from the date the notice is submitted pursuant to paragraph (b)(5) of this section.

(iii) Those manufacturers that are exempt from fee payment requirements pursuant to paragraph (a)(2)(v) or (a)(3)(v) of this section must maintain manufacturing and other business records related to compliance with the exemption criteria described in paragraph (a)(2)(v) or (a)(3)(v) of this section, respectively, such as production volume, plans of study, information from research and development notebooks, study reports, or notice solely for research and development use. These records must be maintained for a period of five years from the date the notice is submitted pursuant to paragraph (b)(5) of this section.

(iv) Those manufacturers that are exempt from fee payment requirements pursuant to paragraph (a)(2)(vi) or (a)(3)(vi) of this section must maintain production volume records related to compliance with the exemption criteria described in paragraph (a)(2)(vi) or (a)(3)(vi) of this section, respectively. These records must be maintained for a period of five years from the date the notice is submitted pursuant to paragraph (b)(5) of this section.

* * * * *

(c) *Fees for the 2024, 2025, and 2026 fiscal years.*

(1) * * *

(i) *Premanufacture notice and consolidated premanufacture notice.* Persons shall remit a fee totaling \$6,480 for each premanufacture notice (PMN) or consolidated PMN submitted in accordance with part 720 of this chapter.

(ii) *Significant new use notice.* Persons shall remit a fee totaling \$6,480 for each significant new use notice (SNUN) submitted in accordance with part 721 of this chapter.

(iii) *Exemption application.* Persons shall remit a fee totaling \$2,180 for each of the

following exemption requests submitted under TSCA section 5:

(A) * * *

(iv) *Instant photographic film article exemption notice*. Persons shall remit a fee totaling \$2,180 for each instant photographic film article exemption notice submitted in accordance with § 723.175 of this chapter.

(v) *Microbial commercial activity notice and consolidated microbial commercial activity notice*. Persons shall remit a fee totaling \$6,480 for each microbial commercial activity notice (MCAN) or consolidated MCAN submitted in accordance with §§ 725.25 through 725.36 of this chapter.

(vi) Persons shall remit a total of twenty percent of the applicable fee under paragraph (c)(2)(vi), (vii) or (viii) of this section for a test rule, test order, or enforceable consent agreement.

(vii) Persons shall remit a total fee of twenty percent of the applicable fee under paragraphs (c)(2)(ix) of this section for an EPA-initiated risk evaluation.

(viii) Persons shall remit the total fee under paragraph (c)(2)(x) or (xi) of this section, as applicable, for a manufacturer-requested risk evaluation.

(2) * * *

(i) *PMN and consolidated PMN*. Persons shall remit a fee totaling \$37,000 for each PMN or consolidated PMN submitted in accordance with part 720 of this chapter.

(ii) *SNUN*. Persons shall remit a fee totaling \$37,000 for each significant new use notice submitted in accordance with part 721 of this chapter.

(iii) *Exemption applications*. Persons shall remit a fee totaling \$10,870 for each of the following exemption requests, and modifications to previous exemption requests, submitted under section 5 of the Act:

(A)* * *

(iv) *Instant photographic film article exemption notice.* Persons shall remit a fee totaling \$10,870 for each exemption notice submitted in accordance with § 723.175 of this chapter.

(v) *MCAN and consolidated MCAN.* Persons shall remit a fee totaling \$37,000 for each MCAN or consolidated MCAN submitted in accordance with §§ 725.25 through 725.36 of this chapter.

(vi) *Test rule.* Persons shall remit a fee totaling \$50,000 for each test rule.

(vii) *Test order.* Persons shall remit a fee totaling \$25,000 for each test order.

(viii) *Enforceable consent agreement.* Persons shall remit a fee totaling \$50,000 for each enforceable consent agreement.

(ix) *EPA-initiated chemical risk evaluation.* Persons shall remit a fee totaling \$4,287,000.

(x) *Manufacturer-requested risk evaluation of a Work Plan Chemical.* Persons shall remit an initial fee of \$1,414,924, a second payment of \$1,414,924, and final payment to total 50% of the actual costs of this activity, in accordance with the procedures in paragraph (g) of this section. The final payment amount will be determined by EPA, and invoice issued to the requesting manufacturer.

(xi) *Manufacturer-requested risk evaluation of a non-work plan chemical.* Persons shall remit an initial fee of \$2,829,847, a second payment of \$2,829,847, and final payment to total 100% of the actual costs of the activity, in accordance with the procedures in paragraph (g) of this section. The final payment amount will be determined by EPA, and invoice issued to the requesting manufacturer.

* * * * *

(d) *Fees for 2026 fiscal year and beyond.*

(1) Fees for the 2026 and later fiscal years will be adjusted on a three-year cycle by

multiplying the fees in paragraph (c) of this section by the current PPI index value with a base year of 2024 using the following formula:

$$FA = F \times I$$

Where:

FA = the inflation-adjusted future year fee amount.

F = the fee specified in paragraph (c) of this section.

I = Producer Price Index for Chemicals and Allied Products inflation value with 2024 as a base year.

(2) Updated fee amounts for PMNs, SNUNs, MCANs, exemption notices, exemption applications, and manufacturer-requested risk evaluation requests apply to submissions received by the Agency on or after October 1 of every three-year fee adjustment cycle beginning in fiscal year 2024 (October 1, 2023). Updated fee amounts also apply to test rules, test orders, enforceable consent agreements and EPA-initiated risk evaluations that are “noticed” on or after October 1 of every three-year fee adjustment cycle, beginning in fiscal year 2026.

(3) The Agency will initiate public consultation through notice-and-comment rulemaking prior to making fee adjustments beyond inflation. If it is determined that no additional adjustment is necessary beyond for inflation, EPA will provide public notice of the inflation-adjusted fee amounts through posting to the Agency's web page by the beginning of each three-year fee adjustment cycle (October 1, 2026, October 1, 2029, etc.). If the Agency determines that adjustments beyond inflation are necessary, EPA will provide public notice of that determination and the process to be followed to make those adjustments.

* * * * *

(f)* * *

(2) * * *

(i) The consortium must identify a principal sponsor and provide notification to EPA that a consortium has formed. The notification must be accomplished within 90 days of the publication date of a test rule under section 4 of the Act, or within 90 days of the effective date of a test order under section 4 of the Act, or within 90 days of the signing of an enforceable consent agreement under section 4 of the Act. EPA may permit additional entities to join an existing consortium after the expiration of the notification period if the principal sponsor provides updated notification.

* * * * *

(3) * * *

(i) Notification must be provided to EPA that a consortium has formed. The notification must be accomplished within 90 days of the publication of the final scope of a chemical risk evaluation under section 6(b)(4)(D) of the Act or within 90 days of EPA providing notification to a manufacturer that a manufacturer-requested risk evaluation has been granted. EPA may permit additional entities to join an existing consortium after the expiration of the notification period if the principal sponsor provides updated notification.

* * * * *

(4) If multiple persons are subject to fees triggered by section 4 or 6(b) of the Act and no consortium is formed, EPA will determine the portion of the total applicable fee to be remitted by each person subject to the requirement. Each person's share of the applicable fees triggered by section 4 of the Act specified in paragraph (c) of this section shall be in proportion to the total number of manufacturers and/or processors of the chemical substance, with lower fees for small businesses:

$$P_s = 0.2 \times \left[\frac{F}{M_t} \right]$$

$$P_o = \frac{F - [0.2 \times \left(\frac{F}{M_t}\right) \times M_s]}{(M_t - M_s)}$$

Where:

P_s = the portion of the fee under paragraph (c) of this section that is owed by a person who qualifies as a small business concern under § 700.43 of this chapter.

P_o = the portion of the fee owed by a person other than a small business concern.

F = the total fee required under paragraph (c) of this section.

M_t = the total number of persons subject to the fee requirement.

M_s = the number of persons subject to the fee requirement who qualify as a small business concern.

Each person's share of the applicable fees triggered by section 6(b) of the Act specified in paragraph (c) of this section shall be in proportion to the total number of manufacturers and their reported production volume as described in 700.45(b)(v) of the chemical substance, with lower fees for small businesses:

$$P_s = 0.2 \times \left[\frac{F}{M_t}\right]$$

$$F_o = F - [0.2 \times \left(\frac{F}{M_t}\right) \times M_s]$$

Remaining manufacturers (i.e., those that do not qualify as a small business concern) are then ranked in ascending order (from lowest to highest) based on reported production volume as described in 700.45(b)(v). Each remaining manufacturer is assigned a number with 1 for lowest production volume, 2 for second lowest production volume, etc.

Table 1 to Paragraph (f)(4): Example of placing manufacturers that do not qualify as a small business concern in ascending order.

Manufacturer(s)	Assigned number (N)
Manufacturer with lowest production volume	1
Manufacturer with 2 nd lowest production volume	2
Manufacturer with 3 rd lowest production volume	3
... etc.	...

$$N_{20\text{th}} = [0.8 \times [M_t - M_s]]$$

$$P_{\geq 20\text{th}} = \frac{0.8 \times F_o}{M_{\geq 20\text{th}}}$$

$$P_{< 20\text{th}} = \frac{[F_o - [0.8 \times F_o]]}{M_{< 20\text{th}}}$$

Where:

P_s = the portion of the fee under paragraph (c) of this section that is owed by a person who qualifies as a small business concern under § 700.43 of this chapter.

$P_{\geq 20\text{th}}$ = the portion of the fee owed by a person other than a small business concern in the top 20th percentile.

$P_{< 20\text{th}}$ = the portion of the fee owed by a person other than a small business concern not in the top 20th percentile.

F = the total fee required under paragraph (c) of this section.

M_t = the total number of persons subject to the fee requirement.

M_s = the number of persons subject to the fee requirement who qualify as a small business concern.

$N_{20\text{th}}$ = The assigned number as illustrated in Table 1 to the manufacturer(s) with a production volume as described in 700.45(b)(v) at which the manufacturers with production volume greater than or equal to are in the top 20th percentile.

$M_{\geq 20\text{th}}$ = the total number of persons with production volume as described in 700.45(b)(v) greater than or equal to the manufacturer(s) with a production volume as $N_{20\text{th}}$.

$M_{< 20\text{th}}$ = the total number of persons with production volume as described in 700.45(b)(v) less than the manufacturer(s) with a production volume as $N_{20\text{th}}$.

F_o = the total fee required under paragraph (c) of this section by all person(s) other than a small business concern.

In the event there are three or less manufacturers identified for a chemical substance, EPA will distribute the fee evenly among those three or less 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 as described in 700.45(b)(v) greater than or equal to the top 20th percentile.

In the event multiple manufacturers report the same production volume as described in 700.45(b)(v) 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.

(5) If multiple persons are subject to fees triggered by section 4 of the Act and some inform EPA of their intent to form a consortium while others choose not to associate with the consortium, EPA will take the following steps to allocate fee amounts:

(i) Count the total number of manufacturers, including the number of manufacturers within any consortia; divide the total fee amount by the total number of manufacturers; and allocate equally on a per capita basis to generate a base fee;

(ii) Provide all small businesses who are either not associated with a consortium, or associated with an all- small business consortium, with an 80% discount from the base fee referenced previously;

(iii) Calculate the total remaining fee and total number of remaining manufacturers by subtracting out the discounted fees and the number of small businesses identified;

(iv) Reallocate the remaining fee across those remaining individuals and groups in equal amounts, counting each manufacturer in a consortium as one person; and

(v) Inform consortia and individuals of their requisite fee amount.

Small businesses in a successfully- formed consortium, other than a consortium of all small businesses, will not be afforded the 80% discount by EPA, but consortia managers are strongly encouraged to provide a discount for small business concerns.

(6) If multiple persons are subject to fees triggered by section 6(b) of the Act and some inform EPA of their intent to form a consortium while others choose not to associate with the consortium, EPA will take the following steps to allocate fee amounts:

(i) Count the total number of manufacturers, including the number of manufacturers within any consortia; divide the total fee amount by the total number of manufacturers; and allocate equally on a per capita basis to generate a base fee;

(ii) Provide all small businesses who are either not associated with a consortium, or associated with an all-small business consortium, with an 80% discount from the base fee referenced previously;

(iii) Calculate the total remaining fee and total number of remaining manufacturers by subtracting out the discounted fees and the number of small businesses identified;

(iv) Place remaining manufacturers in ascending order (from lowest to highest) based on reported production volume as described in 700.45(b)(v). Assign each remaining manufacturer a number with 1 for lowest production volume, 2 for second lowest production volume, etc.;

(v) Determine the manufacturer(s) in the top 20th percentile by multiplying the total number of remaining manufacturers by 0.8. then comparing that number to the manufacturer(s) with that assigned number as described in paragraph (iv) of this section;

(vi) Reallocate 80% of the total remaining fee evenly across that manufacturer(s) with a production volume amount equal to or larger than that manufacturer(s) (the top 20th percentile), counting each manufacturer in a consortium as one person;

(vii) Reallocate the remaining fee evenly across the remaining manufacturers, counting

each manufacturer in a consortium as one person; and

(v) Inform consortia and individuals of their requisite fee amount.

Small businesses in a successfully-formed consortium, other than a consortium of all small businesses, will not be afforded the 80% discount by EPA, but consortia managers are strongly encouraged to provide a discount for small business concerns.

* * * * *

(g) * * *

(3) * * *

(i) *Test orders and test rules.* The applicable fee specified in paragraph (c) of this section shall be paid in full not later than 180 days after the effective date of a test rule or test order under section 4 of the Act.

(ii) * * *

(iv) *Risk evaluations.* (A) For EPA-initiated risk evaluations, the applicable fee specified in paragraph (c) of this section shall be paid in two installments, with the first payment of 50% due 180 days after publishing the final scope of a risk evaluation and the second payment for the remainder of the fee due 545 days after publishing the final scope of a risk evaluation under section 6(b)(4)(D) of the Act.

(B) For manufacturer-requested risk evaluations under section 6(b)(4)(C)(ii) of the Act, the applicable fees specified in paragraph (c) of this section shall be paid as follows:

(1) The applicable fee specified in paragraph (c) of this section shall be paid in three installments. The first payment shall be due no later than 180 days after EPA provides the submitting manufacture(s) notice that it has granted the request.

(2) The second payment shall be due no later than 545 days after EPA provides the submitting manufacturer(s) notice that it has granted the request.

(3) The final payment shall be due no later than 30 days after EPA publishes the final risk evaluation.

* * * * *

(5) *Small business certification.* (i) Each person who remits the fee identified in paragraph (c)(1) of this section for a PMN, consolidated PMN, or SNUN shall insert a check mark for the statement, “The company named in part 1, section A is a small business concern under 40 CFR 700.43 and has remitted a fee of \$6,480 in accordance with 40 CFR 700.45(c).” under “CERTIFICATION” on page 2 of the Premanufacture Notice for New Chemical Substances (EPA Form 7710-25).

(ii) Each person who remits the fee identified in paragraph (c)(1) of this section for a LVE, LoREX, TERA, TME, or Tier II exemption request under TSCA section 5 shall insert a check mark for the statement, “The company named in part 1, section A is a small business concern under 40 CFR 700.43 and has remitted a fee of \$2,180 in accordance with 40 CFR 700.45(c).” in the exemption application.

(iii) Each person who remits the fee identified in paragraph (c)(1) of this section for an exemption notice under § 723.175 of this chapter shall include the words, “The company or companies identified in this notice is/are a small business concern under 40 CFR 700.43 and has/have remitted a fee of \$2,180 in accordance with 40 CFR 700.45(c).” in the certification required in § 723.175(i)(1)(x) of this chapter.

(iv) Each person who remits the fee identified in paragraph (c)(1) of this section for a MCAN or consolidated MCAN for a microorganism shall insert a check mark for the statement, “The company named in part 1, section A is a small business concern under 40 CFR 700.43 and has remitted a fee of \$6,480 in accordance with 40 CFR 700.45(c).” in the certification required in § 725.25(b) of this chapter.

(6) *Payment certification statement.* (i) Each person who remits a fee identified in paragraph (c)(2) of this section for a PMN, consolidated PMN, or SNUN shall insert a check mark for the statement, “The company named in part 1, section A has remitted the fee of \$37,000 specified in 40 CFR 700.45(c).” under “CERTIFICATION” on page 2 of the Premanufacture Notice for New Chemical Substances (EPA Form 7710-25).

(ii) Each person who remits a fee identified in paragraph (c)(2) of this section for a LVE, LoREX, TERA, TME, or Tier II exemption request under TSCA section 5 shall insert a check mark for the statement, “The company named in part 1, section A has remitted the fee of \$10,870 specified in 40 CFR 700.45(c).” in the exemption application.

(iii) Each person who remits the fee identified in paragraph (c)(2) of this section for an exemption notice under § 723.175 of this chapter shall include the words, “The company or companies identified in this notice has/have remitted a fee of \$10,870 in accordance with 40 CFR 700.45(c).” in the certification required in § 723.175(i)(1)(x) of this chapter.

(iv) Each person who remits the fee identified in paragraph (c)(2) of this section for a MCAN for a microorganism shall insert a check mark for the statement, “The company named in part 1, section A has remitted the fee of \$37,000 in accordance with 40 CFR 700.45(c).” in the certification required in § 725.25(b) of this chapter.

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