



40 CFR Part 700

[EPA-HQ-OPPT-2020-0493; FRL-10018-40]

RIN 2070-AK64

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

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing updates and adjustments to the 2018 fees rule established under the Toxic Substances Control Act (TSCA). 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 proposed modifications to the TSCA fees and fee categories for fiscal years 2022, 2023 and 2024, and explains the methodology by which these TSCA fees were determined. EPA is proposing to add three new fee categories: a Bona Fide Intent to Manufacture or Import Notice, a Notice of Commencement of Manufacture or Import, and an additional fee associated with test orders. In addition, EPA is proposing exemptions for entities subject to certain fee triggering activities; including: an exemption for research and development activities, an exemption for entities manufacturing less than 2,500 lbs. of a chemical subject to an EPA-initiated risk evaluation fee; an exemption for manufacturers of chemical substances produced as a non-isolated intermediate; and 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 is updating its cost estimates for administering TSCA, relevant information management activities and individual fee calculation methodologies. EPA is proposing a volume-based fee allocation for EPA-initiated risk evaluation fees in any scenario where a consortium is not formed and is proposing to require export-only manufacturers to pay fees

for EPA-initiated risk evaluations. EPA is also proposing various changes to the timing of certain activities required throughout the fee payment process.

DATES: Comments must be received on or before [INSERT DATE 45 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPPT-2020-0493, through the *Federal eRulemaking Portal* at <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

Please note that due to the public health emergency the EPA Docket Center (EPA/DC) and Reading Room was closed to public visitors on March 31, 2020. Our EPA/DC staff will continue to provide customer service via email, phone, and webform. For further information on EPA/DC services, docket contact information and the current status of the EPA/DC and Reading Room, please visit <https://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: *For technical information contact:* Marc Edmonds, Existing Chemicals Risk Management Division, 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.

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554-1404; email address: TSCA-Hotline@epa.gov.

I. Executive Summary

A. Does this action apply to me?

You may be affected by this action if you manufacture (including import), distribute in commerce, 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 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 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 proposed rule under TSCA section 26(b), 15 U.S.C. 2625(b).

C. What action is the Agency taking?

Pursuant to TSCA section 26(b), EPA is issuing this proposed rule to establish, update and/or revise fees collected from manufacturers (including importers) and, in some

cases, processors, to defray some of the Agency's costs related to activities under TSCA sections 4, 5, and 6, and collecting, processing, reviewing, and providing access to and protecting from disclosure as appropriate under TSCA section 14 information on chemical substances. EPA is proposing updates and changes to the 2018 Fee Rule (Ref. 2), including:

- (a) The addition of three new fee categories – a Bona Fide Intent to Manufacture or Import Notice (bona fide notice), Notice of Commencement of Manufacture or Import (NOC), and an additional fee related to test orders;
- (b) The addition of exemptions for manufacturers subject to fees for EPA-initiated risk evaluations under TSCA section 6(b), including: exemptions for manufacturers if the chemical substance is imported in an article, produced as a byproduct, or produced or imported as an impurity (as discussed in the March 25, 2020 EPA Press Release announcing its plan and summarized at <https://www.epa.gov/tsca-fees/information-plan-reduce-tsca-fees-burden-and-no-action-assurance> (Ref. 3)), an exemption for research and development activities, an exemption for manufacturers of chemical substances produced as a non-isolated intermediate, and an exemption for entities manufacturing less than 2,500 lbs. of a chemical;
- (c) Updates to TSCA sections 4, 5, and 6 costs and costs of relevant information management activities as well as fee calculation methodology; and
- (d) Various changes to how the fee regulations are implemented including certain timing requirements throughout the fee payment process.

EPA is not proposing to change the “small business concerns” definition. Although EPA is required to review and, if necessary, amend the TSCA fees every three years, EPA may propose additional amendments to TSCA fees, when warranted, based on its experience with implementing the requirements or analysis of future cost and revenue data.

D. Why is the Agency taking this action?

The proposed fees 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. These activities include

designating applicable substances as High- and Low-Priority for future risk evaluation, conducting risk evaluations to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, requiring testing of chemical substances and mixtures, and evaluating and reviewing new chemical submissions, as required under TSCA sections 4, 5 and 6, as well as collecting, processing, reviewing, and providing access to and protecting from disclosure as appropriate under TSCA section 14 information on chemical substances under TSCA. EPA reviewed fees established in the 2018 Fee Rule and determined that it is necessary to adjust the fees. EPA is proposing changes to the TSCA fee requirements established in the 2018 Fee Rule based upon over two years of TSCA fee implementation and is proposing to adjust the fees based on changes to program costs and inflation and address certain issues related to implementation of the fee requirements.

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

EPA has evaluated the potential incremental economic impacts of this proposed rule for FY 2022 through FY 2024. The “Economic Analysis of the Proposed Rule for Fees for the Administration of the Toxic Substances Control Act” (Economic Analysis) (Ref. 4), which is available in the docket, is discussed in Unit IV., and is briefly summarized here.

1. *Benefits.* The principal benefit of the proposed rule is to provide EPA a sustainable source of funding necessary to administer certain provisions of TSCA.

2. *Cost.* The fees collected from industry for this proposed rule under the proposed options, annualized over the period from fiscal year 2022-2024, are approximately \$22 million (at both 3% and 7% discount rates), 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. Total annual fee collection for manufacturer-requested risk evaluations is estimated to be \$1.9 million for chemicals included in the 2014 TSCA Work Plan (TSCA Work Plan)

(based on two requests over the three-year period) and approximately \$5.7 million for chemicals not included in the TSCA Work Plan (based on three requests over the three-year period) (Ref. 4). EPA analyzed a three-year period because the statute requires EPA to reevaluate and adjust, as necessary, the fees every three years.

3. *Small entity impact.* EPA estimates that 35% of section 5 submissions will be from small businesses that are eligible to pay the section 5 small business fee because they meet the definition of “small business concern.” “Small business concern” means a manufacturer or processor who meets the size standards at 40 CFR § 700.43. Total annualized fee collection from small businesses submitting notices under section 5 is estimated to be \$411,000 (Ref. 4). For 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 identified 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 section 4 and section 6 would be approximately \$8,000 and \$922,000, respectively. For each of the three years covered by this proposed rule, EPA estimates that total fee revenue collected from small businesses will account for about 6 percent of the approximately \$22 million total fee collection, for an annual average total of approximately \$1.3 million.

4. *Environmental justice.* The fees will enable the Agency to better protect human health and the environment, including in low-income and minority communities.

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

F. What should I consider as I prepare my comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through <http://www.regulations.gov> or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, mark the

outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at <http://www.epa.gov/dockets/comments.html>.

II. Background

A. Statutory Requirements for TSCA Fees

The proposed Fee Rule (83 FR 8212, February 26, 2018) (FRL-9974-31) provides a robust overview of the history of fees under TSCA and the 2016 amendments to TSCA. 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 25% of the Agency's costs to carry out a broader set of activities under sections 4, 5, and 6 and relevant information management activities. In addition, in the case of manufacturer-requested risk evaluations, the Agency is directed to establish fees sufficient to defray 50% of the costs associated with conducting a manufacturer-requested risk evaluation on a chemical included in the *TSCA Work Plan for Chemical Assessments: 2014 Update*, and 100% of the costs of conducting a manufacturer-requested risk evaluation 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. EPA is fulfilling that obligation with this rulemaking.

B. History of TSCA Fees

On October 17, 2018, EPA finalized the TSCA Fee Rule (Ref. 2), following the issuance of a proposed Fee Rule on February 26, 2018 and a 60-day comment period. As required by TSCA 26(b)(4)(E), EPA also consulted and met with stakeholders that were

potentially subject to fees, including as part of several meetings with individual stakeholders through the development of the final rule.

In the 2018 Fee Rule, EPA established eight distinct fee categories: (1) Test orders, (2) test rules and (3) enforceable consent agreements (ECA), all under TSCA section 4; (4) notices and (5) exemptions, both under TSCA section 5; and (6) EPA-initiated risk evaluations, (7) manufacturer-requested risk evaluations for chemicals on the TSCA Work Plan, and (8) manufacturer-requested risk evaluations for chemicals not on the TSCA Work Plan, all under TSCA section 6. The activities in these categories are fee-triggering events that result in obligations to pay fees.

In addition, EPA established standards for determining which persons qualify as “small business concerns” and thus would be subject to lower fee payments. As discussed in the 2018 Fees Rule, EPA adopted an employee-based size standard modeled after the SBA’s standards. EPA is not proposing to change the “small business concerns” definition in this rule.

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 manufacturer-requested risk evaluations) and conducting relevant information management activities; identifying the full cost amount to be defrayed by fees under TSCA section 26(b) (*i.e.*, 25% of those annual costs); and allocating that amount across the fee-triggering events in TSCA sections 4, 5, and 6, weighted more heavily toward TSCA section 6 based on early industry feedback. EPA afforded small businesses an approximate 80% discount, in accordance with TSCA section 26(b)(4)(A), and established, for the two fee-triggering events where manufacturers would not already be self-identified (TSCA section 4 test rules and TSCA section 6 EPA-initiated risk evaluations), a process to identify manufacturers (including importers) subject to these fees.

At the time of promulgation of the 2018 Fee Rule, EPA had many new

responsibilities under amended TSCA and relatively little information and experience to inform assumptions on costs or activity levels. EPA has gained valuable experience over two years of implementing the initial fee structure and has used this initial experience and information gained from tracking actual costs to refine methodologies for calculating fees and to inform the development of proposed revisions to the fee structure. These proposed updates are discussed in Unit III. Additional discussion on the updates to program cost estimates is discussed in Unit II.C.

C. Program Cost Estimates and Activity Assumptions

The estimated annual Agency costs of carrying out relevant activities under TSCA sections 4, 5, and 6 and relevant information management activities are based on cost data from fiscal years 2019 and 2020 which are the first full fiscal years after EPA implemented a time reporting system that tracks employee hours worked on administering TSCA. Total Agency costs of carrying out those relevant activities are estimated at approximately \$87.5 million each year. Based on these cost estimates, EPA anticipates collecting approximately \$22 million in fees collected from all fee-triggering events, except manufacturer-requested risk evaluations. In addition, the Agency intends to collect fees to recover 50% or 100% of the actual costs incurred by EPA in conducting chemical risk evaluations requested by manufacturers, depending on whether the chemical substance is included in the TSCA Work Plan. EPA expects the amount collected will be approximately \$2.84 million per chemical for chemicals on the TSCA Work Plan and \$5.67 million per chemical for chemicals not on the TSCA Work Plan.

EPA determined the anticipated costs associated with relevant activities under TSCA sections 4, 5, and 6 and relevant information management activities, including both direct program costs and indirect costs (see Table 1). For fiscal year 2022 through fiscal year 2024, these costs were estimated to be approximately \$87.5 million per year.

Table 1—Estimated Annual Costs to EPA
[Fiscal Year 2022 through Fiscal Year 2024]

	Annual costs
TSCA section 4	\$3,543,000
TSCA section 5	\$34,713,248
TSCA section 6	\$41,998,820
TSCA section 8	\$3,974,522
TSCA section 14.....	\$1,873,443
Other sections	\$1,432,967
Total	\$87,536,000

Table Note: Numbers may not add due to rounding. The indirect cost rate is estimated at 19.5% for the purposes of this analysis.

After estimating the annual costs of administering relevant activities under TSCA sections 4, 5, and 6 and relevant information management activities, the Agency had to determine how the costs would be allocated over the narrower set of activities under TSCA sections 4, 5 and 6 that trigger a fee. The Agency took an approach to determining fees that tied the payment of fees to individual distinct activity types or “fee-triggering events”. This allows allocation of costs more equitably among the activity types and their related costs.

1. Program costs.

To determine the program costs for implementing relevant activities under TSCA sections 4, 5, and 6 and relevant information management activities, the Agency accounted for the intramural and extramural costs for those activities.

Intramural costs are those costs related to the efforts exerted by EPA staff and management in operating the program, collecting and processing information and funds, conducting reviews, and related activities. Extramural costs are those costs related to the acquisition of contractors to conduct activities such as analyzing data, developing IT systems and supporting the TSCA Help Desk.

The Agency then added indirect costs to the direct program cost estimates. The Agency used an indirect cost rate of 19.5% to calculate the indirect costs associated with all direct program cost estimates for TSCA sections 4, 5, and 6 and relevant information management activities.

a. TSCA section 4 program costs.

TSCA section 4 gives EPA the authority to require (by rule, order, or ECA) manufacturers and processors to conduct testing of identified chemical substances or mixtures. EPA plans to utilize section 4 authorities in connection with the development of section 6(b) risk evaluations which would affect the number of section 4 rules, orders, and ECAs that may be underway at any given time. These activity level assumptions represent EPA's best professional judgment on how the program will be implemented. EPA estimates that, on average, it will undertake work associated with 10 test orders, one test rule and one ECA each year. While EPA expects to work on one test rule and one ECA each year, EPA expects to initiate each of these activities about every other year as it takes approximately two years to complete the work associated with both activities.

EPA estimated TSCA section 4 costs based on prior experience with developing test orders, test rules and ECAs, with consideration given to the information needs under amended TSCA for section 4 activities. Specifically, costs were based on: the Agency's general experience with the rulemaking process; experience with developing an ECA for Octamethylcyclotetrasiloxane (D4); costs associated with reviewing study plans and information received; administration of the High Production Volume Voluntary Testing Program; and information from the development of one test order for pigment violet 29.

EPA's cost estimates included a full suite of activities related to developing and implementing actions under TSCA section 4 authorities including reviewing screening-level hazard and environmental fate information submitted in response to a section 4 rule, order, or ECA, such as tests that provide information on the toxicity of a chemical (*e.g.*, aquatic toxicity, and mammalian toxicity) or occupational monitoring data. EPA also included estimates of the costs of reviewing physical/chemical properties and environmental fate and pathways data and tests.

Based on previous experience and expected work under TSCA as amended, EPA assumes that testing required by test orders is likely to be completed in under a year, and test

rules and ECAs are likely to take two years to complete. To estimate the costs of reviewing test data, we assume that, on average, data will be submitted to EPA to conduct 10 test orders per year over the course of a three-year period, with approximately 120 companies potentially subject to the orders.

Unlike activities conducted under sections 5 and 6, EPA does not have enough data on actual implementation costs with which to base future cost estimates. As a result, EPA is relying on the section 4 cost estimate from the 2018 Fees Rule. Based on this approach, the estimated cost to the Agency of each test order is approximately \$279,000. Each test rule is estimated to cost approximately \$844,000 and each ECA is estimated to cost approximately \$652,000. These cost estimates include submission review and are based on projected full-time equivalent (FTE) and extramural support needed for each activity divided by the number of orders, rules and ECAs that EPA assumes will be issued over a three-year period. As noted earlier, several of these activities (rules and ECAs) are expected to span two years, so those estimates are based on the annual estimated costs multiplied by two. The annual cost estimate of administering TSCA section 4 in fiscal year 2022 through fiscal year 2024 is \$3,543,000.

b. TSCA section 5 program costs.

TSCA section 5 requires that manufacturers and processors provide EPA with notice before initiating the manufacture of a new chemical substance or initiating the manufacturing or processing for a significant new use of a chemical substance. Examples of the notices or other information that manufacturers and processors are required to submit under TSCA section 5 are premanufacture notices (PMNs), significant new use notifications (SNUNs), microbial commercial activity notices (MCANs), and exemption notices and applications including low-volume exemptions (LVEs), test-marketing exemptions (TMEs), low exposure/low release exemptions (LoREXs), TSCA experimental release applications (TERAs), certain new microorganism (Tier II) exemptions, and film article exemptions. EPA is required

to review and make a determination on whether the chemical presents an unreasonable risk of injury to health or the environment and take risk management action, as needed. Recent data on the number of annual submissions is found at <https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/statistics-new-chemicals-review>.

EPA estimates that it will receive 301 PMNs, SNUNs and MCANs per year, and another 320 exemption notices and applications per year, most of which are LVEs. EPA used the average number of section 5 submissions received in FY2019 and FY 2020 for each category of submission as the estimate of the annual number of submissions per section 5 fee category for the next three years. Cost estimates were developed based on information from the Agency's time reporting system that tracks employee hours and contract expenditures for administering TSCA section 5 in FY 2019 and FY 2020.

EPA's cost estimates for administering TSCA section 5 also include the costs associated with processing and retaining records related to a Notice of Commencement of Manufacture or Import (NOC) submission. NOC costs also include the cost of registering the chemical with the Chemical Abstracts Service. EPA has lumped the costs associated with NOCs with those of PMNs, MCANs, and SNUNs. Estimated costs associated with TSCA section 5 exemption notices and applications include the costs of pre-notice consultations, processing and reviewing applications, retaining records, and related activities. This estimate is based on projected FTE and extramural support needed for these actions divided by the number of submissions the Agency assumes will be received each year.

The annual cost estimate of administering TSCA section 5 in fiscal year 2022 through fiscal year 2024 is \$34,713,248 and is attributed to PMNs, SNUNs and MCANs as well as section 5 exemption notices and applications for LVEs, LoREXs, TMEs, TERAs, Tier II exemptions and film article exemptions.

c. TSCA section 6 program costs.

TSCA section 6 directs the EPA to establish a process for assessing and managing existing chemical substances under TSCA. TSCA section 6 addresses: (a) Prioritizing chemicals for evaluation; (b) Evaluating risks from chemicals; and (c) Addressing unreasonable risks identified through the risk evaluation. Under TSCA, EPA is required to regularly undertake a risk-based prioritization process to designate existing chemicals on the TSCA Inventory as either high-priority for risk evaluation or low-priority. For chemicals designated as High-Priority Substances, as well as certain chemicals not subject to prioritization, such as those in manufacturer-requested risk evaluations, EPA must evaluate those chemicals to determine whether they present an unreasonable risk of injury to health or the environment under the conditions of use. The first step in the risk evaluation process, as outlined in TSCA, is to issue a scoping document for each chemical substance within six months of initiation of the risk evaluation (e.g., designation of a High-Priority Substance as announced in the *Federal Register*). The scoping document includes information about the chemical substance, such as conditions of use, hazards, exposures, and potentially exposed or susceptible subpopulations that the Agency expects to consider in the risk evaluation. TSCA requires that these chemical risk evaluations be completed within three years of initiation, allowing for a 6-month extension. During the Risk Evaluation scoping process, EPA will identify the “conditions of use” that the Agency expects to consider during the evaluation. If EPA determines that a chemical substance presents unreasonable risk under its conditions of use, EPA must proceed to risk management action under TSCA section 6(a). For each risk evaluation that the Agency completes (other than a manufacturer-requested risk evaluation), TSCA requires that EPA identify another High-Priority Substance. The Agency expects to have at least 20 risk evaluations (other than manufacturer-requested risk evaluations) ongoing at any time in any given year at different stages in the evaluation process.

TSCA section 6 cost estimates have been informed: by the Agency’s experience

conducting and in some cases completing evaluations for the first 10 chemicals undergoing risk evaluation under amended TSCA, which consist of 1,4 dioxane, 1-bromopropane, asbestos, carbon tetrachloride, cyclic aliphatic bromide cluster (HBCD), methylene chloride, N-methylpyrrolidone, pigment violet 29, trichloroethylene, and tetrachloroethylene; by the Agency's experience developing the scope of the risk evaluations of the 20 chemicals designated as high-priority in December 2019; and by the Agency's experience with risk management actions addressing unreasonable risks identified from particular chemical activities. TSCA section 6 risk evaluations include the cost of information gathering (distinct from data collection via section 4), evaluating human and environmental hazards and environmental fate, and conducting exposure assessments. Costs also include the use of the ECOTOX knowledge and Health and Environmental Research Online (HERO) databases, scoping, developing and publishing the draft risk evaluation, conducting and responding to peer review and public comment, and developing the final evaluation, which includes risk determinations.

Under TSCA section 6, the Agency also must take action to address the unreasonable risks identified during risk evaluation. Cost estimates for risk management activities have been informed, in part, by EPA's recent risk management actions on several chemicals, including development of the proposed rules regarding the use of N-methylpyrrolidone and methylene chloride in paint and coating removal, and the use of trichloroethylene in both commercial vapor and aerosol degreasing and for spot cleaning in dry cleaning facilities, and the development of the final rule regarding methylene chloride in consumer paint and coating removal.

The estimated annual cost to EPA of administering relevant activities under TSCA section 6 in fiscal year 2022 through 2024 is \$41,998,820. The costs are attributed to risk evaluation work on chemical risk evaluations (other than manufacturer-requested risk evaluations); risk management efforts; support from the Office of Research and

Development (ORD) for alternative animal testing and methods development and enhancement, data integration, meta-analysis of studies, and providing access to other models, tools and information already developed by ORD; and the process of prioritizing chemical substances.

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 sections 4, 5, 6 and 14 but do not include the costs of administering other authorities for collection such as those in TSCA section 8 and 11. EPA does not believe that Congress intended EPA to offset costs associated with administering authorities under these other sections. The statutory text clearly points to the authorities of TSCA sections 4, 5, 6 and 14. If the costs of administering activities under TSCA sections 8 and 11 were intended to be defrayed with fees, Congress would have specifically included those authorities in the statutory text. Cost estimates in the proposed rule consider costs associated with managing information that, for instance, was received pursuant to a TSCA section 8 rule but not the costs of developing the TSCA section 8 rule.

Specific activities considered when developing this estimate for activities under 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 costs associated with coordinating, reviewing, issuing, and defending TSCA CBI claim final determinations, and supporting guidance, policy and regulation development for TSCA section 14 activities, *e.g.*, implementing the unique identifier provisions, ensuring access to TSCA CBI for emergency personnel, states, tribes and local governments, and developing the TSCA CBI sunset provisions, among others.

Other chemical information management activities included in the analysis are: costs

for implementing the requirements in TSCA section 14(d); costs for implementing the CBI sunset requirements; costs for Notice of Activity chemical identity CBI claim reviews; costs for Freedom of Information Act-Related CBI claim reviews; costs for providing public access to Non-CBI Data; and IT costs for operating and maintaining the CBI Local Area Network (LAN). The annual cost estimate of collecting, processing, reviewing, and providing access to and protecting from disclosure as appropriate information on chemical substances under section 14 of TSCA, including FTE and extramural costs, from fiscal year 2022 through fiscal year 2024 is \$1,873,443 (Ref. 4).

2. Indirect costs.

Indirect costs are the intramural and extramural costs that are not accounted for in the direct program costs, but are important to capture because of their necessary enabling and supporting nature, and so that EPA's proposed fees will accomplish full cost recovery up to that provided by law. Indirect costs typically include such cost items as accounting, budgeting, payroll preparation, personnel services, purchasing, centralized data processing, and rent.

Indirect costs are disparate and more difficult to track than the other cost categories, because they are typically incurred as part of the normal flow of work (*e.g.*, briefings and decision meetings involving upper management) at many offices across the Agency. EPA accounts for some indirect costs in the costs associated with carrying out relevant activities under TSCA sections 4, 5, and 6, and costs of collecting, processing, reviewing, and providing access to and protecting from disclosure as appropriate under TSCA section 14 information on chemical substances, by the inclusion of an indirect cost factor. This rate is multiplied by and then added to the program costs. An indirect cost rate is determined annually according to EPA's indirect cost methodology and as required by Federal Accounting Standards Advisory Board's Statement of Federal Financial Accounting Standards No. 4: Managerial Cost Accounting Standards and Concepts. An indirect cost rate

of 19.5% was applied to direct program costs of work conducted by EPA’s Office of Chemical Safety and Pollution Prevention, based on FY 2019 data. Some of the direct program costs included in the estimates for TSCA sections 4, 5, and 6 and collecting, processing, reviewing, and providing access to and protecting from disclosure as appropriate under TSCA section 14 information on chemical substances are for work performed in other Agency offices (*e.g.*, the Office of Research and Development and the Office of General Counsel). Appropriate indirect cost rates were applied to those cost estimates and are based on EPA’s existing indirect cost methodology. Indirect cost rates are calculated each year and therefore subject to change. Indirect costs were included in the program cost estimates in the previous sections.

3. Total costs of fee-triggering events.

The annual estimated costs for fee categories under TSCA section 4, including both direct and indirect program costs, are shown in Table 2. Note that the costs presented in Tables 2, 3, and 4 include only the costs of fee- triggering events and so do not include costs associated with activities such as CBI reviews, alternative testing methods development, risk management for existing chemicals, or prioritization of existing chemicals. Costs associated with those activities are part of the overall costs of administering relevant activities under TSCA sections 4, 5, and 6 and relevant information management activities and, as such, are included in the overall cost estimates provided previously in Table 1.

Table 2—TSCA Section 4 Costs*

Fee category	Estimated number of ongoing actions/year	Estimated cost to Agency/action	Estimated annual cost to Agency
Test Order	10	\$279,000	\$2,795,000
Test Rule	1	\$844,000	\$422,000
Enforceable Consent Agreement	1	\$652,000	\$326,000

* **Table Note:** Numbers may not add due to rounding.

The estimated annual costs for fee categories under TSCA section 5, including both direct and indirect program costs are shown in Table 3.

Table 3—TSCA Section 5 Costs *

Fee category	Estimated number of ongoing actions/year	Total Estimated annual cost to Agency
PMN and consolidated PMN, SNUN, MCAN and consolidated MCAN	301	
Bona Fide Notice	207	
Notice of Commencement	175	
LoREX, LVE, TME, Tier II exemption, TERA, Film Article	320	
		\$34,713,428

* **Table Note:** Numbers may not add due to rounding. Costs were not broken out and therefore are not shown in the Total estimated annual cost to Agency column.

The estimated annual costs for fee categories under TSCA section 6, including both program and indirect costs are shown in Table 4.

Table 4—TSCA Section 6 Costs *

Fee category	Estimated number of ongoing actions/year	Estimated cost to Agency/action	Estimated annual cost to Agency
EPA-initiated risk evaluation.....	20	\$5,671,000	\$41,998,820
Manufacturer-requested risk evaluation: Work Plan chemical	2	\$5,671,000	\$3,783,000
Manufacturer-requested risk evaluation: Non-Work Plan chemical	3	\$5,671,000	\$5,671,000

* **Table Note:** Numbers may not add due to rounding.

III. Overview of the Proposed Rule.

A. Regulatory Approach

Pursuant to TSCA section 26(b), EPA is issuing this proposed rule to update and revise the fee collection from manufacturers (including importers) and, in some cases, processors, to defray approximately 25% of the Agency's costs related to relevant activities under TSCA sections 4, 5, and 6, and relevant information management activities.

The proposed rule applies to manufacturers and processors who are required to submit information under TSCA section 4, manufacturers and processors who submit certain notices and exemptions under TSCA section 5, and manufacturers who are subject to risk evaluation under TSCA section 6(b), including manufacturers who submit requests for risk

evaluation under TSCA section 6(b)(4)(C)(ii).

1. 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. All of these outreach meetings are summarized at <https://www.epa.gov/tsc-fees/outreach-materials-tsc-administration-fees-rule>. In fall and winter 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.

EPA is committed to continued stakeholder outreach and intends to meet with companies, trade associations and consortia that represent affected manufacturers and processors. EPA will also consult with the Small Business Administration regarding engagement with small businesses.

2. Request for comment on proposed and alternative regulatory actions.

EPA requests comment on all aspects of the proposed and alternative regulatory actions discussed in this unit, including comment on whether the proposed regulatory actions would

improve fee collection processes and ensure fair fee distribution among fee payers. EPA is also seeking additional information and data that could facilitate EPA's further evaluation of the potentially affected industries and firms, including data related to potential impacts on those small businesses that would be subject to fees.

B. Methodology for Calculating Fees

1. Description of the proposed regulatory action.

EPA does not implement an actual cost approach for TSCA sections 4, 5, and 6 (excluding the costs of manufacturer-requested risk evaluations) fee-triggering events and is not proposing to do so through this proposed rule. EPA does, however, implement an actual cost approach for calculating fees for manufacturer-requested risk evaluations. Specifically, EPA currently requires an initial payment of \$1,250,000 (for a chemical on the TSCA Work Plan) or \$2,500,000 (for a chemical not on the TSCA Work Plan), and a final invoice to total either 50% or 100% of the remaining actual costs in line with the percentage requirements in TSCA, or a refund to achieve these requirements, if warranted.

The 2018 Fee Rule established a two-payment approach for manufacture-requested risk evaluations—an initial payment, followed by a final invoice at the conclusion of the risk evaluation for the total remaining due, or a refund to achieve these requirements, if warranted. EPA is proposing a change to this approach by proposing a payment plan that enables entities to pay approximately 1/3 each year with a final invoice at the conclusion of the risk evaluation. Specifically, EPA is proposing to allow an initial payment of \$945,000 and a second payment by the end of the second year of \$945,000 (for a chemical on the TSCA Work Plan) or an initial payment of \$1,890,000 and a second payment of \$1,890,000 by the end of the second year (for a chemical not on the TSCA Work Plan), followed by a final invoice at the conclusion of the risk evaluation, or a refund, if warranted.

EPA is proposing this change to allow manufacturers to budget and better prepare for paying the manufacture-requested risk evaluation fees. These fee payments are in line with

the estimated cost of a manufacturer-requested risk evaluation of approximately \$5,671,000.

EPA is requesting comments on the proposed modifications to the payment plan.

EPA is also proposing changes to how EPA would allocate fees for EPA-initiated risk evaluations under TSCA section 6. Specifically, EPA is proposing to reallocate the remaining fee, after allocating the fees for small businesses, across the remaining manufacturers based on their percentage of total volume produced of that chemical minus the amount produced by the small businesses. This differs from the 2018 Fee Rule allocation by considering volume produced. EPA believes this approach for calculating TSCA section 6 fee allocations will result in a more representative distribution of fees and better account for the wide variation in production volume sometimes associated with a particular chemical substance.

In any scenario where there is not a single consortium comprised of all manufacturers of the chemical undergoing the EPA-initiated risk evaluation, EPA would take the following steps to allocate fees:

- 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 to generate a base fee.
- 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% discount from the base fee referenced previously.
- Calculate the total fee amount to be split among the total number of small manufacturers and distribute it based on their percentage of the average annual production volume from the four calendar years prior to the year certification was made.
- Calculate the total remaining fee amount to be split among the total number of remaining manufacturers by subtracting out the discounted fees and the number of small

businesses identified.

- Reallocate the remaining fee across those remaining manufacturers based on their percentage of average annual production volume from the four calendar years prior to the year certification was made minus the amount produced by the small businesses, counting each manufacturer in a consortium as one person.

EPA is not proposing these calculation and methodology changes for the fee allocations under TSCA section 4 activities. Fees for section 4 activities are significantly lower than those for a risk evaluation and, therefore, less burdensome, obviating the need to allocate the fees based on production volume.

Table 5—Proposed Changes to TSCA Section 6(b) Fee Allocations

2018 Fee Rule	2020 Proposed Fee Rule
<p>In any scenario where there is not a single consortium comprised of all manufacturers of the chemical undergoing the EPA-initiated risk evaluation, EPA will take the following steps to allocate fees:</p> <ul style="list-style-type: none"> • 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. • 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% discount from the base fee referenced previously. • Calculate the total remaining fee and total number of remaining manufacturers by subtracting out the discounted fees and the number of small businesses identified. • Reallocate the remaining fee across those remaining individuals and groups in equal amounts, counting each manufacturer in a consortium as one person. 	<p>In any scenario where there is not a single consortium comprised of all manufacturers of the chemical undergoing the EPA-initiated risk evaluation, EPA will take the following steps to allocate fees:</p> <ul style="list-style-type: none"> • 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 to generate a base fee for the purpose of calculating the fee for small businesses. • 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% discount from the base fee referenced previously. • Calculate the total fee amount to be split among the total number of small manufacturers and distribute it based on their percentage of the average annual production volume from the four calendar years prior to the year certification was made. • Calculate the total remaining fee amount to be split among the total number of remaining manufacturers by subtracting out the discounted fees and the number of small businesses identified. • Reallocate the remaining fee across those remaining manufacturers based on their percentage of average annual production volume from the four calendar years prior to the year certification was made minus the amount produced by the small businesses,

	counting each manufacturer in a consortium as one person.
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EPA recognizes that the incorporation of production volume into the fee calculation methodologies changes the current relationship between individual small business fees and other manufacturer fees and may even result in some small businesses paying higher fees if they produce significantly more than other manufacturers, dependent on the number of entities identified per fee-triggering event and their production volume of that chemical substance. EPA is requesting comments on this proposed methodology, how it impacts the small business fee payments, and whether caps for fees for small business entities should be considered.

EPA requests comment on the use of production volume and the methodology used in assigning fee amounts in TSCA section 6 activities. EPA is requesting comment on EPA's proposed calculation using production volume to determine fee allocations (*i.e.*, the average annual production volume from the four calendar years prior to the year certification was made). Additional information on the fee amounts can be found in Unit III.G.

Lastly, EPA is proposing modifications to the time allowed for payment established under the 2018 Fee Rule for EPA-initiated risk evaluation fees, enabling the fee payer to pay in installments. This proposed change includes a two-payment process – first payment of 50% to be due 180 days after EPA publishes the final scope of a chemical risk evaluation and the second payment for the remainder no later than 545 days after EPA publishes the final scope of a chemical risk evaluation. EPA believes that a two-payment process will reduce the burden on fee payers and allow them to have more money on hand for operating and other expenses that are incurred between payments.

2. Description of the primary alternative regulatory action considered.

EPA is requesting comment on alternative approaches for calculating average volume and assigning fees based on volume produced. For example, EPA could calculate fees based on

average volume over the last five years or based on the most recent year of reporting.

Alternatively, EPA could use production volume ranges and calculate fees based on those ranges. In addition, EPA has considered caps for fee payers, including those that qualify as a “small business concern.” However, EPA believes imposing a cap on fees for individual entities could result in EPA not collecting the full cost associated with that risk evaluation. EPA requests comment on alternative approaches for calculating and assigning fees based on production volume.

C. Fee Categories

EPA has eight distinct fee categories: (1) Test orders, (2) test rules and (3) ECAs, all under TSCA section 4; (4) notices and (5) exemptions, both under TSCA section 5; and (6) EPA-initiated risk evaluations, (7) manufacturer-requested risk evaluations for chemicals on the TSCA Work Plan, and (8) manufacturer-requested risk evaluations for chemicals not on the TSCA Work Plan, all under TSCA section 6. The activities in these categories are fee-triggering events that result in obligations to pay fees under the 2018 Fee Rule. EPA is proposing three additional categories, as discussed in the following subsections of this unit.

If a recipient of a test order fails to follow terms or conditions in the order, including testing protocols outlined in TSCA section 4, EPA may give the test order recipient the option to redo the testing and submit the new data. Under the current rule, the Agency would incur extra costs from reviewing this resubmitted data, costs that would not be accounted for via the original fee payment by the recipient of the test order. To address this, EPA is proposing to create a new fee for test orders payable by recipients that elect to resubmit data per request of the Agency if EPA determines that the recipient did not comply with the terms or conditions of the order, such as the testing protocols, or if a company later determines that data submitted under a testing order is incomplete, inconsistent, or deficient. As presented in the Economic Analysis (Ref. 4), EPA estimated that 10 test orders will be issued annually with one being amended. EPA requests public comment on these estimates. EPA also requests public comment on whether this new fee

will incentivize companies to correctly follow section 4 test order guidelines.

Companies that do not comply with section 4 test orders may be subject to enforcement action by EPA. If a company does not comply with the terms or conditions of the test order but subsequently resubmits the data required under the testing order, EPA is proposing to charge a fee associated with the submission of the new testing data. This new fee would be equal to the initial fee levied on the recipient of the initial test order. EPA is proposing changes to the regulations so that any submission of data intended to comport with a test order for which the order recipient was found to be in noncompliance. Additional fees will be levied on companies which subsequently resubmit such data, each time they resubmit the data until EPA determines that the testing is consistent with the requirements of the original test order and the data are acceptable for purposes of the data need identified in the order. Because of the amount of time it takes for a testing order to be issued and implemented (upwards of one year), levying a fee for this purpose would further incentivize companies to fully understand and follow the terms and conditions of the order, including testing guidelines under section 4.

Additionally, EPA is correcting an error with the section 4 fees of the 2018 Fee Rule regulations in which the fees for test orders and test rules were reversed. The amount of the fees that would be charged under section 4 was incorrect in the regulations, making the distinctions between test rule and test order fees unclear. In this proposal, EPA is proposing changes in the regulatory language to reflect the correct fees for test orders and test rules.

Under regulations implementing TSCA section 5, a company that intends to manufacture (including import) a chemical substance not listed by specific chemical name in the public portion of the TSCA Inventory may submit a Bona Fide Intent to Manufacture or Import Notice (“bona fide notice”) to obtain written determination from EPA whether the chemical substance is included in the confidential Inventory (40 CFR 720.25). The costs of the review process for bona fide notices were not recovered under the 2018 Fee Rule. To recover the costs of reviewing bona fide notices, EPA is proposing changes to the

regulations to require a fee for bona fide notices. EPA requests public comment on whether these fees for bona fide notices will result in a more equitable allocation of fees.

TSCA section 26(b)(1) states that “[t]he Administrator may, by rule, require the payment from any person required to submit...a notice or other information to be reviewed by the Administrator under section [5],...of a fee that is sufficient and not more than reasonably necessary to defray the cost related to such chemical substance of administering section[5]...” Bona fide notices submitted under regulations that are part of EPA’s implementation of section 5. EPA is proposing to utilize its authority under section 26(b)(1) to collect section 5 fees for bona fide notices. Assessing a fee for bona fide notices will allow allocation of fees that will more equitably account for the costs of carrying out all relevant section 5 activities. The proposed fee amount for a bona fide notice is \$500 and \$90 for small businesses.

After PMN review has been completed under TSCA section 5, the submitters of the PMN must provide a Notice of Commencement of Manufacture or Import (NOC) to EPA within 30 calendar days of the date the chemical substance is first manufactured or imported for nonexempt commercial purposes (40 CFR 720.102). Once a complete NOC is received by EPA, the reported chemical substance is considered to be on the TSCA Inventory and becomes an existing chemical.

As described in Unit II.C., under the 2018 Fee Rule, EPA grouped the costs associated with NOCs with those of PMNs, MCANs, and SNUNs. EPA is proposing changes to the 2018 Fee Rule to include a separate fee for NOC submissions. TSCA section 26(b)(1) states that “[t]he Administrator may, by rule, require the payment from any person required to submit...a notice or other information to be reviewed by the Administrator under section [5],...of a fee that is sufficient and not more than reasonably necessary to defray the cost related to such chemical of administering section [5]...” NOC submissions are part of EPA’s implementation of section 5; they ensure that chemical substances manufactured after

TSCA section 5(a)(3) review appear on the TSCA Inventory. EPA is proposing to utilize its authority under section 26(b)(1) to collect section 5 fees for NOC submissions. NOC fees will help defray the costs of reviewing, processing, and retaining NOC records and the costs of registering the chemical substance with the Chemical Abstract Service. The proposed fee amount for NOC submissions is \$500 and \$90 for small businesses.

D. Entities Subject to Fees

The 2018 Fee Rule applies to manufacturers and processors who are required to submit information under TSCA section 4, manufacturers and processors who submit certain notices and exemptions under TSCA section 5, and to manufacturers who are subject to risk evaluation under TSCA section 6(b), including manufacturers who submit requests for risk evaluation under TSCA section 6(b)(4)(C)(ii).

EPA is proposing modifications to certain groups of manufacturers subject to TSCA section 6 fee activity requirements; including the addition of manufacturers that exclusively export chemicals subject to EPA-initiated risk evaluations whenever such chemical substances are manufactured, processed, or distributed in commerce (by any other entity) for any purpose other than export from the United States, as well as five additional exclusions to entities subject to the fees for TSCA section 6 activities.

1. Description of the proposed regulatory action.

EPA is proposing to add manufacturers that exclusively export chemicals subject to EPA-initiated risk evaluations whenever such chemical substances are manufactured, processed, or distributed in commerce (by any other entity) for any purpose other than export from the United States. This change recognizes that manufactures that exclusively export High-Priority Substances are part of the risk evaluation process and should, therefore, share in defraying the cost of EPA-initiated risk evaluations. This regulatory action remains consistent with TSCA section 12(a)(1).

Specially, TSCA section 12(a)(1) states that except as provided in paragraph (2) and

subsections (b) and (c), TSCA (other than TSCA section 8) “shall not apply to any chemical substance, mixture, or to an article containing a chemical substance or mixture, if— (A) it can be shown that such substance, mixture, or article is being manufactured, processed, or distributed in commerce for export from the United States, unless such substance, mixture, or article was, in fact, manufactured, processed, or distributed in commerce, for use in the United States, and (B) such substance, mixture, or article (when distributed in commerce), or any container in which it is enclosed (when so distributed), bears a stamp or label stating that such substance, mixture, or article is intended for export.”

TSCA section 12(a) exempts manufacturers from TSCA coverage only when such substance, mixture, or article is being manufactured, processed, or distributed in commerce solely for export from the United States. EPA does not anticipate that this exemption would generally apply to chemical substances designated as High-Priority Substances for risk evaluation since those chemical substances are anticipated to have a range of conditions of use outside of export-only manufacture, processing, and distribution. EPA acknowledges the ambiguity of this aspect of TSCA section 12(a) and believes the statutory context here (*i.e.*, fee collection for risk evaluations for under TSCA section 6(b)) supports interpreting the export-only exemption narrowly. Therefore, export-only manufacturers of such chemical substances will be subject to fee payment obligations under this proposal.

EPA is also proposing to exclude certain manufacturers from EPA-initiated risk evaluation fee requirements. On January 27, 2020, EPA released the preliminary list of manufacturers subject to fee payments for manufacture of chemicals subject to EPA-initiated risk evaluations and received significant stakeholder feedback regarding the practicalities of self-identifying under the TSCA Fee Rule given its broad definition of “manufacture.” As stated in EPA’s memorandum issued on March 18, 2020, concerns were raised regarding fee payment obligations for “importers of articles containing any one of the twenty listed chemicals...” and that these entities “could potentially be required to test

thousands of imported articles and [it]would be difficult if not impossible to complete in the time allotted for self-identification under the TSCA Fee Rule” (Ref. 3). EPA recognizes that manufacturers of chemicals as byproducts or impurities may face similar challenges to pinpointing and tracking when impurities and byproducts are produced, particularly because the ‘manufacture’ of even very small amounts of a high-priority chemical triggers the TSCA Fee Rule requirement to self-identify.

In response to these concerns, EPA recognized that the current TSCA Fee Rule may unintentionally impose potentially significant burdens on three categories of manufacturers, causing compliance challenges with self-identification and inconsistencies with other TSCA regulatory contexts (Ref. 3). EPA also announced its plan to consider a proposed rule that would look at potential exemptions to the TSCA Fee Rule in response to stakeholder concerns about implementation challenges. Consequently, EPA proposes to exempt these three categories of manufacturers from EPA-initiated Risk Evaluation fees and associated regulatory requirements: 1) importers of articles containing a chemical substance subject to an EPA-initiated risk evaluation; 2) manufacturers of a substance subject to an EPA-initiated risk evaluation that is produced as a byproduct; and 3) manufacturers (including importers) of a substance subject to an EPA-initiated risk evaluation that is produced or imported as an impurity. More information on byproducts and impurities can be found here: <https://www.epa.gov/tsca-fees/frequent-questions-about-tsca-fees-epa-initiated-risk-evaluations>.

EPA is also proposing to exempt manufacturers of a substance subject to an EPA-initiated risk evaluation that is produced as a non-isolated intermediate. A non-isolated intermediate, as defined in 40 CFR part 704.3, referenced by 40 CFR part 711.3., is “any intermediate that is not intentionally removed from the equipment in which it is manufactured, including the reaction vessel in which it is manufactured, equipment which is ancillary to the reaction vessel, and any equipment through which the substance passes during a continuous flow

process, but not including tanks or other vessels in which the substance is stored after its manufacture. Mechanical or gravity transfer through a closed system is not considered to be intentional removal, but storage or transfer to shipping containers isolates the substance by removing it from process equipment in which it is manufactured.”

EPA believes exempting manufacturers of substances produced as a non-isolated intermediate is consistent with other TSCA programs, including the Chemical Data Reporting (CDR) described in 40 CFR 711.10(c) and the TSCA section 5 notice requirements described in 40 CFR 720.30.

In addition, EPA is proposing an exemption from EPA-initiated *risk evaluation fees and associated regulatory requirements for manufacturers (including importers)* of small quantities of a chemical solely for research and development, as to be defined in 40 CFR 700.43. Small quantities solely for research and development is defined to mean quantities of a chemical substance manufactured, imported, or processed or proposed to be manufactured, imported, or processed solely for research and development that are not greater than reasonably necessary for such purposes. This exemption will avoid imposing burdensome costs to those manufacturers of small quantities of a chemical solely for research and development, given the critical importance of this activity to the detection, quantification and control of chemical substances. Manufacturers that meet the research and development exemption must meet it for the five-year period preceding publication of the preliminary list and meet it in the successive five years.

Finally, EPA is proposing an exemption from EPA-initiated risk evaluation fees and associated regulatory requirements for entities that manufacture (including import) a chemical substance in quantities not to exceed 2,500 lbs. This limit is consistent with requirements in the CDR described in 40 CFR 711.8(b) and 40 CFR 711.15, where the reporting threshold is 2,500 lbs. (1,134 kg) for any person who manufactured a chemical substance that is the subject of certain rules, orders, or relief under TSCA section 5, 6, and

7. This exception does not apply if all manufacturers of a chemical substance manufacture that chemical in quantities below a 2,500 lbs. annual production volume. EPA is proposing this exemption to reduce the burden on entities producing small amounts of the chemical substance undergoing an EPA-initiated risk evaluation.

EPA is not proposing a concentration-based exemption. EPA believes the exemption should be based on the amount of a chemical instead of the concentration to ensure that the exemption only applies to the manufacture of small quantities of a chemical. A concentration-based exemption could result in manufacturers of large quantities of chemicals being exempt from fee obligations. For this reason, EPA's proposal contains an exemption based on a volume limit. EPA requests public comment on the previously discussed exemptions, any other exemptions that EPA should consider, and any data related to potential impacts.

Manufacturers of a chemical substance undergoing TSCA section 6 EPA-initiated risk evaluations that would meet one or more of the exemptions previously discussed for the five-year period preceding publication of the preliminary list and would meet one or more of the exemptions in the successive five years would be exempt from fee those payment requirements. This five-year period is consistent with the current criteria under the 2018 TSCA Fees rule for certification of cessation.

2. Description of the primary alternative regulatory action considered.

EPA has considered an alternative regulatory action of no exemptions and requests comment on this approach. TSCA requires EPA to evaluate chemicals under their conditions of use, and conditions of use evaluated may involve manufacture of chemicals that are exempt under this proposal including impurities or byproducts, chemicals imported in articles, or chemicals in small amounts solely for the purposes of research and development. In addition, EPA does not consider these exemptions in designating chemical substances as high priority substances for risk evaluation, and there may be chemicals designated where that chemical's

primary condition of use is covered under one of the five exemptions listed within this Unit, resulting in little to no manufacturers obligated to pay the fee. This could result in higher fees for entities that do not meet the exemption or no fee payments for a chemical substance risk evaluation.

E. Self-Identification

1. Description of the proposed regulatory action.

Under the 2018 Fee Rule, after the close of a comment period for the preliminary list of manufacturers subject to a fee obligation for chemicals subject to EPA-initiated risk evaluations, EPA makes any associated updates or corrections, and then publishes a final list of manufacturers. This list indicates if any manufacturers were identified in error, if any additional manufacturers were identified through the comment period and/or reporting form, and if any manufacturers certified that they have already ceased manufacture prior to the applicable cutoff date described in the regulations and will not manufacture the subject chemical substance for five years into the future. The final list is published concurrently with the final scope document for risk evaluations initiated by EPA under TSCA section 6, and with the final test rule under TSCA section 4. Currently, there is no added flexibility to modify the list of fee payers in the event of receipt of additional information after publication of the final list.

EPA is proposing added flexibility to allow for potential changes to the list of fee payers after it is finalized. Specifically, EPA is proposing to allow for modification of the list upon receipt of information indicating that such a change is warranted.

EPA believes that this proposed process is largely consistent with comments on the 2018 Proposed Fee Rule (83 FR 8212) requiring EPA to publish a preliminary list and engage with stakeholders to identify others who may be missing, correct errors, and provide an opportunity for manufacturers to be removed from the list under certain circumstances.

In addition, EPA has received industry stakeholder feedback regarding the

identification of manufacturers on the preliminary and final list of manufacturers subject to fees for the 20 high priority substances undergoing TSCA risk evaluations. Stakeholders recommended EPA create an avenue for manufacturers to identify other manufacturers that may be subject to these fees not present on the preliminary list of fee payers. EPA appreciates this feedback but is not proposing changes to the issuance of a preliminary list followed by a public comment period. EPA believes this 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) allows for self-identification, correction of errors, and certification of no-manufacture and no intention to manufacture in the next five years. EPA also plans to continue communication with manufacturers and importers that contact EPA with questions or concerns. Manufacturers may also utilize the existing EPA portal to report a tip or complaint to EPA, found here <https://www.epa.gov/enforcement/report-environmental-violation-general-information>, including to report manufacturers once the final list of manufacturers subject to the fees is published.

EPA is also proposing changes to the submission of self-identification information in 40 CFR 700.45 to accompany the proposed changes to the TSCA section 6 fee activities as well as changes to which types of manufacturers are required to self-identify. These changes include exempting manufacturers that meet the criteria of three of the exemptions discussed in Unit III.D. (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. Additionally, EPA is proposing to require manufacturers of small quantities solely for research and development and those that manufacture in quantities not to exceed 2,500 lbs., and manufacturers of chemical substances produced as a non-isolated intermediate to certify that they meet those exemption criteria. EPA is also proposing to require all other non-exempted manufacturers

to provide the volume produced by that manufacturer for the subject chemical. More discussion on the use of production volume in the methodology for calculating fees is in Unit III.B. EPA is also proposing to require all manufacturers that self-identify as meeting the production volume exemption of 2,500 lbs. to maintain production volume records related to compliance with the exemption. EPA is also proposing to require those manufacturers of substances produced as a non-isolated intermediate to maintain ordinary business records related to compliance with this exemption criteria. Additionally, EPA is proposing that all manufacturers that self-identify as meeting the research and development exemption maintain ordinary business records related to compliance, such as plans of study, information from research and development notebooks, study reports, or notice solely for research and development use. EPA is proposing that these required records be kept for a period of five years. EPA has authority under section 6 to require reporting and recordkeeping related to the regulatory requirements imposed by EPA under section 6. This is particularly important where, as here, such records and reports are necessary for effective enforcement of the section 6 rule.

2. Description of the primary alternative regulatory action considered.

EPA has considered an alternative regulatory approach of allowing manufacturers that had previously certified cessation, as described in 40 CFR 700.45 (b)(5)(ii), to then begin manufacturing or importing that chemical within the successive five-year period. Those manufacturers would be required to pay their portion of the fee associated with that chemical substance risk evaluation, but it would occur after the initial invoicing period. EPA believes this would result in a substantial increase in burden to EPA, allowing continued changes to those entities responsible for paying the EPA-initiated risk evaluation fees after the initial invoicing period. In addition, EPA believes this may result in inequity between those manufacturers paying the fees at the time of initial invoicing and those companies being allowed to opt back in any time after that period. Therefore, EPA is not proposing changes to the five-year period associated

with the certification of cessation. As currently drafted, a manufacturer may certify cessation if it has ceased manufacturing prior to the certification cutoff dates and will not manufacture the substance again in the successive five years. Manufacturers that have certified cessation for a substance that then manufacture that substance again within the successive five years would be engaging in a prohibited act under TSCA section 15(1) and therefore would be subject to a penalty under TSCA section 16. Nonetheless, EPA is requesting comment on a regulatory approach that would allow manufacturers that previously certified cessation to begin manufacturing or importing the chemical within the successive five-year period. EPA is particularly interested in suggestions for decreasing the burden associated with allowing changes to manufacturing status (including potential recalculation and reimbursement of fees to manufacturers that were subject to initial fee payments) and comments from entities that might be subject to initial payments and therefore potential inequities.

Additionally, alternatives were considered in regard to EPA's authority to collect fees from processors under section 4 and 6 of TSCA. Although EPA has authority to collect fees from both manufacturers and processors of chemical substances, the 2018 Fee Rule and this subsequent update focus fee collection primarily on manufacturers. EPA will collect fees from processors only when processors submit a SNUN or test-marketing exemptions (TME) under section 5, when a section 4 activity is tied to a SNUN submission by a processor, or when a processor voluntarily joins a consortium and therefore agrees to provide payment as part of the consortium. This approach is consistent with most comments received during the 2018 Fee Rule. EPA believes the allocation primarily to manufacturers, and, in limited circumstances, to processors, is an appropriate balance of the authorities provided by TSCA. As stated in past rules and notices, the effort of trying to identify relevant processors for all fee-triggering actions would be overly burdensome and EPA expected that many processors would be missed. Generally limiting fee obligations to manufacturers is the simplest and most straightforward way to assess fees for conducting risk evaluations under TSCA section 6 and most TSCA section 4

testing activities. Furthermore, EPA expects that manufacturers required to pay fees will have a better sense of the universe of processors and will pass some of the costs on to them.

F. Timing

The 2018 Fee Rule generally requires upfront 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 manufacturer- requested risk evaluation, and within 120 days of publishing the final scope of a risk evaluations). However, for manufacturer-requested risk evaluations, payment is collected in two installments over the course of the activity.

EPA is proposing several changes to the timing of specific stages within this fees process.

These are summarized in table 6 and discussed in more detail throughout this unit.

Table 6—Proposed Changes to Timing Within the Fee Rule *

Stage in the Fees Process	Timing under 2018 Fee Rule	Proposed Timing Changes
Payment of fees	Initial payment within 30 days of EPA providing notice of granting a manufacturer-requested risk evaluation. Payment is collected in two installments over the course of the activity.	Initial payment within 180 days of EPA providing notice of granting a manufacturer-requested risk evaluation. Payments are collected over three installments.
	For EPA-initiated risk evaluations, payment is collected in one installment 120 days after EPA publishes the final scope of a chemical risk evaluation.	For EPA-initiated risk evaluation, payment is collected over two installments, the first payment of 50% to be due 180 days after EPA publishes the final scope of a chemical risk evaluation and the second payment due not later than 545 days after EPA publishes the final scope of a chemical risk evaluation.
Consortia	60 days to notify EPA of intent to form a consortium from the triggering event	90 days to notify EPA of intent to form a consortium from the triggering event

Currently, manufacturers have 60 days to notify EPA of their intent to form a consortium from the triggering event, and 120 days total from the triggering event for

payment. EPA is proposing to allow manufacturers subject to test orders, test rules, ECAs and EPA-initiated risk evaluations additional time to associate with a consortium and work out fee payments within that consortium. Specifically, EPA is proposing to extend the amount of time for manufacturers to notify EPA of their intent to form a consortium to 90 days. EPA believes this additional time will be useful for businesses to financially plan for the additional expense.

For EPA-initiated risk evaluations, full payment is currently due within 120 days of EPA publishing the final scope of a chemical risk evaluation. EPA is proposing to extend that first payment timeline to 180 days and to provide for payment to be made in two installments instead of one, as discussed in Unit III.B. EPA is also proposing an extension to the amount of time for these manufacturers to join a consortium, from 60 days to 90 days to notify EPA of their intent. EPA believes this additional time will assist manufacturers with the process of joining a consortium, if they so choose, and deciding on the partial fee payments each member of the consortium will be responsible for. Manufacturers will have ample warning that a risk evaluation is underway, well before the final scope is published in the *Federal Register*. For manufacturer-requested risk evaluations, EPA is proposing that the initial payment be made 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 as indicated in Unit III.B. of the proposed rule.

G. Fee Amounts

Because the eight existing fee categories and three additional fee categories do not span all of the relevant activities under TSCA sections 4, 5, and 6 and relevant information management activities (*e.g.*, costs of administering TSCA section 14, risk management activities under section 6, prioritization of chemicals for evaluation, support for alternative testing and methods development and enhancement), EPA is proposing fee amounts to ensure these costs would be captured.

As discussed in Unit II, EPA must recover 25% of the costs related to the relevant activities under of TSCA sections 4, 5, 6 and 14. EPA did not propose changes to the fees associated with TSCA section 4 and 5 established under the 2018 Fees Rule. EPA is, however, proposing higher fees for TSCA section 6 activities. The proportion (in percentage) of the estimated cost of the activity is higher for TSCA section 6 fees to ensure EPA is recovering the required 25% of the total cost for implementing the relevant sections of TSCA. Additional justification for each TSCA section is discussed within this Unit. EPA requests public comment on this approach with higher fees for section 6 activities and no changes to section 4 and 5 fees established under the 2018 Fees Rule.

1. Fee amounts for TSCA section 4 activities.

EPA issues three fee amounts—one for each of the TSCA section 4 fee categories: Test orders, test rules and ECAs. As proposed, the fees for section 4 activities amount to approximately 4.1% of the total estimated activity cost. The lower fee relative to program costs takes into account that manufacturers will be responsible for paying to develop the test information in addition to paying the TSCA fee and is reflected in assigning lower proposed fee amounts. EPA is not proposing changes to the section 4 fees established under the 2018 Fees Rule at this time. However, EPA may modify these in the future with more implementation experience.

2. Fee amounts for TSCA section 5 activities.

EPA currently issues two fee amounts for TSCA section 5 activities—one for notices (PMNs, SNUNs and MCANs), and one for exemptions (LVEs, LoREX, TME, Tier II, TERA and film articles). EPA is proposing two additional fee amounts for bona fide notices and NOCs. As proposed, the fees for section 5 activities amount to approximately 13% of the estimated cost of the activities. EPA is currently working on process improvements for the review of section 5 submissions, which are anticipated to lower agency costs. Since EPA does not want to stifle economic development in the chemical industry, EPA is not proposing

changes to the section 5 fees established under the 2018 Fees Rule at this time. However, EPA may modify these in the future with more implementation experience.

3. Fee amounts for TSCA section 6 activities.

EPA issues one fee amount for EPA-initiated risk evaluations at approximately 35% of the estimated cost of the activity. EPA takes an actual cost approach for manufacturer-requested risk evaluations, whereby the requesting manufacturer (or requesting consortia of manufacturers) would be obligated to pay either 50% or 100% of the actual costs of the activity, depending on whether or not the chemical was listed on the TSCA Work Plan, respectively.

Due to the increases to TSCA section 6 program cost estimates, decreases in the activity assumptions for TSCA section 5 submissions, early feedback received from industry stakeholders during the 2018 rulemaking, and to ensure EPA is able to defray 25% of the Agency’s costs, EPA is proposing higher fees for TSCA section 6 activities (Ref. 2; Ref. 4).

The proposed fee amounts are described in Table 7. EPA is requesting comment on the changes discussed in Unit II.C.

Table 7—Proposed Changes to TSCA Fee Amounts

Fee category	2018 Fee Rule	2020 Proposed Fee Rule
TSCA section 4:		
Test order.....	\$9,800.	\$9,800.
Amended test order.....	\$0.	\$9,800.
Test rule.....	\$29,500.	\$29,500.
Enforceable consent agreement.....	\$22,800.	\$22,800.
TSCA section 5:		
PMN and consolidated PMN, SNUN, MCAN and consolidated MCAN.....	\$16,000.	\$16,000.
LoREX, LVE, TME, Tier II exemption, TERA, Film Articles.....	\$4,700.	\$4,700.
Bona Fide Notice	\$0.	\$500.
Notice of Commencement	\$0.	\$500.
TSCA section 6:		

EPA-initiated risk evaluation	\$1,350,000.	\$2,560,000.
Manufacturer-requested risk evaluation on a chemical included in the TSCA Work Plan.	Initial payment of \$1.25M, with final invoice to recover 50% of Actual Costs.	Two payments of \$945,000, with final invoice to recover 50% of Actual Costs.
Manufacturer-requested risk evaluation on a chemical <i>not</i> included in the TSCA Work Plan.	Initial payment of \$2.5M, with final invoice to recover 100% of Actual Costs.	Two payments of \$1.89M, with final invoice to recover 100% of Actual Costs.

4. Fee amounts for small businesses.

The proposed fee amounts for small businesses summarized in Table 8 represent an approximate 80% reduction compared to the proposed base fee for each category. In one case, for TSCA section 5 notices (*i.e.*, PMNs, MCANs and SNUNs), the small business reduction is 82.5%. For all fee categories, the proposed reduced fee is only available when the only entity or entities are small businesses, including when a consortium is paying the fee and all members of that consortium are small businesses. Consistent with the 2018 Fee Rule, reduced fees are not available for small business manufacturers requesting a risk evaluation, as TSCA requires those fees to be set at a specific percentage of the actual costs of the activity.

These discounts were established in the 2018 Fees Rule and were the result of stakeholder input. EPA believes the approximate 80% discount in the 2018 Fee Rule is appropriate and that the discount is generally in line with EPA’s discount for small businesses in the pesticides program (*i.e.*, 75%), but slightly higher based on significant stakeholder input regarding the need to minimize impacts on small businesses. EPA is not proposing changes to these discounts.

EPA is requesting comment on the small business discount as it relates to the proposed volume-based fee calculations changes discussed in Unit III.B.

Table 8—Proposed Changes to TSCA Fee Amounts for Small Businesses

Fee category	2018 Fee Rule	2020 Proposed Fee Rule
TSCA section 4:		

Test order.....	\$1,950.	\$1,960.
Amended test order.....	\$0.	\$1,960.
Test rule.....	\$5,900.	\$5,900.
Enforceable consent agreement.....	\$4,600.	\$4,600.
TSCA section 5:		
PMN and consolidated PMN, SNUN, MCAN and consolidated MCAN.....	\$2,800.	\$2,800.
LoREX, LVE, TME, Tier II exemption, TERA, Film Articles.....	\$940.	\$940.
Bona Fide Notice	\$0.	\$90.
Notice of Commencement	\$0.	\$90.
TSCA section 6:		
EPA-initiated risk evaluation	\$270,000.	\$512,000.
Manufacturer-requested risk evaluation on a chemical included in the TSCA Work Plan.	\$1,250,000 initial payment + 50% of total actual costs.	Two payments of \$945,000 with final invoice to recover 50% of actual costs.
Manufacturer-requested risk evaluation on a chemical <i>not</i> included in the TSCA Work Plan.	\$2,500,000 initial payment + 100% of total actual costs.	Two payments of \$1.89M with final invoice to recover 100% of actual costs.

5. Description of the primary alternative regulatory action considered.

EPA has considered an alternative regulatory action where the fees remain unchanged except for an adjustment for inflation. In the absence of any substantive adjustments or updates, the 2018 TSCA Fees Rule provides for adjusting the fee structure of the current period (fiscal years 2019-2021) according to inflation rate, in setting a fee structure for the next period. This adjustment occurs automatically if no other updates are put forth by EPA. EPA has considered this regulatory alternative, but has found it unsuitable, because it would not recoup the statutorily required 25% of estimated EPA costs for TSCA related actions. EPA requests public comment on this approach.

IV. Projected Economic Impacts

EPA has evaluated the potential costs for entities potentially subject to this proposed rule. More details can be found in the Economic Analysis (Ref. 4). For the

baseline, EPA used the number of section 5 submissions received in FY2019 and 2020 for each of the types of fee-triggering section 5 categories to estimate the number of submissions per section 5 fee category for the next three years in the absence of the rule. The average numbers of test orders, test rules, and ECAs per year represent an EPA estimate based on previous experience and expected work under TSCA as amended. Amended TSCA specifies the minimum number of risk evaluations that EPA must have ongoing over the next three years. The Agency expects to have between 20 and 30 risk evaluations ongoing in any given year at different stages in the review process, including manufacturer-requested evaluations.

Various alternative fee structures were considered in the original fee rule but are not being revisited in this proposal. This proposed rule would establish a few new fees and would revise existing fee levels based on actual cost information and updated estimates but would not re-open the fee structure. EPA also requests public comment on this approach.

EPA calculated fees by estimating the total annual costs of administering relevant activities under TSCA sections 4, 5, and 6 (excluding the costs of manufacturer-requested risk evaluations) and relevant information management activities; identifying the full amount to be defrayed by fees under TSCA section 26(b) (*i.e.*, 25% of those annual costs); and allocating that amount across the fee-triggering events in sections 4, 5, and 6, weighted more heavily toward section 6 based on industry feedback on the 2018 Fees Rule Proposal. EPA estimates the total fee collection by multiplying the fees with the number of expected fee-triggering events under full implementation for each fee category, for a total of approximately \$22 million in average annual fee revenue. This total does not include the fees collected for manufacturer-requested risk evaluations. EPA estimates that section 4 fees account for less than one percent of the total fee collection, section 5 fees for approximately 25 percent, and section 6 fees for approximately 74 percent.

Total annual fee collection for manufacturer-requested risk evaluations is estimated

to be \$1.9 million for chemicals included in the TSCA Work Plan (based on two requests over the three- year period) and approximately \$5.67 million for chemicals not included in the TSCA Work Plan (based on three requests over the three-year period).

For small businesses, EPA estimates that 35 percent of section 5 submissions will be from small businesses that are eligible to pay the small business fee because they are classified as small businesses based on the SBA small business thresholds.

Total annualized fee collection from small businesses submitting notices under section 5 is estimated to be \$411,000 (Ref. 4). For 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 is dependent on the number of entities identified per fee-triggering event. EPA relied on past experience with Test Rules for HPV chemicals under section 4 as well as work to date on the first 10 chemicals to undergo risk evaluation under section 6 to inform its estimates of the average number of small businesses impacted per action. EPA estimates that average annual fee collection from small businesses impacted by section 4 activities would be approximately \$8,000, and the average annual fee collection from small businesses impacted by section 6 would be approximately \$922,000. For each of the three years covered by this proposed rule, EPA estimates that total fee revenue collected from small businesses will account for about 6 percent of the approximately \$22 million total fee collection, for an annual average total of approximately \$1.3 million.

This proposed rule would establish fee requirements for affected manufacturers (including importers) and, in some cases, processors of chemical substances. The proposed fees to be paid by industry would defray the cost for EPA to administer relevant activities under TSCA sections 4, 5, and 6 and relevant information management activities. Absent this proposed rule, EPA costs to administer these sections of TSCA would be solely borne by taxpayers through budget appropriations from general revenue. As a result of this proposed rule, 25% of EPA costs to administer relevant activities under TSCA sections 4, 5,

and 6 and relevant management activities, and activities paid from general revenue would be transferred to industry via fee payments.

Although these fees may be perceived by industry as direct private costs, from an economic perspective, they are transfer payments from industry to taxpayers rather than real social costs. Therefore, the total social cost of this proposed rule does not include the fees collected from industry by EPA. Rather, it includes the opportunity costs incurred by industry, such as the cost to read and familiarize themselves with the rule; determine their eligibility for paying reduced fees; register for Central Data Exchange (CDX); form, manage and notify EPA of participation in consortia; notify EPA and certify whether they will be subject to the action or not; and arrange to submit fee payments via *Pay.gov*. Total social costs also include the additional costs to EPA to administer fee assessment and collection for relevant activities under TSCA sections 4, 5, and 6, and relevant information management activities. The total additional annualized opportunity cost to industry, relative to the 2018 TSCA Fees Rule, is approximately \$12,000. It is estimated that the EPA will incur no additional burden, relative to the 2018 TSCA Fees Rule, as a result of the proposed Fee Rule amendments. Thus, it is estimated that the agency will incur no additional opportunity costs, and that total annual opportunity costs amount to approximately \$12,000.

V. References

The following is a listing of the documents that are 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.
2. 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. EPA. Request for No Action Assurance Regarding Self-Identification Requirement for Certain “Manufacturers” Subject to the TSCA Fees Rule. March 2020.

https://www.epa.gov/sites/production/files/2020-03/documents/tsca_fees_-_naa_request_final.pdf.

4. EPA. Economic Analysis of the Proposed Rule for Fees for the Administration of the Toxic Substances Control Act. September 2020.

5. 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.

6. EPA. Information Collection Request for the TSCA section 26(b) Proposed Reporting Requirements Associated with the Payment of TSCA Fees (EPA ICR No. 2569.01; OMB Control No. 2070–[NEW]). November 2020.

VI. 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 13563: Improving Regulation and Regulatory Review.

This action is a significant regulatory action that was submitted to the Office of Management and Budget (OMB) for review under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011). Any changes made in response to OMB recommendations have been documented in the docket for this action as required by section 6(a)(3)(E) of Executive Order 12866.

EPA prepared an economic analysis of the potential costs and benefits associated with this action (Ref. 4). A copy of this economic analysis is available in the docket and is briefly summarized in Unit IV.

B. Executive Order 13771: Reducing Regulation and Controlling Regulatory Costs

This action is considered a regulatory action under Executive Order 13771 (82 FR 9339, February 3, 2017). Details on the estimated costs of this rule can be found in the Economic Analysis (Ref. 4), which briefly summarized in Unit IV.

C. Paperwork Reduction Act (PRA)

The information collection activities in this rule have been submitted for approval to OMB under the PRA, 44 U.S.C. 3501 *et seq.* The Information Collection Request (ICR) document that the EPA prepared has been assigned EPA ICR No. 2569.03 and OMB Control No. 2070–0208. A copy of the ICR is available in the docket for this proposed rule (Ref. 6), and it is briefly summarized here. The information collection requirements are not enforceable until OMB approves them.

The information collection activities associated with the rule include familiarization with the regulation; reduced fee eligibility determination; CDX registration; 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(b).

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

Estimated number of respondents: 1,348

Frequency of response: On occasion.

Total estimated burden: 581 hours (per year). Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: \$273,388 (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's regulations in 40 CFR part 700 are listed in 40 CFR part 9. Submit your comments on the Agency's need for this information, the accuracy of the provided burden estimates and any suggested methods for minimizing respondent burden to the EPA using the docket identified at the beginning of this rule. You may also send your ICR-related comments to OMB's Office of Information and Regulatory Affairs via email to OIRA_submission@omb.eop.gov, Attention: Desk Officer for the EPA.

D. 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. 84 small businesses may be affected annually by section 4 actions; 190 small businesses may be affected by section 5 actions; and 24 small businesses may be affected by section 6 actions.

EPA estimates the median annual sales for small businesses likely to be affected by TSCA section 4 and TSCA section 6 actions to be approximately \$5,445,000; and \$3,475,000 for small businesses likely to be affected by TSCA section 5 actions. The average annual incremental cost per affected small business is expected to be about \$150 for section 4; \$120 for section 5, and \$16,200 for section 6. As a result, EPA estimates that, of the 429 small businesses paying fees every year, all may have annual cost-revenue impacts less than 1%.

E. 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 will not significantly or uniquely affect small governments. The rule is not expected to result in expenditures by State, local, and Tribal governments, in the aggregate, or by the private sector, of \$100 million or more (when adjusted annually for inflation) in any one year. Accordingly, this proposed rule is not subject to the requirements of sections 202, 203, or 205 of UMRA. The total quantified annualized social costs for this proposed rule are approximately \$12,000 (at both 3% and 7% discount rate), which does not exceed the inflation-adjusted unfunded mandate threshold of \$160 million.

F. Executive Order 13132: Federalism

This action does not have federalism implications because it is not expected to 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 as specified in Executive Order 13132 (64 FR 43255, August 10, 1999).

Thus, Executive Order 13132 does not apply to this action.

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

This action does not have tribal implications because it is not expected to 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, as specified in Executive Order 13175 (65 FR 67249, November 9, 2000). Thus, Executive Order 13175 does not apply to this rule.

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

EPA interprets Executive Order 13045 (62 FR 19885, April 23, 1997), as applying only to those regulatory actions that concern environmental health or safety risks that EPA has reason to believe may disproportionately affect children, per the definition of “covered

regulatory action” in section 2–202 of Executive Order 13045. This action is not subject to Executive Order 13045 because it does not establish an environmental standard intended to mitigate environmental health risks or safety risks.

I. 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 energy supply, distribution, or use of energy and has not been designated by the Administrator of the Office of Information and Regulatory Affairs as a significant energy action.

J. National Technology Transfer and Advancement Act (NTTAA)

This rulemaking does not involve any technical standards. Therefore, NTTAA section 12(d), 15 U.S.C. 272 *note*, does not apply to this action.

K. Executive Order 12898: Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations.

EPA believes that this action does not have disproportionately high and adverse health or environmental effects on minority populations, low-income populations and/or indigenous peoples, as specified in Executive Order 12898 (59 FR 7629, February 16, 1994). The documentation for this decision is contained in the Economic Analysis (Ref. 4), which is in the public docket for this action.

List of Subjects 40 CFR Part 700

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

Andrew Wheeler,

Administrator.

Therefore, for the reasons presented in this document, the Environmental Protection Agency proposes to amend 40 CFR part 700 as follows:

PART 700—GENERAL

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

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

2. Amend Section 700.43 by:

a. Adding in alphabetical order a definition for “Production volume”;

b. Revising the definition of “Section 5 notice”; and

c. Adding in alphabetical order a definition for “Small quantities solely for research and development”.

The additions and revisions read as follows:

§ 700.43 Definitions applicable to this subpart.

* * * * *

Production volume means average annual manufactured (or imported) amount in pounds from the four calendar years prior to the year certification was made.

* * * * *

Section 5 notice means any PMN, consolidated PMN, intermediate PMN, significant new use notice, exemption notice, exemption application, MCAN, consolidated MCAN, *bona fide* intent to manufacture (including import) a chemical substance under § 720.25(b)(2) of this chapter, or notice of commencement of manufacture or import under § 720.102 of this chapter.

* * * * *

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, imported, or processed or proposed to be manufactured, imported, or processed solely for research and development that

are not greater than reasonably necessary for such purposes.

* * * * *

3. Amend § 700.45 by:

a. Revising paragraph (a)(3);

b. Revising the paragraph (b) subject heading and paragraphs (b)(5)(ii) and (iii):

c. Adding paragraphs (b)(5)(iv) through (vi);

d. Revising paragraph (b)(7);

e. Revising the paragraph (c) subject heading and paragraphs (c)(1)(i) and (c)(1)(vi) through (viii);

f. Adding paragraphs (c)(1)(ix) and (x);

g. Revising paragraphs (c)(2)(vi) through (xi);

h. Adding paragraphs (c)(2)(xii) through (xiv);

i. Revising paragraphs (d), (f)(2)(i), (f)(3)(i), (f)(4), (f)(5)(iv), (g)(3)(iv), and (g)(5)(ii);

j. Adding paragraphs (g)(5)(v) and (vi);

k. Revising paragraph (g)(6)(ii); and

l. Adding paragraphs (g)(6)(v) and (vi).

The revisions and additions read as follows:

§ 700.45 Fee payments.

(a) * * *

(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. For the purposes of this section, entities that manufacture a chemical substance subject to a risk evaluation under section 6(b) of the Act solely for export are subject

to fee requirements in this section whenever such substance is manufactured, processed, or distributed in commerce by any other entity for any purpose other than export from the United States. 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 paragraphs (a)(3)(i) through (v) of this section for the five-year period preceding publication of the preliminary list and will meet one or more of the exemptions in paragraph (a)(3)(i) through (v) in the successive five years. Those manufacturers are excluded from fee payment requirements in this section, if they exclusively:

- (i) Import articles containing that chemical substance;
- (ii) Produce that chemical substance as a byproduct;
- (iii) Manufacture (including import) that chemical substance as an impurity;
- (iv) Manufacture that chemical substance as a non-isolated intermediate as defined in § §

704.3

(v) Manufacture (including import) small quantities of that chemical substance solely for research and development, as defined in § 700.43; and/or

(vi) Manufacture (including import) 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 described in § 700.43, in which case this exemption is not applicable.

* * * * *

(b) *Identifying manufacturers subject to fees for section 4 test rules and section 6 EPA-initiated risk evaluations*

* * * * *

(5) *Self-identification.* All manufacturers other than those listed in paragraph (a)(3)(i) through (iii) of this section who have manufactured or 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:

* * * * *

(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) 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) 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 meets one or more of the exemptions in paragraphs (a)(3)(i) through (vi) of this section for the five-year period preceding publication of the preliminary list and will meet one or more of the exemptions in paragraphs (a)(3)(i) through (vi) in the successive five years, 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 and to not be obligated to pay the fee under this section. If a manufacturer is not on a preliminary list and

meets one or more of the exemptions in paragraphs (a)(3)(i) through (vi) for the five-year period preceding publication of the preliminary list and will meet one or more of the exemptions in paragraphs (a)(3)(i) through (vi) 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) and will not be obligated to pay the fee under this section.

(v) *Recordkeeping.* After [**DATE 60 CALENDAR DAYS AFTER THE DATE OF PUBLICATION OF THE FINAL RULE**]:

(A) All manufacturers other than those listed in paragraphs (a)(3)(i) through (vi) of this section must maintain production volume records related to compliance with paragraph (vi) 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.

(B) Those manufacturers that are exempt from fee payment requirements pursuant to paragraph (a)(3)(vi) of this section must maintain production volume records related to compliance with the exemption criteria described in paragraph (a)(3)(vi). These records must be maintained for a period of five years from the date the exemption is claimed.

(C) Those manufacturers that are exempt from fee payment requirements pursuant to paragraph (a)(3)(v) of this section must maintain ordinary business records related to compliance with the exemption criteria described in paragraph (a)(3)(v), such as 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 record is generated.

(D) Those manufacturers that are exempt from fee payment requirements pursuant to paragraph (a)(3)(iv) of this section must maintain ordinary business records related to compliance with the exemption criteria described in paragraph (a)(3)(iv). These records must be maintained for a period of five years from the date the record is generated.

(vi) *Production volume.* A manufacturer submitting notice to EPA under paragraph (b)(5) of this section, other than those manufacturers listed in paragraphs (a)(3)(i) through (v) of this section, must submit to EPA its production volume as defined in § 700.43 for the applicable chemical substance.

* * * * *

(7) *Publication of final list.* EPA will 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 or no manufacture pursuant to paragraph (b)(5)(ii) or (iii). The final list will be published no later than concurrently with the final scope document for risk evaluations initiated by EPA under section 6, and with the final test rule for test rules under section 4. EPA may modify the list after the publication of the final list.

* * * * *

(c) *Fees for the 2022, 2023, and 2024 fiscal years.* Persons shall remit fee payments to EPA as follows:

(1)* * *

(i) *Premanufacture notice and consolidated premanufacture notice.* Persons shall remit a fee totaling \$2,800 for each premanufacture notice (PMN) or consolidated PMN submitted in accordance with part 720 of this chapter.

* * * * *

(vi) *Bona fide intent to manufacture (including import) a chemical substance.* Persons shall remit a fee totaling \$90 for each *bona fide* intent to manufacture (including import) submitted in accordance with § 720.25 of this chapter.

(vii) *Notice of commencement of manufacture or import.* Persons shall remit a fee totaling \$90 for each notice of commencement of manufacture or import submitted in accordance with §

720.102 of this chapter.

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

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

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

(2) * * *:

(vi) *Bona fide intent to manufacture (including import) a chemical substance.* Persons shall remit a fee totaling \$500 for each *bona fide* intent to manufacture (including import) submitted in accordance with § 720.25 of this chapter.

(vii) *Notice of commencement of manufacture or import.* Persons shall remit a fee totaling \$500 for each notice of commencement of manufacture or import submitted in accordance with § 720.102 of this chapter.

(viii) *Test rule.* Persons shall remit a fee totaling \$29,500 for each test rule.

(ix) *Test order.* Persons shall remit a fee totaling \$9,800 for each test order.

(x) *Resubmitted data.* Persons shall remit a fee totaling \$9,800 for data submitted following submission of deficient data in response to a test order.

(xi) *Enforceable consent agreement.* Persons shall remit a fee totaling \$22,800 for each enforceable consent agreement.

(xii) *EPA-initiated chemical risk evaluation.* Persons shall remit a fee totaling \$2,560,000.

(xiii) *Manufacturer-requested risk evaluation of a Work Plan Chemical.* Persons shall remit an initial fee of \$945,000, a second payment of \$945,000 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 EPA will issue an invoice to the requesting manufacturer.

(xiv) *Manufacturer-requested risk evaluation of a non-work plan chemical.* Persons shall remit an initial fee of \$1,890,000, a second payment of \$1,890,000, 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 EPA will issue an invoice to the requesting manufacturer.

* * * * *

(d) *Fees for 2025 fiscal year and beyond.* (1) Fees for the 2025 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 2022 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 2022 as a base year.

(2) Updated fee amounts for PMNs, SNUNs, MCANs, exemption notices, exemption applications, *bona fide* intent to manufacture (including import) a chemical substance, notice of commencement of manufacture or import, and manufacturer-requested chemical 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 2022 (October 1, 2021). Updated fee amounts also apply to test rules, test orders, enforceable consent agreements and EPA-initiated chemical evaluations that are “noticed” on or after October 1 of every three-year fee adjustment cycle, beginning in fiscal 2022.

(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 most likely through posting to the Agency's web page by the beginning of each three-year fee adjustment cycle (October 1, 2024, October 1, 2027, 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 issuance 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 prior to 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.

* * * * *

(4)(i) 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:

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

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

$$P_o = \frac{F_o}{(M_t - M_s)}$$

(ii) 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 of the chemical substance, with lower fees for small businesses:

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

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

$$P_s = F_s \times V_s$$

$$P_o = F_o \times V_o$$

Where:

F_s = the total fee required under paragraph (c) of this section by a person(s) who qualifies as a small business concern under § 700.43 of this chapter.

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

V_s = the production volume of a person who qualifies as a small business concern under paragraph (c) as a percentage of the total production volume as defined in § 700.43 of person(s) who qualify as a small business concern under paragraph (c) of this section.

V_o = the production volume of a person other than a small business concern as a percentage of the total production volume as defined in § 700.43 of person(s) other than a small business concern.

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.

(5) * * *

(iv) Reallocate the remaining fee across those remaining individuals and groups based on the portion of total production volume as defined in § 700.43, considering the production volume of each manufacturer not in a consortium and the total production volume of the manufacturers in a consortium; and

* * * * *

(g) * * *

(3) * * *

(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) * * *

(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) * * *

(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 § 700.43 and has remitted a fee of \$940 in accordance with § 700.45(c).” in the exemption application.

* * * * *

(v) Each person who remits the fee identified in paragraph (c)(1) of this section for a *bona fide* intent to manufacture (including import) a chemical substance shall insert a check mark for the statement, “The company named in part 1, section A is a small business concern under § 700.43 and has remitted a fee of \$90 in accordance with § 700.45(c).” when submitting a request in accordance with § 720.25(b)(2) of this chapter.

(vi) Each person who remits the fee identified in paragraph (c)(1) of this section for a notice of commencement of manufacture or import shall insert a check mark for the statement, “The company named in part 1, section A is a small business concern under § 700.43 and has remitted a fee of \$90 in accordance with § 700.45(c).” when submitting a notice in accordance with § 720.102(d)(2) of this chapter.

(6) * * *

(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 \$4,700 specified in § 700.45(c).” in the exemption application.

* * * * * (v) Each person who remits the fee identified in

paragraph (c)(2) of this section for a *bona fide* intent to manufacture (including import) a chemical substance shall insert a check mark for the statement, “The company named in part 1, section A has remitted the fee of \$500 in accordance with § 700.45(c).” when submitting a request in accordance with § 720.25(b)(2) of this chapter.

(vi) Each person who remits the fee identified in paragraph (c)(2) of this section for a notice of commencement of manufacture or import shall insert a check mark for the statement, “The company named in part 1, section A has remitted the fee of \$500 in accordance with § 700.45(c).” when submitting a notice in accordance with § 720.102(d)(2) of this chapter.

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