



**BILLING CODE 6560-50-P**

**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Parts 700, 720, 723, 725, 790, and 791**

**[EPA-HQ-OPPT-2016-0401; FRL-9974-31]**

**RIN 2070-AK27**

**User Fees for the Administration of the Toxic Substances Control Act**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Proposed rule.

**SUMMARY:** As permissible under section 26(b) of the Toxic Substances Control Act (TSCA or the Act), the Environmental Protection Agency (EPA or the Agency) is proposing to set user fees applicable to any person required to submit information to EPA under the TSCA section 4 or a notice, including an exemption or other information, to be reviewed by the Administrator under TSCA section 5, or who manufactures (including imports) a chemical substance that is the subject of a risk evaluation under TSCA section 6(b). This notice of proposed rulemaking provides a description of proposed TSCA fees and fee categories for fiscal years 2019, 2020, and 2021, and explains the methodology by which the proposed TSCA user fees were determined and would be determined for subsequent fiscal years. In proposing these new TSCA user fees, the Agency also proposes amending long standing user fee regulations governing the review of premanufacture notices, exemption applications and notices, and significant new use notices. After implementation of final TSCA user fees regulations, certain manufacturers and processors would be required to pay a prescribed fee for each notice, exemption application and data set submitted or chemical substance subject to a

risk evaluation in order for EPA to recover certain costs associated with carrying out certain work under TSCA. With this action, EPA is also proposing standards for determining which persons qualify as small business concerns and thus would be subject to lower fee payments.

**DATES:** Comments must be received on or before [*insert date 60 days after date of publication in the Federal Register*].

**ADDRESSES:** Submit your comments, identified by docket identification (ID) number EPA-HQ-OPPT-2016-0401, by one of the following methods:

- *Federal eRulemaking Portal:* <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.

- *Mail:* Document Control Office (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

**FOR FURTHER INFORMATION, CONTACT:** *For technical information contact:* Mark Hartman, Immediate Office, Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 564-3810; email address: [hartman.mark@epa.gov](mailto:hartman.mark@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](mailto:TSCA-Hotline@epa.gov).*

## **SUPPLEMENTARY INFORMATION:**

### **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), and
- Chemical, Petroleum and Merchant Wholesalers (NAICS code 424).

#### *B. What is the Agency's Authority for Taking this Action?*

The Toxic Substances Control Act (TSCA), 15 U.S.C. 2601 *et seq.*, as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act (P.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 information about chemical substances from disclosure as appropriate under TSCA section 14. EPA is proposing this 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 proposing to establish and collect fees from certain manufacturers (including importers) and processors to defray some of the Agency costs related to activities under TSCA sections 4, 5, 6 and 14. EPA is requesting comment on its proposed user fees and the methodology used for determining the amounts. EPA is also proposing and taking comment on standards for determining which persons qualify as small business concerns and thus would be subject to lower fee payments. Paragraph 4 of TSCA section 26(b) requires that EPA, in setting fees, establish lower fees for small businesses.

*D. Why is the Agency Taking this Action?*

The 2016 amendments to TSCA authorize EPA to establish fees to defray some of the costs of administering certain provisions of the law. The TSCA Service Fee Fund (the Fund) in the U.S. Treasury will hold funds to defray some of the costs of administering TSCA sections 4, 5, and 6 and of “collecting, processing, reviewing, and providing access to and protecting from disclosure as appropriate” information on chemical substances under TSCA section 14. The Agency proposes to collect payment from manufacturers and processors, as appropriate, who: are required to submit information under TSCA section 4; submit a notice, exemption application, or other information under TSCA section 5; and who manufacture a chemical substance that is the subject of a risk evaluation under TSCA section 6(b). These fees are intended to achieve the goals articulated by Congress to provide a sustainable source of funds for EPA to fulfill its legal obligations to conduct

activities such as risk-based screenings, designation of applicable substances as High- and Low-Priority, 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 manufacturing and processing notices, as required under TSCA sections 4, 5 and 6, as well as management of chemical information under TSCA section 14.

*E. What are the Estimated Incremental Impacts of this Action?*

EPA has evaluated the potential incremental economic impacts of this action. The Agency analyzed a three-year period, since the statute requires EPA to reevaluate and adjust, as necessary, the fees every three years. The Economic Analysis (Ref. 2), which is available in the docket, is briefly summarized here and discussed in more detail in Unit IV.

The annualized fees collected from industry for the proposed option (identified as Option C in the Economic Analysis (Ref. 2)), are approximately \$20.05 million. This total does not include the fees collected for manufacturer-requested risk evaluations. Total fee collections were calculated by multiplying the estimated number of actions per fee category anticipated each year, by the corresponding proposed fee. For the proposed option, TSCA section 4 fees account for less than one percent of the total fee collection, TSCA section 5 fees for approximately 43 percent, and TSCA section 6 fees for approximately 56 percent. Annual fees collected by EPA are expected to total approximately \$20.05 million.

Under the proposed option, the total fees collected from industry for a risk evaluation requested by manufactures are estimated to be \$1.3 million for chemicals included in the Work Plan and \$2.6 million for chemicals not included in the Work Plan.

EPA estimates that 18.5 percent of TSCA section 5 submissions will be from small businesses that are eligible to pay discounted fees because they have average annual sales of less than \$91 million in the three preceding years. Total annualized fees for TSCA section 5 collected from small businesses are estimated to be \$550,000 (Ref. 2).

For TSCA sections 4 and 6, discounted fees for eligible small businesses and fees for all other affected firms may differ over the three-year period that was analyzed, since the fee paid by each firm is dependent on the number of affected firms per action. Based on past TSCA section 4 actions and data related to the first ten chemicals identified for risk evaluations under TSCA as amended, EPA estimates annualized fees collected from small businesses for TSCA section 4 and TSCA section 6 to be approximately \$37,000 and \$2.6 million, respectively.

EPA estimates that total fees paid by small businesses will account for about 16 percent of the approximately \$20.05 million fees to be collected for TSCA sections 4, 5, and 6 actions. The annualized total industry fee collection for small businesses is estimated to be approximately \$3.2 million.

*F. What Should I Consider as I Prepare My Comments for EPA?*

1. *Submitting CBI.* Do not submit this information to EPA through 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, information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the comment that does not contain the information claimed as CBI must be submitted for

inclusion in the public docket.

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. History of Fees Under TSCA*

In 1976, TSCA section 26(b) provided EPA with authority to require, by rule, the payment of fees by persons required to submit data under TSCA sections 4 and 5. TSCA section 26(b) capped the maximum fees for small business at \$100 and fees for all other entities at \$2,500. It was not until the Agency published a final rule in 1988 that EPA began requiring and collecting fees from manufacturers and processors to pay for premanufacture notices (PMNs), and other submissions under TSCA section 5. Although authorized under the statute, the Agency has not historically collected fees for data submitted under TSCA section 4 and no TSCA section 4 fees rule was ever promulgated by EPA.

Since 1988, with regard to submissions by small business concerns, the Agency has collected \$100 for each TSCA section 5 PMN, consolidated PMN, significant new use notice (SNUN), and certain exemption applications and notices. For submissions by all other manufacturers or processors, EPA has collected \$2,500 for each TSCA section 5 PMN, and consolidated PMN notices other than intermediate PMNs, SNUNs and certain exemption applications and notices and \$1,000 for intermediate PMNs. These fees were set prior to the June 2016 amendments to TSCA and do not reflect the current cost of administering the TSCA sections associated with these submissions. In the past several fiscal years, EPA has consistently generated approximately \$1.1 million annually in fee revenue. The fees go to the General Fund of the U.S. Treasury and do not defray EPA's costs. With

the finalization of the TSCA User Fees rule, EPA's annually appropriated funds will be supplemented with the user fees to cover some of the costs of administering TSCA, including the costs incurred by the Agency in addressing additional requirements imposed by the June 2016 amendments.

*B. Recent Amendments to TSCA.*

On June 22, 2016, the "Frank R. Lautenberg Chemical Safety for the 21st Century Act" was signed into law, amending numerous sections of TSCA. The amendments give EPA improved authority to take actions to protect people and the environment from the effects of chemicals. The amendments also expand EPA's existing TSCA fee authority and allow the Agency to establish and collect fees sufficient to defray some of the costs of administering certain TSCA requirements.

The amendments remove the \$100 cap on fees collected from small businesses and the \$2,500 cap on fees from other manufacturers and processors. Instead, the amendments require that, if fees are established for work under TSCA sections 4, 5 and/or 6, the Agency set lower fees for small business concerns and establish the fees so that they are designed to collect 25% of the Agency's costs to carry out work under section 4, 5, 6 and 14 of the Act or \$25,000,000, whichever is lower. In addition, in the case of a manufacturer-requested risk evaluation, the Agency is authorized 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 the full costs of conducting a manufacturer-requested risk evaluation for all other chemicals. The amendments also authorize fee revenue to be deposited into a new TSCA Service Fee Fund. This is intended to ensure that resources are made available to the Agency to defray some of the costs that EPA incurs in carrying out activities under section 4, 5, 6 and 14 of TSCA.

Currently, fees are only collected for certain submissions under section 5 of TSCA. These

fees are established in 40 CFR §700.45. Under the Lautenberg Act's amendments to TSCA, EPA has authority to require payment from manufacturers and processors who:

- Are required to submit information by test rule, test order or enforceable consent agreement (TSCA section 4);
- Submit notification of or information related to intent to manufacture a new chemical or significant new use of a chemical (TSCA section 5);
- Manufacture or process a chemical substance that is subject to a risk evaluation, including a risk evaluation conducted at the request of a manufacturer (TSCA section 6(b)).

Beginning in fiscal year 2019 (October 1, 2018 through September 30, 2019), EPA is required to adjust fees, as necessary, every three years to reflect inflation and ensure that fees are sufficient to collect 25% of the costs to the Agency in administering sections 4, 5, 6 and 14 of the Act. Before establishing new fees or revising any existing fees, the Agency is required to consult with manufacturers and processors, or their representatives.

Additional information on the new law is available on EPA's website at <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/frank-r-lautenberg-chemical-safety-21st-century-act>.

### *C. Stakeholder Involvement*

Prior to this notice of proposed rulemaking, EPA engaged with members of the public (or their representatives) potentially subject to the fees. The Agency held a public meeting and webinar on August 11, 2016, and an industry-specific consultation meeting and webinar on September 13, 2016, in accordance with TSCA section 26(b)(4)(E). The Agency sought comments from industry on

various aspects of the proposed rulemaking, including the amendment of existing TSCA section 5 fees, the establishment of new fees for TSCA sections 4 and 6 activities, and small business considerations. As part of EPA's efforts to consult with industry on the proposed fees and the methodology for establishing the fees, the Agency also opened a docket and collected written comments from stakeholders. To view the comments received prior to this notice of proposed rulemaking, go to <http://www.regulation.gov> and search for docket number: EPA-HQ-OPPT-2016-0401.

The commenters included representatives from industry, trade associations, and an environmental group and provided a diversity of perspectives. Overall, there was a general expression of support for the new law, for ensuring that the Agency has the funding necessary to implement the requirements of the recent amendments to TSCA, and for EPA's inclusive approach for gathering industry input into the setting of fees. Most of the commenters expressed support for a fair, simple, and efficient fee structure. The majority of commenters also expressed support for industry consortia-based management of fee collection for TSCA sections 4 and 6 activities.

EPA sought input from industry on the relative apportionment of fees that should be assessed for administering TSCA sections 4, 5, and 6 activities and on the factors that the Agency should consider when structuring the fees. All industry commenters recommended that fees be assessed based on the level of effort required of EPA for undertaking the activity supported by the fee. A number of commenters opposed assessment of fees under TSCA section 4. Others indicated a willingness to accept nominal fees under TSCA section 4 or fees solely to account for EPA's effort in reviewing submissions. Many commenters expressed concern that higher fees imposed on bringing new chemicals to market (i.e., TSCA section 5 submissions) could create an economic barrier to innovation. Several commenters recommended that the bulk of the fees the rule establishes should

be from manufacturers and processors of chemicals subject to risk evaluation under TSCA section 6.

The Agency also sought comment from industry on lower fees for small businesses. Many trade associations reaffirmed the need for lower fees for small businesses. All commenters that mentioned small businesses recommended that the TSCA definition of a small business be updated, though there was diverse opinion on how; recommendations included an inflation-adjusted, revenue-based standard and an employee-based definition.

EPA considered all of these comments in the development of the proposed rule. EPA welcomes comment from stakeholders on all aspects of the Agency's proposed fee structure during the public comment period opened with this document.

#### *D. Federal User Fee Design Guidance*

EPA also looked to federal user fee guidance in designing the proposed TSCA user fees. Office of Management and Budget Circular A-25 on User Charges (Ref. 3) and the GAO User Fees Design Guide (Ref. 4) contain information that is relevant to the administrative processes of setting, revising, collecting, and administration of fees. As EPA discusses its rationale for setting the TSCA fees in the remainder of this preamble, the Agency will rely on the policies and principles identified in these two federal guidance documents. Circular A-25 explains, for executive agencies, the scope and type of activities subject to user fee charges and the basis on which user fees should be set. EPA followed the Circular A-25 guidance in identifying the relevant direct and indirect costs to be recovered by user fees including, but not limited to, an appropriate share of personnel costs, including salaries and fringe benefits; management and supervisory costs; costs of research, establishment of standards and regulations; physical overhead; and other indirect costs including supply costs and travel.

The Agency plans to periodically review the user fees to provide assurance that existing charges are adjusted to reflect unanticipated changes in costs, and plans to readjust, as necessary, the fees to account for these changes, as well as inflation. TSCA 26(b)(4)(F) sets the readjustment schedule at three year intervals. As required in TSCA section 26 and discussed in the GAO Guide, parties potentially subject to fees or their representatives will be consulted and asked to provide input when the fees are reviewed and updated to reflect changes in program costs.

The Agency is proposing a process by which TSCA user fees would be established for fiscal year 2019 through 2022 and then adjusted for inflation every three years, beginning in fiscal year 2022, based on applicable Producer Price Index (PPI) values available from the U.S. Department of Labor. Fees for fiscal year 2022 and later would be calculated by multiplying each fee identified for fiscal years 2019 through 2021 by the most current PPI value available at the beginning of the three-year adjustment period, beginning with October 1, 2021. EPA would provide public notice of the inflation-adjusted fee amounts most likely through posting to the Agency's webpage by the beginning of each three-year fee adjustment cycle (i.e., October 1, 2021, October 1, 2024, etc.). The Agency may also identify the need to update program costs underlying the fee amounts, and/or propose any changes to the fees beside adjustment for inflation. The Agency will initiate industry consultation as required under TSCA 26(b)(4)(E) in either case and provide public notice for any fee changes based on inflation. EPA expects to undertake notice and comment rulemaking for more substantial changes to the fees. EPA seeks comment on this approach for readjusting fees every three years.

### **III. Detailed Discussion of the Proposed Rule**

EPA is proposing to establish and collect fees from manufacturers and processors of

chemical substances pursuant to TSCA section 26(b). As discussed previously in Unit II.A., EPA currently collects fees for PMNs, certain PMN exemption applications and notices, and SNUNs submitted under TSCA section 5. The Agency is proposing to expand the categories of activities for which fees are collected and increase the amount of fees required for certain activities under TSCA sections 4, 5 and 6. This proposal lays out the fee categories and payment amounts that the Agency believes are both reasonable and appropriate to begin collecting in fiscal year 2019; they are intended to provide a sustainable source of funds to defray approximately 25 percent of the costs to carry out the activities specified in TSCA section 26(b), as well as 50% or 100% of the costs of risk evaluations requested by manufacturers, depending on the chemical.

Because EPA will not begin collecting fees until fiscal year 2019, EPA believes it is appropriate to look to TSCA section 26(b)(4)(F) for the parameters which must be applied for setting fees. TSCA section 26(b)(4)(F) requires EPA, “beginning with the fiscal year that is 3 years after the date of enactment [June 22, 2016],” to adjust fees as necessary so they are sufficient to defray approximately 25 percent of the costs to carry out the activities of TSCA sections 4, 5, 6 and 14, other than the costs of manufacturer-requested risk evaluations. Further, the fees shall defray 50% or 100% of the costs of risk evaluations requested by manufacturers, depending on the chemical. EPA acknowledges that fees were initially to be established under the authority of TSCA section 26(b)(4)(B), which provides different parameters, most notably a cap on fees of \$25 million. However, given the timing of this fee rule proposal such that fees won’t be collected under fiscal year 2019, EPA believes it is more appropriate to set these fees based on the parameters that are required to be in effect by fiscal year 2019. EPA also notes that because the estimated costs for covered activities are under \$100 million and costs defrayed under \$25 million, the cap on fees found in TSCA 26(b)(4)(B) would have had no bearing on the proposed fees in any case.

EPA considered industry comments regarding the fee structure. Several predominant themes emerged through consultation with industry. Many commenters felt that EPA should charge fees that are proportional to EPA costs for undertaking the activities. This was consistent with one of the considerations that EPA applied in setting the proposed fees – equity as determined by proportionality between EPA costs and the fee associated with each activity. EPA notes that the statute does not require such proportionality. In fact, the fee triggers under the law (for example, submission of a section 5 notice) are distinct from EPA activities for which costs can be defrayed by the fees collected. Thus, EPA could, consistent with TSCA, collect fees for section 5 submissions that exceed the cost of processing the section 5 submissions, so long as the fees in the aggregate are not designed to exceed 25% of the costs to EPA of carrying out sections 4, 5, 6 and 14. Nonetheless, none of the fees that EPA is proposing exceed the Agency's costs associated with the activities associated with a given fee.

*A. Who will be charged fees?*

As mentioned previously in Unit II.B., EPA has authority to collect fees from manufacturers and processors who:

- Are required by test rule, test order or enforceable consent agreement to submit information (TSCA section 4);
- Submit notification of or information related to intent to manufacture a new chemical or significant new use of a chemical (TSCA section 5);
- Manufacture or process a chemical substance that is subject to a risk evaluation, including a risk evaluation conducted at the request of a manufacturer (TSCA section 6(b)).

Although EPA has authority to collect fees from both manufacturers and processors of chemical substances, EPA is proposing to focus fee collection on manufacturers. EPA is proposing to collect fees from processors only when processors submit a SNUN under section 5 or when a section 4 activity is tied to a SNUN submission by a processor. The Agency feels the effort of trying to identify a representative group of processors for the other three fee-triggering actions would be overly burdensome and expects many processors would be missed. The Agency believes this approach is the simplest and most straightforward way to assess fees for conducting risk evaluations under TSCA section 6 and other TSCA section 4 testing. Furthermore, EPA expects that manufacturers required to pay user fees will have a better sense of the universe of processors and will pass some of the costs on to them. The Agency is seeking public comment on this approach.

For certain actions for which a fee will be charged, such as new chemical submissions under section 5, fee payers will self-identify by virtue of the submission they make to the Agency. For others, such as risk evaluations under section 6, EPA plans to look to recent Chemical Data Reporting (CDR) submissions to identify manufacturers (including importers) subject to section 6 fees. The CDR Rule, issued under the authority of TSCA section 8(a), requires chemical substance manufacturers to give EPA information on the chemicals they manufacture domestically or import into the United States. Information is collected every four years; data were most recently collected in 2016, including 2012-2015 production volume information and 2015 manufacturing, processing and use information. The next submission period will be in 2020. EPA acknowledges that CDR data may not contain the entire list of companies subject to a fee, and failure by EPA to identify companies subject to a fee does not remove their obligation to pay. EPA proposes to use CDR data to identify a preliminary list of companies. EPA also seeks comment on whether to adopt a process that would allow time for public input for adding to that preliminary list before finalization. EPA seeks public

comment on this approach.

The Agency is also interested in comments on using other sources to identify those subject to payment of fees. These sources include, for example, information reported to the Toxics Release Inventory (TRI), and notice of commencement (NOC) submissions under EPA's TSCA New Chemicals Review Program. EPA may also look to information reported to the Agency under the TSCA inventory active/inactive notification rule. Each of these data sources provides information that may be useful in identifying manufacturers and processors of chemical substances who may be required to pay TSCA user fees. The TRI under section 313 of the Emergency Planning and Community Right-to-Know Act, currently covers over 650 chemicals. Facilities that manufacture, process or otherwise use these chemicals in amounts above established levels must submit annual TRI reports on each chemical. Facilities that report to TRI include larger facilities involved in chemical manufacturing. Under section 5 of TSCA, manufacturers are required to submit a NOC to the Agency within 30 days following the start of manufacture of a new chemical substance (i.e., any substance that is not on the TSCA Inventory). Upon receipt of the NOC form, EPA places the substance on the TSCA Inventory. EPA finalized the TSCA inventory active/inactive notification rule in June 2017. The rule requires manufacturers to report to EPA chemical substances on the TSCA Inventory that were in U.S. commerce during the 10-year period prior to the TSCA amendments of June 2016. The rule also requires manufacturers and processors to notify EPA in the future when they intend to re-introduce an "inactive" substance on the Inventory into U.S. commerce. The Agency plans to include a limitation in the final regulatory text to ensure a manageable approach for the identification of manufacturers who are subject to a particular fee. EPA welcomes comment on these approaches for identifying those subject to TSCA user fees.

*B. How did EPA calculate user fees?*

1. *Background.* EPA is presenting for comment its proposed methodology for determining the user fees that will be assessed under amended TSCA. The Act provides EPA authority to establish fees to defray a portion of the costs associated with administering TSCA sections 4, 5 and 6, as well as the costs of collecting, processing, reviewing, and providing access to and protecting from disclosure, as appropriate, information on chemical substances under TSCA section 14. The events that trigger a fee payment however, involve a narrower set of activities under TSCA sections 4, 5 and 6. While the collection of fees is tied to the submission of particular information under sections 4 and 5 or the manufacturing of a particular chemical substance undergoing a risk evaluation under section 6, in general, the use of these fees is not limited to defraying the cost of the action that was the basis for payment of the fee.

EPA believes that assigning fees across TSCA sections 4, 5 and 6 is the most equitable and efficient approach for allocating costs to the manufacturers and processors detailed in Unit III.A. Those manufacturers and processors would be expected to bear the burden, and receive benefits, of TSCA reviews conducted by the Agency.

The Agency's proposed fee methodology is intended to fully recover the amount specified in the statute per TSCA section 26(b)(4)(F). The estimated annual Agency costs of carrying out TSCA section 4, 5, 6 and 14, without including the costs associated with manufacturer-requested chemical risk evaluations, are approximately \$80.2 million. Based on these cost estimates, EPA anticipates collecting approximately \$20.05 million in fees each year. In addition, the Agency intends to collect fees from manufacturers to recover a portion of costs incurred by EPA in conducting chemical risk evaluations requested by manufacturers. EPA expects this fee amount will be \$1.3 million for per chemical for chemicals on the Work Plan and \$2.6 million per chemical for chemicals not on the Work Plan.

EPA determined the anticipated costs associated with TSCA sections 4, 5, 6 and 14 activities, including both program costs and indirect costs (see Table 1). For fiscal year 2019 through fiscal year 2021, these costs were estimated to be approximately \$80.2 million per year. More detail on how anticipated costs were calculated follows in Unit III.B.2.

**Table 1: Estimated Annual Costs to EPA (Fiscal Year 2019 through Fiscal Year 2021)**

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

Notes: Numbers may not add due to rounding. The indirect cost rate for Office of Chemical Safety and Pollution Prevention is estimated at 28.14% for the purposes of this analysis.

After estimating the annual costs of administering TSCA section 4, 5, 6 and 14, the Agency had to determine how the costs would be allocated over the narrower set of activities under TSCA section 4, 5 and 6, which trigger a fee. The Agency took an approach to determining user fees that parsed the fees based on the type of submission or fee triggering event. This allows allocation of costs more equitably among the submissions and their related costs.

2. *Program costs.* To determine the program costs for implementing sections 4, 5, 6 and 14

of TSCA, the Agency accounted for the intramural and extramural costs for activities under these sections. 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 28.14% to calculate the indirect costs associated with all TSCA section 4, 5, 6 and 14 direct program cost estimates.

*a. TSCA section 4 program costs.* TSCA section 4, Testing of Chemical Substances and Mixtures, gives EPA the authority to require, by rule, order, or enforceable consent agreement (ECA), manufacturers and processors to conduct testing of identified chemical substances or mixtures. EPA estimated TSCA section 4 submission costs based on prior experience with developing test rules and ECAs, reviewing study plans, and reviewing the data received. 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, we expect to initiate each of these activities about every other year. It takes approximately two years to complete the work associated with both of these activities.

Costs assume that each TSCA section 4 activity will cover one to 7 chemicals. While testing required by test orders is likely to be completed in under a year, test rules and enforceable consent agreements are likely to take two years to complete. This estimate is based on EPA's prior experience with test rules and ECAs. To estimate the costs of reviewing test data, we assume that on average, data will be submitted to EPA for seven tests on each chemical.

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 enforceable consent agreement 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 EPA assumes will be worked on over a three-year period. Several of these activities (rules and ECAs) are expected to span two years, as noted earlier 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 2019 through fiscal year 2021 is \$3,543,000 (Ref. 5: Table 8).

*b. TSCA section 5 program costs.* TSCA section 5, Manufacturing and Processing Notices, 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. EPA is required to review and make determinations on the notices and take risk management action, as needed.

Examples of the notices or other information that manufacturers and processors are required to submit under TSCA section 5 are PMNs, significant new use notifications (SNUNs), microbial commercial activity notices (MCANs), and numerous types of exemption notices and applications (e.g., 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, film article exemptions, etc.).

EPA's TSCA section 5 efforts under the previous law are well understood through experience that spans several decades. The Agency has historical data on costs, as well as the number of

different section 5 submission types sent to the Agency each year. In 1987, the costs for the Agency to process a PMN were approximately up to \$15,000 per submission, depending on the amount of detailed analysis necessary; these estimates did not include indirect costs. 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>. (Ref. 6) In calendar year 2016, EPA received 577 PMNs, SNUNs and MCANs, and another 560 exemption notices and applications, most of which were LVEs.

The provisions of TSCA, as amended, result in additional TSCA section 5 Agency costs that arise primarily from the requirement to review the intended, known or reasonably foreseen activities associated with the chemical, and the requirement to make an affirmative risk determination, and from development of significant new use rules (SNURs) and orders that result from our analysis and findings under TSCA, as amended. Therefore, the Agency used the cost estimates from prior experience as a starting point and then added estimates for the costs of these additional responsibilities.

EPA's cost estimates include the costs of processing, reviewing, and making determinations, and the Agency's costs of taking any regulatory action such as with a SNUR or an order. Costs of reviewing any data that is submitted to EPA as a result of an order is also included. EPA's cost estimates for administering TSCA section 5 also include the costs associated with processing, retaining records, related to a 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 (totaling an estimated \$1,700,000 per year) with those of PMNs, MCANs and SNUNs. The average cost of a PMN, MCAN and SNUN is approximately \$55,200. 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 once fees are in place which is 462. Our estimate of number of submissions is based on submissions received FY 16 reduced by 20% due to the anticipated impact of higher fees on the number of submissions (Ref. 5: Table 9).

Costs associated with section 5 exemption notices and applications include processing and reviewing the application, retaining records, and related activities. The average cost of an exemption is \$5,600. 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 once fees are in place which is 560. Our estimate of number of submissions is based on submissions received in FY 16 (Ref. 5: Table 10).

The annual cost estimate of administering TSCA section 5 in fiscal year 2019 through fiscal year 2021 is \$28,600,000. Approximately \$25,500,000 is attributed to PMNs, SNUNs and MCANs; another approximately \$3,149,000 is attributed to section 5 exemptions notices and applications for LVEs, LoREXs, TMEs, TERAs, Tier IIs and film articles.

*c. TSCA section 6 program costs.* TSCA section 6, Prioritization, Risk Evaluation, and Regulation of Chemical Substances and Mixtures, describes EPA's process for assessing and managing chemical safety 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 now required to undergo 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, EPA must evaluate existing chemicals to determine whether they "present an unreasonable risk of injury to health or the environment." Under the conditions of use for each chemical, the Agency will assess the

hazard(s), exposure(s), and the potentially exposed or susceptible subpopulation(s) that EPA determines are relevant. This information will be used to make a final determination as to whether the chemical presents an unreasonable risk 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 its designation in the **Federal Register**. The scoping document will include information about the chemical substance, such as conditions of use, exposures, including potentially exposed or susceptible subpopulations, and hazards, 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. By the end of calendar year 2019, EPA must have at least 20 chemical risk evaluations ongoing at any given time on high-priority chemicals plus industry-requested evaluations. For each risk evaluation that the Agency completes, TSCA requires that EPA begin another. The Agency expects to have between 20 and 30 risk evaluations ongoing in any given year at different stages in the review process.

TSCA section 6 cost estimates have been informed by the Agency's experience completing assessments for several TSCA Work Plan Chemicals, including N-methylpyrrolidone, antimony trioxide, methylene chloride, trichloroethylene, and 1,3,4,6,7,8-Hexahydro-4,6,6,7,8,8-hexamethylcyclopenta[ $\gamma$ ]-2-benzopyran (HHCB) and by the Agency's experience addressing risks identified from particular uses of a chemical. TSCA section 6 risk evaluation costs include the cost of information gathering, considering human and environmental hazard, environmental fate, and exposure assessments. Costs also include the use of the ECOTOX knowledge and Health and Environmental Research Online (HERO) databases, among others. Other costs include scoping (including problem formulation, conceptual model and analysis plan), developing and publishing the draft evaluation, conducting and responding to peer review and public comment, and developing

the final evaluation, which includes a risk determination.

Under TSCA section 6, the Agency also has obligations to take action to address any unreasonable risks identified from a chemical. Cost estimates for risk management activities have been informed, in part, by EPA's recent risk reduction actions on several chemicals, including the use of N-methylpyrrolidone in paint and coating removal and trichloroethylene in both commercial vapor degreasing and aerosol degreasing and for spot cleaning in dry cleaning facilities. Section 6(a) of TSCA provides authority for EPA to ban or restrict the manufacture, processing, distribution in commerce, and commercial use of chemicals, as well as any manner or method of disposal of chemicals.

In addition to considering previous experience with TSCA Workplan chemicals described above, EPA also benchmarked risk evaluation costs against cost associated with conducting risk assessments for pesticides under the Pesticide Registration Improvement Act (PRIA). The Agency chose the costs of conducting reviews for new conventional food-use pesticide active ingredients as the most relevant comparison to an existing chemical review under TSCA based on the scope and complexity of the assessments and the data considered in conducting the reviews. EPA estimates the cost of completing a risk assessment and risk management decision for a new conventional food use pesticide active ingredient to be approximately \$2,900,000 which includes direct cost estimates provided by the Office of Pesticide Programs and indirect costs at 28.14%. The primary rationale for the increased cost estimate for a risk evaluation under TSCA when compared to a new pesticide review under PRIA are that the scope of an existing chemical assessment under TSCA is expected to be broader in terms of conditions of use and exposure scenarios that must be assessed and uncertainties associated with implementing a new evaluation program. EPA also expects that risk management costs will be higher under TSCA since rulemaking is required to implement any

mitigation that is considered appropriate whereas most mitigation for a pesticide can be achieved directly through changes to the product labeling and/or terms and conditions of the registration.

The breakdown of costs for an average three-year EPA-initiated chemical risk evaluation is shown in Table 2.

**Table 2: Estimated Costs (Direct and Indirect) Associated with an Average EPA-Initiated Chemical Risk Evaluation**

<b>Risk Evaluation Activity</b>	<b>Estimated Cost</b>
Risk Evaluation: Data Gathering (i.e., literature search)	\$395,000
Risk Evaluation: Databases (e.g., ECOTOX and HERO)	\$147,000
Risk Evaluation: Hazard Assessment	\$1,008,000
Risk Evaluation: Exposure Assessment	\$1,038,000
Risk Evaluation: Scoping	\$235,000
Risk Evaluation: Draft Evaluation	\$502,000
Risk Evaluation: Peer Review & Responding to Comment	\$230,000
Risk Evaluation: Final Evaluation	\$329,000
<b>Total:</b>	<b>\$3,884,000</b>

For purposes of this proposal, EPA is estimating that manufacturer-requested risk evaluations will cost less than EPA-initiated risk evaluations on high-priority substances. Specifically,

EPA is estimating the average actual cost of a manufacturer-requested risk evaluation to be \$2,600,000. There are number of factors supporting this cost estimate and the assumption that manufacturer-requested risk evaluations will actually cost less than EPA-initiated risk evaluations. First, as required in the Risk Evaluation rule finalized in June 2017, (40 CFR 702.37) manufacturers requesting a risk evaluation must provide EPA with a list of existing information that would be adequate for EPA to conduct an evaluation. The upfront provision of data by manufacturers would limit the amount of subsequent work that the Agency would need to undertake to evaluate the chemical. Second, EPA believes that manufacturers who choose to submit risk evaluation requests to EPA will likely do so in cases where they believe the chemical is less likely to present an unreasonable risk. At this time, EPA believes that manufacturers are more likely to request risk evaluations on chemicals that are low hazard or low exposure, or are otherwise fairly straightforward to analyze. As such, EPA is estimating that these risk evaluations will less costly than an average EPA-initiated risk evaluation on a high-priority chemical. While EPA does not yet have experience in receiving these types of requests from manufacturers, or undertaking these risk evaluations, these cost estimates represent EPA's best judgment based on past and current activities and the expectation that manufacturers are more likely to submit low hazard, low exposure chemicals for review. For the first 10 chemical risk evaluations that EPA is currently undergoing, for example, there are significant differences in the level of effort necessary to complete the evaluations, with some being substantially less complicated and therefore less burdensome than others. EPA expects manufacturer-requested risk evaluations to be on the less complicated end of the spectrum.

The annual cost estimate of administering TSCA section 6 in fiscal year 2019 through 2021 is \$43,618,000. Approximately \$32,370,000 is attributed to risk evaluation work on 25 chemical risk

evaluations; another approximately \$6,584,000 is attributed to risk management efforts; another approximately \$2,091,000 is attributed to support from the Office of Research and Development (ORD) for alternative animal testing and methods development and enhancement, and approximately \$2,573,000 is attributed to the annual process of designating chemicals as High- or Low-priority substances (Ref. 5: Table 11).

*d. TSCA section 14 program costs.* The June 2016 amendments to TSCA provided EPA with new obligations under section 14, Confidential Information. EPA must now review most chemical identity CBI claims within 90 days and 25 percent of a subset of other types of CBI claims within 90 days. This increased workload, along with the IT infrastructure to support this work was included in EPA's cost estimates for administering section 14. The annual cost estimate of administering TSCA section 14 from fiscal year 2019 through 2021 is \$4,346,000. These estimates include FTE and extramural costs of conducting CBI reviews and operating and maintaining the CBI Local Area Network (LAN) (Ref. 5).

*3. 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 our proposed user 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 TSCA sections 4, 5, 6 and

14 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 for all of EPA offices by the Agency's Office of the Controller, 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 28.14% was applied to direct program costs of work conducted by EPA's Office of Chemical Safety and Pollution Prevention, based on FY 2016 data (Ref. 7). Some of the direct program costs included in the TSCA sections 4, 5, 6 and 14 estimates 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 (i.e., 25.56% and 8.05%). These indirect rates are based on an EPA's existing indirect cost methodology (Ref. 7). 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.

4. *Fee categories.* In addition to Agency costs, another piece of information relevant to determining applicable user fees is the type of events that trigger a fee payment (e.g., information submission, exemption notice). Under this proposal, EPA would require payment of fees for most types of fee triggering events under TSCA sections 4, 5 and 6. This includes the requirement to submit information to comply with a test order, test rule, or enforceable consent agreement under TSCA section 4. Payment would also be required for the following TSCA section 5 notices and exemptions: PMNs and consolidated PMNs, SNUNs, MCANs and consolidated MCANs, TMEs, LoREXs, LVEs, Tier II, film article exemptions and TSCA experimental release applications TERAs. Payment would also be required for chemicals undergoing both EPA-initiated and manufacturer-requested risk evaluations under TSCA section 6. See Unit III.D. for a detailed discussion of small business concerns.

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

Two categories of fees, with different fee amounts, are being proposed for TSCA section 5 submissions. EPA chose to lump activities with similar Agency costs together in order to develop a simple fee structure. The fee being proposed for each PMN, SNUN and MCAN is \$16,000. The proposed fee for each LoREX, LVE, TME, Tier II, film article and TERA is \$4,700.

EPA is proposing to continue the practice of allowing consolidation of PMNs, consolidation of MCANs, and in some cases, consolidation of a synthetic sequence, for up to six closely similar chemical substances with similar use, structure, and probable toxicology at the same time and for the same fee as a single chemical substance. See 48 FR 21734, May 13, 1983. Consolidated PMNs (and MCANs) benefit submitters by reducing the administrative burden of developing multiple section 5 submission forms for manufacture of two or more structurally related new chemical substances that have similar use, exposure, environmental release, and test data. EPA's review process is also better facilitated by reviewing similar substances simultaneously.

EPA limits the number of substances that may be included in a consolidated PMN to six. EPA announced a policy that it would accept submission of consolidated notices, subject to the approval

of each submission, in the preamble of the May 13, 1983 **Federal Register** (Ref. 8). When EPA initially accepted consolidations, there was no limit on the number of substances which could be submitted in one consolidation. A consolidation, though less demanding of EPA's resources than the same number of separate submissions of related chemicals, still requires a substantially increased amount of effort over the assessment of a single submission. EPA has decided that it is appropriate to continue to limit the number of substances in a consolidation to six.

Persons who intend to submit a consolidated notice should first contact EPA for approval before submission of the notice; through that process, EPA can determine if the criteria for consolidation are met. Substances should be adequately similar chemically and toxicologically; planned uses must be similar enough for combined review; and intended volumes must not be excessively different. Consolidations are typically not granted for more than six substances in one notice, nor for substances which are not chemically and toxicologically similar. Novel or category chemicals are more likely to be approved for consolidation if the intended uses and volumes are similar.

EPA intends to eliminate the "intermediate PMN" fee class. EPA currently charges a reduced fee of \$1,000 for the submission of PMN for each chemical intermediate in a synthetic pathway when accompanied by a PMN for the final substance on that pathway, and a full \$2,500 user fee for the final substance. The original intent of this reduced fee was to encourage manufacturers to submit these notices together. The Agency however, has not realized advantages in reviewing these notices together; each intermediate takes about the same amount of effort to review as does the "final" chemical substance on that pathway. For this reason, the Agency proposes to eliminate the reduced fee for intermediate PMN submissions and will take comment on this approach.

EPA is not proposing to assess greater fees for submissions containing CBI claims. At least six commenters opposed fees for such claims, or suggested that the Agency collect only nominal payments under TSCA section 14. While the CBI costs are considered in the fee-defrayable costs, EPA is not proposing to charge an additional fee for submissions and activities that contain CBI.

In order to distribute the full costs to be defrayed among the fee payment-triggering events in a way that is proportional to the costs of the work associated with those events, EPA identified different fee categories, based on the section of TSCA under which the event is covered and the effort and burden for EPA to conduct the work associated with the triggering event. EPA identified eight distinct fee categories. The two fee categories under section 5 are further broken out below for transparency.

The annual estimated costs for fee categories under TSCA section 4, including both direct and indirect program costs are shown in Table 3. Please note that the costs presented in Tables 3, 4 and 5 do not include costs associated with 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 sections 4, 5, 6 and 14 and, as such, are included in the overall cost estimates previously in Table 1.

**Table 3: TSCA Section 4 Costs\***

<b>Fee Category</b>	<b>Estimated # of Ongoing Actions/Year</b>	<b>Estimated Cost to Agency/Action</b>	<b>Estimated Annual Cost to Agency</b>
Test Order	10	\$279,000	\$2,795,000
Test Rule	1	\$844,000	\$422,000

Enforceable Consent Agreement	1	\$652,000	\$326,000
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\*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 4.

**Table 4: TSCA Section 5 Costs\***

Fee Category	Estimated # of Ongoing Actions/Year	Estimated Cost to Agency/Action	Estimated Annual Cost to Agency
PMN and consolidated PMN	462	\$55,200	\$25,500,000
SNUN			
MCAN and consolidated MCAN			
LoREX	560	\$5,600	\$3,149,000
LVE			
TME			
Tier II exemption			
TERA			
Film Article			

\*Numbers may not add due to rounding.

The estimated annual costs for fee categories under TSCA section 6, including both program and indirect costs are shown in Table 5.

**Table 5: TSCA Section 6 Costs\***

<b>Fee Category</b>	<b>Estimated # of Ongoing Actions/Year</b>	<b>Estimated Cost to Agency/Action</b>	<b>Estimated Annual Cost to Agency</b>
EPA-initiated risk evaluation	25	\$3,884,000	\$32,370,000
Manufacturer-requested risk evaluation: Work Plan chemical	2	\$2,600,000	\$1,733,000
Manufacturer-requested risk evaluation: Non-Work Plan chemical	3	\$2,600,000	\$2,600,000

\*Numbers may not add due to rounding.

5. *Calculating user fees.* Almost all industry commenters expressed support for a fair, simple, and efficient fee structure and all industry commenters recommended that fees be assessed based on the level of effort required of EPA as a result of the submission or undertaking the activity for which a fee is charged. The Agency considered these comments in developing this proposal. The Agency is proposing a general fee structure that is generally proportional to the Agency's costs, yet takes into account the numerous comments received from industry regarding the desire to limit

costs associated with information submission under TSCA section 4. Two other alternate fee structure proposals are included in this preamble. When providing comments to the Agency on the various options, please recognize that there are tradeoffs between decreasing fees in one area and increasing fees in another. At the end of the day, the fee structure that the Agency finalizes, must result in the collection of funds sufficient to defray “approximately but not more than 25 percent” of the costs to the Administrator of carrying out section 4, 5, 6, and of collecting, processing, reviewing, and providing access to and protecting from disclosure as appropriate under section 14.

Because of the different costs associated with the different fee triggering events, the Agency chose to start by differentiating fees among the 8 categories discussed in Table 6. Fees for each triggering activity were then calculated for each of these separate fee categories using the following mathematical expression:

$$\text{User Fee}_{\text{cat } x} = \frac{(\text{Program Costs}_{\text{cat } x}) \times (1 + \text{Indirect Cost Factor})}{\# \text{ Submissions}_{\text{cat } x}}$$

Where:

**cat x** = category of similar types of submissions from manufacturers and processors requiring similar effort and burden on the part of EPA.

**Program Costs** = All EPA intramural costs and extramural costs associated with a particular category of similar submission types under TSCA section 4, 5 or 6.

6. *Amount of fees.* EPA used the formula in Unit III.B.5. to calculate the fees per submission

for each fee category. However, the Agency needed to further adjust the fees to ensure that 25% of the costs of administering TSCA sections 4, 5, 6 and 14 would be collected in any given year (i.e., approximately \$20.05 million annually in fiscal year 2019 through 2021). Because the Agency includes the costs of administering TSCA section 14, risk management activities under section 6, prioritization of chemicals for evaluation and ORD support for alternative testing and methods development\enhancement in the costs, but can't collect a specific fee for these actions, the Agency calculated fees at 33% of the associated costs for TSCA sections 4, 5 and 6, as a baseline to ensure collecting 25% of costs and then adjusted the fees from there.

During the public meeting in August 2016 and the Industry-specific consultation meeting in September 2016, some commenters suggested that the bulk of the Agency's cost recovery should fall under TSCA section 6. About half of the industry commenters explicitly opposed assessment of fees for submission of information under TSCA section 4. Several of these and other commenters were willing to consider fees for TSCA section 4 submissions, but only to account for the Agency's effort to review the data from these submissions and only if the fees were kept to a nominal amount, representing a minimal portion of EPA'S overall cost recovery. Further, commenters requested that the Agency consider impacts of fees on innovation and competitive standing.

EPA considered a number of options for setting fee levels taking into account feedback received during the consultation with industry stakeholders. With respect to the section 4 fees, the Agency is proposing to set fee levels for each subcategory at roughly 3.5% of the activity cost. This low fee level relative to program costs was chosen in part to take into account the fact that manufacturers and processors are investing resources already in conducting the testing yet recognizes that the Agency does expend resources issuing orders and reviewing data under this section of the statute (Ref. 5).

With respect to the section 5 fees, the Agency is proposing to set two basic fee levels as mentioned above. The Agency is proposing to set fee levels for each notice subcategory at roughly 29% of the activity cost. Exemption category fees were then set at roughly 1/3 of the PMN amount which accounts for approximately 89% of the cost of the activity (Ref. 5).

To make up the difference in funds that would not be collected under TSCA section 4 or 5 based on these proposed fee levels, the Agency proposes to set the risk evaluation fee to be approximately 35% of the costs of those (Ref. 5). Overall, that results in the bulk of the fees expected to be collected under this proposed allocation coming from manufacturers of chemicals subject to EPA-initiated risk evaluations. The Agency considered this approach in part to try to set section 5 fees at levels that would minimize the potential impact on innovation and competitive standing.

TSCA states the percentage of costs to be collected for manufacturer-requested risk evaluations. Namely, TSCA specifies that manufacturers be assessed fifty percent of the costs of a risk evaluation for a chemical on EPA's Work Plan and 100 percent of the costs incurred by the Agency to conduct a risk evaluation for a chemical not on the Work Plan.

The fee amounts being proposed today are summarized in Table 6.

**Table 6: Proposed TSCA User Fees**

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

Enforceable consent agreement	\$22,800
<b>TSCA Section 5</b>	
PMN and consolidated PMN	\$16,000
SNUN	
MCAN and consolidated MCAN	
LoREX	\$4,700
LVE	
TME*	
Tier II exemption	
TERA	
Film Articles	
<b>TSCA Section 6</b>	
EPA-initiated risk evaluation	\$1,350,000
Manufacturer-requested risk evaluation on a chemical included in the Work Plan	\$1,300,000
Manufacturer-requested risk evaluation on a chemical <u>not</u> included in the Work Plan	\$2,600,000

\*EPA is proposing to waive the TME fee for submissions from companies that have graduated from EPA's Sustainable Futures program.

The Agency is interested in hearing from stakeholders regarding this approach for setting fees for the different categories of activities.

EPA's Sustainable Futures program encourages chemical developers to use the Agency's models and methods to screen new chemicals for potential risk early in the development process, with the goal of producing safer chemicals more reliably and more quickly, saving time and money, and in turn, getting safer chemicals into the market. Companies that graduate from Sustainable Futures can earn expedited review of TSCA section 5 for prescreened new chemical notices. Prescreening chemicals for hazard concerns helps companies anticipate and avoid developing chemicals of concern. As described in the **Federal Register** Notice announcing Sustainable Futures (Ref. 9), the expedited review is achieved by allowing the graduate's submission to be considered both as a PMN and a TME. The graduate simultaneously submits two separate notices, the PMN, MCAN or SNUN and the TME, as a combined Sustainable Futures submission. The advantage of the simultaneous submission is that the case will be considered a TME and the submitter will be able to manufacture at day 45 instead of having to wait until the PMN 90-day review period ends. This in effect cuts the review time in half. EPA would like to encourage companies to graduate from the Sustainable Futures program and is proposing to waive the TME fee for submissions from graduates that come in with a valid PMN, MCAN or SNUN. In fiscal year 2016, 13 Sustainable Futures graduates accounted for 7.6% of the PMNs, 37.5% of MCANs and 0% of SNUNs submitted to the Agency.

The annualized fees estimated to be collected under this proposed approach total approximately \$20.05 million in fiscal year 2019 through 2021, with an additional \$3.5 million in annualized fees expected from manufacturer-requested chemical risk evaluations during the three-year period. While TSCA section 6(b)(4)(E)(ii) sets minimum requirements on the number of ongoing

manufacturer-requested risk evaluations if EPA receives a sufficient number of compliant requests (25% of the number of ongoing EPA-initiated chemical risk evaluations), we do not expect to receive a sufficient number of manufacturer requests over the next three years to meet this threshold. Manufacturers are likely to wait until the initial chemical risk evaluations are completed to see how the process plays out. The Agency estimates receiving a total of five manufacturer requests for chemical risk evaluations during the next three years – two for risk evaluations on Work Plan chemicals and three for risk evaluations on chemicals not included in the Work Plan.

In developing this proposal, the Agency considered its experiences in implementing its fee collection program for pesticide registration actions. Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) amendments passed by Congress in 2004 created a registration service fee system for applications for specific pesticide registration, amended registration, and associated tolerance actions.

Activities conducted as part of the pesticide registration program and those to be conducted as part of the new chemical approval review program are similar in many respects. Both involve applications to the Agency to make a risk determination for a chemical substance prior to its introduction into the marketplace. In each program, the Agency conducts an independent evaluation of potential risks presented by the proposed uses of the chemical based on the best available scientific information and in the event that risks are identified seeks to manage those risks as needed through various mitigation strategies.

In conducting this analysis, the Agency recognizes that while there are valuable insights to be gained from its experiences implementing PRIA for the past 13 years that there are also important differences that also need to be understood when applying lessons learned from that program to a fee collection program under TSCA. One difference is that comprehensive data requirements have been established for pesticide registration applications under 40 CFR 158

whereas similar data requirements are not in place for chemical substances under TSCA.

Another difference is the time frames allowed for making a determination on a pesticide registration application vs. reviews of chemical substances. The time frames for pesticide registration decisions vary significantly based on the type of application being submitted to the Agency. For a new pesticide active or inert ingredient, the closest relatable set of categories to a new chemical under TSCA, the time frames for a decision range from 8 to 24 months. Under TSCA, the Agency has a shorter time frame, 90 days with possible extension to 180 days, in which to make a decision on most new chemicals. The length of the decision time frames can have an impact on the queuing of actions and resources in that having to conduct a similarly scoped review in a shorter time period would be more resource intensive.

In seeking to benchmark the fees being proposed for new chemical activities under TSCA, the Agency compared expected level of effort for a new chemical review to PRIA categories which might be expected to have a similar level of effort. EPA focused on the categories for the registration of new active ingredients in pesticides. The time frames associated with these reviews range from 8 months (new inert ingredient not for use on food) to 24 months (several categories). The fees for these categories range from \$11,025 for a new non-food inert ingredient to \$627,568 for a new conventional active ingredient for use on food crops. The most analogous PRIA categories to a new chemical review under TSCA based on data and/or the nature of the assessments needed are believed to be: PRIA Category I004- Approval of new non-food use inert ingredient (\$11,025 fee and 8-month review period), and PRIA Category B600 - New biopesticide active ingredient; non-food use (\$19,146 fee and 13-month review period). The fees identified in this proposal for new chemicals fall within the range of these analogous categories.

Considering the 90-day review period for a new chemical under TSCA, the Agency also considered PRIA categories with a similar decision time frame. Only six of the 189 PRIA categories

have decision time frames of three months. One of these is to repackage an existing end use product as a manufacturing use product with identical uses (a relatively small change to a product label with no data review) while the others are for reviewing a single study protocol, reviewing a rebuttal to an Agency protocol review or to make a preliminary determination on a waiver request for a biopesticide. Each have a fee of \$2,530. All of these categories are very limited in terms of data review and the scope of the decision to be made and would not be considered analogous to a new chemical determination under TSCA.

*C. What other options were considered?*

In addition to the proposed fee structure, the Agency considered two other methodologies for calculating user fees. Option A involved setting the fees for each fee category at 33% of the estimated costs to the Agency in conducting work associated with that particular activity without further adjustment. In this option, fees for test orders, test rules, and enforceable consent agreements are considerably higher than the fees being proposed today and new chemical notices fees are increased while risk evaluations and new chemical exemptions are lower.

The Agency also considered an approach, Option B, in which test orders, test rule and ECA fees were set at 10% of the estimated costs to the Agency but PMN fees were set based on the inflation-adjusted amount of currently existing fees. That resulted in lower PMN, MCAN, and SNUN fees. Exemption fees were set at 1/3 the amount of the PMN fees. To make up the difference, EPA adjusted the risk evaluation fees resulting in an increase in risk evaluation fees to approximately 43% of the estimated costs to the Agency. See Table 7 for a summary of alternate fees associated with Alternate Options A and B.

**Table 7: Other Alternative TSCA User Fees Considered**

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<b>ALTERNATIVE FEE CATEGORY</b>	<b>ALTERNATE FEE "A"</b>	<b>ALTERNATE FEE "B"</b>
<b>TSCA Section 4</b>		
Test order	\$92,000	\$28,000
Test rule	\$278,000	\$84,000
Enforceable consent agreement	\$215,000	\$65,000
<b>TSCA Section 5</b>		
PMN and consolidated PMN		
SNUN	\$18,200	\$10,400
MCAN and consolidated MCAN		
LoREX		
LVE		
TME	\$1,850	\$3,500
Tier II exemption		
TERA		
<b>TSCA Section 6</b>		
EPA-initiated risk evaluation	\$1,280,000	\$1,670,000
Manufacturer-requested risk evaluation on a chemical included in	\$1,300,000	\$1,300,000

the Work Plan		
Manufacturer-requested risk evaluation on a chemical <u>not</u> included in the Work Plan	\$2,600,000	\$2,600,000

The annualized fees estimated to be collected under these alternative approaches are approximately the same as those estimated to be collected under the approach being proposed today.

*C. How did EPA take into account small business concerns?*

EPA is proposing reduced fees for small businesses. These reduced fees are summarized in Table 8.

**Table 8: Proposed TSCA User Fees for Small Businesses**

PROPOSED FEE CATEGORY	PROPOSED SMALL BUSINESS FEE
<b>TSCA Section 4</b>	
Test order	\$1,950
Test rule	\$5,900
ECA	\$4,600
<b>TSCA Section 5</b>	
PMN and consolidated PMN	
SNUN	\$2,800

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

EPA set the proposed small business fees at an 80% reduction compared to the base fee for each category. In one case, for PMN and related actions, the proposed small business fee reduction is 82.5%. This slightly higher percentage reduction is due to the concern for the potential impact on small businesses of higher fee levels. The proposed small business fees for each category fee is only triggered when there is one entity subject to the fee, and that entity is a small business or if there is a consortium paying the fee and all members of that consortium are small businesses. By way of comparison, PRIA fees may be reduced for small businesses by a maximum of 75% under certain

conditions.

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

The Agency is proposing several changes to this definition. Consistent with the definition of small manufacturer or importer at 40 CFR 704.3, EPA proposes to increase the current revenue threshold of \$40 million using the Producer Price Index (PPI) for Chemicals and Allied Products, as compiled by the U.S. Bureau of Labor Statistics. [Data series WPU06 at <http://data.bls.gov/cgi-bin/srgatet>.] Using a base year of 1988 and inflating to 2015 dollars results in a value of approximately \$91 million (Ref. 10).

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

The Agency is seeking comment on this approach and is specifically interested in comment on whether an employee-based size standard would be more appropriate than a receipts-based size

standard and what that employee level should be; whether the size standard, be it receipts-based or employee-based, should vary from industry to industry to reflect differences among the impacted industries; and what other factors and data sources the Agency should consider, besides inflation, when developing the size standard to qualify for reduced fee amounts.

Further, with respect to small business size standards, the Agency has recently committed to revisiting the definition of small businesses as it relates to the TSCA section 8(a) data reporting regulations (82 FR 56824). Due to the urgent need for the Agency to promulgate this regulation and expeditiously collect the fees, the Agency believes that upcoming rulemaking will provide a venue for a more expansive consideration of appropriate size standards for industries subject to TSCA and offer the public with further opportunities to comment on the size standard. In addition to considering comments submitted in response to this proposal, the Agency is committed to evaluating the results of the 8(a) rulemaking process and, in the event that the reporting and fee standards differ, to determine if the size standards set through that process should be harmonized with the small business definition for fees. This harmonization could be implemented in a subsequent rulemaking for the next three-year fee cycle (FY22- FY25).

*D. How Would the Agency Handle Fees from Multiple Parties?*

Not every person subject to this rule must individually submit fees to EPA. TSCA section 26(b)(4)(C) allows for payment of fees by consortia of manufacturers and processors. EPA is proposing to allow joint submissions under TSCA section 5 and is permitting the formation of, and payment by, consortia for submissions under TSCA sections 4 and 6. Joint submitters of a TSCA section 5 notice would be required to remit the applicable fee identified in paragraph (b) of this section for each section 5 notice submitted. Only one fee is required for each submission, regardless of the number of joint submitters for that notice. To qualify for the fee identified in paragraph (b)(1)

of this section, each joint submitter of a TSCA section 5 notice must qualify as a small business concern under §700.43. This approach aligns with comments received from industry during the consultation process.

Any consortium formed to jointly submit TSCA user fees would be expected to notify EPA of such intent. Once established, it would be up to the consortium to determine how the user fee would be split among the members. EPA strongly encourages consortia to set lower fees for small business concerns; Congress intended small business to be afforded lower fee payments (TSCA 26(b)(4)(A)).

If, after 30 days, a consortium is unable to reach agreement on splitting the user fee, the principal sponsor must notify EPA, so EPA can calculate the individual fee for each consortium member. The Agency proposes to divide the total fee by the number of members. Small businesses will be afforded an 80% discount, which the remaining consortium members will be required to cover in equal amounts. EPA requests comment on this default approach.

#### *F. What Methods of Payment Would Be Accepted?*

The U.S. Department of the Treasury has determined that federal agencies should move away from receiving payments by check, and transition to electronic methods of payment. EPA proposes to accept payment of fees through two different electronic payment options: Pay.gov and Fedwire.

Pay.gov is a secure government-wide collection portal that helps federal agencies meet the directives outlined in the Government Paperwork Elimination Act (P. L. 105-277) (Ref. 11), primarily by reducing the number of paper transactions and utilizing electronic transaction processing.

Pay.gov, accessible online at <http://www.pay.gov>, currently processes payments for hundreds of

federal government agencies. It provides a full suite of services, allowing federal agencies to process collections quickly and easily; it also provides reports that can assist in integrating information into other financial systems. Pay.gov provides customers the ability to electronically complete forms and make payments twenty-four hours a day. Because the application is web-based, customers can access their accounts from any computer with internet access.

Fedwire is generally used for foreign payments. With this method of electronic payment, payers authorize a financial institution to initiate an electronic (wire transfer) payment to the Federal Reserve Bank of New York. Credit Gateway, which is operated by a commercial bank, then allows federal agencies to access their money from Fedwire. Credit Gateway processes transactions and settles them at Federal Reserve Banks.

EPA proposes that those subject to fees could use any payment method of their choice supported by the Department of the Treasury's Pay.gov electronic payment collection services (or any applicable alternative or successor to Pay.gov developed by Treasury) or Fedwire, as long as EPA's financial tracking systems are able to obtain and process the selected method of payment. Specifically, manufacturers and processors would be expected to create payment accounts in Pay.gov and use one of the electronic payment methods currently supported by Pay.gov (e.g., Automated Clearing House debits (ACH) from bank accounts, credit card payments, debit card payments, PayPal or Dwolla) or use Fedwire to authorize an electronic payment. Because Pay.gov and Fedwire do not accept paper checks as payment, EPA will not accept paper checks as payment for TSCA services. Additional instructions for making payments to EPA using Pay.gov and Fedwire are found at <https://www.epa.gov/financial/additional-instructions-making-payments-epa>. The Agency requests comment on this approach.

### *G. When Would Payment of Fees Be Required?*

There is precedent for advance payments of user fees in several of the Agency's existing user fee programs. For example, EPA's Office of Pesticide Programs and EPA's Office of Air and Radiation fee programs typically require advance payment prior to administering program services involving the review of applications for the various certifications and registrations administered by those programs. This follows the guidance outlined in OMB Circular No. A-25, which states that user charges will "be collected in advance of, or simultaneously with, the rendering of services." (Ref. 3)

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

EPA is proposing to allow fee submitters for test orders, test rules, ECAs and EPA-initiated chemical risk evaluations time to associate with a consortium and work out fee payments within that consortium. Payment for fee categories under TSCA section 4 (i.e., test orders, test rules and ECAs) is due within 60 days of the effective date of the order or rule, or 60 days upon signing of an enforceable consent agreement. For EPA-initiated risk evaluations, full payment is due within 60 days of EPA publishing the final scope of a chemical risk evaluation. EPA believes this provides sufficient time for manufacturers to associate as a consortium, if they so choose, and to decide on the partial fee payments each member of the consortium will be responsible for. 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 to collect a fee when EPA

grants the request to conduct the evaluation. Payment will be required within 30 days of EPA providing such notice.

EPA is also proposing that user fees will begin to be incurred starting on October 1, 2018. As discussed above, TSCA section 26(b)(4)(F) requires EPA, “beginning with the fiscal year that is 3 years after the date of enactment [June 22, 2016],” to adjust fees as necessary so they are sufficient to defray a portion of EPA’s costs. Since Congress expected fees to already be in place by October 1, 2018 such that they may need adjusting, EPA believes it is reasonable for all actions for which a fee is proposed to be subject to fees as of October 1, 2018. EPA will not, however, collect any fees until the final rule resulting from this proposal is effective. Instead, EPA intends to record actions that would be expected to trigger payment of fees and once the rule is final send invoices to the affected parties indicating. The invoices would reflect timing for payments and amounts based on the final rule.

#### *H. Under What Circumstances will EPA Refund Payments?*

EPA will continue to refund any fee paid for a section 5 notice whenever EPA determines that the notice or fee was not required. See, e.g., 40 CFR 720.62. This can happen, for example, when the intended use described in the PMN is not actually subject to TSCA jurisdiction or when the substance is already on the Inventory.

TSCA section 26(b)(4)(G) permits EPA to refund fees, or a portion of fees, for notices submitted under TSCA section 5 that are later withdrawn and for which the Agency conducts no substantive work unless the Agency determines that the submitter unduly delayed the process. EPA proposes to refund a consistent 75% of the user fee to the submitter if the notice is withdrawn within 10 business days. This percentage is consistent with the approach for refunds for withdrawn

actions under PRIA. Beyond ten business days, EPA is likely to have already conducted substantial review work that qualifies as substantive work for which no refund is authorized under TSCA 26(b)(4)(G). Up to three significant milestones of the PMN review process can take place within 10 business days. The Chemical Review/Search Strategy Meeting occurs between Day 8 and 12; the Structure Activity Team Meeting occurs between Day 9 and 13; and Development of Exposure/Release Assessments occurs between Day 10 and 19. EPA feels that tying the refund time period to a certain number of days is a simpler and more efficient approach than tying it to a specific milestone of the review process.

EPA does not have authority to, and therefore will not, provide refunds under any other circumstances.

*I. What are the Consequences of Failing to Pay a Fee?*

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

*J. Compliance Date*

EPA is proposing to start collecting fees the day after the final TSCA user fees regulations are

published in the **Federal Register**. Stakeholders were provided notice during public meetings in August of 2016 requesting comment through EPA Docket: EPA -HQ -2016-0401 and indicating that the Agency intended to start collecting new fees for TSCA section 4 and section 6 activities and that fees associated with the submission of notices under TSCA section 5 would increase. EPA believes that we have provided sufficient notice to, and opportunity for, industry to provide comment regarding the user fees. (See Unit II.C. titled, "Stakeholder Involvement".) Furthermore, for EPA to sufficiently address the increased workload under TSCA as amended in June 2016, the Agency must start collecting fees as soon as possible for use in defraying some of the costs of activities spelled out in TSCA section 26 paragraph (b)(1). EPA is seeking comment on this approach.

*K. What Other Amendments Are Being Proposed?*

EPA is proposing minor changes to several of its regulations that cross-reference the part 700 fees regulations, specifically parts 720, 723, 725, 790 and 791. Amending the regulatory text in these parts will ensure that existing regulations appropriately reference the regulatory text being proposed. EPA is proposing minor updates for implementing the fee requirements for test marketing exemptions at §720.38; premanufacture notification regulations at §720.45(a)(5); instant photographic and peel-apart film articles exemptions at §723.175; amendments to regulations covering MCANs and exemption requests at §725.25 and §725.33; minor amendments at §790.45 and §790.59; and a modification to the general provisions for data reimbursement found at §791.39.

**IV. Projected Economic Impacts of TSCA User Fees**

EPA has evaluated the potential costs for manufacturers and processors of chemical substances for this proposed rule. Overall, EPA developed eight fee categories for activities under TSCA sections 4, 5, and 6. TSCA section 4 fee categories include test orders, test rules, and ECAs.

TSCA section 5 fee categories include PMNs and consolidated PMNs, SNUNs, MCANs and consolidated MCANs, LoREXs, LVEs, TMEs, Tier II exemptions and TERAs. Finally, TSCA section 6 fee categories include Agency-initiated risk evaluations, manufacturer-requested risk evaluations for Work Plan chemicals, and manufacturer-requested risk evaluations for non-Work Plan chemicals.

For the baseline, EPA used a historical average of the 2013 through 2016 submissions for each TSCA section 5 action (Ref. 12) as the estimate of the number of submissions per fee category for the next three years. TSCA section 4 test orders are new under TSCA and the average number of such actions expected per year represents an EPA estimate. For the other TSCA section 4 actions (test rules and ECAs), EPA also estimated the expected number of such actions per year. The amended TSCA regulations specify the number of risk evaluations that EPA must have ongoing over the next three years. EPA uses the mandated number of risk evaluations to estimate the cost of the proposed rule for TSCA section 6 activities. Under the recent amendments to TSCA, EPA assumes that the number of TSCA section 4 activities (test rules and ECAs) would change from the baseline as the Agency seeks additional test data and information on chemical substances, TSCA section 5 activities would decrease as a result of higher fees and the new statutory requirement for affirmative determination, and TSCA section 6 risk evaluations initiated over the next several years would increase before leveling off in accordance with statutory requirements. 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. The Agency seeks comment on these assumptions.

EPA estimates the total fee collection by multiplying the proposed fees with the number of expected activities under full implementation for each section. For test rules and ECAs, EPA has not promulgated any in the recent past and has estimated the number of activities that EPA will likely

need to issue to meet our requirements. EPA based the estimates of the future number of TSCA section 5 submissions on the historical number of submissions for all TSCA section 5 notices and exemptions. EPA further assumes that the number of submissions under each TSCA section 5 fee category will decline by approximately 10% as a result of (a) higher fees on PMNs, MCANs, and SNUNs; (b) new fees for exemption notices; and (c) the requirement that EPA make an affirmative determination on every new chemical. Previously, new chemicals could enter the marketplace unless EPA made a specific determination that regulatory controls were needed. Now, an affirmative safety determination must be made before a new chemical can enter the marketplace and before a significant new use is allowed for an existing chemical. EPA's assumption that there will be a 10% decrease in submissions under TSCA section 5 follows the same assumption made back in 1987 when TSCA section 5 fees were first proposed (Ref. 12).

TSCA section 6 risk evaluations are a new activity under the amended TSCA. In the past, EPA developed risk assessments. This risk assessment process has been replaced by risk evaluations and EPA uses manufacturer data for the first 10 chemicals identified for this process to estimate the average number of impacted firms per chemical and proportion of firms impacted that are small businesses.

The annualized fees collected from industry for the proposed option (identified as Option C in the Economic Analysis (Ref. 2)) are approximately \$20.05 million. This total does not include the fees collected for manufacturer-requested risk evaluations. Total fee collections were calculated by multiplying the estimated number of actions per fee category anticipated each year, by the corresponding proposed fee. For the proposed option, TSCA section 4 fees account for less than one percent of the total fee collection, TSCA section 5 fees for approximately 43 percent, and TSCA section 6 fees for approximately 56 percent. Annual fees collected by EPA are expected to total approximately \$20.05 million.

Under the proposed option, the total fees collected from industry for a risk evaluation requested by manufactures are estimated to be \$1.3 million for chemicals included in the Work Plan and \$2.6 million for chemicals not included in the Work Plan.

For small businesses, EPA estimates that 18.5 percent of TSCA section 5 submissions will be from small businesses that are eligible to pay discounted fees because they have average annual sales of less than \$91 million in the three preceding years. Total annualized fees for TSCA section 5 collected from small businesses are estimated to be \$550,000 (Ref. 2).

For TSCA sections 4 and 6, discounted fees for eligible small businesses and fees for all other affected firms may differ over the three-year period that was analyzed, since the fee paid by each firm is dependent on the number of affected firms per action. Based on past TSCA section 4 actions and data related to the first ten chemicals identified for risk evaluations under TSCA as amended, EPA estimates annualized fees collected from small businesses for TSCA section 4 and TSCA section 6 to be approximately \$37,000 and \$2.6 million, respectively.

For each of the three years to be covered by this proposed rule, EPA estimates that total fees paid by small businesses will account for about 16 percent of the approximately \$20.05 million fees to be collected for TSCA sections 4, 5, and 6 actions. The annualized total industry fee collection for small businesses is estimated to be approximately \$3.2 million.

For this proposed rule, affected manufacturers (including importers) and processors of chemical substances would be required to pay a specified user fee to be established for actions regulated under TSCA. The fees to be paid by industry would defray the cost for EPA to administer TSCA sections 4, 5, 6, and 14. Absent this proposed regulation, EPA costs to administer these sections of TSCA would be borne by taxpayers through budget appropriations from general revenue.

As a result of this proposed rule, 25% of EPA costs to administer TSCA section 4, 5, 6, and 14 and activities paid from general revenue would be transferred via the user fees to industry. Although these user fees may be perceived by industry as direct private costs, from an economic perspective, they are transfer payments 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 proposed rule, determine their eligibility for paying reduced fees, notify EPA of participation in a consortium, and arrange to submit fee payments. The total social cost of the proposed rule also includes the additional costs to EPA to administer TSCA sections 4, 5, 6, and 14.

The total opportunity cost to industry is approximately \$58,000 and the additional Agency burden is approximately \$1,000, yielding a total social cost of approximately \$59,000 for this proposed rule.

## **V. Request for Comments**

### *A. Affected Industry*

EPA is specifically seeking additional information and data that the Agency could consider in developing the final economic analysis. In particular, EPA is seeking data that could facilitate EPA's further evaluation of the potentially affected industry and firms, including data related to potential impacts on those small businesses that would be subject to user fees.

### *B. User Fees Categories*

EPA seeks comments on all aspects of the fee categories being proposed for manufacturers and processors in Unit III.B.4 and welcomes comments on how the various fees and fee categories

discussed could be combined in different ways to achieve an overall fee structure amounting to 25% of the Agency's costs to administer TSCA sections 4, 5, 6 and 14.

In addition, the Agency would appreciate specific comments on the decision to not include a fee category for risk management under TSCA section 6(a) and the decision to eliminate the existing intermediate PMN fee category, which currently provides a discount to manufacturers who submit intermediate PMNs at the same time as a final PMN. The Agency will still accept intermediate PMN submissions, but will charge a full PMN fee for each chemical. We recognize there may be minimal efficiencies with intermediate submissions submitted at the same time as a final PMN and are seeking comment on the elimination of this fee category for PMN submissions.

The Agency is interested in comments on the fee amounts being proposed today, as well as the alternative fees considered; proposed and alternative fee amounts are shown in Table 9. EPA is also interested in comments on the proposal to waive exemption fees on TMEs submitted at the same time as a PMN, SNUN, or MCAN from a company that has graduated from the Agency's Sustainable Futures program.

**Table 9: Comparison of Proposed TSCA User Fees and the Alternative**

**Fees Considered**

<b>PROPOSED FEE CATEGORY</b>	<b>PROPOSED FEE</b>	<b>ALTERNATE FEE "A"</b>	<b>ALTERNATE FEE "B"</b>
<b>TSCA Section 4</b>			
Test order	\$9,800	\$92,000	\$28,000
Test rule	\$29,500	\$278,000	\$84,000

Enforceable consent agreement	\$22,800	\$215,000	\$65,000
<b>TSCA Section 5</b>			
PMN and consolidated PMN	\$16,000	\$18,200	\$10,400
SNUN			
MCAN and consolidated MCAN			
LoREX	\$4,700	\$1,850	\$3,500
LVE			
TME			
Tier II exemption			
TERA			
<b>TSCA Section 6</b>			
EPA-initiated risk evaluation	\$1,350,000	\$1,280,000	\$1,670,000
Manufacturer-requested risk evaluation on a chemical included in	\$1,300,000	\$1,300,000	\$1,300,000

the Work Plan			
Manufacturer- requested risk evaluation on a chemical <u>not</u> included in the Work Plan	\$2,600,000	\$2,600,000	\$2,600,000

### *C. Small Business Concerns*

EPA is proposing several changes to the size standard used to identify businesses that can qualify as a “small business concern” for purposes of fees and seeks comment on the proposed approach as discussed in Unit III. The Agency is also interested in comments on the reduced fee amounts being proposed for those businesses that can qualify as a “small business concern.”

The Agency is seeking comment on this approach and is specifically interested in comment on whether an employee-based size standard would be more appropriate than a receipts-based size standard and what that employee level should be; whether the size standard, be it receipts-based or employee-based, should vary from industry to industry to reflect differences among the impacted industries; and what other factors and data sources the Agency should consider, besides inflation, when developing the size standard to qualify for reduced fee amounts.

Further, with respect to small business size standards, the Agency has recently committed to revisiting the definition of small businesses as it relates to the TSCA Section 8(a) data reporting regulations (82 FR 56824). Due to the urgent need for the Agency to promulgate this regulation and expeditiously collect fees, the Agency believes that upcoming rulemaking will provide a venue for a

more expansive consideration of appropriate size standards for industries subject to TSCA and offer the public with further opportunities to comment on the size standard. In addition to considering comments submitted in response to this proposal, the Agency is committed to evaluating the results of the 8(a) rulemaking process and, in the event that the reporting and fee standards differ, to determine if the size standards set through that process should be harmonized with the small business definition for fees. This harmonization could be implemented in a subsequent rulemaking for the next three-year fee cycle (FY22- FY25).

#### *D. Electronic Payment of Fees*

The Agency is interested in comments pertaining to the electronic payment of fees. If, for some reason, neither Pay.gov nor Fedwire meets the needs of those required to pay user fees, the Agency would appreciate the identification of other appropriate electronic payment methods to consider.

## **VI. 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. 2016. The Frank R. Lautenberg Chemical Safety for the 21st Century Act. June 22, 2016.
2. 2017. EPA. Economic Analysis for the TSCA Section 26(b) Proposed Fees Rule. December

2017.

3. 1993 OMB. Circular No. A-25 Revised. July 8, 1993.

4. 2008. GAO. Federal User Fees: A Design Guide. Report to Congressional Requesters. GAO-08-386SP. May 2008.

5. 2017. EPA. Technical Background Document for TSCA Fees. December 2017.

6. 2017. EPA. Statistics for the New Chemicals Review Program under TSCA.

*<https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/statistics-new-chemicals-review>*.

7. 2017. EPA. Interagency Agreement and Oil Indirect Cost Rates for FY 2018 and Beyond. September 28, 2017.

8. 1983. EPA. 48 FR 21722, 27134-35.

9. 2002. EPA. 67 FR 238. Sustainable Futures – Voluntary Pilot Project Under the TSCA New Chemicals Program.

10. 2016. Abt Associates. Memorandum: Inflation of Small Business Definition under section 5 of TSCA. August 31, 2016.

11. 1998. Government Paperwork Elimination Act. P.L. 105-277.

12. 1987. EPA. Proposed Fees for Processing Premanufacture Notices, Exemption Applications and Notices, and Significant New Use Notices. 42 FR 12940.

13. 2017. 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]). December 2017.

## **VII. 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. 2), which is available in the docket and discussed in Unit IV.

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

This action is expected to be subject to the requirements for regulatory actions specified in Executive Order 13771 (82 FR 9339, February 3, 2017). Details on the estimated costs of this proposed rule can be found in EPA's analysis (Ref. 2) of the potential costs and benefits associated with this action, which is available in the docket and is summarized in Unit IV.

### *C. Paperwork Reduction Act (PRA)*

The information collection requirements in this proposed rule have been submitted to OMB for review and approval under the PRA, 44 U.S.C. 3501 *et seq.* The Information Collection Request (ICR) prepared by EPA has been assigned EPA ICR number 2569.01. You can find a copy of the ICR in the docket for this proposed rule (Ref. 13), and it is briefly summarized here.

The information collection activities associated with the proposed rule include familiarization with the regulation, small business discount eligibility determination, informing EPA of participation in consortia, and electronic payment of fees through *Pay.gov* or Fedwire.

*Respondents/affected entities:* Persons who manufacture, distribute in commerce, use, dispose, process a chemical substance (or any combination of such activities) and are required to submit information to EPA under TSCA sections 4, 5, or 6, or if you manufacture or process a chemical substance that is the subject of a risk evaluation under TSCA section 6(b).

*Respondent's obligation to respond:* Mandatory.

*Estimated number of respondents:* 1,414 respondents.

*Frequency of response:* On occasion to EPA as needed.

*Total estimated burden:* 740 hours (per year). Burden is defined at 5 CFR 1320.3(b).

*Total estimated cost:* \$59,540 (per year).

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 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 EPA using the docket identified at the beginning of this proposed rule. You may also send your ICR-related comments to OMB's Office of Information and Regulatory Affairs via email to [oir\\_submission@omb.eop.gov](mailto:oir_submission@omb.eop.gov), Attention: Desk Officer for EPA. Since OMB is required to make a decision concerning the ICR between 30 and 60 days after receipt, OMB must receive your ICR-related comments no later than [*insert date 30 days after date of publication in the **Federal Register***]. EPA will respond to any ICR-related comments with the final rule.

#### *D. Regulatory Flexibility Act (RFA)*

Pursuant to section 605(b) of the RFA, 5 U.S.C. 601 *et seq.*, I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. 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.

EPA has determined that 84 small businesses may be affected annually by section 4 actions; 190 small businesses may be affected by section 5 actions (164 may pay discounted fees and the remaining 26 would pay the general industry fee); and 24 small business firms may be affected by section 6 actions. As a result, EPA estimates that, of the 298 small businesses paying fees every year, all may have annual cost-revenue impacts less than 1%.

EPA continues to be interested in the potential impacts of this proposed rule on small entities that are required to pay user fees and welcomes comments on issues related to such impacts.

*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 does not significantly or uniquely affect small governments. As such, the requirements of sections 202, 203, 204, or 205 of UMRA, 2 U.S.C. 1531–1538, do not apply to this action.

*F. Executive Order 13132: Federalism*

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

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

This action does not have tribal implications because it will not have any effect 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).

*H. Executive Order 13045: Protection of Children from Environmental Health Risks 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. This action is proposing service fees for TSCA, which will not have a significant effect on the supply, distribution or use of energy.

*J. National Technology Transfer and Advancement Act (NTTAA)*

Since this action does not involve any technical standards, 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 human 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). This action does not affect the level of protection provided to human health or the environment.

When implemented, the user fees collected under this proposed rule will assist the Agency in carrying out various requirements under TSCA, including conducting risk evaluations, risk-based screenings, authorizing testing of chemical substances and mixtures, and evaluating and reviewing manufacturing and processing notices, as required under TSCA sections 4, 5, and 6. Although not directly impacting environmental justice-related concerns, the fees will enable the Agency to better

protect human health and the environment, including in low-income and minority communities.

### **List of Subjects**

#### *40 CFR Part 700*

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

#### *40 CFR Part 720*

Chemicals, Environmental protection, Hazardous substances, Imports, Reporting and recordkeeping requirements.

#### *40 CFR Part 723*

Chemicals, Environmental protection, Hazardous substances, Phosphate, Reporting and recordkeeping requirements.

#### *40 CFR Part 725*

Administrative practice and procedure, Chemicals, Environmental protection, Hazardous substances, Imports, Labeling, Occupational safety and health, Reporting and recordkeeping requirements.

#### *40 CFR Part 790*

Administrative practice and procedure, Chemicals, Confidential business information, Environmental protection, Hazardous substances, Reporting and recordkeeping requirements.

#### *40 CFR Part 791*

Administrative practice and procedure, Chemicals, Environmental protection, Hazardous substances, Reporting and recordkeeping requirements.

Dated: February 7, 2018,

E. Scott Pruitt, Administrator.

Therefore, EPA proposes to amend 40 CFR parts 700, 720, 723, 725, 790 and 791 as follows:

**PART 700--[AMENDED]**

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. Section 700.40 is revised to read as follows:

**§700.40 Purpose and applicability.**

(a) *Purpose.* The purpose of this subpart is to establish and collect fees from manufacturers (including importers) and processors to defray part of EPA's cost of administering the Toxic Substances Control Act (15 U.S.C. 2601-2692), as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act (P.L. 114-182).

(b) *Applicability.* This subpart applies to all manufacturers (including importers) and processors who are required to submit information under section 4 of the Act; who submit certain notices and exemption requests to EPA under section 5 of the Act; and who manufacture a chemical

substance that is subject to a risk evaluation under TSCA section 6(b)(4) of the Act.

(c) After [DATE 1 DAY AFTER PUBLICATION OF THE FINAL RULE IN THE **FEDERAL REGISTER**], all persons specified in §700.45 and paragraph (a) of this section must comply with this subpart.

3. Section 700.43 is amended by:

a. Revising the section heading;

c. Revising the introductory text;

d. Adding in alphabetical order definitions for “Consortium”, “Enforceable consent agreement”, and “EPA-initiated risk evaluation”;

e. Removing the definitions of “Exemption application” and “Intermediate premanufacture notice”;

f. Revising the definition of “Joint submitters”;

g. Adding in alphabetical order a definition for “Manufacturer-requested risk evaluation”;

h. Revising the definition of “Person”;

i. Adding in alphabetical order definitions for “Principal sponsor” and “Risk evaluation”;

i. Revising the definitions of “Significant new use notice” and “Small business concern”; and

k. Adding in alphabetical order definitions for “Test order” and “Test rule”.

The revisions and additions read as follows:

**§700.43 Definitions applicable to this subpart.**

Definitions in section 3 of the Act (15 U.S.C. 2602), as well as definitions contained in §§704.3, 720.3, 723.175(b), 725.3, and 790.3 of this chapter, apply to this subpart unless otherwise specified in this section. In addition, the following definitions apply:

\* \* \* \* \*

*Consortium* means an association of manufacturers (including importers) and/or processors who have made an agreement to jointly split the cost of applicable user fees.

\* \* \* \* \*

*Enforceable consent agreement* means a consent agreement used by EPA to accomplish testing where a consensus exists among EPA and interested parties (as identified in §790.22(b)(2)) concerning the need for and scope of testing under section 4 of the Act.

*EPA-initiated risk evaluation* means any risk evaluation conducted pursuant to section 6(b)(4)(C)(i) of the Act.

\* \* \* \* \*

*Joint submitters* mean two or more persons who submit a TSCA section 5 notice together.

*Manufacturer-requested risk evaluation* means any chemical substance risk evaluation conducted at the request of one or more manufacturers of that chemical substance pursuant to section 6(b)(4)(C)(ii) of the Act.

\* \* \* \* \*

*Person* means a manufacturer (including importer) or processor.

\* \* \* \* \*

*Principal sponsor* means a person who assumes primary responsibility for the direction of study, the payment of user fees to EPA, and for oral and written communication with EPA.

*Risk evaluation* means any risk evaluation conducted pursuant to section 6(b) of the Act.

\* \* \* \* \*

*Significant new use notice* or *SNUN* means any notice submitted to EPA pursuant to section 5(a)(1)(B) of the Act in accordance with part 721 of this chapter.

*Small business concern* means any person whose average total annual sales over the person's three fiscal years preceding the date the fee is assessed, when combined with those of the parent company (if any), are less than \$91 million.

*Test order* means an order to develop information pursuant to section 4(a) of the Act.

*Test rule* refers to a regulation requiring the development of information pursuant to section 4(a) of the Act.

4. Section 700.45 is revised to read as follows:

**§700.45 Fee payments.**

(a) *Persons who must pay fees.* (1) Manufacturers and/or processors submitting a TSCA section 5 notice to EPA shall remit for each such notice the applicable fee identified in paragraph (b) of this section in accordance with the procedures in paragraphs (d) and (e) of this section.

(2) Manufacturers and/or processors of chemical substances and mixtures required to test these chemical substance and mixtures under a TSCA section 4(a) test rule, test order, or enforceable consent agreement shall remit for each such test rule, order, or enforceable consent agreement the applicable fee identified in paragraph (b) of this section in accordance with the procedures in paragraphs (d) and (e) of this section.

(3) Manufacturers of chemical substances and mixtures required to test these chemical substance and mixtures under a TSCA section 4(a) test rule, test order, or enforceable consent agreement other than a test rule, test order, or enforceable consent agreement described in paragraph (a)(2) of this section shall remit for each such test rule, order, or enforceable consent agreement the applicable fee identified in paragraph (b) of this section in accordance with the procedures in paragraphs (d) and (e) of this section.

(4) 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 (b) of this section in accordance with the procedures in paragraphs (d) and (e) of this section. Manufacturers will be identified through the most current Chemical Data Reporting (CDR) submissions. While EPA will attempt to identify manufacturers through CDR data, failure to identify a manufacturer that is subject to a risk evaluation fee does not remove their obligation to pay the associated fee.

(b) *Fees for the 2019, 2020 and 2021 fiscal years.* Persons shall remit fee payments to EPA as follows:

(1) *Small business concerns.* Small business concerns shall remit fees as follows:

(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.

(ii) *Significant new use notice*. Persons shall remit a fee totaling \$2,800 for each significant new use notice (SNUN) submitted in accordance with part 721 of this chapter.

(iii) *Exemption application*. Persons shall remit a fee totaling \$940 for each of the following exemption requests submitted under section 5 of the Act:

(A) *Low releases and low exposures exemption* or *LoREX* request submitted to EPA pursuant to section 5(a)(1) of the Act in accordance with §723.50(a)(1)(ii) of this chapter.

(B) *Low volume exemption* or *LVE* request submitted to EPA pursuant to section 5(a)(1) of the Act in accordance with §723.50(a)(1)(i) of this chapter.

(C) *Test marketing exemption* or *TME* application submitted to EPA pursuant to section 5 of the Act in accordance with §§725.300 through 725.355 of this chapter.

(D) *TSCA Experimental Release Application* or *TERA* application submitted to EPA pursuant to section 5 of the Act for research and development activities involving microorganisms in accordance with §§725.200 through 725.260 of this chapter.

(E) *Tier II exemption* application submitted to EPA pursuant to section 5 of the Act in accordance with §§725.428 through 725.455 of this chapter.

(iv) *Instant photographic film article exemption notice*. Persons shall remit a fee totaling \$940 for each instant photographic film article exemption notice submitted in accordance with §723.175 of this chapter.

(v) *Microbial commercial activity notice and consolidated microbial commercial activity notice.*

Persons shall remit a fee totaling \$2,800 for each microbial commercial activity notice (MCAN) or consolidated MCAN submitted in accordance with §§725.25 through 725.36 of this chapter.

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

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

(2) *Others.* Persons other than small business concerns shall remit fees as follows:

(i) *PMN and consolidated PMN.* Persons shall remit a fee totaling \$16,000 for each PMN or consolidated PMN submitted in accordance with part 720 of this chapter.

(ii) *SNUN.* Persons shall remit a fee totaling \$16,000 for each significant new use notice submitted in accordance with part 721 of this chapter.

(iii) *Exemption applications.* Persons shall remit a fee totaling \$4,700 for each of the following exemption requests, and modifications to previous exemption requests, submitted under section 5 of the Act:

(A) *Low releases and low exposures exemption* or *LoREX* request submitted to EPA pursuant to section 5(a)(1) of the Act in accordance with §723.50 (a)(1)(ii) of this chapter.

(B) *Low volume exemption* or *LVE* request submitted to EPA pursuant to section 5(a)(1) of the Act in accordance with §723.50 (a)(1)(i) of this chapter.

(C) *Test marketing exemption* or *TME* application submitted to EPA pursuant to section 5 of the Act in accordance with §§725.300 through 725.355 of this chapter, unless the submitting company has graduated from EPA's Sustainable Futures program, in which case this exemption fee is waived.

(D) *TSCA Experimental Release Application* or *TERA* application submitted to EPA pursuant to section 5 of the Act for research and development activities involving microorganisms in accordance with §§725.200 through 725.260 of this chapter.

(E) *Tier II exemption* application submitted to EPA pursuant to section 5 of the Act in accordance with §§725.428 through 725.455 of this chapter.

(iv) *Instant photographic film article exemption notice*. Persons shall remit a fee totaling \$4,700 for each exemption notice submitted in accordance with §723.175 of this chapter.

(v) *MCAN and consolidated MCAN*. Persons shall remit a fee totaling \$16,000 for each MCAN or consolidated MCAN submitted in accordance with §§725.25 through 725.36 of this chapter.

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

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

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

(ix) *EPA-initiated chemical risk evaluation*. Persons shall remit a fee totaling \$1,350,000.

(x) *Manufacturer-requested risk evaluation of a Work Plan Chemical*. Persons shall remit a fee totaling \$1,300,000.

(xi) *Manufacturer-requested risk evaluation of a Non-Work Plan Chemical.* Persons shall remit a fee totaling \$2,600,000.

(c) *Fees for 2022 fiscal year and beyond.* (1) Fees for the 2022 and later fiscal years will be adjusted on a three-year cycle by multiplying the fees in paragraph (b) by the current PPI index value with a base year of 2019 using the following formula:

$$FA = F \times I$$

Where:

FA = the inflation-adjusted future year fee amount.

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

I = Producer Price Index for Chemicals and Allied Products inflation value with 2019 as a base year.

(2) Updated fee amounts for PMNs, SNUNs, MCANs, exemption applications 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 industry consultation prior to making fee adjustments. 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 webpage by the beginning of each three-year fee adjustment cycle (i.e., October 1, 2021, October 1, 2024, 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.

(d) *No fee required.* Persons are exempt from remitting any fee for Tier I exemption submissions under §725.424 and polymer exemption reports submitted under §723.250 of this chapter.

(e) *Multiple parties, including joint submitters and consortia.* (1) Joint submitters of a TSCA section 5 notice are required to remit the applicable fee identified in paragraph (b) of this section for each section 5 notice submitted. Only one fee is required for each submission, regardless of the number of joint submitters for that notice. To qualify for the fee identified in paragraph (b)(1) of this section, each joint submitter of a TSCA section 5 notice must qualify as a small business concern under §700.43 of this chapter.

(2) Any consortium formed to split the cost of the applicable user fee under section 4 of the Act is required to remit the appropriate fee identified in paragraph (b) of this section for each test rule, test order, or enforceable consent agreement regardless of the number of manufacturers and/or processors in that consortium. For the consortium to qualify for the fee identified in paragraph (b)(1) of this section, each person in the consortium must qualify as a small business concern under §700.43 of this chapter. Failure to provide notice or submit fee payment pursuant to this paragraph (e)(2) constitutes a violation by each consortium member.

(i) Notification must be provided to EPA that a consortium has formed. The notification must be accomplished within 30 days of the effective date of a test order or test rule under section 4 of the Act or within 30 days of the signing of an enforceable consent agreement under section 4 of the

Act. If timely notification has occurred, additional entities may join the consortia after the notification period.

(ii) Notification must be rendered in a .pdf file and submitted electronically via the Agency's electronic reporting software (e.g., Central Data Exchange (CDX)). The following information must be included:

(A) Full name, address, telephone number and signature of principal sponsor;

(B) Name(s) and contact information for each manufacturer and/or processor associating with the consortium.

(iii) It is up to the consortium to determine how fees will be split among the persons in the consortium.

(iv) Consortia are encouraged to set lower fees for small business concerns participating in the consortium.

(v) If a consortium is unable to come to terms on how user fees will be split among the persons in the consortium, the principal sponsor must notify EPA in writing before the user fee is due under paragraph (e)(2) of this section.

(vi) If a consortium provides notice to EPA under paragraph (e)(2)(v) of this section, EPA will assess fees to all persons of the consortium as described under paragraph (e)(4) of this section and provide an additional 30 days for those persons to submit fees.

(3) Any consortium formed to split the cost of the applicable user fee supporting a risk evaluation under section 6(b) of the Act is required to remit the appropriate fee identified in paragraph (b) of this section for each risk evaluation, regardless of the number of manufacturers in

that consortium. For the consortium to qualify for the fee identified in paragraph (b)(1)(vii) of this section, each person in the consortium must qualify as a small business concern under §700.43 of this chapter. Failure to provide notice or submit fee payment pursuant to this paragraph (e)(3) constitutes a violation by each consortium member.

(i) Notification must be provided to EPA that a consortium has formed. The notification must be accomplished within 30 days of the publication of the final scope of a chemical risk evaluation under section 6(b)(4)(D) of the Act or within 30 days of EPA providing notification to a manufacturer that a manufacturer-requested risk evaluation has been granted.

(ii) Notification must be rendered in a .pdf file and submitted electronically via the Agency's electronic reporting software (e.g., CDX). The following information must be included:

(A) Full name, address, telephone number and signature of principal sponsor;

(B) Name(s) and contact information for each manufacturer and/or processor associating with the consortium.

(iii) It is up to the consortium to determine how fees will be split among the persons in the consortium.

(iv) Consortia are encouraged to set lower fees for small business concerns participating in the consortium.

(v) If a consortium is unable to come to terms on how user fees will be split among the persons in the consortium, the principal sponsor must notify EPA in writing before the user fee is due.

(vi) If a consortium provides notice to EPA under paragraph (e)(3)(v) of this section, EPA will assess fees to all persons of the consortium as described under paragraph (e)(4) of this section and provide an additional 30 days for those persons to submit fees.

(4) If multiple persons are subject to user 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 user fee to be remitted by each person subject to the requirement. Each person's share of the applicable user fee specified in paragraph (b) of this section shall be in proportion to the total number of manufacturers and/or processors of the chemical substance, with lower fees for small businesses:

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

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

Where:

$P_s$  = the portion of the user fee under paragraph (b) 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 user fee owed by a person other than a small business concern.

$F$  = the total user fee required under paragraph (b) of this section.

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

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

(5) If multiple persons are subject to user fees triggered by section 4 or 6(b) of the Act and some inform EPA of their intent to form a consortium while others choose not to associate with the consortium, EPA will determine the portion of the total applicable user fee to be remitted by each person outside the consortium and by the consortium, per paragraph (e)(4) of this section. For purposes of calculating the portion of the total applicable user fee to be remitted by each person outside the consortium, EPA will consider each person within the consortium as “one” person. The balance of the applicable user fee remaining is the responsibility of the consortium; EPA will inform consortium of this requisite user fee amount.

(f) *Remittance procedure.* (1) Electronic payment: Each remittance under this section shall be paid electronically in U.S. dollars, using one of the electronic payment methods supported by the Department of the Treasury’s Pay.gov or Fedwire online electronic payment service, or any applicable additional or successor online electronic payment service offered by the Department of Treasury.

(2) Timing of payment for user fees incurred between October 1, 2018 and [the effective date of this rule will be inserted at the final rule stage]. User fees required by paragraph (b) of this section for which the fee-triggering action or event occurred between October 1, 2018, and [EFFECTIVE DATE OF FINAL RULE] shall be paid in response to invoices EPA will send within 30 days of the effective date of this rule.

(3) Timing of payment for user fees incurred after [EFFECTIVE DATE OF FINAL RULE]. User fees required by paragraph (b) of this section for which the fee-triggering action or event occurred after [EFFECTIVE DATE OF FINAL RULE] shall be paid at the following time:

(i) *Test orders and test rules.* The applicable user fee specified in paragraph (b) of this section shall be paid in full not later than 60 days after the effective date of a test rule or test order under section 4 of the Act.

(ii) *Enforceable consent agreements.* The applicable user fee specified in paragraph (b) of this section shall be paid in full not later than 60 days after the signing of an enforceable consent agreement under section 4 of the Act.

(iii) *Section 5 notice.* The applicable user fee specified in paragraph (b) of this section shall be paid in full immediately upon submission of a TSCA section 5 notice.

(iv) *Risk evaluations.* (A) For EPA-initiated risk evaluations, the applicable user fee specified in paragraph (b) of this section shall be paid in full not later than 60 days after EPA publishes the final scope of a chemical risk evaluation under section 6(b)(4)(D) of the Act.

(B) For manufacturer-requested risk evaluations under section 6(b)(4)(C)(ii) of the Act, the applicable user fee specified in paragraph (b) of this section shall be paid in full not later than 30 days after EPA provides the submitting manufacture(s) notice that it has granted the request.

(4)(i) Persons who submit a TSCA section 5 notice shall place an identifying number and a payment identity number on the front page of each TSCA section 5 notice submitted. The identifying number must include the letters "TS" followed by a combination of 6 numbers (letters may be substituted for some numbers). The payment identity number may be a "Pay.gov" transaction

number or FedWire wire transfer number used to transmit the user fee. The same TS number and the submitter's name must appear on the corresponding fee remittance under this section. If a remittance applies to more than one TSCA section 5 notice, the person shall include the name of the submitter and a new TS number for each TSCA section 5 notice to which the remittance applies, and the amount of the remittance that applies to each notice.

(ii) Persons who are required to submit a letter of intent to conduct testing per §790.45 of this chapter shall place a payment identity number on the front page of each letter submitted. The identifying number must include the letters "TS" followed by a combination of 6 numbers (letters may be substituted for some numbers). The payment identity number may be a "Pay.gov" transaction number or FedWire wire transfer number used to transmit the user fee. The same TS number and the submitter's name must appear on the corresponding fee remittance under this section. If a remittance applies to more than one letter of intent to conduct testing, the person shall include the name of the submitter and a new TS number for each letter of intent to conduct testing to which the remittance applies, and the amount of the remittance that applies to each letter of intent.

(iii) Persons who sign an enforceable consent agreement per §790.60 of this chapter shall place a payment identity number within the contents of the signed agreement. The identifying number must include the letters "TS" followed by a combination of 6 numbers (letters may be substituted for some numbers). The payment identity number may be a "Pay.gov" transaction number or FedWire wire transfer number used to transmit the user fee. The same TS number and the submitter's name must appear on the corresponding fee remittance under this section. If a remittance applies to more than one enforceable consent agreement, the party or parties shall include the name of the submitter(s) and a new TS number for each enforceable consent agreement

to which the remittance applies, and the amount of the remittance that applies to each enforceable consent agreement.

(5)(i) Each person who remits the fee identified in paragraph (b)(1) of this section for a PMN, consolidated PMN, intermediate PMN, or SNUN shall insert a check mark for the statement, “The company named in part 1, section A is a small business concern under 40 CFR 700.43 and has remitted a fee of \$2,800 in accordance with 40 CFR 700.45(b).” under “CERTIFICATION” on page 2 of the Premanufacture Notice for New Chemical Substances (EPA Form 7710-25). This form is available on EPA’s website at [https://cdx.epa.gov/SSL/PMN/Outbound/Electronic\\_PMN\\_Form\\_version2.pdf](https://cdx.epa.gov/SSL/PMN/Outbound/Electronic_PMN_Form_version2.pdf).

(ii) Each person who remits the fee identified in paragraph (b)(1) of this section for a LVE, LoREX, TERA, TMEA, or Tier II exemption request under TSCA section 5 shall insert a check mark for the statement, “The company named in part 1, section A is a small business concern under 40 CFR 700.43 and has remitted a fee of \$940 in accordance with 40 CFR 700.45(b).” in the exemption application.

(iii) Each person who remits the fee identified in paragraph (b)(1) of this section for an exemption notice under §723.175 of this chapter shall include the words, “The company or companies identified in this notice is/are a small business concern under 40 CFR 700.43 and has/have remitted a fee of \$940 in accordance with 40 CFR 700.45(b).” in the certification required in §723.175(i)(1)(x) of this chapter.

(iv) Each person who remits the fee identified in paragraph (b)(1) of this section for a MCAN or consolidated MCAN for a microorganism shall insert a check mark for the statement, “The company named in part 1, section A is a small business concern under 40 CFR 700.43 and has remitted a fee of

\$2,800 in accordance with 40 CFR 700.45(b).” in the certification required in §725.25(b) of this chapter.

(6)(i) Each person who remits a fee identified in paragraph (b)(2) of this section for a PMN, consolidated PMN, intermediate PMN, or SNUN shall insert a check mark for the statement, “The company named in part 1, section A has remitted the fee of \$16,000 specified in 40 CFR 700.45(b).” under “CERTIFICATION” on page 2 of the Premanufacture Notice for New Chemical Substances (EPA Form 7710-25).

(ii) Each person who remits a fee identified in paragraph (b)(2) of this section for a LVE, LoREX, TERA, TMEA, 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 40 CFR 700.45(b).” in the exemption application.

(iii) Each person who remits the fee identified in paragraph (b)(2) of this section for an exemption notice under §723.175 of this chapter shall include the words, “The company or companies identified in this notice has/have remitted a fee of \$4,700 in accordance with 40 CFR 700.45(b).” in the certification required in §723.175(i)(1)(x) of this chapter.

(iv) Each person who remits the fee identified in paragraph (b)(2) of this section for a MCAN for a microorganism shall insert a check mark for the statement, “The company named in part 1, section A has remitted the fee of \$16,000 in accordance with 40 CFR 700.45(b).” in the certification required in §725.25(b) of this chapter.

(g) *Full fee refunds.* EPA will refund, in totality, any fee paid for a section 5 notice whenever the Agency determines:

(i) That the chemical substance that is the subject of a PMN, consolidated PMN, exemption request, or exemption notice, is not a new chemical substance as of the date of submission of the notice,

(ii) In the case of a SNUN, that the notice was not required,

(iii) The notice is incomplete under either § 720.65(c), § 723.50(e)(3) or § 725.33, of this chapter,

(iv) That as of the date of submission of the notice: the microorganism that is the subject of a MCAN or consolidated MCAN is not a new microorganism; nor is the use involving the microorganism a significant new use; or

(v) When the Agency fails to make a determination on a notice by the end of the applicable notice review period under § 720.75 or § 725.50 of this chapter, unless the Agency determines that the submitter unduly delayed the process, or

(vi) When the Agency fails to approve, or deny an exemption request within the applicable period under § 720.38(d), § 723.50(g) or § 725.50(b) of this chapter, unless the Agency determines that the submitter unduly delayed the process.

(h) *Partial fee refunds.* (1) If a TSCA section 5 notice is withdrawn during the first 10 business days after the beginning of the applicable review period under §720.75(a) of this chapter, the Agency will refund all but 25% of the user fee as soon as practicable.

(2) Once withdrawn, any future submission related to the TSCA section 5 notice must be submitted as a new notice.

5. Section 700.49 is revised to read as follows:

**§700.49 Failure to remit fees.**

(a) EPA will not consider a TSCA section 5 notice to be complete unless the appropriate certification under § 700.45(e) is included and until the appropriate remittance under § 700.45(b) has been submitted as provided in § 700.45(e). EPA will notify the submitter of a section 5 notice that it is incomplete in accordance with §§ 720.65(c) and 725.33(b)(1) of this chapter.

(b) Failure to submit the appropriate remittance specified under § 700.45(b) for a test order, test rule, enforceable consent agreement, or EPA-initiated risk evaluation as provided in § 700.45(e) is a violation of TSCA and enforceable under section 15 of the Act.

(c) EPA will not initiate a manufacturer-requested risk evaluation that the Agency has otherwise determined to be complete unless the appropriate remittance under § 700.45(b) has been submitted as provided in § 700.45(e).

**PART 720--[AMENDED]**

6. The authority citation for part 720 continues to read as follows:

**Authority:** 15 U.S.C. 2604, 2607, and 2613.

7. Section 720.38 is amended by adding paragraphs (b)(6) and (f) to read as follows:

**§720.38 Exemptions for test marketing.**

\* \* \* \* \*

(b) \* \* \*

(6) A user fee payment identity number, as required in 40 CFR 700.45(e)(3).

\* \* \* \* \*

(f) When applying for a test marketing exemption, persons are subject to user fees in accordance with 40 CFR 700.45.

18. Section 720.45 is amended by revising paragraph (a)(5) to read as follows:

**§720.45 Information that must be included in the notice form.**

\* \* \* \* \*

(a) \* \* \*

(5) If a manufacturer cannot provide all the information specified in paragraphs (a) (1) and (2) of this section because the new chemical substance is manufactured using a reactant having a specific chemical identity claimed as confidential by its supplier, the manufacturer must submit a notice directly to EPA containing all the information known by the manufacturer about the chemical identity of the reported substance and its proprietary reactant. In addition, the manufacturer must ensure that the supplier of the confidential reactant submit a letter of support directly to EPA providing the specific chemical identity of the confidential reactant, including the CAS number, if available, and the appropriate PMN or exemption number, if applicable. The letter of support must reference the manufacturer's name and PMN User Fee Identification Number. The statutory review period will commence upon receipt of both the notice and the letter of support.

\* \* \* \* \*

**PART 723--[AMENDED]**

9. The authority citation for part 723 continues to read as follows:

**Authority:** 15 U.S.C. 2604.

10. Section 723.175 is amended by adding paragraph (a)(2)(iv) and by revising paragraphs (h)(3)(i)(1)(ii)(C) and (h)(3)(i)(1)(iii), and adding paragraph (h)(3)(i)(1)(xi) to read as follows:

**§723.175 Chemical substances used in or for the manufacture or processing of instant photographic and peel-apart film articles.**

(a) \* \* \*

(2) \* \* \*

(iv) Remit the applicable user fee specified in § 700.45(b) of this chapter.

\* \* \* \* \*

(h) \* \* \*

(3) \* \* \*

(1) \* \* \*

(ii) \* \* \*

\* \* \* \* \*

(C) *Polymers.* For a polymer, the notice must identify monomers and other reactants used in the manufacture of the polymer by chemical name and CAS Registry Number. The notice must indicate the amount of each monomer used (by weight percent of total monomer); the maximum residual of each monomer present in the polymer; and a partial or incomplete structural diagram, if available. The notice must indicate the number average molecular weight of the polymer and

characterize the anticipated low molecular weight species. The notice must include this information for each typical average molecular weight composition of the polymer to be manufactured.

(iii) *Impurities*. The notice must identify the impurities that can be reasonably anticipated to be present in the new chemical substance when manufactured under the exemption by name and CAS Registry Number, by class of substances, or by process or source. The notice also must estimate the maximum percent (by weight) of each impurity in the new chemical substance and the percent of unknown impurities present.

\* \* \* \* \*

(xi) User fee payment ID number. The manufacturer or processor must include a payment identity number on the front page of the notice.

\* \* \* \* \*

#### **PART 725--[AMENDED]**

11. The authority citation for part 725 continues to read as follows:

**Authority:** 15 U.S.C. 2604, 2607, 2613, and 2625.

12. Section 725.25 is amended by adding paragraph (i) to read as follows:

#### **§725.25 General administrative requirements.**

\* \* \* \* \*

(i) *Fees*. Persons submitting MCANs and exemption requests to EPA under this part are subject to the applicable user fees and conditions specified in §§ 700.40, 700.45(b), and 700.49 of

this chapter.

13. Section 725.33 is amended by revising paragraphs (a)(9) and (10) to read as follows:

**§725.33 Incomplete submissions.**

(a) \* \* \*

(9) The submitter does not remit the fees required by §700.45(b) of this chapter.

(10) The submitter does not include an identifying number and a payment identity number.

\* \* \* \* \*

**PART 790--[AMENDED]**

14. The authority citation for part 790 continues to read as follows:

**Authority:** 15 U.S.C. 2603.

15. Section 790.45 is amended by adding paragraphs (c)(7) and (g) to read as follows:

**§790.45 Submission of letter of intent to conduct testing or exemption application.**

\* \* \* \* \*

(c) \* \* \*

(7) A payment identity number on the front page of the letter, as required in §700.45(e)(3)

of this chapter.

\* \* \* \* \*

(g) Manufacturers and processors subject to a test rule described in § 790.40 and required to comply with the requirements of that test rule as provided in § 790.42(a) must remit the applicable user fee specified in § 700.45(b) of this chapter.

16. Section 790.59 is amended by adding paragraph (c) to reads as follows:

**§790.59 Failure to comply with a test rule.**

\* \* \* \* \*

(c) Persons who fail to pay the requisite user fee as specified in §700.45(b) of this chapter will be in violation of the rule.

17. Section 790.60 is amended by adding paragraphs (a)(18) and (d) to read as follows:

**§790.60 Contents of consent agreements.**

(a) \* \* \*

(18) Payment identity number, as required in §700.45(e)(3) of this chapter.

\* \* \* \* \*

(d) *Fees.* Manufacturers and/or processors signing the consent agreement are subject to the applicable user fee specified in §700.45(b) of this chapter.

18. Section 790.65 is amended by revising paragraph (b) to read as follows:

**§790.65 Failure to comply with a consent agreement.**

\* \* \* \* \*

(b) The Agency considers failure to comply with any aspect of a consent agreement, including the failure to pay requisite user fees as specified in §700.45 of this chapter, to be a “prohibited act” under section 15 of TSCA, subject to all the provisions of the Act applicable to violations of section 15. Section 15(1) of TSCA makes it unlawful for any person to fail or refuse to comply with any rule or order issued under section 4. Consent agreements adopted pursuant to this part are “orders issued under section 4” for purposes of section 15(1) of TSCA.

\* \* \* \* \*

**PART 791--[AMENDED]**

19. The authority citation for part 791 continues to read as follows:

**Authority:** 15 U.S.C. 2603 and 2607.

20. Section 791.39 is amended by removing paragraph (a)(3) and revising paragraph (b).

The revision reads as follows:

**§791.39 Fees and expenses.**

\* \* \* \* \*

(b) *Expenses.* All expenses of the hearing, including the cost of recording (though not transcribing) the hearing and required traveling and other expenses of the hearing officer and of American Arbitration Association representatives, and the expenses of any witness or the cost of any proofs produced at the direct request of the hearing officer, shall be borne equally by the parties, unless they agree otherwise, or unless the hearing officer, in the award, assesses such expenses or any part thereof against any specified party or parties.

\* \* \* \* \*

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