Prepublication Copy Notice:

The EPA Acting Administrator signed the following *Federal Register* document on September 27, 2018:

Title: **Fees for the Administration of the Toxic Substances Control Act**

Action: Final Rule

FRL: 9984-41

Docket No.: **EPA-HQ-OPPT-2016-0401**

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For further information about the docket and, if applicable, instructions for commenting, please consult the ADDRESSES section in the front of the *Federal Register* document.

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ENVIRONMENTAL PROTECTION AGENCY

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

[EPA-HQ-OPPT-2016-0401; FRL-9984-41]

RIN 2070-AK27

Fees for the Administration of the Toxic Substances Control Act

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: As permissible under section 26(b) of the Toxic Substances Control Act (TSCA or the Act), EPA is establishing fees applicable to any person required to submit information to EPA under TSCA section 4; or a notice, including an exemption or other information, to be reviewed by EPA 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 final rulemaking describes the final TSCA fees and fee categories for fiscal years 2019, 2020, and 2021, and explains the methodology by which the final TSCA fees were determined. It identifies some factors and considerations for determining fees for subsequent fiscal years; and includes amendments to existing fee regulations governing the review of premanufacture notices, exemption applications and notices, and significant new use notices. As required in TSCA section 26(b), EPA is also establishing standards for determining which persons qualify as "small business concerns" and thus would be subject to lower fee payments. Requiring manufacturers and processors of certain chemical substances to pay a fee for specific fee-triggering events under TSCA sections 4, 5, and 6, will defray part of the EPA cost of administering TSCA.

DATES: This final rule is effective on [*insert date 1 day after date of publication in the* **Federal Register**].

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPPT-2016-0401, is available at *http://www.regulations.gov* or at the Office of Pollution Prevention and Toxics Docket (OPPT Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPPT Docket is (202) 566-0280. Please review the visitor instructions and additional information about the docket 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*.

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*.

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).

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

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

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 of 2016 (Pub. L. 114-182) (Ref. 1), provides EPA with authority to establish fees to defray a portion of the costs associated with administering TSCA sections 4, 5, and 6, as amended, as well as the costs of "collecting, processing, reviewing, and providing access to and protecting information about chemical substances from disclosure as appropriate under TSCA section 14." EPA is finalizing 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 finalizing a rule to establish and collect fees from manufacturers (including importers) and, in some cases, processors, to defray some of the Agency's costs related to activities under TSCA sections 4, 5, and 6, and collecting,

processing, reviewing, and providing access to and protecting information about chemical substances from disclosure as appropriate under TSCA section 14. EPA is also finalizing standards for determining which persons qualify as small business concerns and thus would be subject to lower fee amounts. TSCA section 26(b)(4) 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 a portion of the costs of administering TSCA sections 4, 5, and 6 and collecting, processing, reviewing, providing access to, and protecting information about chemical substances from disclosure as appropriate under TSCA section 14. Pursuant to the final rule, the Agency will collect payment from manufacturers who: are required to submit information under TSCA section 4; are required to submit a notice, exemption application, or other information under TSCA section 5; or manufacture a chemical substance that is the subject of a risk evaluation under TSCA section 6(b). The Agency will also collect payment from processors in limited scenarios, i.e., where a processor submits a Significant New Use Notice (SNUN) under TSCA section 5; or where a fee-triggering TSCA section 4 activity is tied to a SNUN submission by a processor. These fees are intended to achieve the goals articulated by Congress by providing a sustainable source of funds for EPA to fulfill its legal obligations to conduct activities such as designating 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 new chemical submissions, as required under TSCA sections 4, 5 and 6, as well as and collecting, processing, reviewing,

and providing access to and protecting information about chemical substances from disclosure as appropriate under TSCA section 14.

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

EPA has evaluated the potential incremental economic impacts of this final rule. 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 are approximately $20 million, excluding fees collected for manufacturer-requested risk evaluations. Total annualized fee collection was calculated by multiplying the estimated number of fee-triggering events anticipated each year by the corresponding fees. EPA estimates that section 4 fees account for less than one percent of the total fee collection, section 5 fees for approximately 43 percent, and section 6 fees for approximately 56 percent.

Total annual fee collection for manufacturer-requested risk evaluations is estimated to be $1.3 million for chemicals included in the 2014 TSCA Work Plan (TSCA Work Plan) (based on two requests over the three-year period) and approximately $3.9 million for chemicals not included in the TSCA Work Plan (based on three requests over the three-year period).

EPA estimates that 18.6 percent of section 5 submissions will be from small businesses that are eligible to pay the section 5 small business fee because they meet the definition of "small business concern." Total annualized fee collection from small businesses submitting under section 5 is estimated to be $339,000 (Ref. 2). For sections 4 and 6, reduced fees paid by eligible small businesses and fees paid by non-small businesses may differ over

the three-year period that was analyzed, since the fee paid by each entity is dependent on the number of entities identified per fee-triggering event. EPA estimates that average annual fee collection from small businesses impacted by section 4 and section 6 would be approximately $7,000 and $926,000, respectively. For each of the three years covered by this rule, EPA estimates that total fee revenue collected from small businesses will account for about 6 percent of the approximately $20 million total fee collection, for an annual average total of approximately $1.3 million. For fees paid through consortia for activities under section 4 and 6, since consortia will be required to pay the full fee amount, general industry firms that are not eligible for reduced fees will pay more to ensure the fee is covered. Therefore, although more firms are eligible for small business discounts under the SBA definition used in the final rule, the total annual fee revenue estimate remains relatively stable at approximately $20 million.

Total social cost represents the total burden a regulation will impose on the economy. It can be defined as the sum of all opportunity costs incurred as a result of the regulation. The opportunity cost incurred by industry to carry out these activities is the foregone value of the time (burden) and investments required to comply with rule. Total social cost for this final rule does not include the fees collected from industry by EPA, as these fees are considered transfer payments. Rather, total social cost includes the opportunity costs incurred by industry, such as the cost to read and familiarize themselves with the rule; determine their eligibility for paying reduced fees; register for CDX; form, manage and notify EPA of participation in consortia; notify EPA and certify whether they will be subject to the action or not; and arrange to submit fee payments via Pay.gov. Total social costs also include the additional costs to EPA to administer fee assessment and collection for TSCA sections 4, 5,

and 6, and collecting, processing, reviewing, and providing access to and protecting information about chemical substances from disclosure as appropriate under TSCA section 14. The total annualized opportunity cost to industry is approximately $231,000 and the additional annualized Agency cost is approximately $7,000, yielding a total annualized social cost of approximately $238,000.

II. Background

A. Statutory Requirements for TSCA Fees

The proposed rule provides a robust overview of the history of fees under TSCA and the 2016 amendments to TSCA (83 FR 8212, February 26, 2018) (FRL-9974-31). TSCA authorizes EPA to establish, by rule, fees for activities under TSCA sections 4, 5 and/or 6. In so doing, the Agency must set lower fees for small business concerns and establish the fees at a level such that they'll offset 25% of the Agency's costs to carry out a broader set of activities under sections 4, 5, and 6 and of collecting, processing, reviewing, and providing access to and protecting from disclosure as appropriate under section 14 information on chemical substances under TSCA. 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 100% of the costs of conducting a manufacturer-requested risk evaluation for all other chemicals. TSCA now requires fee revenue to be deposited into a new dedicated TSCA fund 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 sections 4, 5, and 6, and of collecting, processing, reviewing, and providing access to and protecting from disclosure as appropriate under section 14

information on chemical substances under TSCA. EPA is also required in TSCA section 26(b)(4)(F) to review and adjust the fees established in this rule every three years, and to consult with parties potentially subject to fees when the fees are reviewed and updated to reflect changes in program costs.

B. Overview of Final Rule

Pursuant to TSCA section 26(b), this final rule establishes fees for certain activities under TSCA sections 4, 5, and 6 to defray approximately 25% of the costs to carry out a broader set of activities under these sections of TSCA and of collecting, processing, reviewing, and providing access to and protecting from disclosure, as appropriate under TSCA section 14, information on chemical substances under TSCA. In addition, the final rule establishes fees for risk evaluations requested by manufacturers to defray 50% or 100% of the costs, depending on whether the chemical is listed on the TSCA Work Plan or not, respectively.

After consideration of public comments, EPA is finalizing a number of provisions from the proposed rule without modification, including the general methodology for calculating fees (except in the case of manufacturer-requested risk evaluations), the program cost estimates, the eight proposed fee categories, the fee amounts, the allowance of payment of fees through consortia, the discounted fees for small business concerns, and the provision of refunds under certain circumstances.

Based on consideration of public comments, the final rule also includes certain modifications and clarifications related to the proposal. For example, in response to comments, the final rule includes a new process for identifying manufacturers subject to fee obligations for TSCA section 4 test rules and TSCA section 6 EPA-initiated risk evaluations,

including publication of a preliminary list, opportunity for public comment, self-identification, and/or certification of no manufacture, and publication of a final list defining the universe of manufacturers obligated to pay. The final rule also reflects modifications to the proposed methodology for calculating fees for manufacturer-requested risk evaluations, the timing for consortia formation, payment due dates, and the standard for small business concerns. Finally, the final rule provides the additional clarity requested by commenters in areas including: the allocation of fees in complex multi-payer scenarios, the estimation of program costs and activity level assumptions, and the circumstances for providing refunds. The content of the final rule and these changes are discussed in greater detail in Unit III.

III. Discussion of the Final Rule and Response to Comments

A. Purpose and Applicability

As described in 40 CFR 700.40, the purpose of the final rule is to establish and collect fees from manufacturers (including importers) and processors to defray a portion of EPA's TSCA implementation costs. The rule applies to manufacturers who are required to submit information under TSCA section 4, manufacturers and processors who submit certain notices and exemptions under TSCA section 5, and to manufacturers who are subject to risk evaluation under TSCA section 6(b), including manufacturers who submit requests for risk evaluation under TSCA section 6(b)(4)(C)(ii).

B. Entities Subject to Fees

Although EPA has authority to collect fees from both manufacturers and processors of chemical substances, the final rule focuses fee collection primarily on manufacturers. EPA will collect fees from processors only when processors submit a SNUN or test-marketing exemptions (TME) under section 5, when a section 4 activity is tied to a SNUN submission

by a processor, or when a processor voluntarily joins a consortium and therefore agrees to provide payment as part of the consortium. This approach is consistent with the proposed rule and with most comments received. Although a few commenters urged EPA to allocate more of the fee burden to processors, EPA is declining to do so at this time. EPA believes the allocation primarily to manufacturers, and, in limited circumstances, to processors, is an appropriate balance as required in TSCA. As noted in the proposal, the effort of trying to identify relevant processors for all fee-triggering actions would be overly burdensome and EPA expected many processors would be missed. Generally limiting fee obligations to manufacturers is the simplest and most straightforward way to assess fees for conducting risk evaluations under TSCA section 6 and most TSCA section 4 testing activities. Furthermore, EPA expects that manufacturers required to pay fees will have a better sense of the universe of processors and will pass some of the costs on to them.

C. Identifying Manufacturers Subject to Fee Obligations

The proposed rule suggested that EPA would use Chemical Data Reporting (CDR) data to identify manufacturers subject to fee obligations, but would also rely on self-identification from other manufacturers not subject to CDR reporting requirements. EPA also proposed to include a "manageable approach" in the final rule for identifying manufacturers subject to fees for TSCA section 4 and 6 activities, and requested public comment in this area. See 83 FR 8212, 8216. EPA also requested comment on whether to adopt a process that would allow time for public input before finalizing a list. A number of commenters agreed that such a process was necessary, and EPA is codifying a process in the final rule to provide the necessary clarity and certainty for those potentially subject to fees.

1. In general. EPA intends the process to include publication of a preliminary list that

identifies manufacturers (based on information available to EPA through CDR reporting and other sources), a public comment period (to allow for self-identification, correction of errors, and certification of no-manufacture and no intention to manufacture in the next five years), and publication of a final list defining the universe of manufacturers responsible for payment. Further, EPA will follow this process for only two fee-triggering events: TSCA section 4 test rules and TSCA section 6 EPA-initiated risk evaluations. EPA believes that for all other fee-triggering events, the relevant manufacturer(s) will already be apparent to the Agency and a specific identification process will not be necessary. This process is not necessary for TSCA section 5 activities, TSCA section 4 enforceable consent agreements (ECAs), or TSCA section 6 manufacturer-requested risk evaluations as manufacturers are self-identified through those activities. The process is also not necessary for TSCA section 4 test orders, as EPA will ultimately select the manufacturer(s) subject to the order prior to or during the development of the order.

2. *Data sources*. To compile the preliminary list, EPA will use the most up-to-date information available, including information submitted to the Agency (e.g., information submitted under TSCA sections 5(a), 8(a) (including CDR), 8(b), and to the Toxics Release Inventory) as well as other information available to the Agency, such as publicly available information (e.g., Panjiva) or information submitted to other agencies to which EPA has access (e.g., U.S. Custom and Border Patrol data). To be able to include the most recent CDR data (collected every four years) and to account for annual or other typical fluctuations in manufacturing (including import), EPA will use five years of data submitted or available to the Agency to create the preliminary list. Although some commenters suggested looking back a greater or fewer number of years, EPA believes that a five-year period enables EPA to

utilize a number of data sources described earlier and increase accuracy.

3. Publication of preliminary list. EPA will publish this preliminary list in the **Federal Register** concurrently with a relevant milestone for each action. For risk evaluations initiated by EPA under TSCA section 6, the preliminary list will be published at the time of final designation of the chemical substance as a High-Priority Substance. For test rules under TSCA section 4, the preliminary list will be published with the proposed test rule.

4. Public comment period. Publication of the preliminary list will be followed by a comment period of no less than 30 days, during which manufacturers and the public will have the opportunity to correct errors, self-identify as a manufacturer, and/or certify to already having exited the market and that they will not return for a period of 5 years. EPA believes this process is largely consistent with comments on the proposal encouraging EPA to publish a preliminary list and engage with stakeholders to identify others who may be missing, correct errors, and provide an opportunity for manufacturers to be removed from the list under certain circumstances.

5. Self-identification and certification. If a manufacturer is on the preliminary list, or is not on the preliminary list but is a manufacturer of the chemical substance at issue, they must report to EPA and self-identify with certain basic contact information. Although EPA expects reporting to occur through CDX, EPA has developed a form to reflect the self-identification statements, for reference purposes. (Ref. 9.) Manufacturers on the preliminary list also have an opportunity to certify through CDX that (1) they have already ceased manufacturing prior to the defined cutoff dates and will not manufacture for five years into the future, or (2) they have not ever manufactured the chemical substance. If EPA receives such a certification statement from a manufacturer, the manufacturer will not be obligated to

pay the fee. Manufacturers who are not listed on the preliminary list and otherwise believe they can "certify out" as described previously, may choose to attest these facts to EPA. However, if information received during the public comment period would prompt the addition of manufacturers to the final list, EPA will first notify those manufacturers. Manufacturers who plan to cease manufacture in the future (but have not yet done so), or those who have already ceased but may re-enter the market within the next five years, would not be permitted to certify out, and would still be subject to the fee obligation. The cutoff date (i.e., the date by which manufacture must have ceased in order to certify out) for an EPA-initiated risk evaluation is the date upon which the prioritization process is initiated for that chemical (i.e., approximately 9-12 months before the risk evaluation begins and 9-12 months before the preliminary list is published). The cutoff date for a TSCA section 4 test rule is the date upon which the proposed test rule is published. EPA chose an earlier cutoff date for risk evaluations to provide greater assurance that the manufacturer has exited the market and will not return for five years. Numerous commenters expressed concerns that some manufacturers may only temporarily stop manufacture to avoid potentially significant fee obligations, and subsequently return to the market. The earlier cutoff date provides an extra measure of protection against that scenario. See paragraph 7 for additional discussion regarding free riders and late entrants.

6. Publication of final list. After the comment period for the preliminary list of entities subject to a fee obligation, EPA will make any associated updates or corrections, and then publish a final list of manufacturers. This list will indicate if any manufacturers were identified in error, any additional manufacturers that were identified through the comment period and/or reporting form, and if any manufacturers have certified that they have already

ceased manufacture prior to the cutoff date described earlier and will not manufacture the subject chemical substance for five years into the future. The final list will be published concurrently with the final scope document for risk evaluations initiated by EPA under TSCA section 6, and with the final test rule under TSCA section 4.

7. Free riders and late entrants. A number of commenters raised concerns about the potential for manufacturers to exit the market shortly before or during the fee-triggering event, and avoid their fee obligations. Commenters expressed further concern about those same manufacturers re-entering the market shortly after the fee-triggering event, thereby getting a "free ride." Other commenters suggested that EPA also impose fees on "late entrants" (i.e., manufacturers who enter the market after the fee-triggering event has concluded), and reallocate fees accordingly, and provide partial refunds as appropriate. EPA believes that the identification process will help prevent the problems identified by some commenters regarding free riders and manufacturers who may otherwise too easily exit and reenter the market to avoid fee obligations. Specifically, the final rule requires manufacturers to self-identify, and, for those who have exited the market, certify that they will not manufacturer for at least 5 years or face penalties for violating TSCA. For chemicals with ongoing uses, there is no requirement for new market entrants to provide notice to EPA. Furthermore, it is impracticable for EPA to administer fees to such late entrants by reallocating fee amounts, collecting additional monies, and providing partial refunds to previously identified manufacturers. Those entities who truly begin to manufacture during or after the fee event would not be subject to fees, late charges or other penalties, but this is consistent with how TSCA operates in the new chemicals context: new manufacturers, not subsequent chemical manufacturers, are required to submit PMNs and pay fees and

subsequent manufacturers are not obligated to reimburse a PMN submitter.

Existing manufacturers who fail to identify themselves as required by this rule is a prohibited act under TSCA section 15(1) and therefore subject to a penalty under TSCA section 16. EPA views each day of failed identification by a manufacturer past the payment due date as a separate event subject to penalty. Likewise, manufacturers who falsely certify to having ceased manufacture and/or not re-initiating manufacture within five years will also be subject to penalty.

D. Methodology for Calculating Fees

For the proposed rule, EPA calculated fees by estimating the total annual costs of administering TSCA sections 4, 5, and 6 (excluding the costs of manufacturer-requested risk evaluations) and of collecting, processing, reviewing, and providing access to and protecting from disclosure as appropriate under TSCA section 14; identifying the full cost amount to be defrayed by fees under TSCA section 26(b) (i.e., 25% of those annual costs); and allocating that amount across the fee-triggering events in TSCA sections 4, 5, and 6, weighted more heavily toward TSCA section 6 based on early industry feedback. EPA specifically requested comment on this methodology. While a number of commenters generally supported the allocation as an appropriate balance of fees amongst activities in TSCA sections 4, 5, and 6, many commenters offered alternative suggestions for calculating fees, such as an actual cost approach or level-of-effort approach.

A common theme from commenters was that fees, particularly those for TSCA section 6 activities, should more closely align with EPA's actual costs for carrying out the specific activity on the specific chemical. Some commenters pointed to the likelihood for variability in costs stemming from the number of uses evaluated, extent of exposures, amount

of existing information such as assessments from other government bodies, the level of contractor support necessary, the complexity and number of tests required, and other factors.

As a general matter, EPA believes it is important to track costs on a chemical and activity basis in light of the increased responsibilities under TSCA and the need to better understand associated new costs. The Agency is working towards building this capability and, consistent with commenters' suggestions, expects to begin tracking actual costs on a chemical basis as soon as feasible. EPA plans to use our time reporting system to track employee hours and contract expenditures for each chemical undergoing risk evaluation and at the fee category level for section 4 and 5 activities. EPA also plans to track CBI claim review direct and programmatic support costs as well as cross cutting costs, direct costs and indirect costs associated with section 4, 5, 6, and collecting, processing, reviewing, and providing access to and protecting from disclosure as appropriate under section 14 information on chemical substances under TSCA. However, EPA does not currently track costs with this level of specificity and, as with any new activity, expects there to be some initial challenges as it works to do so. As such, EPA does not believe it would be feasible or appropriate to implement an actual cost approach for all fee-triggering events at this time. Furthermore, because actual costs of individual activities are unknown at this time and unknowable in advance (i.e., every activity will be unique and bear different actual costs), and because the fee-triggering events are a narrower subset of the activities that TSCA fees must defray, it is unclear how EPA could ensure that an actual cost approach would yield fee revenue sufficient to defray 25% of the overall TSCA implementation costs associated with section 4, 5, and 6, and collecting, processing, reviewing, and providing access to and protecting from disclosure as appropriate under section 14 information on chemical

substances under TSCA, absent a better understanding of the actual costs of these new activities. More generally, EPA has many new responsibilities under TSCA and relatively little information and experience to inform assumptions on costs or activity levels. EPA expects to gain valuable experience implementing this initial fee structure. Ultimately, EPA believes this initial experience and information gained from tracking actual costs will help EPA to continue refining methodologies for calculating fees, and will inform potential revisions to the fee structure in the future. To inform these revisions EPA plans to use our time reporting system to track employee hours and contract expenditures for each chemical undergoing risk evaluation and at the fee category level for section 4 and 5 activities. EPA also plans to track CBI claim review direct and programmatic support costs as well as cross cutting costs, direct costs and indirect costs associated with section 4, 5, 6, and collecting, processing, reviewing, and providing access to and protecting from disclosure as appropriate under section 14 information on chemical substances under TSCA. Congress implicitly recognized the benefit of gained experience and understanding over time by requiring EPA to revisit the fees structure every three years. Therefore, after considering the comments, for the final rule, EPA has determined to calculate the fees using the same approach as used in the proposed rule for most fee categories.

EPA is, however, finalizing an actual cost approach for calculating fees for manufacturer-requested risk evaluations. Although EPA proposed a static fee for manufacturer-requested risk evaluations based on general cost estimates for risk evaluation activities, upon further consideration and in light of public comments received, EPA will include a provision in the final rule to align this fee with the actual costs of the activity as a plain reading of TSCA would require. Specifically, EPA will require an initial payment of

$1,250,000 (for a chemical on the TSCA Work Plan) or $2,500,000 (for a chemical not on the TSCA Work Plan), payable within 30 days after granting the request, and a final invoice to total either 50% or 100% of the actual costs in line with the percentage requirements in TSCA, or a refund to achieve these requirements, if warranted. As described in this unit, EPA estimates the cost of a manufacturer-requested risk evaluation to be approximately $3.88M. The initial payment amounts were calculated to capture approximately two thirds of either 50% or 100% of that estimated cost, with the expectation that approximately the last third would come from the final payment. This approach is well-supported in the language of TSCA, which explicitly requires the Agency to collect a percentage of costs incurred "in conducting the risk evaluation" (i.e., 50% or 100%, depending on whether or not the chemical is on the TSCA Work Plan). TSCA section 26(b)(4)(D) specifies that EPA shall establish a fee for manufacturer-requested risk evaluations sufficient to defray the full costs (or 50% of the costs for TSCA Work Plan chemicals) and the approach being finalized is consistent with that. Commenters had a variety of suggestions for how to implement an actual cost approach (e.g., multiple payments at various milestones, small upfront payments or application fees followed by one or more additional payments, multiple payments based on target cost estimate ranges, etc.), but EPA determined that a simple two-payment approach – an initial payment, followed a final invoice at the conclusion of the risk evaluation for the total remaining due, or a refund – was a fair, understandable and practical approach in line with EPA's goals for the rulemaking.

EPA is confident that the actual cost approach for manufacturer-requested risk evaluations will be implementable for these activities beginning in FY19. Because fees collected for manufacturer-requested risk evaluations do not count towards the requirement

that fees defray 25% of overall implementation costs in TSCA section 26(b)(4)(F), there is not a need to count manufacturer-requested risk evaluation fees towards achieving a specific percentage of total revenue collected. Additionally, EPA continues to believe that these types of requests will generally be less complex (i.e., companies will request risk evaluations on chemicals that are likely to present fewer significant risk issues) than most EPA-initiated risk evaluations, and therefore easier/simpler to assess and track for actual costs.

E. Fee Categories

EPA proposed 8 distinct fee categories: (1) test orders, (2) test rules and (3) enforceable consent agreements, all under TSCA section 4; (4) notices and (5) exemptions, both under TSCA section 5; and (6) EPA-initiated risk evaluations, (7) manufacturer-requested risk evaluations for chemicals on the TSCA Work Plan, and (8) manufacturer-requested risk evaluations for chemicals not on the TSCA Work Plan, all under TSCA section 6. Although EPA received some comment on these and other potential fee categories as described later in this discussion, EPA is not altering these fee categories for the final rule. The activities in these categories are fee-triggering events that result in obligations to pay fees under this final rule.

As a general matter, EPA received very few comments on the categories proposed for TSCA section 4 activities. One commenter expressed concern that testing requirements that are associated with TSCA section 5 or 6 activities should not be subject to a separate TSCA section 4 fee, otherwise it would amount to double-charging. EPA disagrees with this characterization. Cost estimates for TSCA section 4 activities do not overlap with cost estimates for TSCA section 5 or 6 activities, and the expenses defrayed by the fees are different. There is a cost to the Agency to (1) develop an order, rule or consent agreement,

and (2) to review the data. These costs are separate from and in addition to the costs associated with review of a TSCA section 5 notice or exemption, or undertaking a TSCA section 6 risk evaluation.

EPA received a number of comments related to TSCA section 5 fee categories – most pertaining to the proposed fees for low-volume exemptions (LVEs) and other exemptions. A number of commenters sought to eliminate the exemption fee category entirely, and particularly for LVE fees. Historically, EPA has not charged a fee for TSCA section 5 exemption applications (e.g., LVE, low exposure/low release exemptions (LoREX), test-marketing exemptions (TME), TSCA experimental release applications (TERA), etc.). EPA's prior fee structure was set in 1988 and, while TSCA authorized EPA to collect fees for exemption applications, EPA only implemented fees for PMNs, SNUNs, and MCANs. EPA is imposing fees in this rule for all exemption submissions, except Tier I and polymer exemptions because the expected revenue from those activities would be largely negated by the administrative costs of collection. Some commenters suggested that fees for any exemption application would become a barrier to research, development and innovation. While EPA shares commenters' general concerns for impacts to innovation, EPA does not believe the LVE fee – a onetime $4,700 cost per submission ($940 for small business concerns) - will be a significant barrier to chemical industries seeking to introduce a new chemical to market. There is already a regulatory exemption from the TSCA section 5 notice requirements for those who manufacture only for research and development purposes (see 40 CFR 720.36). Another commenter asked EPA to clarify whether there would be a fee for bona fide submissions to ascertain whether or not a chemical is on the TSCA Inventory. EPA did not propose a fee for bona fide submissions, and there is no fee in the final rule for such

submissions. Moreover, if a PMN was determined not to be a new chemical substance, the submitter would be due a full refund.

No commenters opposed the proposed fee categories for TSCA section 6 activities. However, several suggested exclusions or discounts for those who manufacture a chemical as an impurity or byproduct, or those who manufacturer chemicals for small, niche markets as their revenue may be insufficient to support a risk evaluation. As indicated earlier, EPA is not adjusting the fee categories in the final rule. TSCA requires EPA to evaluate chemicals under their conditions of use, and conditions of use evaluated may involve manufacture of impurities or byproducts, or chemicals used in niche market applications. As such, EPA does not believe it would be appropriate to exclude these manufacturers from fee obligations for TSCA section 6 activities.

Finally, EPA solicited comment in the proposed rule about the potential for additional fee categories for other TSCA activities such as CBI claims or risk management activities. A majority of commenters opposed fee categories or surcharges associated with submission of CBI claims, with the exception of some who noted that requiring payment of fees could help reduce the number of unwarranted claims. Commenters were split regarding a separate risk management fee. Several opposed a separate fee, suggesting there was no authority in TSCA to implement one. Other commenters encouraged EPA to include a separate fee category for risk management activities to both place the costs of this activity on companies choosing to use more dangerous chemicals, and to incentivize companies to move to safer chemistries. After further consideration, EPA has determined not to add these additional categories. EPA already accounted for both CBI and risk management activities in the baseline cost estimates in the proposed rule, meaning that EPA will recover a portion of these costs through the other

fee categories. EPA believes this approach is in line with TSCA section 26, which does not explicitly authorize EPA to assign fees for CBI claims or risk management activities. EPA expects that the historical problem of unwarranted CBI claiming will be mitigated to a certain extent by enhanced CBI review requirements for EPA and substantiation requirements in TSCA. Similarly, EPA believes that the new general requirements for prioritization and evaluation of existing chemicals will themselves be a disincentive to manufacturing chemicals with more significant risks.

F. Program Cost Estimates and Activity Assumptions

The estimated annual Agency costs of carrying out TSCA section 4, 5, and 6, and of collecting, processing, reviewing, and providing access to and protecting from disclosure as appropriate under TSCA section 14 information on chemical substances under TSCA, are approximately $80.2 million excluding the estimated cost of having 5 manufacturer-requested risk evaluations underway each year. Because the 25% cap on cost recovery does not apply to manufacturer-requested risk evaluations, the total cost to which the cap applies is $80.2 million. Based on these cost estimates, EPA anticipates collecting approximately $20 million in fees not associated with manufacturer-requested risk evaluations. In addition, the Agency intends to collect fees from manufacturers to recover 50% or 100% of the actual costs incurred by EPA in conducting chemical risk evaluations requested by manufacturers. EPA expects the amount collected will be approximately $1.94 million per chemical for chemicals on the TSCA Work Plan and $3.9 million per chemical for chemicals not on the TSCA Work Plan.

EPA determined the anticipated costs associated with TSCA sections 4, 5, and 6 of collecting, processing, reviewing, and providing access to and protecting from disclosure as

appropriate under TSCA section 14 information on chemical substances under TSCA, including both direct 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)

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

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, and 6, and of collecting, processing, reviewing, and providing access to and protecting from disclosure as appropriate under TSCA section 14 information on chemical substances under TSCA, 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 fees that tied the payment of fees to individual distinct activity types or "fee-triggering events". This allows allocation of costs more equitably among the activity types and their related costs.

1. Program costs. To determine the program costs for implementing TSCA sections 4, 5, and 6, of collecting, processing, reviewing, and providing access to and protecting from disclosure as appropriate under TSCA section 14 information on chemical substances under 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 direct program cost estimates for TSCA sections 4, 5, 6 and collecting, processing, reviewing, and providing access to and protecting from disclosure as appropriate under TSCA section 14 information on chemical substances under TSCA.

Some commenters expressed concerns that agency cost estimates and fee amounts were too low while other commenters expressed concerns that general or specific cost estimates, or fee amounts were too high or were not well substantiated. EPA continues to believe that the estimates presented represent the best estimates possible given our reliance, to the extent possible, on past experience and consideration of the additional work under the expanded authorities in the amended statute. Given this limited experience with novel obligations and authorities, our costs are estimates and subject to change and become more precise over time. However, EPA informed these estimates by relying on past experience with similar activities coupled with significant interaction and discussion with programmatic staff and management to develop estimates.

Because of the novelty and expanded scope of many aspects of the program under amended TSCA, EPA is not able to fully benchmark or substantiate all our estimates through past staffing or contract budget needs for identical activities. However, EPA carefully took into account the expanded requirements for risk evaluation, risk management, and new chemical review activities as well as the new test order authority when developing the cost estimates. Furthermore, EPA believes that Congress understood the uncertainty in standing

up a new chemical review and management program and therefore required EPA to perform annual audits and reassess fees every three-years to allow for costs estimates and the associated fees to be refined.

a. TSCA section 4 program costs. TSCA section 4 gives EPA the authority to require (by rule, order, or ECA) manufacturers and processors to conduct testing of identified chemical substances or mixtures. EPA estimated TSCA section 4 activity costs based on prior experience with developing test rules and ECAs, reviewing study plans, and reviewing the data received. These activity level assumptions represent EPA's best professional judgment on how the program will be implemented in the first 3-year fees cycle. 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 as it takes approximately two years to complete the work associated with both of these activities. While not EPA's current practice, these estimates represent EPA's best estimate on the work that will be required as a result of the 2016 amendments to TSCA, including the requirements to prioritize chemicals for risk evaluation review and to have 20 risk evaluations underway at all times beginning in December 2019.

EPA used historical averages of the number of affected firms per chemical from the three most recent section 4 test rules for high production volume (HPV) chemicals (71 FR 13708, March 16, 2006) (FRL-7335-2); (76 FR 4549, January 26, 2011) (FRL-8862-6); and (76 FR 65385, October 21, 2011) (FRL-8885-5) and assumed an average of seven chemicals involved per TSCA section 4 action and four affected firms per chemical. EPA based Section 4 costs on our general experience with the rulemaking process, our experience with the

developing an ECA for Octamethylcyclotetrasiloxane (D4) and costs associated with reviewing information received, and administration of, the HPV Voluntary Testing Program. EPA relied on this past experience augmented thorough a process of coordination with programmatic staff and management to estimate the TSCA section 4 costs.

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

Some commenters felt that EPA cost estimates were too low. However, EPA's estimates reflect the best estimates currently available, rely on past programmatic experience, and fully consider the information needs under amended TSCA for section 4 activities. In addition, TSCA section 4 actions have historically included multiple chemicals per action. EPA TSCA section 4 test orders, for example, could cover a group of similar chemicals allowing EPA to collect information on more than 10 chemicals in a given year. Further, if EPA learns that more activities are needed per year or that costs are higher than expected, EPA will appropriately revise the requirements during the annual and three-year review of fees.

Based on previous experience and expected work under TSCA as amended, EPA assumed that testing required by test orders is likely to be completed in under a year, and test rules and ECAs are likely to take two years to complete. To estimate the costs of reviewing test data, we assume that on average, data will be submitted to EPA for seven chemicals in

each TSCA section 4 activity and that each chemical would have 4 associated companies to test for a total of 28 firms per action.

Based on this approach, the estimated cost to the Agency of each test order is approximately $279,000. Each test rule is estimated to cost approximately $844,000 and each 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. 3: Table 8).

b. TSCA section 5 program costs. TSCA section 5 requires that manufacturers and processors provide EPA with notice before initiating the manufacture of a new chemical substance or initiating the manufacturing or processing for a significant new use of a chemical substance. EPA is required to review and make affirmative determinations for new chemical submission 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 prior to the 2016 amendments to TSCA are well understood through experience that spans several decades. The Agency has 40 years of experience and historical data on costs, as well as the number of different TSCA section 5 submission types sent to the Agency each year under the previous statute. 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.* In calendar year 2016, EPA received 577 PMNs, SNUNs and MCANs, and another 560 exemption notices and applications, most of which were LVEs.

Cost estimates were developed based on our historical understanding of costs, extensive consultation with programmatic staff and management and careful consideration of the requirements for new chemical reviews under amended TSCA, including the requirement to make an affirmative safety determination, and costs of pre-notice consultation. Based on the extent of past experience to rely upon for costs estimation, TSCA section 5 costs are some the best understood in terms of anticipated activity level and per activity cost.

Some commenters commented that EPA did not fully consider the statutory requirements under amended TSCA. However, EPA feels the costs are developed using our robust historical cost understanding, extensive discussion with programmatic staff and management, and consideration of the requirements under amended TSCA to evaluate intended, known, or reasonably foreseen conditions of use and the Agency's costs of taking

any related required regulatory action such as with a SNUR and/or a consent order. Costs of reviewing any data that is submitted to EPA as a result of an order is also included in EPA's estimates. EPA's cost estimates for administering TSCA section 5 also include the costs associated with processing and retaining records related to a Notice of Commencement (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 estimated average cost for EPA to review 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. EPA estimated that there will be 462 submissions annually. EPA's estimate of number of submissions is based on submissions received in FY 16, and reduced by 20% due to the anticipated impact of increased fees on the number of submissions (Ref. 3: Table 9). EPA does not believe that this estimated reduction in submissions will translate into a reduction in new chemicals entering commerce as only roughly 57% of new chemicals reviewed by EPA have historically entered commerce. Furthermore, EPA acknowledges that these activity level assumptions are only estimates and there is underlying uncertainty regarding the true impact of these fees.

Estimated costs associated with TSCA section 5 exemption notices and applications include pre-notice consultation, processing and reviewing the application, retaining records, and related activities. The average cost for EPA to review 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. EPA estimates that there will be 560 exemptions submitted annually. While EPA did not assume a reduction in the number of exemption submissions, EPA acknowledges that these activity level assumptions are only estimates and there is underlying uncertainty regarding the true impact of fees on exemption submissions. Our estimate of number of submissions is based on submissions received in FY 16 (Ref. 3: 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 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. EPA is also currently considering approaches for identifying potential candidates for prioritization and has included estimates for this the EPA costs for TSCA section 6. 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" (TSCA section 6(a)). Under the conditions of use the Agency expects to consider 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, have identified at least 20 low-priority substances for which risk evaluation is not warranted at this time, and have an additional 5-10 manufacturer-requested risk evaluations underway, if sufficient requests and fee payments have been made. For each risk evaluation that the Agency completes for a High-Priority Substance, TSCA requires that EPA identify another High-Priority Substance. The Agency expects to have between 25 and 30 risk evaluations ongoing at any time 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[γ]-2-benzopyran (HHCB) and by the Agency's experience with risk management actions addressing risks identified from particular uses of a chemical. In addition, EPA relied on our experience with work to date on the first ten 10 chemicals currently undergoing risk evaluation. 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 the unreasonable risks identified from a chemical. TSCA section 6(a) provides authority for EPA to prohibit or otherwise restrict the manufacture, processing, distribution in commerce, and commercial use of chemicals, as well as any manner or method of disposal of chemicals. Cost estimates for risk management activities have been informed, in part, by EPA's recent risk reduction actions on several chemicals, including development of the proposed rules regarding the use of N-methylpyrrolidone and methylene chloride in paint and coating removal and trichloroethylene in both commercial vapor degreasing and aerosol degreasing and for spot cleaning in dry cleaning facilities.

In addition to considering previous experience with TSCA Work Plan chemicals described in this Unit, 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 will be assessed.

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. Some commenters commented that risk evaluation costs were over-estimated since risk assessments by private firms are less expensive. EPA does not agree with this as the scope of an assessment from a private firm could be significantly lower than that required under amended TSCA.

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 Chemical Risk Evaluation

Risk Evaluation Activity	**Estimated Cost**
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
Total:	**$3,884,000**

Upon further consideration and in light of public comments received, EPA cost estimates for manufacturer-requested risk evaluations were revised from those in the

proposed rule to be consistent with the costs of EPA-initiated risk evaluations and to increase accountability and transparency by using an actual cost approach when determining the fee for a specific manufacturer-requested chemical review. In the proposed rule, EPA estimated the costs of a manufacturer-requested risk evaluation to be $2.6M, and the costs of an EPA-initiated risk evaluation to be $3.88M. Upon consideration of comments and further analysis, for purposes of the economic analysis and burden analysis, EPA estimated the same costs for both manufacturer-requested and EPA-initiated risk evaluations at $3.88M. However, EPA also carefully considered commenters that expressed concern that some risk evaluations may be less burdensome. In order to address concerns with potentially overcharging for some risk evaluations, EPA is implementing an actual cost approach to fees for manufacturer-requested risk evaluations as described in Unit III.

The estimated annual cost 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 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, data integration, meta-analysis of studies, and providing access to other models, tools and information already developed by ORD, and approximately $2,573,000 is attributed to the process of designating chemicals as High- or Low-priority substances (Ref. 3: Table 11).

d. Costs of collecting, processing, reviewing, and providing access to and protecting from disclosure as appropriate under section 14 information on chemical substances under TSCA. EPA's cost estimates for TSCA section 14 as presented for the proposed rule are

unchanged for the final rule.

Some commenters thought that the statutory requirement that EPA collect fees to defray 25% of the costs of "collecting, processing, reviewing, and providing access to and protecting from disclosure as appropriate under section 14" would apply to costs beyond those to manage information related to activities in TSCA section 4, 5 and 6. EPA generally agrees and is clarifying that cost estimates do fully consider these costs of general information management but do not include the costs of administering other authorities for collection such as those in TSCA section 8 and 11. EPA does not believe that Congress intended EPA to offset costs associated with administering authorities under these other sections. The statutory text clearly points to the authorities of sections 4, 5, 6 and 14 but not others. If the costs of administering activities under sections 8 and 11 were intended to be defrayed with fees, Congress would have specifically included those authorities in the statutory text. Therefore, cost estimates in the proposed rule already considered costs associated with managing information that for instance, comes in pursuant to a TSCA section 8 rule, but not the costs of developing the TSCA section 8 rule.

In response to commenter's requests to better substantiate costs related to information management, EPA expanded upon the categories in the cost estimates provided in the Technical Background Document (Ref. 3) from those released in the proposed rule to provide a cost breakout that better elaborates which activities were included and the associated cost estimates. Specific activities considered when developing this estimate for these activities include: prescreening/initial review; substantive review and making final determinations; documents review and sanitization; regulation development; IT systems development; and transparency/communications. Estimates also include Office of General Counsel costs

associated with issuing TSCA CBI claim final determinations, and supporting guidance, policy and regulation development for TSCA Section 14 activities, e.g., implementing the unique identifier provisions, access to TSCA CBI for emergency personnel, states, tribes and local governments, the TSCA CBI sunset provisions, among others.

Other chemical information management activities included in the analysis are: the costs for implementation of the Unique Identifier Rule; costs for implementing the requirements in TSCA section 14(d); costs for implementing the CBI sunset requirements; costs for Notice of Activity chemical identity CBI claim reviews, costs for Freedom of Information Act-Related CBI claim reviews; and costs for providing public access to Non-CBI Data and IT costs for operating and maintaining the CBI Local Area Network (LAN). The annual cost estimate of collecting, processing, reviewing, and providing access to and protecting from disclosure as appropriate under TSCA section 14 information on chemical substances under TSCA, including FTE and extramural costs, from fiscal year 2019 through fiscal year 2021 is $4,346,000 (Ref. 3).

1. 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, and 6, costs of collecting, processing, reviewing, and providing access to and protecting from disclosure as appropriate under TSCA section 14 information on chemical substances under TSCA 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. 4). Some of the direct program costs included in the estimates for TSCA sections 4, 5, and 6 and collecting, processing, reviewing, and providing access to and protecting from disclosure as appropriate under TSCA section 14 information on chemical substances under TSCA 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. 4). 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.

2. *Total costs of fee-triggering events.* The annual estimated costs for fee categories under TSCA section 4, including both direct and indirect program costs are shown in Table 3. Note that the costs presented in Tables 3, 4 and 5 include only the costs of fee-triggering events and so 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 TSCA sections 4, 5, 6 and of collecting, processing, reviewing, and providing access to and protecting from disclosure as appropriate under TSCA section 14 information on chemical substances under TSCA and, as such, are included in the overall cost estimates previously in Table 1.

Table 3: TSCA Section 4 Costs*

Fee Category	Estimated # of Ongoing Actions/Year	Estimated Cost to Agency/Action	Estimated Annual Cost to Agency
Test Order	10	$279,000	$2,795,000
Test Rule	1	$844,000	$422,000
Enforceable Consent Agreement	1	$652,000	$326,000

*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*

Fee Category	Estimated # of Ongoing Actions/Year	Estimated Cost to Agency/Action	Estimated Annual Cost to Agency
EPA-initiated risk evaluation	25	$3,884,000	$32,370,000
Manufacturer-requested risk evaluation: Work Plan chemical	2	$3,884,000	$2,589,000
Manufacturer-requested risk evaluation: Non-Work Plan chemical	3	$3,884,000	$3,884,000

*Numbers may not add due to rounding.

G. Fee Amounts.

With the exception of manufacturer-requested risk evaluations, EPA is finalizing the fee amounts as described in the proposed rule. EPA applied the same formula to calculate the fees per submission for each fee category as used in the proposal to ensure that 25% 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 under TSCA section 14 information on chemical substances under TSCA would be collected in any given year (i.e., approximately $20 million annually in fiscal years 2019 through 2021). Because the eight fee categories do not span all of the activities (e.g., costs of administering TSCA section 14, risk management activities under section 6, prioritization of chemicals for evaluation, support for alternative testing and methods development and enhancement, etc.), EPA set fee amounts to ensure these costs were captured.

1. *Fee amounts in general.* EPA received a number of comments on the specific fee amounts in the proposed rule. Commenters generally had suggestions for adjusting fee amounts in various ways: some specific to fee categories (described in the subsequent

paragraphs) and some more generally applicable across all fee categories. For example, one commenter suggested a maximum fee for scenarios where there is a small number of manufacturers subject to a large fee. Another commenter suggested that fee amounts should be adjustable based on the number of identified manufacturers for the particular chemical and activity. Ultimately, EPA determined not to adjust fee amounts for the final rule based on these general comments. As a primary matter, EPA does not know in advance how many manufacturers will be identified for a particular fee-triggering activity. As such, it would be impossible to provide some type of discount when the number of identified manufacturers is low, while still ensuring that EPA collects sufficient fees overall to defray 25% of implementation costs. EPA made a significant effort to explain its methodology for calculating fees and basis for determining fee amounts in the proposed rule, and has further clarified certain aspects in the final rule. EPA has many new responsibilities under TSCA, and this presents challenges for developing cost estimates for the fees rule. With more experience, EPA may be able to refine estimates and potentially adjust fee amounts when revisiting this rule in the future as required under TSCA.

2. *Fee amounts for TSCA section 4 activities.* EPA is finalizing three fee amounts – one for each of the TSCA section 4 fee categories: test orders, test rules and ECAs. These fees amount to approximately 3.5% of the total estimated activity cost. Several commenters expressed general support for the lower fee amounts for TSCA section 4 activities. Another commenter felt that section 4 fees were set too low – that they should be more proportional to actual costs, noting that Congress set a national policy that industry should pay for development of information. One commenter suggested that EPA consider assigning lower fees when companies agree to collaborate and produce data. EPA recognizes that

manufacturers will be responsible for paying to develop the test information in addition to paying the TSCA fee, and reflected this in assigning lower fee amounts in the proposed rule. While EPA strongly encourages collaboration amongst manufacturers when developing data, EPA does not believe that such collaboration should result in lower fees. If manufacturers collaborate to voluntarily produce and provide data that EPA needs, that may obviate the need for a test rule or order. If, however, EPA issues a test rule and companies subsequently form a consortium to jointly produce data, no discount would be warranted. EPA would still incur the cost of developing the test rule and reviewing data regardless of the extent of collaboration amongst manufacturers.

3. *Fee amounts for TSCA section 5 activities*. EPA is finalizing two fee amounts for TSCA section 5 activities – one for notices (PMNs, SNUNs and MCANs) at approximately 29% of the estimated cost of the activities, and one for exemptions (LVEs, LoREX, TME, Tier II, TERA and film articles) at approximately 89% of the estimated cost of the activities.

A number of commenters indicated that the proposed TSCA section 5 fees were too high and should be kept as low as possible to promote innovation. Some of these commenters argued that these fees will result in reduced new chemical submissions and lost social benefits, and will reduce research and development efforts in the industry. Another commented that EPA was not permitted under TSCA to set fees based on promoting innovation. Others had more specific comments or requests. Some commenters, for example, suggested that EPA also apply a PMN discount for graduates of EPA's Sustainable Futures program (Ref. 5). Another commenter expressed concern regarding EPA's proposal to establish the same fee amount for both individual and consolidated notices, even though EPA acknowledges that consolidated submissions are more costly to review.

EPA appreciates commenters' concerns regarding increased TSCA section 5 fees and potential impacts to chemical innovation. First, amongst the fee categories for TSCA sections 4, 5, and 6 activities, EPA proposed to collect the bulk of fees from manufacturers subject to TSCA section 6 EPA-initiated risk evaluations, in part, to minimize impacts to innovation and competitive standing for new chemical manufacturers. TSCA calls for EPA to implement TSCA in a manner that does not "impede" or create "unnecessary barriers to technological innovation." See TSCA section 2(b)(3). Second, the proposed fee amount for PMNs, MCANs and SNUNs was only moderately higher than the current fee adjusted for inflation (i.e., $10,400). As discussed in the proposed rule preamble, EPA also benchmarked the proposed new chemicals fees against similar activities conducted in EPA's pesticide program and found them to fall within an appropriate range of costs. With respect to specific requests to lower fee amounts, EPA has similarly determined not to make any adjustments for the final rule. Sustainable Futures program graduates do not currently receive a PMN discount and EPA did not propose to provide one. While one aim of the program is to encourage better quality submissions, there is no evidence to support that such submissions are categorically any less complex or expensive to review. EPA chose to lump PMN, MCAN and SNUN fees into a single category, setting a single fee applicable to each, for practical implementation reasons. Although certain activities (i.e., consolidated PMNs and MCANs) may cost the agency more than other activities in the same category (i.e., individual PMNs and MCANs), EPA chose to assign the same fee amount for individual and consolidated submissions in furtherance of EPA's goal to develop a practicable, implementable TSCA fee structure. EPA believes that there is value in keeping the fee structure relatively simple from an implementation perspective, but also because EPA currently lacks the experience and

information to more narrowly tailor fees while still meeting the collection requirements in TSCA. Finally, EPA is finalizing the fee amount for section 5 exemptions. EPA is finalizing the proposal to eliminate the ''intermediate PMN'' fee category. As discussed in the preamble to proposed rule, discounted fees are not warranted for intermediate PMNs as EPA has not realized costs savings in review of these submissions. Reviewing and processing these exemptions is not an insignificant amount of work, and EPA believes the exemption fee - set at a fraction of the fee for PMNs and other notices - is well within reason.

4. *Fee amounts for TSCA section 6 activities.* EPA is finalizing one fee amount for EPA-initiated risk evaluations at approximately 35% of the estimated cost of the activity. As indicated earlier, EPA is finalizing an actual cost approach for manufacturer-requested risk evaluations, whereby the requesting manufacturer (or requesting consortia of manufacturers) would be obligated to pay either 50% or 100% of the actual costs of the activity, depending on whether or not the chemical was listed on the TSCA Work Plan, respectively. EPA received a number of comments on the proposed section 6 fee amounts. Some expressed concern that the amounts were too high, and could result in manufacturers abandoning production of critical substances. Others suggested discounts when data/analytical needs were low, when companies voluntarily submit additional data, or if a company would – prior to or during the risk evaluation - agree to voluntarily phase out manufacture of the substance. One commenter requested clarification that only one fee will be required for a risk evaluation, even if it is completed in phases as contemplated in the Risk Evaluation framework rule, and that only one fee will be required for risk evaluations performed on categories of chemicals.

While EPA recognizes the possibility for variation in complexity of a risk evaluation

for any number of reasons (e.g., availability of data, number and type of associated uses, etc.), and therefore variation in cost, EPA has limited experience in conducting risk evaluations under new TSCA except for that related to ongoing work associated with the first 10 chemicals, and no experience or evidence to justify specific cost reductions related to number or type of uses, availability of more information, etc. In assigning fees across activities in TSCA sections 4, 5, and 6, EPA believes it achieved an appropriate balance in the proposal: a structure that was both efficient and practical to implement, while also distributing the fee burden across the fee-triggering events consistent with stakeholder input and the goals and policies of TSCA. With respect to commenter's request for clarification, EPA will only charge one fee for each risk evaluation activity, including risk evaluations on a category of substances, regardless of how unreasonable risk determinations may be communicated.

The final fee amounts are described in Table 6.

Table 6: Final TSCA Fee Amounts

FEE CATEGORY	FEE AMOUNT
TSCA Section 4	
Test order	$9,800
Test rule	$29,500
Enforceable consent agreement	$22,800
TSCA Section 5	
PMN and consolidated PMN	$16,000
SNUN	
MCAN and consolidated MCAN	
LoREX	$4,700
LVE	
TME*	
Tier II exemption	
TERA	
Film Articles	
TSCA Section 6	
EPA-initiated risk evaluation	$1,350,000
Manufacturer-requested risk evaluation on a chemical	Initial payment of $1.25M,

included in the TSCA Work Plan	with final invoice to recover 50% of Actual Costs
Manufacturer-requested risk evaluation on a chemical not included in the TSCA Work Plan	Initial payment of $2.5M, with final invoice to recover 100% of Actual Costs

*EPA will waive the TME fee for submissions from companies that have graduated from EPA's Sustainable Futures program.

5. *Fee amounts for small businesses.* EPA is finalizing reduced fee amounts for small businesses, consistent with the proposed rule and without change. EPA is, however, adjusting the small business size standard as discussed in Unit III. The reduced fee amounts are summarized in Table 7. These fee amounts represent an approximate 80% reduction compared to the base fee for each category. In one case, for TSCA section 5 notices (i.e., PMNs, MCANs and SNUNs), the small business reduction is 82.5%. For all fee categories, the reduced fee is only available when the only entity or entities are small businesses, including when a consortium is paying the fee and all members of that consortium are small businesses. Consistent with the proposed rule, reduced fees are not available for small business manufacturers requesting a risk evaluation, as TSCA requires those fees to be set at a specific percentage of the actual costs of the activity.

Some commenters expressed concern regarding accommodations made to small businesses in the proposed rule. For example, a few commenters argue that reduced fees for companies with annual sales of $91 million is an undue accommodation for companies that can clearly support fees, and the discount relief was unjustified and excessive. Another commenter urged EPA to clarify and better support its proposed discount of 80%. With respect to the approximate 80% discount in the proposed rule, EPA continues to believe this is appropriate. The discount is generally in line with EPA's discount for small businesses in the pesticides program (i.e., 75%), but slightly higher in line with significant stakeholder

input regarding the need to minimize impacts to small businesses.

Table 7: Final TSCA Fees for Small Businesses

FEE CATEGORY	SMALL BUSINESS FEE
TSCA Section 4	
Test order	$1,950
Test rule	$5,900
ECA	$4,600
TSCA Section 5	
PMN and consolidated PMN	$2,800
SNUN	
MCAN and consolidated MCAN	
LoREX	$940
LVE	
TME	
Tier II exemption	
TERA	
Film Articles	
TSCA Section 6	
EPA-initiated risk evaluation	$270,000
Manufacturer-requested risk evaluation on a chemical included in the Work Plan	$1,250,000 initial payment + 50% of total actual costs
Manufacturer-requested risk evaluation on a chemical not included in the Work Plan	$2,500,000 initial payment + 100% of total actual costs

H. Definition for "Small Business Concerns"

EPA is also finalizing a revision to the size standard used to identify businesses that can qualify as a "small business concern" under TSCA for the purposes of fee collection. EPA proposed to adjust the 1988 size standard used to identify businesses that can qualify as a "small business concern" from a prior revenue threshold of $40 million to approximately $91 million (See Ref. 6). EPA also proposed to use average annual sales values over the three years preceding the activity, instead of just one year. Further, EPA proposed to apply this definition to all fee categories in TSCA, not just TSCA section 5 submissions.

EPA specifically requested comment on this proposal and some alternative approaches, and commenters provided a variety of views. A number of commenters

expressed support for SBA's employee based definition. Other commenters suggested that EPA apply only the inflation-adjusted approach in proposal, or else risk over-identifying small business concerns. At least one commenter expressed support for the proposed revenue-based definition, arguing that an employee-based metric is antiquated. A number of commenters supported an "either/or" approach, where a company could choose to certify as a small business under either the EPA's proposed revenue standard or SBA's employee-based standards. One commenter suggested that EPA consider an additional "micro business" category of 1-9 employees with an associated fee cap of $100.

After further consideration, review of the public comments and consultation with SBA, including the Office of Advocacy, EPA has determined to adopt an employee-based size standard modeled after SBA's standards. When establishing its size standards, SBA examines various industry characteristics such as average firm size, degree of competition within an industry, start-up costs and entry barriers, and distribution of firms by size. SBA also evaluates federal market factors including a small business's share in total industry's receipts. For more details, please see the "SBA's Standards Methodology" white paper, available at www.sba.gov/size. The SBA size standards are industry-specific mostly based on either average annual revenue or number of employees, for reference please see the SBA size standards at 13 C.F.R. 121.202. In order for an entity to be classified as a small business for federal contracting and other small business programs, its enterprise level revenue or number of employees (including all affiliates) shall not exceed the size standard for the applicable industry. These size thresholds are determined at the 6-digit North American Industry Classification System (NAICS) levels. SBA's employee-based size thresholds range from 100 to 1,500 employees to account for differences among NAICS codes.

The Small Business Jobs Act of 2010 (Jobs Act) (Pub. L. 111-240, 124 Stat. 2504, Sept. 27, 2010) requires SBA to review every five years all size standards and make adjustments to reflect current industry and market conditions. SBA completed the first 5-year review of size standards in early 2016 and is currently performing the second 5-year review. As part of that effort, SBA plans to publish for public comments a series of proposed rules on size standards revisions in the coming years.

For the final rule, EPA has incorporated the 2017 NAICS codes and SBA's associated size thresholds most likely to apply to manufacturers and processors subject to TSCA fees, see table 700.43. For those NAICS codes not represented on the table provided in 700.43 of the final rule, the manufacturer or processor must have 500 or fewer employees to be considered as a "small business concern" under TSCA for the purposes of fee collection. As a general matter, the reduction in revenue collection was minimal when applying an employee-based standard versus a revenue-based standard, and EPA deferred to the expertise of SBA in relying on an employee-based standard for this rulemaking. The definition in the final rule is updated accordingly, as well as supporting materials.

EPA considered several other options offered by commenters including an "either/or" approach and a "micro-business" category. With respect to the first, EPA did not believe it was appropriate to allow small businesses to choose to certify either under a revenue-based standard, or an employee-based standard. Doing so would potentially result in a significant increase to the total number of businesses identified as small, resulting in a shortfall in EPA's overall fee revenue and the need to adjust the fee structure – either by providing small businesses with a lower discount, or by increasing fees for other businesses. Adding a "micro-business" category would likely create similar issues with revenue shortfalls for EPA

and a need to increase fee amounts elsewhere. Further, such a standard is not currently used anywhere in the federal government, including SBA. Ultimately, EPA did not believe the TSCA fees rule was an appropriate venue to introduce a micro-business standard. As indicated in the proposed rule, EPA believes a forthcoming TSCA section 8(a) rulemaking will provide for more consideration of appropriate size standards for industries subject to TSCA and offer the public further opportunities to comment on small business size standards, and EPA is committed to considering the results of that rulemaking, as well as the experience and information gained from implementing this final rule and future rulemaking to update the TSCA fees rule for the next three-year cycle.

I. Payment of Fees and Refunds

1. *Timing.* The final rule generally requires upfront payment of fees (i.e., payment due prior to reviewing a TSCA section 5 notice, within 120 days of publication of final test rule, within 120 days of issuance of a test order, within 120 days of signing an ECA, within 30 days of granting a manufacturer-requested risk evaluation, and within 120 days of publishing the final scope of a risk evaluations). However, for manufacturer-requested risk evaluations, payment will now be collected in two installments over the course of the activity.

A number of commenters encouraged EPA to allow for phased payments, particularly for TSCA section 6 activities. Some of these commenters suggested that payment at specific milestones would better hold EPA accountable and assist with business planning efforts. EPA is finalizing an actual cost approach for manufacturer-requested risk evaluations which will, in effect, allow for phased payments (i.e., initial payment followed later by a final invoice).

This final rule is effective the day after publication and will apply to all submissions that are received starting October 1, 2018. Section 553(d)(3) of the Administrative Procedure Act (''APA''), 5 U.S.C. 553(d), provides that final rules shall not become effective until 30 days after publication in the Federal Register ''except . . . as otherwise provided by the agency for good cause.'' The purpose of this provision is to ''give affected parties a reasonable time to adjust their behavior before the final rule takes effect.'' Omnipoint Corp. v. Fed. Commc'n Comm'n, 78 F.3d 620, 630 (D.C. Cir. 1996); see also United States v. Gavrilovic, 551 F.2d 1099, 1104 (8th Cir. 1977) (quoting legislative history). Thus, in determining whether good cause exists to waive the 30-day delay, an agency should ''balance the necessity for immediate implementation against principles of fundamental fairness which require that all affected persons be afforded a reasonable amount of time to prepare for the effective date of its ruling.'' Gavrilovic, 551 F.2d at 1105. EPA has determined that there is good cause for making this final rule effective immediately because, under TSCA, as amended, EPA was directed to institute a fee collection program to ensure that the Agency has a sustainable source of funding to ensure successful implementation of TSCA as Congress intended. As is clear by the fact that Congress provided different parameters for setting fees both before October 1, 2018 (26(b)(4)(B)) and after (26(b)(4)(F)), EPA believes it was Congress' intent for EPA to be able to start assessing fees as quickly as possible after the enactment of the fee provisions and that fees would already be in place by October 1, 2018 when they would need to be updated. As required by TSCA 26(b)(4)(E), EPA consulted and met with stakeholders that were potentially subject to fees in August 2016, held and industry-specific consultation meeting and webinar in September 2016, participated in a Small Business Roundtable discussion in March 2018, and had several

meetings with individual stakeholders through the development of the final rule, always stressing the urgency of collecting fees and the expected timing of collections. In addition, EPA provided public notice when including this effective date in the proposed rule, did not receive any comments on this provision, and proposed that all submissions starting October 1 would be subject to fees regardless of when the rule becomes effective. The fee amounts being finalized have not changed from the proposal other than those for manufacturer-requested risk evaluations, which will initially incur a smaller upfront fee. For these reasons, EPA believes that reasonable notice, including opportunity for comment has been provided regarding the date when fee collections will occur and that persons subject to the fees have had reasonable time to prepare to pay the fees. Between October 1, 2018 and when the rule is effective, EPA will track submissions and then send invoices to affected companies within 30 days of the effective date. Since all submitters will be subject to the fees starting October 1, 2018, and to minimize the need for after-the-submission invoicing, EPA believes there is good cause for an effective date one day after publication. For these reasons, the agency finds that good cause exists under APA section 553(d)(3) to make finalize its proposed approach to collect fees for all submissions that are received starting October 1, 2018.

2. *Consortium formation and payment.* Additionally, EPA is extending the amount of time for manufacturers to notify EPA of their intent to form a consortium and the time to provide payment for certain TSCA section 4 and 6 activities. EPA believes this additional time will be useful for businesses to financially plan for the additional expense. Specifically, the final rule allows manufacturers subject to 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 120 days of certain events as described previously. For EPA-initiated risk evaluations, full payment is due within 120 days of EPA publishing the final scope of a chemical risk evaluation. The proposed rule provided 60 days for these activities. EPA believes this additional time will assist manufacturers with the process of joining a consortium, if they so choose, and 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**. However, for manufacturer-requested risk evaluations, EPA will still require the initial payment within 30 days of when EPA grants the request to conduct the evaluation, as indicated in the proposed rule. A manufacturer or manufacturers who make such a request have complete control of the timing of the request, and are better positioned to sort out payment and fee allocation issues related to a consortium before the request is ever sent to EPA.

3. *Applicability to ongoing activities*. As described at length in the proposed rule, EPA proposed to begin recording fee obligations starting on October 1, 2018, even if the final rule is not yet effective. EPA is codifying this approach in the final rule. Specifically, EPA intends to record actions that would trigger payment of fees per the final rule and, once the final rule is effective, send invoices to the affected parties within 30 days containing information on timing, fee amounts and other details based on this final rule.

A number of commenters requested that EPA explicitly state whether fees will apply to certain ongoing activities, such as the first 10 chemical risk evaluations and TSCA section 5 submissions under review at the time the rule is finalized. To be clear, EPA will not collect fees for events that started prior to October 1, 2018 such as the first ten risk evaluations, or

any TSCA section 5 activities initiated before that date. In these cases, the fee event is already ongoing, and EPA has determined not to retroactively apply fee obligations on these manufacturers. In addition, the costs of completing these risk evaluations has been included in the overall program cost estimates for TSCA section 6 activities, and EPA expects to recover 25% of these costs through implementation of this rule.

4. *Payment method.* EPA originally proposed to accept payment of fees through two different electronic payment options: Pay.gov and Fedwire. However, upon further review, EPA has determined that Fedwire is not a viable option for the Agency's current financial systems. As such, the final rule will only allow electronic payment through the secure, Pay.gov collection portal. As indicated in the proposed rule, 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. Manufacturers (and processors, where appropriate) 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). Because Pay.gov does 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 are found at *https://www.epa.gov/financial/additional-instructions-making-payments-epa.*

5. *Refunds.* EPA proposed to issue full and partial refunds in certain circumstance related to TSCA section 5 activities, consistent with EPA's authority under TSCA sections 5(a)(4)(B) and 26(b)(4)(G). EPA is finalizing those provisions, with some additional

clarifications and corrections in light of public comments. EPA will issue full refunds for (1) PMN submissions that are determined not to be a new chemical substance, (2) MCAN submissions when the microorganism is determined not to be a new microorganism or significant new use, (3) SNUN submissions if the use is determined not to be a significant new use, (4) when the Agency fails to make a determination on a notice by the end of the applicable notice review period, unless the submitter unduly delayed the process, and (5) when the Agency fails to approve or deny an exemption with the applicable review period, unless the submitter unduly delayed the process. EPA will issue partial refunds (i.e., 75% of the fee amount) if a TSCA section 5 submission is withdrawn during the first 10 business days after the beginning of the applicable review period. EPA is not able to issue refunds for the entire fee amount because work begins as soon as EPA receives and application. Due to concerns with administrative burden and potential delays in issuing refunds, EPA will not calculate and refund a unique amount for each withdrawn submission. Although EPA originally proposed to issue a full refund for certain incomplete submissions, EPA's existing regulations already provide a process and timeline for EPA and the submitter to correct the issue. EPA believes the existing approach is more efficient than immediately issuing a full refund, and requiring the submitter to provide a new, complete submission.

A number of commenters had suggestions with respect to the refund provisions in the proposed rule. Several asked EPA to clarify the circumstances under which a full refund would be granted in the event the review is not completed within the applicable review period and what was meant by "undue delay" by the submitter that would prevent the submitter from receiving that full refund. Relatedly, a few commenters argued that voluntary suspensions shouldn't pause the review period.

With respect to full refunds, EPA is generally required to complete TSCA section 5 reviews within 90 days, and can unilaterally extend that period to 180 days under certain circumstances in TSCA. Consistent with longstanding practice, EPA and the submitter can, and often do, agree to suspend the review period to allow the submitter to develop new information, or to provide EPA with time to review new information. EPA has also historically allowed the submitter to amend their submission at any time during the review period. EPA intends to continue these practices. A voluntary suspension pauses the applicable review period. "Undue delay" by the submitter, as contemplated in the proposal, might occur if the submitter submits an amended submission or significant new information late in the review process and does not agree to suspend the review period. In such a case, EPA does not believe it should be required to issue a refund if the TSCA review period expires. As a practical matter, EPA believes that a scenario in which as EPA has authority to unilaterally extend the review period for an additional 90 days. Moreover, most submitters have appreciated the flexibility to suspend the review period, as doing so is often in their best interest.

A few commenters asked EPA to clarify the circumstances, if any, where EPA would issue refunds in the TSCA sections 4 or 6 context, such as when a manufacturer-requested risk evaluation fee exceeds the actual costs. EPA did not propose any refund provisions for TSCA sections 4 or 6 EPA-initiated risk evaluation activities. EPA does not expect to exceed actual costs for these costs given that fee amounts are set significantly below estimated costs of these activities. See Technical Background Document, (Ref. 3). For example, fees for TSCA section 4 activities are set at approximately 3.5% of the estimated costs of those activities. For both categories of fee-triggering events, EPA also believe that refunds are not

appropriate based on late entrants or other timing reasons. In the context of manufacturer-requested risk evaluations, EPA is finalizing an actual cost approach, so there may be – in rare circumstances –a scenario where a manufacturer might be charged more than the cost of completing the activity and would be entitled to a refund. EPA has updated the final regulatory text to account for this possibility.

J. Multiple Parties Subject to Fee Obligations

The final rule allows joint submissions under TSCA section 5, and the formation of, and payment by, consortia for submissions under TSCA sections 4 and 6. Manufacturers who seek to jointly submit a TSCA section 5 notice would be required to remit the applicable fee for each TSCA 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 small business discount, each joint submitter of a TSCA section 5 notice must qualify as a small business concern as defined in this rule. Manufacturers may also form a consortium to pay TSCA user fees for section 4 and 6 activities. The consortium must notify EPA of such intent. Once established, the consortium determines how the user fee would be split among the members, and ultimately paid to EPA. In response to comments, EPA made some minor modifications to this process, and provides some additional clarification on related issues:

1. *Consortia: Timing of formation and payment.* Under the proposed rule, manufacturers would have been required to notify EPA of their intent to form a consortium within 30 days of the fee-triggering event and pay EPA within 60 days of the fee-triggering event. A significant number of commenters urged EPA to extend the time for consortia to form and pay, with suggestions of anywhere from 90 to 180 days. EPA recognizes the likelihood of challenges and complexities associated with forming consortia and managing

payments. In response to public comments, EPA will extend the amount of time for consortia to notify EPA of their intent to form, as well as the payment due date, each by 30 days. Thus, manufacturers will have 60 days to notify EPA of their intent to form a consortium from the triggering event, and 120 days total from the triggering event for payment.

2. *Consortia: Complex scenarios.* EPA is providing some additional clarification on the division of costs amongst consortia and individual manufacturers for certain complex scenarios identified by commenters. The ideal scenario is that a single consortium forms and independently agrees upon allocation of payment amongst its members. In such a scenario, EPA would send a single invoice to the consortium, and receive a single payment in return. It is possible, however, for any number of more complicated scenarios to arise, such as formation of multiple consortia, or a combination of consortia and individual manufacturers not associated with the consortia. Adding discounts for small business concerns further complicates the allocation of fees in these scenarios.

Consistent with the formula in the proposed rule, in any scenario where there is not a single consortium comprised of all manufacturers subject to a single fee, EPA will take the following steps to allocate fees:

- Count the total number of manufacturers, including the number of manufacturers within any consortia.
- Divide the total fee amount by the total number of manufacturers, and allocate equally on a per capita basis to generate a base fee.
- Provide all small businesses who are either (a) not associated with a consortium, or (b) associated with an all-small business consortium with an 80% discount from the base fee referenced previously.

- Calculate the total remaining fee and total number of remaining manufacturers by subtracting out the discounted fees and the number of small businesses identified.
- Reallocate the remaining fee across those remaining individuals and groups in equal amounts, counting each manufacturer in a consortium as one person.

Small businesses in a successfully-formed consortium (other than an all-small business consortium) cannot be afforded the 80% discount by EPA. Association with consortia for purposes of jointly paying fees is a voluntary activity; EPA lacks the authority to compel consortia managers to provide small businesses with discounts. However, consortia are strongly encouraged to provide a discount for small business concerns.

For example, consider a scenario in which there is one consortium formed (with a mix of small businesses and non-small businesses), plus some additional individual small businesses and non-small businesses not associated with the consortium. There are 10 total manufacturers, with 5 in the consortium and 5 individuals (2 small businesses and 3 non-small businesses). Assume the total fee is $100,000. The base fee would be $10,000 ($100,000 divided by 10 manufacturers). The two individual small businesses (not associated with consortium) would be responsible for $2,000 each ($10,000 base fee x 0.2). That leaves $96,000 to be paid across 8 total remaining manufacturers. The consortium (5 of 8 remaining manufacturers) would responsible for 62.5% of the remaining fee or $60,000, and they would be free to determine how to allocate that amount amongst their membership. Any small businesses within the consortium are not provided a discount by EPA. Each of the 3 individual non-small business manufacturers would be responsible for 12.5%. of the remaining fee or $12,000.

3. *Consortia: Failure to reach agreement.* If a consortium is unable to reach

agreement on splitting the fee, the principal sponsor must notify EPA prior to the expiration of the 60-day notification period. EPA defines the principal sponsor as a person who assumes primary responsibility for the direction of the study, the payment of fees to EPA, and for oral and written communication with EPA. This notification by the principal sponsor effectively nullifies the formation of the consortium, and each member will be treated as an individual manufacturer, and must pay their portion of the fee – as calculated by EPA - within the time period remaining. The Agency will divide the total fee by the number of manufacturers. Small businesses will be afforded an 80% discount.

4. *Consortia: Small business concerns.* EPA strongly encourages consortia to set lower fees for small business concerns; Congress generally intended small businesses to be afforded lower fee payments (TSCA section 26(b)(4)(A)). Some commenters suggested that EPA should go further in prescribing fairness in consortia dealings, including dealings with small businesses. At least one commenter suggested that an expectation that consortia would assign lower fees to small businesses is unrealistic. Another commenter suggested EPA should require consortia to give a small business discount. One commenter suggested that the proposal would result in formation of all small business consortia every time, given that small businesses would surrender their small business protections by consorting with non-small businesses. However, association with a consortium is a voluntary activity; a small business will always have the choice to not associate with a consortium and to receive the small business discount. Further, EPA does not believe it has the authority in TSCA to compel consortia managers to provide a discount to small businesses. Nevertheless, EPA strongly encourage consortia to do so.

5. *Consortia: Administrative costs and burden.* Several commenters suggested that

EPA recognize administrative costs associated with consortia formation and management that companies would be expected to bear, and to set those expectations in final rule. The administrative costs of consortia management would be set by third parties and completely outside the control of EPA, and would not be appropriate for EPA to factor this into program cost estimates or otherwise reflect in the fee amounts. However, based on public comments, EPA is including some minor updates to the economic analysis to reflect this additional administrative burden and costs associated with forming consortia for the distinct purpose of submitting fee payments.

K. Enforcement

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. 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 a consortium. 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. EPA may develop enforcement response policy guidance provisions for this rule. In the meantime, EPA's Office of Enforcement will rely on TSCA section 16(a)(2)(B) and GM 21 at *https://www.epa.gov/enforcement/policy-civil-penalties-epa-general-enforcement-policy-gm-21.*

L. Compliance Date

EPA will be able to start collecting fees the day after the final TSCA user fees regulations are published in the **Federal Register**. For EPA to sufficiently address the increased workload under TSCA, the Agency must start collecting fees as soon as possible for use in defraying implementation costs. All submissions starting October 1, 2018 are subject to the fees in this rule regardless of when the rule becomes effective. For submissions received between October 1, 2018 and the effective date of the rule, EPA will invoice submitters within 30 days.

M. Conforming and Other Technical Amendments

EPA is finalizing minor changes to several of its regulations that cross-reference the part 700 fees regulations, specifically 40 CFR 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 finalized today. These include 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

EPA has evaluated the potential costs for entities potentially subject to this final rule. More details can be found in the Economic Analysis (Ref. 2) for this rule.

For the baseline, EPA used the number of section 5 submissions received in FY 2016 for each of the types of fee-triggering section 5 categories (Ref. 7) as the estimate of the number of submissions per section 5 fee category for the next three years in the absence of

the rule. As a result of the final rule, EPA expects that the number of PMNs, MCANs, and SNUNs submitted would decline by 20% from the baseline, while the number of exemptions would remain the same, on average. Test orders under section 4 are new under TSCA as amended and the average number of test orders expected per year represents an EPA estimate based on previous experience and expected work under TSCA as amended. Similarly, for the other fee categories under section 4 (test rules and ECAs), EPA also estimated the expected number of such actions per year based on previous experience and expected work under TSCA as amended. The amended TSCA regulations specify the number of risk evaluations that EPA must have ongoing over the next three years. The Agency expects to have between 20 and 30 risk evaluations ongoing in any given year at different stages in the review process, including manufacturer-requested evaluations.

EPA calculated fees by estimating the total annual costs of administering TSCA sections 4, 5, and 6 (excluding the costs of manufacturer-requested risk evaluations) and of collecting, processing, reviewing, and providing access to and protecting from disclosure as appropriate under section 14; identifying the full amount to be defrayed by fees under TSCA section 26(b) (i.e., 25% of those annual costs); and allocating that amount across the fee - triggering events in sections 4, 5, and 6, weighted more heavily toward section 6 based on early industry feedback. EPA estimates the total fee collection by multiplying the fees with the number of expected fee-triggering events under full implementation for each fee category, for a total of approximately $20 million in average annual fee revenue. This total does not include the fees collected for manufacturer-requested risk evaluations. EPA estimates that section 4 fees account for less than one percent of the total fee collection, section 5 fees for approximately 43 percent, and section 6 fees for approximately 56 percent.

Total annual fee collection for manufacturer-requested risk evaluations is estimated to be $1.3 million for chemicals included in the Work Plan (based on two requests over the three-year period) and approximately $3.9 million for chemicals not included in the Work Plan (based on three requests over the three-year period).

For small businesses, EPA estimates that 18.6 percent of section 5 submissions will be from small businesses that are eligible to pay the small business fee because they are classified as small businesses based on the SBA small business thresholds. Total annualized fee collection from small businesses submitting under section 5 is estimated to be $ 339,000 (Ref. 2). For sections 4 and 6, reduced fees paid by eligible small businesses and fees by paid non-small businesses may differ over the three-year period that was analyzed, since the fee paid by each entity is dependent on the number of entities identified per fee-triggering event. EPA relied on past experience with Test Rules for HPV chemicals under section 4 as well as work to date on the first ten 10 chemicals currently undergoing risk evaluation under section 6 to inform its estimates of average number of small businesses impacted per action, and estimates that average annual fee collection from small businesses impacted by section 4 and section 6 would be approximately $7,000 and $926,000, respectively. For each of the three years covered by this rule, EPA estimates that total fee revenue collected from small businesses will account for about 6 percent of the approximately $20 million total fee collection, for an annual average total of approximately $1.3 million.

This rule establishes fee requirements for affected manufacturers (including importers) and, in some cases, processors of chemical substances. The fees to be paid by industry would defray the cost for EPA to administer TSCA sections 4, 5, 6, and collecting, processing, reviewing, and providing access to and protecting information about chemical

substances from disclosure as appropriate under TSCA section 14. Absent this 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 rule, 25% of EPA costs to administer TSCA section 4, 5, 6, and collecting, processing, reviewing, and providing access to and protecting information about chemical substances from disclosure as appropriate under TSCA section 14, and activities paid from general revenue would be transferred via the 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 rule does not include the fees collected from industry by EPA. Rather, it includes the opportunity costs incurred by industry, such as the cost to read and familiarize themselves with the rule; determine their eligibility for paying reduced fees; register for CDX; form, manage and notify EPA of participation in consortia; notify EPA and certify whether they will be subject to the action or not; and arrange to submit fee payments via Pay.gov. Total social costs also include the additional costs to EPA to administer fee assessment and collection for TSCA sections 4, 5, 6, and collecting, processing, reviewing, and providing access to and protecting information about chemical substances from disclosure as appropriate under TSCA section 14. The total annualized opportunity cost to industry is approximately $231,000 and the additional annualized Agency cost is $7,000, yielding a total annualized social cost of approximately $238,000.

V. References

The following is a listing of the documents that are specifically referenced in this document. The docket includes these documents and other information considered by EPA, including documents that are referenced within the documents that are included in the docket,

even if the referenced document is not physically located in the docket. For assistance in locating these other documents, please consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

1. 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. 2018. EPA. Updated Technical Background Document for TSCA Fees. September 2018.

4. 2017. EPA. Interagency Agreement and Oil Indirect Cost Rates for FY 2018 and Beyond. September 28, 2017.

5. 2002. EPA. 67 FR 76282. Sustainable Futures – Voluntary Pilot Project Under the TSCA New Chemicals Program.

6. 2016. Abt Associates. Memorandum: Inflation of Small Business Definition under section 5 of TSCA. August 31, 2016.

7. 1987. EPA. Proposed Fees for Processing Premanufacture Notices, Exemption Applications and Notices, and Significant New Use Notices. 42 FR 12940.

8. 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.

9. 2018. EPA. TSCA Fee Reporting Notice. September 2018.

VI. Statutory and Executive Order Reviews

Additional information about these statutes and Executive Orders can be found at

https://www.epa.gov/laws-regulations/laws-and-executive-orders.

A. *Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review*

This action is a significant regulatory action that was submitted to the Office of Management and Budget (OMB) for review under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011). Any changes made in response to OMB recommendations have been documented in the docket for this action as required by section 6(a)(3)(E) of Executive Order 12866. EPA prepared an economic analysis of the potential costs and benefits associated with this action (Ref. 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 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 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 final 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 No. 2569.01 and OMB Control No. 2070-0208. You can find a copy of the ICR in the docket (Ref. 8), and it is briefly summarized here.

The information collection activities associated with the rule include familiarization with the regulation; reduced fee eligibility determination; CDX registration; formation,

management and notification to EPA of participation in consortia; self-identification and certification; and electronic payment of fees through *Pay.gov*.

Respondents/affected entities: Persons who manufacture, 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 or 5, or 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: 1,418 respondents.

Frequency of response: On occasion to EPA as needed.

Total estimated burden: 539 hours (per year). Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: $230,607 (per year), includes $0 annualized capital or operation and maintenance costs.

An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The OMB control numbers are displayed either by publication in the Federal Register or by other appropriate means, such as on the related collection instrument or form, if applicable. The OMB control numbers for certain EPA regulations are listed in 40 CFR part 9.

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; and 24 small businesses may be affected by section 6 actions. For section 5 actions, the total discounted annual fee collections and opportunity cost for the affected small businesses is expected be about $344,000. For section 4 and section 6 actions, total discounted annual fee collections and opportunity cost for the affected small business is expected to be about $14,000 and $927,000 respectively. In total, the annual fee collections and opportunity costs for the 298 affected small businesses is expected to be about $1.3 million.

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 estimates the median annual sales for small businesses likely to be affected by TSCA section 4 and TSCA section 6 actions to be approximately $5,445,000; and $3,475,000 for small businesses likely to be affected by TSCA section 5 actions. The average annual cost per affected small business is expected to be about $170 for section 4; $1,800 for section 5, and $38,600 for section 6.

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 would establish 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*

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.

The fees collected under this rule will assist the Agency in carrying out various requirements under TSCA, including conducting risk evaluations, requiring testing of chemical substances and mixtures, and evaluating and reviewing new chemical submissions, 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.

L. Congressional Review Act (CRA)

This action is subject to the CRA, 5 U.S.C. 801 *et seq.*, and EPA will submit a rule report to the U.S. Senate, and the U.S. House of Representatives, and the Comptroller General of the United States. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects

40 CFR Part 700

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

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: 9-27-18

Andrew R. Wheeler,
Acting Administrator.

Therefore, 40 CFR chapter I, subchapter R, is amended 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 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 (Pub. L. 114-182).

(b) *Applicability*. This subpart applies to all manufacturers 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, who manufacture a chemical substance that is subject to a risk evaluation under TSCA section 6(b)(4) of the Act, and who process a chemical substance that is the subject of a Significant New Use Notice (SNUN) or Test Market Exemption (TME) under section 5 of the Act and who are required to submit information under section 4 of the Act related to a SNUN submission.

(c) *Effective date.* After [*insert date 1 day after date of publication 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;

b. Revising the introductory text;

c. Adding in alphabetical order definitions for "Consortium", "Enforceable consent agreement", and "EPA-initiated risk evaluation";

d. Removing the definitions of "Exemption application" and "Intermediate premanufacture notice";

e. Revising the definition of "Joint submitters";

f. Adding in alphabetical order a definition for "Manufacturer-requested risk evaluation";

g. Revising the definition of "Person";

h. 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 and/or processors who have made an agreement to jointly split the cost of applicable 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 or processor.

* * * * *

Principal sponsor means a person who assumes primary responsibility for the direction of study, the payment of 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 a manufacturer or processor who meets the size standards identified in the following table. The number of employees indicates the maximum

allowed for a manufacturer or processor to be considered small. If the North American Industry Classification System (NAICS) code of a manufacturer or processor is not represented in the table, it will be considered small if it has 500 or fewer employees. When calculating the number of employees, a manufacturer or processor must include the employees of all companies they "own or control," as defined by 40 CFR 704.3. The number of employees are calculated as the average number of people employed for each pay period of the business' latest 12 calendar months, regardless of hours worked or temporary status.

Potentially Affected NAICS	**NAICS Description**	**Small Business Concern Size Standards (# of employees)**
324110	Petroleum Refineries	1500 or fewer
325110	Petrochemical Manufacturing	1000 or fewer
325120	Industrial Gas Manufacturing	1000 or fewer
325130	Synthetic Dye and Pigment Manufacturing	1000 or fewer
325180	Other Basic Inorganic Chemical Manufacturing	1000 or fewer
325193	Ethyl Alcohol Manufacturing	1000 or fewer
325194	Cyclic Crude, Intermediate, and Gum and Wood Chemical Manufacturing	1250 or fewer
325199	All Other Basic Organic Chemical Manufacturing	1250 or fewer
325211	Plastics Material and Resin Manufacturing	1250 or fewer
325212	Synthetic Rubber Manufacturing	1000 or fewer
325220	Artificial and Synthetic Fibers and Filaments Manufacturing	1000 or fewer
325311	Nitrogenous Fertilizer Manufacturing	1000 or fewer
325312	Phosphatic Fertilizer Manufacturing	750 or fewer
325314	Fertilizer (Mixing Only) Manufacturing	500 or fewer
325320	Pesticide and Other Agricultural Chemical Manufacturing	1000 or fewer
325411	Medicinal and Botanical Manufacturing	1000 or fewer
325412	Pharmaceutical Preparation Manufacturing	1250 or fewer
325413	InVitro Diagnostic Substance Manufacturing	1250 or fewer

325414	Biological Product (except Diagnostic) Manufacturing	1250 or fewer
325510	Paint and Coating Manufacturing	1000 or fewer
325520	Adhesive Manufacturing	500 or fewer
325611	Soap and Other Detergent Manufacturing	1000 or fewer
325612	Polish and Other Sanitation Good Manufacturing	750 or fewer
325613	Surface Active Agent Manufacturing	750 or fewer
325620	Toilet Preparation Manufacturing	1250 or fewer
325910	Printing Ink Manufacturing	500 or fewer
325920	Explosives Manufacturing	750 or fewer
325991	Custom Compounding of Purchased Resins	500 or fewer
325992	Photographic Film, Paper, Plate and Chemical Manufacturing	1500 or fewer
325998	All Other Miscellaneous Chemical Product and Preparation Manufacturing	500 or fewer
424690	Other Chemical and Allied Products Merchant Wholesalers	150 or fewer
424710	Petroleum Bulk Stations and Terminals	200 or fewer
424720	Petroleum and Petroleum Products Merchant Wholesalers (except Bulk Stations and Terminals)	200 or fewer

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 submitting a TSCA section 5 notice to EPA shall remit for each such notice the applicable fee identified in paragraph (c) of this section in accordance with the procedures in paragraphs (f) and (g) of this section.

(2) 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 shall remit for each such test rule, order, or enforceable consent agreement the applicable fee identified in paragraph (c) of this section in accordance with the procedures in paragraphs (f) and (g) of this section.

(3) Manufacturers of a chemical substance that is subject to a risk evaluation under section 6(b) of the Act, shall remit for each such chemical risk evaluation the applicable fee identified in paragraph (c) of this section in accordance with the procedures in paragraphs (f) and (g) of this section.

(4) Processors submitting a SNUN or TME under TSCA section 5 to EPA shall remit for each such notice the applicable fee identified in paragraph (c) of this section in accordance with the procedures in paragraphs (f) and (g) of this section.

(5) Processors of chemical substances and mixtures subject to a TSCA section 4(a) test rule, test order, or enforceable consent agreement in association with a SNUN submission referenced in paragraph (a)(4) of this section shall remit for each such test rule, order, or enforceable consent agreement the applicable fee identified in paragraph (c) of this section in accordance with the procedures in paragraphs (f) and (g) of this section.

(b) Identifying Manufacturers Subject to Fees

(1) *In general.* For purposes of identifying manufacturers subject to fees for section 4 test rules and section 6 EPA-initiated risk evaluations, EPA will publish a preliminary list of manufacturers identified through a review of data sources described in paragraph (b)(2) of this subsection; provide an opportunity for public comment; and publish a final list specifying the manufacturers responsible for payment.

(2) *Data sources.* To compile the preliminary list, EPA will rely on information

submitted to the Agency (such as the information submitted under sections 5(a), 8(a), 8(b), and to the Toxics Release Inventory) as well as other information available to the Agency, including publicly available information or information submitted to other agencies to which EPA has access. To be able to include the most recent CDR data and to account for annual or other typical fluctuations in manufacturing, EPA will use the five most recent years of data submitted or available to the Agency to develop the preliminary list.

(3) *Publication of preliminary list.* – (i) For risk evaluations initiated by EPA under section 6, the preliminary list will be published at the time of final designation of the chemical substance as a High-Priority Substance.

(ii) For test rules under section 4, the preliminary list will be published with the proposed test rule.

(4) *Public comment period.* Following publication of the preliminary list, EPA will provide a period of public comment that is no less than 30 days.

(5*) Self-identification.* All manufacturers who have manufactured or imported the chemical substance in the time period specified in paragraph (2) must submit notice to EPA, irrespective of whether they are included in the preliminary list specified in paragraph (3). The notice must be submitted electronically via EPA's Central Data Exchange (CDX), the Agency's electronic reporting portal, using the Chemical Information Submission System (CISS) reporting tool, and must contain the following information:

(i) *Contact information.* The name and address of the submitting company, the name and address of the authorized official for the submitting company, and the name and telephone number of a person who will serve as technical contact for the submitting company and who will be able to answer questions about the information submitted by the company to

EPA.

(ii) *Certification of cessation.* If a manufacturer has manufactured in the five-year period preceding publication of the preliminary list, but has ceased manufacturer prior to the certification cutoff dates identified in paragraph (b)(6) of this subsection and will not manufacture the substance again in the successive five years, the manufacturer may submit a certification statement attesting to these facts. If EPA receives such a certification statement from a manufacturer, the manufacturer will not be obligated to pay the fee under this section.

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

(6) *Certification cutoff date* – (i) For a section 6 EPA-initiated risk evaluation, the cutoff date for purposes of paragraph (b)(5)(ii) of this subsection is the day prior to initiation of the prioritization process for the applicable chemical substance.

(ii) For a section 4 test rule, the cutoff date for purposes of paragraph (b)(5)(ii) of this subsection is the day prior to publication of the proposed test rule for the applicable chemical substance.

(7) *Publication of final list.* EPA expects to publish a final list of manufacturers to identify the specific manufacturers subject to the applicable fee. This list will indicate if additional manufacturers self-identified pursuant to paragraph (b)(5) of this subsection, if other manufacturers were identified through credible public comment, and if manufacturers submitted certification of cessation or no manufacture pursuant to paragraph (b)(5)(ii) or (iii).

The final list will be published no later than concurrently with the final scope document for risk evaluations initiated by EPA under section 6, and with the final test rule for test rules under section 4.

(8) *Effect of final list.* Manufacturers who are listed on the final list are subject to the applicable fee identified in paragraph (c).

(9) *Identifying manufacturers for other fee categories.* For Section 4 Test Orders and enforceable consent agreements, and Section 6 Manufacturer-Requested Risk Evaluations, EPA will not conduct the identification process described in paragraph (b)(1)-(8), as manufacturers self-identify through a submission or are already otherwise known to Agency. However, those manufacturers are required to provide an information submission to EPA for the purposes of fee administration. The notice must be submitted electronically via the Agency's electronic reporting software (e.g., Central Data Exchange (CDX)) and must contain the manufacturers: full name, address, telephone number and email address. Timing of this submission must be as follows:

(i) For section 4 test orders and enforceable consent agreements, the informational submission in paragraph (9) must be provided within 30 days following notification from EPA.

(ii) For section 6 manufacturer-requested risk evaluations, the informational submission in paragraph (9) is required as part of the procedural process for making such requests, and must be completed at the time of making the request.

(c) *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 fee under paragraph (c)(2)(vi), (c)(2)(vii) or (c)(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 fee under paragraphs (c)(2)(ix) of this section for an EPA-initiated risk evaluation.

(viii) Persons shall remit the total fee under paragraph (c)(2) (x) or (c)(2)(xi) of this section, as applicable, for a manufacturer-requested 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 an initial fee of $1,250,000, and final payment to total 50% of the actual costs of this activity, in accordance with the procedures in paragraph (g) of this section. The final payment amount will be determined by EPA, and invoice issued to the requesting

manufacturer.

(xi) *Manufacturer-requested risk evaluation of a non-work plan chemical.* Persons shall remit an initial fee of $2,500,000, and final payment to total 100% of the actual costs of the activity, in accordance with the procedures in paragraph (g) of this section. The final payment amount will be determined by EPA, and invoice issued to the requesting manufacturer.

(d) *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 (c) by the current PPI index value with a base year of 2019 using the following formula:

FA = F x I

Where:

FA = the inflation-adjusted future year fee amount.

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

I = Producer Price Index for Chemicals and Allied Products inflation value with 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 public consultation through notice-and-comment rulemaking prior to making fee adjustments beyond inflation. If it is determined that no

additional adjustment is necessary beyond for inflation, EPA will provide public notice of the inflation-adjusted fee amounts most likely through posting to the Agency's 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.

(e) *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.

(f) *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 (c) 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 (c)(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 fee under section 4 of the Act is required to remit the appropriate fee identified in paragraph (c) 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 (c)(1) of this section, each person in the consortium must qualify as a small business concern under §700.43 of this chapter. Failure to submit fee payment pursuant to this paragraph, or to provide notice of failure to reach agreement pursuant to paragraph (f)(2)(v) constitutes a violation by each consortium member.

(i) The consortium must identify a principal sponsor and provide notification to EPA that a consortium has formed. The notification must be accomplished within 60 days of the publication date of a test rule under section 4 of the Act, or within 60 days of the issuance of a test order under Section 4 of the Act, or within 60 days of the signing of an enforceable consent agreement under section 4 of the Act. EPA may permit additional entities to join an existing consortium prior to the expiration of the notification period if the principal sponsor provides updated notification.

(ii) Notification must be submitted electronically via the Agency's electronic reporting software - Central Data Exchange (CDX) – and include the following information:

(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 strongly 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 fees will be split among the persons in the consortium, the principal sponsor must notify EPA in writing before the end of the notification period in paragraph (f)(2)(i) of this section.

(vi) If a consortium provides notice to EPA under paragraph (f)(2)(v) of this section that they failed to reach agreement on payment, EPA will assess fees to all persons as individuals described under paragraph (f)(4) of this section.

(3) Any consortium formed to split the cost of the applicable fee supporting a risk

evaluation under section 6(b) of the Act is required to remit the appropriate fee identified in paragraph (c) 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 (c)(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 (f)(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 60 days of the publication of the final scope of a chemical risk evaluation under section 6(b)(4)(D) of the Act or within 60 days of EPA providing notification to a manufacturer that a manufacturer-requested risk evaluation has been granted.

(ii) Notification must be submitted electronically via the Agency's electronic reporting software - Central Data Exchange (CDX) – and include the following information:

(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 strongly 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 fees will be split among the persons in the consortium, the principal sponsor must notify EPA in writing before the end of the notification period in paragraph (f)(3)(i) of this section.

(vi) If a consortium provides notice to EPA under paragraph (f)(3)(v) of this section that they failed to reach agreement on payment, EPA will assess fees to all persons as individuals as described under paragraph (f)(4) of this section.

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

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

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

Where:

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

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

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

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

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

(5) If multiple persons are subject to 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 take the following steps to allocate fee amounts:

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

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

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

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

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

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

(g) *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 online electronic payment service, or any applicable additional or successor online electronic payment service offered by the Department of Treasury.

(2) *Fees incurred prior to effective date of rule* - Timing of payment for fees incurred between October 1, 2018 and *[insert date 1 day after date of publication in the* **Federal**

Register*]*. Fees required by paragraph (c) of this section for which the fee-triggering action or event occurred between October 1, 2018, and *[insert date 1 day after date of publication in the* **Federal Register***]* shall be paid in response to invoices EPA will send within 30 days of *[insert date 1 day after date of publication in the* **Federal Register***]*.

(3) *Fees incurred after effective date of rule* - Timing of payment for fees incurred after *[insert date 1 day after date of publication in the* **Federal Register***]*. Fees required by paragraph (c) of this section for which the fee-triggering action or event occurred after *[insert date 1 day after date of publication in the* **Federal Register***]* shall be paid at the following time:

(i) *Test orders and test rules*. The applicable fee specified in paragraph (c) of this section shall be paid in full not later than 120 days after the effective date of a test rule or test order under section 4 of the Act.

(ii) *Enforceable consent agreements*. The applicable fee specified in paragraph (c) of this section shall be paid in full not later than 120 days after the signing of an enforceable consent agreement under section 4 of the Act.

(iii) *Section 5 notice*. The applicable fee specified in paragraph (c) 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 fee specified in paragraph (c) of this section shall be paid in full not later than 120 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 fees specified in paragraph (c) of this section shall be paid as follows:

(1) the first payment towards the applicable fee specified in paragraph (c) 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.

(2) the final payment towards the applicable fee specific in paragraph (c) of this section shall be paid in full not later than 30 days after EPA publishes a final risk evaluation in the **Federal Register.**

(4) *Payment identity* - (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 used to transmit the 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 used to transmit the 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 used to transmit the 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) *Small business certification* - (i) Each person who remits the fee identified in paragraph (c)(1) of this section for a PMN, consolidated PMN, or SNUN shall insert a check mark for the statement, "The company named in part 1, section A is a small business concern under 40 CFR 700.43 and has remitted a fee of $2,800 in accordance with 40 CFR 700.45(c)." under "CERTIFICATION" on page 2 of the Premanufacture Notice for New Chemical Substances (EPA Form 7710-25). This form is available on EPA's website at *https://cdx.epa.gov/SSL/PMN/Outbound/Electronic_PMN_Form_version2.pdf.*

(ii) Each person who remits the fee identified in paragraph (c)(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(c)." in the exemption application.

(iii) Each person who remits the fee identified in paragraph (c)(1) of this section for an exemption notice under §723.175 of this chapter shall include the words, "The company or companies identified in this notice is/are a small business concern under 40 CFR 700.43 and has/have remitted a fee of $940 in accordance with 40 CFR 700.45(c)." in the certification required in §723.175(i)(A)(10) of this chapter.

(iv) Each person who remits the fee identified in paragraph (c)(1) of this section for a MCAN or consolidated MCAN for a microorganism shall insert a check mark for the statement, "The company named in part 1, section A is a small business concern under 40 CFR 700.43 and has remitted a fee of $2,800 in accordance with 40 CFR 700.45(c)." in the certification required in §725.25(b) of this chapter.

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

(ii) Each person who remits a fee identified in paragraph (c)(2) of this section for a LVE, LoREX, TERA, 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(c)." in the exemption application.

(iii) Each person who remits the fee identified in paragraph (c)(2) of this section for an exemption notice under §723.175 of this chapter shall include the words, "The company or companies identified in this notice has/have remitted a fee of $4,700 in accordance with 40

CFR 700.45(c)." in the certification required in §723.175(i)(A)(10) of this chapter.

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

(h) *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) 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

(iv) 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

(v) 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.

(i) *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 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.

(3) If EPA determines that the initial payment for a manufacturer-requested risk evaluation exceed the applicable fee in paragraph (c) of this subsection, EPA will refund the difference.

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(g) is included and until the appropriate remittance under § 700.45(c) has been submitted as provided in § 700.45(g). 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(c) for a test order, test rule, enforceable consent agreement, or EPA-initiated risk evaluation as provided in § 700.45(g) is a violation of TSCA and enforceable under section 15 of the Act.

(c) EPA will not initiate a manufacturer-requested risk evaluation the request for which the Agency has otherwise determined to be complete unless EPA has determined to grant the request and the appropriate initial remittance under § 700.45(c) has been submitted as provided in § 700.45(g).

(d) Failure to submit the appropriate final remittance specified under § 700.45(c) for a manufacturer-requested risk evaluation as provided in § 700.45(g) is a violation of TSCA and enforceable under section 15 of the Act.

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 fee payment identity number, as required in 40 CFR 700.45(g)(4).

* * * * *

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

8. 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 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. Revise section 723.175 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) *Purpose and scope.* (1) This section grants an exemption from the premanufacture notice requirements of section 5(a)(1)(A) of the Toxic Substances Control Act (15 U.S.C. 2604(a)(1)(A)) for the manufacture and processing of new chemical substances used in or for the manufacture or processing of instant photographic and peel-apart film articles. This section does not apply to microorganisms subject to part 725 of this chapter.

(2) To manufacture a new chemical substance under the terms of this exemption, a manufacturer of instant photographic or peel-apart film articles must:

(i) Submit an exemption notice when manufacture begins under paragraph (i) of this section.

(ii) Comply with certain requirements to limit exposure to the new chemical substance under paragraphs (e), (f), (g), and (h) of this section.

(iii) Comply with all recordkeeping requirements under paragraph (j) of this section.

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

(b) *Definitions*—(1) *Act* means the Toxic Substances Control Act (15 U.S.C. 2601 *et seq.*).

(2) An *article* is a manufactured item (i) which is formed to a specific shape or design during manufacture, (ii) which has end use function(s) dependent in whole or in part upon its shape or design during end use, and (iii) which has either no change of chemical composition during its end use or only those changes of composition which have no commercial purpose separate from that of the article and that may occur as described in §710.2 of this chapter except that fluids and particles are not considered articles regardless of shape or design.

(3) The terms *byproduct, EPA, impurities, person,* and *site* have the same meanings as in §710.3 of this chapter.

(4) The term *category of chemical substances* has the same meaning as in section 26(c)(2) of the Act (15 U.S.C. 2625).

(5) The terms *chemical substance, distribute in commerce, distribution in commerce, environment, manufacture, new chemical substance,* and *process* have the same meanings as in section 3 of the Act (15 U.S.C. 2602).

(6) *Director of the Office of Pollution Prevention and Toxics* means the Director of the EPA Office of Pollution Prevention and Toxics or any EPA employee designated by the Office Director to carry out the Office Director's functions under this section.

(7) The term *exemption category* means a category of chemical substances for which a person(s) has applied for or been granted an exemption under section 5(h)(4) of the Act (15 U.S.C. 2604).

(8) The term *instant photographic film article* means a self-developing photographic film article designed so that all the chemical substances contained in the article, including the

chemical substances required to process the film, remain sealed during distribution and use.

(9) *Intermediate* means any chemical substance which is consumed in whole or in part in a chemical reaction(s) used for the intentional manufacture of another chemical substance.

(10) *Known to or reasonably ascertainable* means all information in a person's possession or control, plus all information that a reasonable person similarly situated might be expected to possess, control, or know, or could obtain without unreasonable burden or cost.

(11) The term *peel-apart film article* means a self-developing photographic film article consisting of a positive image receiving sheet, a light sensitive negative sheet, and a sealed reagent pod containing a developer reagent and designed so that all the chemical substances required to develop or process the film will not remain sealed within the article during and after the development of the film.

(12) *Photographic article* means any article which will become a component of an instant photographic or peel-apart film article.

(13) *Special production area* means a demarcated area within which all manufacturing, processing, and use of a new chemical substance takes place, except as provided in paragraph (f) of this section, in accordance with the requirements of paragraph (e) of this section.

(14) *Test data* means: (i) Data from a formal or informal study, test, experiment, recorded observation, monitoring, or measurement.

(ii) Information concerning the objectives, experimental methods and materials, protocols, results, data analyses (including risk assessments), and conclusions from a study,

test, experiment, recorded observation, monitoring, or measurement.

(15) *Used in or for the manufacturing or processing of an instant photographic or peel-apart film article,* when used to describe activities involving a new chemical substance, means the new chemical substance (i) is included in the article, or (ii) is an intermediate to a chemical substance included in the article or is one of a series of intermediates used to manufacture a chemical substance included in the article.

(16) *Wet mixture* means a water or organic solvent-based suspension, solution, dispersion, or emulsion used in the manufacture of an instant photographic or peel-apart film article.

(c) *Exemption category.* The exemption category includes new chemical substances used in or for the manufacture or processing of instant photographic or peel-apart film articles which are manufactured and processed under the terms of this section.

(d) *Applicability.* This exemption applies only to manufacturers of instant photographic or peel-apart film articles who: (1) Manufacture the new chemical substances used in or for the manufacture or processing of the instant photographic or peel-apart film articles.

(2) Limit manufacture and processing of a new chemical substance to the site(s) listed in the exemption notice for that new chemical substance submitted under paragraph (i) of this section.

(3) Comply with the requirements of paragraphs (e), (f), (g), (h), and (j) of this section.

(4) Do not distribute in commerce or use a peel-apart film article containing a new chemical substance until submission of a premanufacture notice under section 5(a)(1)(A) of

the Act (15 U.S.C. 2604) and until the review period for the notice has ended without EPA action to prevent distribution or use.

(e) *Conditions of manufacture and processing in the special production area.* All manufacturing, processing, and use operations involving the new chemical substance must be performed in a special production area under the conditions set forth in this paragraph until the new chemical substance has been incorporated into a wet mixture, photographic article, or instant photographic or peel-apart film article.

(1) *Exposure limits.* In the special production area, the ambient air concentration of the new chemical substance during manufacture, processing, and use cannot exceed an 8-hour time weighted average (TWA) of 10 ppm for gases and vapors and 50 $\mu g/m^3$ for particulates, with an allowable TWA excursion of 50 percent above those concentrations for a duration of 30 minutes or less.

(2) *Respiratory protection*—(i) *Respirator requirement.* Except as specified in paragraph (e)(2)(ii) of this section, each person in the special production area must wear an appropriate respiratory protection device to protect against dusts, fumes, vapors, and other airborne contaminants, as described in 29 CFR 1910.134. Selection of an appropriate respirator must be made according to the guidance of American National Standard Practices for Respiratory Protection Z88.2-1969 and the NIOSH Certified Equipment List, U.S. Department of Health and Human Services, NIOSH publication No. 80-144.

(ii) *Waiver of respirator requirement.* Employees are not required to wear respirators if monitoring information collected and analyzed in accordance with paragraph (e)(3) of this section demonstrates that the ambient 8-hour TWA concentration of the new chemical substance in the area is less than 1 ppm for gases and vapors and 5 $\mu g/m^3$ for particulates

with an allowable TWA excursion of 50 percent above these concentrations for a duration of 30 minutes or less.

(iii) *Quantitative fit test.* Each respirator must be issued to a specific individual for personal use. A quantitative fit test must be performed for each respirator before its first use by that person in a special production area.

(3) *Monitoring*—(i) *When to monitor.* (A) When suitable sampling and analytic methods exist, periodic monitoring in accordance with this paragraph must be done to ensure compliance with the exposure limits of paragraphs (e)(1) and (2)(ii) of this section.

(B) When suitable sampling and analytic methods do not exist, compliance with the exposure limits of paragraph (e)(1) and the requirements of paragraph (e)(10) of this section must be determined by an evaluation of monitoring data developed for a surrogate chemical substance possessing comparable physical-chemical properties under similar manufacturing and processing conditions.

(ii) *Monitoring methods.* A suitable air sampling method must permit personal or fixed location sampling by conventional collection methods. A suitable analytic method must have adequate sensitivity for the volume of sample available and be specific for the new chemical substance being monitored. If chemical-specific monitoring methods are not available, nonspecific methods may be used if the concentration of the new chemical substance is assumed to be the total concentration of chemical substances monitored.

(iii) *Monitoring frequency.* (A) When suitable air sampling and analytical procedures are available, monitoring must be done in each special production area during the first three 8-hour work shifts involving the manufacture or processing of each new chemical substance. Thereafter, monitoring must be done in each special production area for at least one 8-hour

period per month, during a production run in which the new chemical substance is manufactured or processed. Samples must be of such frequency and pattern as to represent with reasonable accuracy the mean level and maximum 30-minute level of employee exposure during an 8-hour work shift. In monitoring for an 8-hour work shift or the equivalent, samples must be collected periodically or continuously for the duration of the 8-hour work shift. Samples must be taken during a period which is likely to represent the maximum employee exposure.

(B) If the manufacturer demonstrates compliance with the exposure limits for 3 consecutive months, further monitoring of the identical process must be performed only every 6 months thereafter, unless there is a significant change in the process, process design, or equipment. If there is such a change, the manufacturer must begin monitoring again according to the schedule in paragraph (e)(3)(iii)(A) of this section.

(iv) *Location of monitoring.* Air samples must be taken so as to ensure that the samples adequately represent the ambient air concentration of a new chemical substance present in each worker's breathing zone.

(4) *Engineering controls and exposure safeguards.* Engineering controls such as, but not limited to, isolation, enclosure, local exhaust ventilation, and dust collection must be used to ensure compliance with the exposure limits prescribed in paragraphs (e)(1) or (e)(2)(ii) of this section.

(5) *Training, hygiene, and work practices*—(i) *Training.* No employee may enter a special production area before the completion of a training program. The training program must be adapted to the individual circumstances of the manufacturer and must address: The known physical-chemical and toxicological properties of the chemical substances handled in

the area; procedures for using and maintaining respirators and other personal safeguards; applicable principles of hygiene; special handling procedures designed to limit personal exposure to, and inadvertent release of, chemical substances; and procedures for responding to emergencies or spills.

(ii) *Hygiene.* Appropriate standards of hygiene must be observed by all employees handling a new chemical substance in manufacturing, processing, or transfer operations. The manufacturer must provide appropriate facilities for employee changing and wash-up. Food, beverages, tobacco products, and cosmetics must not be allowed in special production areas.

(iii) *Work practices.* Operating procedures such as those related to chemical weighing and filtering, or the charging, discharging and clean-up of process equipment, must be designed and conducted to ensure compliance with the exposure limits prescribed in paragraph (e)(1) or (e)(2)(ii) of this section. Written procedures and all materials necessary for responding to emergency situations must be immediately accessible to all employees in a special production area. Any spill or unanticipated emission must be controlled by specially trained personnel using the equipment and protective clothing described in paragraph (e)(6) of this section.

(6) *Personal protection devices.* All workers engaged in the manufacture and processing of a new chemical substance in the special production area must wear suitable protective clothing or equipment, such as chemical-resistant coveralls, protective eyewear, and gloves.

(7) *Caution signs.* Each special production area must be clearly posted with signs identifying the area as a special production area where new chemical substances are manufactured and processed under controlled conditions. Each sign must clearly restrict

entry into the special production area to qualified personnel who are properly trained and equipped with appropriate personal exposure safeguards.

(8) *Removal for storage or transportation.* A new chemical substance that is not incorporated into a wet mixture, photographic article, or instant photographic or peel-apart film article may be removed from the special production area for purposes of storage between operational steps or for purposes of transportation to another special production area. Such storage or transportation must be conducted in a manner that limits worker and environmental exposure through the use of engineering controls, training, hygiene, work practices, and personal protective devices appropriate to the chemical substance in question.

(9) *Labeling.* (i) Any new chemical substance removed from a special production area or stored or transported between operational steps must be clearly labeled. The label must show the identity of the new chemical substance or an appropriate identification code, a statement of any known hazards associated with it, a list of special handling instructions, first aid information, spill control directions, and where applicable, the appropriate U.S. Department of Transportation notations.

(ii) No label is required if the new chemical substance has been incorporated into a photographic article, or if it is contained in a sealed reaction vessel or pipeline, or if it has been incorporated into an instant photographic or peel-apart film article.

(10) *Areas immediately adjacent to the special production area.* The ambient air concentration of the new chemical substance in areas immediately adjacent to the special production area must not exceed the exposure limit established in paragraph (e)(2)(ii) of this section for waiver of respirator protection within the special production area. Periodic monitoring in accordance with paragraph (e)(3) of this section must be performed in

immediately adjacent areas where it is reasonable to expect a risk of inhalation exposure.

(f) *Conditions of processing outside the special production area.* A wet mixture may be incorporated into a photographic article or an instant photographic or peel-apart film article outside the special production area under the conditions listed in this paragraph:

(1) *Engineering controls and exposure safeguards.* Engineering controls must limit the exposure to a new chemical substance contained in a wet mixture.

(2) *Training, hygiene and work practices*—(i) *Training.* Training of employees involved in the handling of wet mixtures containing a new chemical substance must be adapted to the individual circumstances of the employees' activities and must address: Procedures for using personal exposure safeguards, applicable principles of hygiene, handling procedures designed to limit personal exposure, and procedures for responding to emergencies and spills.

(ii) *Hygiene.* Appropriate standards of hygiene that limit exposure must be observed by all employees handling wet mixtures that contain new chemical substances.

(iii) *Work practices.* Work practices and operating procedures must be designed to limit exposure to any new chemical substance contained in wet mixtures. Any spills or unanticipated releases of a wet mixture must be controlled by trained personnel wearing appropriate protective clothing or equipment such as gloves, eye protection, and, where necessary, respirators or chemically impervious clothing.

(3) *Personal protection devices.* All workers engaged in the processing of a wet mixture containing a new chemical substance must wear suitable protective clothing or equipment such as coveralls, protective eyewear, respirators, and gloves.

(g) *Incorporation of photographic articles into instant photographic and peel-apart*

film articles. A photographic article may be incorporated into the instant photographic or peel-apart film article outside the special production area. The manufacturer must take measures to limit worker and environmental exposure to new chemical substances during these operations using engineering controls, training, hygiene, work practices, and personal protective devices.

(h) *Environmental release and waste treatment*—(1) *Release to land.* Process waste from manufacturing and processing operations in the special production area that contain a new chemical substance are considered to be hazardous waste and must be handled in accordance with the requirements of parts 262 through 267 and parts 122 and 124 of this chapter.

(2) *Release to water.* All wastewater or discharge which contain the new chemical substance must be appropriately pretreated before release to a Publicly Owned Treatment Works (POTW) or other receiving body of water. In the case of release to a POTW, the pretreatment must prevent structural damage to, obstruction of, or interference with the operation of the POTW. The treatment of direct release to a receiving body of water must be appropriate for the new chemical substance's physical-chemical properties and potential toxicity.

(3) *Release to air.* All process emissions released to the air which contain the new chemical substance must be vented through control devices appropriate for the new chemical substance's physical-chemical properties and potential toxicity.

(i) *Exemption notice.* An exemption notices must be submitted to EPA when manufacture of the new chemical substance begins.

(A) *Contents of exemption notice.* The exemption notice must include the following

information:

(1) Manufacturer and sites. The notice must identify the manufacturer and the sites and locations where the new chemical substance and the instant photographic or peel-apart film articles will be manufactured and processed.

(2) Chemical identification. The notice must identify the new chemical substance as follows:

(i) Class 1 substances. For chemical substances whose composition can be represented by a definite structural diagram (Class 1 substances), the notice must provide the chemical name (preferably CAS or IUPAC nomenclature), the molecular formula, CAS Registry Number (if available), known synonyms (including trade names), and a structural diagram.

(ii) Class 2 substances. For chemical substances that cannot be fully represented by a structural diagram, (Class 2 substances), the notice must provide the chemical name, the molecular formula, the CAS Registry Number (if available), and known synonyms (including trade names). The notice must identify the immediate precursors and reactants by name and CAS Registry Number (if available). The notice must include a partial or incomplete structural diagram, if available.

(iii) 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.

(3) 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.

(4) Physical-chemical properties. The notice must describe the physical-chemical properties of the new chemical substance. Where specific physical-chemical data are not available, reasonable estimates and the techniques used to develop these estimates must be provided.

(5) Byproducts. The notice must identify the name, CAS Registry number (if available), and the volume of each byproduct that would be manufactured during manufacture of the new chemical substance.

(6) Production volume. The notice must include an estimate of the anticipated maximum annual production volume.

(7) Test data. The notice must include all information and test data on the new chemical substance's health and environmental effects that are known to or reasonably ascertainable by the manufacturer.

(8) Identity of the article. The notice must identify and describe the instant photographic film article(s) or peel-apart film article(s) that will contain the new chemical substance.

(9) Release to water. The notice must include a description of the methods used to

control and treat wastewater or discharge released to a POTW or other receiving body of water. The notice must also identify the POTW or receiving body of water.

(10) Certification. The manufacturer must certify in the notice that it is familiar with the terms of the exemption and that the manufacture, processing, distribution, use, and disposal of the new chemical substance will comply with those terms.

(B) *Duplication of information in premanufacture notice.* If a manufacturer who submits an exemption notice under this paragraph has already submitted, or simultaneously submits, a premanufacture notice under section 5(a)(1)(A) of the Act for the new chemical substance, it may, in lieu of submitting the information required by this paragraph, reference the required information to the extent it is included in the premanufacture notice. At a minimum, the exemption notice must identify the manufacturer and the new chemical substance, and contain the certification required by paragraph (i)(1)(A)(10) of this section.

(C) *Address.* The exemption notice must be addressed to the Document Control Office (DCO) (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

(j) *Recordkeeping.* (1) Manufacturers of a new chemical substance under this exemption must keep the following records for 30 years from the final date of manufacture.

(i) *Production records.* Each manufacturer must maintain records of the annual production volume of each new chemical substance manufactured under the terms of the exemption. This record must indicate when manufacture of the new chemical substance began.

(ii) *Exposure monitoring records.* Manufacturers must maintain an accurate record of all monitoring required by this section. Monitoring records may be adapted to the individual

circumstances of the manufacturer but, at a minimum, must contain the following information: The chemical identity of the new chemical substance, date of the monitoring, the actual monitoring data for each monitoring location and sampling, and a reference to or description of the collection and analytic techniques. If the manufacturer does not monitor, the manufacturer must maintain a record of the reasons for not monitoring and the methods used to determine compliance with the exposure limits of paragraph (e)(1) of this section.

(iii) *Training and exposure records.* For each employee engaged in the manufacture or processing of a new chemical substance, the company must develop and maintain a record of the worker's participation in required training. This record must also demonstrate the regular use of personal exposure safeguards, including the results of any personal exposure monitoring, the results of the quantitative fit test for the worker's personal respirator, and any additional information related to the worker's occupational exposure.

(iv) *Treatment records.* Manufacturers who release treated wastewater or discharge containing a new chemical substance to a POTW or other receiving body of water must maintain records of the method of treatment.

(2) The manufacturer must make the records listed in paragraph (j)(1) of this section available to EPA upon written request by the Director of the Office of Pollution Prevention and Toxics. The manufacturer must provide these records within 15 working days of receipt of this request.

(k) *Confidentiality.* If the manufacturer submits information under paragraph (i) or (j) of this section which it claims to be confidential business information, the manufacturer must clearly identify the information at the time of submission to the Agency by bracketing, circling, or underlining it and stamping it with "CONFIDENTIAL" or some other

appropriate designation. Any information so identified will be treated in accordance with the procedures in part 2 of this chapter. Any information not claimed confidential at the time of submission will be made available to the public without further notice to the submitter.

(l) *Amendment and repeal.* (1) EPA may amend or repeal any term of this exemption if it determines that the manufacture, processing, distribution, use, and disposal of new chemical substances under the terms of the exemption may present an unreasonable risk of injury to health or the environment. EPA also may amend this exemption to enlarge the exemption category or to reduce the restrictions or conditions of the exemption.

(2) As required by section 5(h)(4) of the Act, EPA will amend or repeal the substantive terms of an exemption granted under this part only by the formal rulemaking procedures described in section 6(c)(2) and (3) of the Act (15 U.S.C. 2605(c)).

(m) *Prohibition of use of the exemption.* The Director of the Office of Pollution Prevention and Toxics may prohibit the manufacture, processing, distribution, use, or disposal of any new chemical substance under the terms of this exemption if he or she determines that the manufacture, processing, distribution in commerce, use, or disposal of the new chemical substance may present an unreasonable risk of injury to health or the environment.

(n) *Enforcement.* (1) A failure to comply with any provision of this part is a violation of section 15 of the Act (15 U.S.C. 2614).

(2) Submitting materially misleading or false information in connection with the requirements of any provision of this part is a violation of this regulation and therefore a violation of section 15 of the Act (15 U.S.C. 2614).

(3) Violators may be subject to the civil and criminal penalties in section 16 of the

Act (15 U.S.C. 2615) for each violation.

(4) EPA may seek to enjoin the manufacture of a new chemical substance in violation of this exemption or act to seize any chemical substances manufactured in violation of the exemption under the authority of section 17 of the Act (15 U.S.C. 2616).

(xi) 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 fees and conditions specified in §§ 700.40, 700.45(c), 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(c) 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(g)(4) 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 fee specified in § 700.45(c) 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 fee as specified in §700.45(c) 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(g)(4) of this chapter.

* * * * *

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

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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.

* * * * *