# Response to Public Comments on the Proposed Rule

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

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## 1. General Support

A fair number of commenters expressed general support for the proposed rule and the imposition of fees, or more generally the need to provide EPA with adequate funding for the implementation of TSCA (0060, 0070, 0043, 0046, and 0062).

*EPA Response:*
*EPA appreciates the comments of support. EPA is committed to successful implementation of the amendments to TSCA, and the collection of fees pursuant to that rule is critical to that effort.*

## 2. Entities Subject to Fees

### a. Processors

EPA proposed to generally exclude processors from fee obligations, with a few exceptions. A majority of commenters (e.g., 0066, 0067, 0068, 0043, 0061, 0042, 0041, 0034) supported this approach. Commenters agreed that this approach was sensible. Some (0071, 0045), however, expressed concern that exclusion of processors from the fee requirements would give processors a "free ride," even when processor activities account for a significant portion of the risk. These commenters further note that the language of TSCA requires an appropriate balance of fees between manufacturers and processors. One commenter (0043) noted an inconsistency between preamble and regulatory text on applicability of fees to processors and suggested that EPA clarify in the final rule.

*EPA Response:*
*As described in the proposed rule, EPA intends to maintain its focus on collecting fees from manufacturers, except in two instances: (1) where a processor submits a SNUN under section 5, or (2) when there is a section 4 activity tied to a SNUN submission by a processor. EPA continues to believe that this approach best serves the Agency's interest in a practical, efficient fee structure. EPA further believes, and commenters affirmed, that manufacturers will pass some of the costs on to processors. As such, EPA believes that, in practice, this approach will likely result in the balance described in TSCA. EPA was unable to find the inconsistency suggested by commenter, but will nonetheless attempt to be clearer on this point in the final rule.*

*EPA noted in the proposed rule preamble that while TSCA provides EPA with the authority to require payment from both processors and manufacturers, the Agency will limit doing so to the circumstances described above. The regulatory text is consistent with this approach.*

b. Manufacturers

One key aspect of the fees rule is the identification of manufacturers subject to particular fees. In the proposed rule, EPA noted that for certain fee-triggering actions like section 5 submissions, manufacturers would self-identify by virtue of submitting a notice (e.g., PMN, SNUN, MCAN, etc.). For other actions, like section 6 risk evaluations, EPA indicated that it would use CDR data to develop a preliminary list of manufacturers of a particular chemical subject to a fee and requested comment on the data sources and process. EPA received numerous comments in this area. Commenters also raised specific issues for EPA to consider in order to establish the process in the final rule. Comments on these specific issues, and the process and data sources suggested for identifying manufacturers are described below:

Specific Issues related to Identification of Manufacturers

*Process for Identification of Manufacturers Subject to Fees.*

The proposed rule suggested the need for a process for identifying manufacturers subject to fees for section 4 and 6 activities, and requested public comment in this area. A number of commenters (0055, 0050, 0058) agreed that such a process was necessary.

*EPA Response:*
*EPA appreciates commenters' concerns and in the final rule has codified a public process for identifying manufacturers subject to fee obligations for purposes of section 4 test rule activities and section 6 EPA-initiated risk evaluation activities. This process includes publication of a preliminary list that identifies manufacturers based on information available to EPA, a public comment period (to allow for self-identification, correction of errors, and certification of market exit for at least 5 years), and publication of a final list.*

*Specifically, EPA will publish a preliminary list of manufacturers that EPA has determined are subject to fee obligations. To determine the entities on this list, EPA will use the most up-to-date information available, including but not limited to the latest submissions under the Chemical Data Reporting (CDR) rule (collected every four years). To be able to include the most recent CDR data and to account for annual or other typical fluctuations in manufacturing (including import), EPA will use five years of data submitted or otherwise available to the Agency to create the preliminary list, as described in Unit III in the final rule.*

*EPA will publish this preliminary list at a relevant milestone for each action. 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. For more information on the prioritization process, see* ***Procedures for Prioritization of Chemicals for Risk Evaluation Under the Toxic Substances Control Act Final Rule*** *(82 FR 33753, July 20, 2017). For test rules under section 4, the preliminary list will be published with the proposed test rule.*

*Publication of the preliminary list will be followed by a comment period, during which manufacturers have the opportunity to correct errors or omissions on the preliminary list (e.g., self-identify if they have not been identified, identify other manufacturers that may have been missed, or certify to the Agency that they have ceased manufacturing and do not intend to re-*

*enter the market). This will entail specific reporting requirements, detailed in Unit III in the final rule and described in the Information Collection Request for this rulemaking. This is consistent with comments supporting such a process and requirement to self-identify.*

*After the comment period for the preliminary list of entities subject to a fee obligation, EPA will publish a final list. The final list will indicate if any manufacturers were identified in error, any additional manufacturers identified through the comment period and/or reporting form, and if any manufacturers have certified that they have already ceased manufacture prior to publication of the preliminary list and will not manufacture the subject chemical again in the future. Manufacturers who either plan to cease manufacture in the future, or those who have already ceased but may still re-enter the market at a future date would not be able to certify out, and would therefore still be subject to the fee obligation.*

*The final list will be published concurrently with another relevant milestone for each action. For risk evaluations initiated by EPA under section 6, the final list will be published with the final scope document. For more information on the scope document and risk evaluation processes, see* ***Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act Final Rule*** *(82 FR 33726, July 20, 2017). For test rules under section 4, the final list will be published with the final test rule.*

*EPA believes that this clear timeframe and certification process will help prevent the problem identified by some commenters regarding manufacturers who may exit and reenter the market to avoid fee obligations. However, in most cases, EPA would not be able to prevent new manufacturers of an existing chemical from initiating manufacturing of that chemical and has no mechanism in place to require that they notify the Agency of such manufacturing. Furthermore, it is impracticable for EPA to administer fees to such late entrants by reallocating fee amounts, collecting additional monies, providing partial refunds to prior identified manufacturers. Those entities who truly begin to manufacture after the fee event would not be subject to fees, late charges or other penalties from EPA. This is consistent with longstanding policy in the new chemical context: new manufacturers of a chemical that has been through the new chemical review process and added to the TSCA Inventory are not obligated to reimburse a PMN submitter.*

*EPA is also codifying in the final rule and clarifying in the preamble that the process for identifying manufacturers subject to fees – including the process for certifying cessation of manufacture activity - applies only to test rules administered under the authority of section 4 and risk evaluations initiated by EPA under section 6. This process does not apply towards the identification of manufacturers for purposes of section 5 activities, section 4 test orders, section 4 enforceable consent agreements (ECAs), or section 6 manufacturer-requested risk evaluations. Manufacturers either self-identify as part of these activities, or, in the case of test orders, EPA selects and identifies the manufacturer(s) subject to the order.*

*Data Source for Developing Preliminary List.*
The proposed rule indicated that EPA plans to use the Chemical Data Reporting (CDR) rule as a potential data source for identifying manufacturers subject to section 6 fees, and requested comment on this and other potential data sources. Some commenters (0043, 0057) supported use

of CDR data as a good starting point for developing a list of responsible manufacturers. Others (0046) noted the limitations of using CDR data. A number of commenters (0066, 0071, 0043, 0060) suggested that EPA use all available data sources to develop the preliminary list and not limit to just one. Some (0071, 0055) had suggestions for better sources of import data such as CBP or the Panjiva database. At least one commenter (0060) suggested tapping chemical industry trade associations as a source of information on manufacturers. One commenter (0034) cautioned against using voluntarily submitted data to identify payees, as doing so might discourage future voluntary submission of information.

*EPA Response:*
*EPA appreciates the comments in this area. To determine the entities subject to fees, EPA will use the most up-to-date information available, including information submitted to the Agency (such as the information submitted under 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., US CBP data). EPA intends to use all available data sources to develop the preliminary list. Examples of the types of data sources EPA has used to identify manufacturers of chemicals for the first ten risk evaluations can be found in the appendices to the Use Documents, as described in* ***Risk Evaluation Scoping Efforts Under TSCA for Ten Chemical Substances; Notice of Public Meeting*** *(82 FR 6545; January 19, 2017).*

*Relevant Time Period of Manufacture.*
Most commenters suggested that EPA should specify in the final rule the time period of manufacture that EPA would consider relevant for identifying manufacturers subject to fee obligations (0061, 0058, 0042, 0041). Some (0067, 0065) suggested that EPA look a certain number of years in the past, and others (0066, 0065, 0050, 0043, 0047, 0067) suggested looking forward for a period of years. As these commenters note, specifying a look-back or look-forward period could help to address the late entrant and free rider issues described earlier. Some commenters offered different perspectives on the specific time periods. For example, some suggested a look-back period of 3 or 4 years, while others suggest a look-forward period of 4 or 5 years. A number of these commenters suggested that these time periods could capture CDR reporting cycle. One commenter (0041) suggested only triggering fee obligations based on current manufacture at the time a fee is assessed.

EPA Response:
*EPA intends for the final list to be an accurate description of active manufacturers of the subject chemical at the time of the fee event. To generate such a list, EPA will 1) use the most up-to-date information available (including publicly available information or information submitted to other agencies to which EPA has access) to generate the preliminary list, looking back 5 years in order to include the most recent CDR data, 2) provide the public an opportunity to examine and correct the preliminary list, and 3) provide manufacturers who have ceased manufacture and will not re-enter the market for at least five years an opportunity to certify to that fact. This information will be used to update the final list with any necessary corrections before it is published.*

*Late Entrants and Free Riders.*

A number of commenters (0060, 0070, 0050, 0043, 0046, 0066, etc.) raised concern about the possibility of "late entrants" – those who enter or re-enter the market after a fee event has concluded and avoid paying fees. These comments focused particularly on section 6 risk evaluations, and suggested that EPA needed to address this issue in the final rule in a fair manner, such as by requiring late entrants to reimburse EPA, a consortia or individual companies. At least one commenter (0058) suggested that some manufacturers might be identified after fees have already been allocated and/or paid to EPA. The proposed rule noted that manufacturers who fail to self-identify would be in violation of TSCA and subject to enforcement. This commenter suggested that the late manufacturers should further be required to reimburse and pay late fees to the consortia.

A number of commenters (0060, 0070, 0047, 0066) raise fairness concerns about those who could simply exit the market before or during the fee event, excuse themselves from fee obligations, and then reenter the market after the fee event has concluded. Commenters noted that if the fee rule allowed manufacturers to easily exit and enter the market, this might encourage "free riders." These commenters suggest that this issue be addressed in the final rule, either through a process of requiring payment from free riders and subsequent EPA reimbursements, or by requiring free riders to reimburse other manufacturers or a consortium directly.

*EPA Response:*
*While EPA recognizes the commenters' interest in fair payment of fees, EPA continues to believe that enforcement for violations of TSCA will be sufficient for providing for equitable application of the requirements of the law with respect to fee payment. EPA is not amending the final rule to require late entrants to the market to pay fees or reimburse consortia. EPA believes that the process described in the final rule that provides for a preliminary list, an ample comment period, and a final list will be sufficient for identification or self-identification of the appropriate manufacturers. 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 intending to re-initiate manufacture within five years will be subject to penalty under TSCA.*

*While the fee event is underway (e.g. during an EPA-initiated risk evaluation) and after fees have been collected, it would be impractical for EPA to continuously adjust, reallocate, and refund fee amounts to originally identified manufacturers due to late identification and/or new entrants to the market. EPA is also not in a position to monitor for new entrants to the market for an existing chemical or otherwise continue to identify manufacturers who failed to self-identify. In most cases, EPA would not be able to prevent new manufacturers of an existing chemical from initiating manufacturing of that chemical and has no mechanism in place to require that they notify the Agency of such manufacturing. Furthermore, it is impracticable for EPA to administer fees to such late entrants by reallocating fee amounts, collecting additional monies, providing partial refunds to prior identified manufacturers. However, EPA does not intend to prevent manufacturers from independently seeking civil remedy or reimbursement from other*

*manufacturers who have violated the TSCA fee collection provision by failing to self-identify, or from new entrants who have not contributed payment towards the fee event.*

*Market Exit or Inactive Manufacturers.*
Some commenters (0070, 0043, 0057, 0058) suggested that EPA should include a provision in the final rule that would allow manufacturers who either no longer manufacture a chemical or express intent to exit the market to avoid any fee obligations.

*EPA Response:*
*EPA agrees with some of these commenters that manufacturers who certify to EPA that they have already exited the market and will not re-initiate manufacture should not be subject to fee obligations. The final rule includes a process for these manufacturers to certify that they have ceased manufacturer and will not re-initiate manufacture in the next five years, as described in detail in the final rule in Unit III. However, the final rule will not allow manufacturers to avoid fee obligations by expressing an intent to exit the market in the future.*

*Exemptions and Exclusions for Certain Manufacturers*
Numerous commenters encouraged EPA to exempt or exclude certain manufacturers from fee obligations. For example, commenters (0066, 0055, 0041, 0042, 0061, 0044) suggested that EPA, for example, exclude those who manufacture from an exempt purpose in 29 CFR 720.30 (g) and (h) (i.e., the exemptions from notice requirements in the new chemicals program); manufacturers of isolated intermediates, impurities, byproducts and small quantities; those who manufacture solely for export, research and development; importers of articles; importers with a negative certification; and importers when used for medical or R&D purposes. One commenter (0055) suggested that EPA exclude recyclers from fee obligations; another (0051) suggested that recyclers should be subject to fees given their role in the market. Another commenter raised concern for double assessment when multiple companies meet definition of manufacturer for same volume of manufactured/imported chemical (0061).

*EPA Response:*
*EPA intends for the final list developed through the process described above to be an accurate description of active manufacturers of the subject chemical at the time of the fee event, regardless of variations in the origins of manufacturing processes (such as recycling, importing, or other types of manufacturing) or downstream uses of subject chemicals. Because manufacturing processes and downstream uses of the subject chemical are not necessarily static or consistent, EPA is not able to exclude manufacturers whose subject chemicals may at one point be used for an exempt purpose or otherwise be exempt from reporting to EPA. Additionally, small quantities of chemicals and chemicals imported in articles may be subject to section 4 test rules and orders, and risk evaluations under section 6. Although EPA may choose to exclude certain conditions of use from the scope of the risk evaluation, such decisions would be made on a case-by-case basis. As such, EPA does not believe it would be appropriate to categorically exempt these manufacturers and importers from fee obligations. Therefore, EPA will not add any exemptions or exclusions from the requirement to pay fees.*

*Publication of Preliminary List*

A number of commenters encouraged EPA to publish and provide an opportunity for comment on a preliminary list of manufacturers subject to fees (0065, 0071, 0050, 0043, 0058). Some (0066) suggested that, for EPA-initiated risk evaluations, this list be published upon the final designation of a chemical as a High-Priority substance. Other commenters (0050, 0046, 0058) encouraged EPA to impose a mandatory reporting requirement for manufacturers to self-identify. One commenter noted that the reporting obligation could be noticed at the same time as publication of the preliminary list (e.g., upon designation as a High-Priority substance).

*EPA Response:*
*EPA appreciates commenters' concerns and, as described earlier, has developed a process for publication of a preliminary list, public comment period, and publication of a final list. As commenters recommended, publication of the preliminary list would occur with the close of the prioritization process, or – as the commenter stated – upon designation as a high priority substance. Details of this process are described earlier and in the final rule in Unit III.*

*Publication of the Final List*
The proposed rule indicates that absence from the preliminary list does not exclude manufacturers from their fee obligation. A few commenters (0050, 0041) expressed strong desire that EPA publish a final list, and to publicize this list as widely as possible to minimize situations where a manufacturer is simply unaware of their responsibility to pay.

*EPA Response:*
*EPA appreciates commenters' concerns and, as described earlier, will be publishing a final list of fee obligations for each test rule and EPA-initiated risk evaluation. Details of this process are described earlier and in the final rule in Unit III. EPA intends to disseminate both the preliminary list and the final list as widely as possible to avoid the situation described by the commenter. Planned methods of communicating the list to the public include posting on EPA's website, publication of a Notice of Document Availability in the Federal Register, issuance of a listserv notification, circulation to trade associations and other stakeholder groups, and communication to states and other Federal agencies involved in chemical safety or manufacturing.*

## Methodology for Calculating of Fees

The methodology for calculating fees in the proposed rule involved an estimation of the total annual costs of administering TSCA section 4, 5, 6 and 14 (except the cost of manufacturer-requested risk evaluations); identification of the full amount recoverable under TSCA (i.e., 25% of those annual costs); and allocating that amount across the fee triggering events in sections 4, 5, and 6. EPA specifically requested comment on this methodology. A number of commenters (0070, 0060) generally supported the allocation as an appropriate balance of fees amongst activities in sections 4, 5, and 6. However, many commenters had suggestions on alternative methodologies for calculating fees as described below.

*Actual Cost Approach.*
A common theme from commenters (0070, 0069, 0050, 0057, 0060, 0058, 0042) was that fees, particularly those for section 6 activities, should more closely align with EPA's actual costs for

carrying out the specific activity on the specific chemical – not an estimate or average cost for that type of activity. Some commenters (0070, 0069, 0057) argued that an actual cost approach was warranted given the likelihood for variability in costs stemming from the number of uses evaluated, extent of exposures, amount of existing information, and the level of contractor support. Some commenters (0070, 0069) went further to suggest that only manufacturers for uses identified in the scoping document should be subject to that fee. One commenter (0070) argued that, even though an actual cost approach was not proposed, one could be finalized without logical outgrowth issue. This same commenter also argued that fees collected for manufacturer-requested risk evaluations should only be used to defray costs of that activity (0070). Finally, a number of commenters (0064, 0057, 0058) suggested that, irrespective of the methodology finalized in the rule, the Agency should be tracking detailed actual cost information, including individual hours and external costs on a per chemical basis for activities under sections 4,5,6 and 14 as well as general TSCA implementation costs.

*EPA Response:*
*EPA appreciates commenters suggestions regarding an actual cost approach, and considered these comments carefully in developing the final rule. Because the actual costs of individual activities are unknown in advance, it is unclear how EPA could ensure that a true, actual cost approach would yield fees sufficient to defray 25% of the relevant TSCA implementation costs. Furthermore, an actual cost approach across all fee categories would not allow for balancing fees as desired by many commenters (e.g., providing lower fees for section 5 fees to promote innovation). However, as a general matter, EPA agrees with commenters regarding the need to track costs on a chemical basis in light of the increased responsibilities under TSCA. The Agency is working towards building this capability and, consistent with commenter suggestions, expects to begin tracking actual costs as soon as feasible. Such information will be valuable when the fee structure is next reevaluated as required under TSCA. EPA expects there to be some challenges as it works to begin collecting fees, and does not believe it would be appropriate to implement an actual cost approach for all fee triggering events at this time.*

*EPA has decided, however, to implement an actual cost approach for manufacturer-requested risk evaluations. This approach is well-supported in the language of TSCA, which explicitly requires the Agency to collect a percentage of costs incurred (i.e., 50% or 100%), depending on whether the chemical is on the TSCA Work Plan. Although EPA proposed a 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. Specifically, EPA will require a flat down 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 upon publication of the final risk evaluation for either 50% or 100% of the actual costs in line with the percentage requirements in TSCA. EPA believes that there will be fewer challenges associated with tracking of actual costs for these activities since the statute specifies that the fee is to cover the costs of risk evaluation of that chemical(s) and is not intended to contribute to defraying 25% of the costs of relevant TSCA implementation as described above.*

*Level of Effort Approach*

A number of commenters (0064, 0052, 0042) suggested that EPA develop and implement a schedule of fees based on the expected level of effort – and range of expected costs - associated with completing an activity. Generally, commenters argued that the fee structure should account for the variation in the level of effort the EPA may encounter with the specific chemical and activity. For risk evaluations, this might include the number and types of uses, exposed populations, prior risk evaluations by other authorities, data availability, etc. For section 4 activities, this might include varying levels of complexity associated with different tests. One commenter (0045) noted that a 1-size fits all approach would not be fair for manufacturers who strive to use safer chemicals. Commenters had different suggestions for EPA to implement a level of effort approach. For example, one commenter (0043) suggested 2 or 3 fee levels with defined criteria per activity (e.g., high, medium or low level of effort). Several other commenters (0070, 0067, 0069) suggested that, in the risk evaluation context, fees be tailored to cost estimates developed at the time of scoping.

*EPA Response:*
*As a general matter, EPA agrees that fees should more closely align with the level of effort associated with the activity. 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. As indicated earlier, EPA also expects to begin tracking actual costs on a per chemical and per action basis. This information, in addition to experience implementing the new requirements of TSCA, will help EPA to consider alternative methodologies for calculating fees, and will inform potential revisions to the fee structure in the future.*

*Market-based Approach*
One commenter (0057) suggested that EPA was required by OMB Circular A-25 to apply a market-based approach to calculating fees. In other words, commenter argued that EPA should have looked to market-based cost estimates for risk assessments and testing to set the fee structure.

*EPA Response:*
*As described in the proposed rule, EPA considered the Office of Management and Budget Circular A-25 on User Charges and the GAO User Fees Design Guide for information relevant to the administrative processes of setting, revising, collecting, and administration of fees. For example, EPA followed the Circular A-25 guidance in identifying the relevant direct and indirect costs to be recovered by user fees. While the Agency's proposal was informed by the policies and principles identified in these two federal guidance documents, they are not binding. EPA was required to, and did, follow the requirements of TSCA section 26(b) for developing a fees structure.*

## Fee Categories

EPA proposed 8 distinct fee categories. These fee-triggering events result in obligations to pay fees. Three categories are for section 4 activities: test orders, test rules and enforceable consent agreements. Two categories are for section 5 activities: notices and exemptions. And three categories are for section 6 activities: EPA-initiated risk evaluations, manufacturer-requested risk evaluations for chemicals on the TSCA Work Plan, and manufacturer-requested risk evaluations

for chemicals not on the TSCA Work Plan. Although EPA received comment on these and other potential fee categories as described below, EPA is not altering the fee categories for the final rule.

*Fee Categories for Section 4 Activities.*
As a general matter, EPA received very few comments regarding the three fee categories proposed for section 4 activities. One commenter (0057) expressed concern that EPA might charge a fee for a section 4 activity, and then also for an associated section 5 or 6 activity, and suggested that this would amount to double-charging.

*EPA Response:*
*EPA disagrees with the "double-charging" characterization. Cost estimates for section 4 activities do not overlap with cost estimates for section 5 or 6 activities, and the expenses defrayed by each of those fee amounts 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 section 5 notice or exemption, or undertaking a section 6 risk evaluation.*

*Fee Categories for Section 5 Activities*
EPA received a number of comments related to section 5 fee categories. Most of these comments pertained to LVE fees. Historically, EPA has not charged a fee for section 5 exemption applications (e.g., LVE, LoREX, TME, TERA, etc.). A number of commenters (0046, 0070, 0047, 0061, 0065, 0053, 0056) generally sought to eliminate the exemption fee category entirely, and particularly for LVE fees. These commenters suggested that fees for any exemption application would become a barrier to research, development and innovation. A few commenters asked for clarification as to whether a testing requirement associated with section 5 review would also receive a section 4 fee (0070, 0053). Commenters split on EPA's proposal to eliminate the intermediate discount fee category. One commenter (0059) supported the elimination, while a few other commenters opposed the eliminations (0057, 0049).

*EPA Response:*
*EPA is not adjusting the fee categories for section 5 activities in the final rule. While EPA is sensitive to commenters' concerns for impacts to innovation, EPA does not believe the proposed LVE fee – a one-time $4,700 review cost - will be a significant barrier to chemical manufacturers seeking to introduce new chemicals to market. There is already a regulatory exemption from the section 5 notice requirements for those who manufacture only for research and development purposes (see 40 CFR 720.36); an LVE would be an inappropriate tool to achieve those ends. As for a section 4 testing requirement (e.g., test order) that may be associated with a section 5 new chemical submission, EPA will not change its determination to charge a fee. As described earlier, the expenses contemplated for section 4 (e.g., developing order and reviewing test data) and section 5 activities (e.g., reviewing and processing applications) are separate and distinct. If EPA chose not to charge a fee for that section 4 action, the fees for other actions would need to be adjusted to compensate.*

*Fee Categories for Section 6 Activities*

EPA did not receive comments opposing the 3 fee categories proposed for section 6 activities. However, several commenters suggested exemptions or discounts for certain manufacturers. For example, one commenter (0067) suggested that those who manufacture a chemical as an impurity or byproduct be exempt from the section 6 fee categories. Another commenter (0054) suggested an alternative section 6 fee category for manufacturers of chemicals for small, niche markets as their revenue may be insufficient to support a risk evaluation.

*EPA Response:*
*EPA is not adjusting the fee categories for section 6 activities in the final rule. As noted earlier, TSCA requires EPA to evaluate chemicals under their conditions of use as determined by the Administrator, which may include conditions of use that involve manufacture of impurities or byproducts, or chemicals used in niche market applications. As such, EPA does not believe it would be appropriate to categorically exclude these manufacturers from fee obligations for section 6 activities.*

*Other Fee Categories Not in Proposed Rule*
EPA did not propose a separate fee category for certain other TSCA activities such as CBI claims or risk management activities. Several commenters commented on the absence of such categories. For example, a majority of commenters (0065, 0041, 0043, 0057, 0061, 0046, 0060, 0049) indicated support for no fee categories or surcharges associated with submission of CBI claims. One commenter (0071), however, expressed concern in light of the historical problem of unwarranted CBI claims. There was a split amongst commenters regarding a separate risk management fee. Several commenters (0066, 0041) opposed a risk management fee category, with one commenter even suggesting that there was no authority in TSCA to implement one. Other commenters (0065, 0071, 0059) encouraged EPA to include a separate fee category for risk management activities to both place the costs/burden of this activity on companies choosing to use more dangerous chemicals, and incentivize companies to move to safer chemistries.

*EPA Response:*
*EPA is not adding additional fee categories for the final rule. There was a strong opposition from public commenters to a CBI fee category, and mixed views on a separate risk management fee category. The costs of both activities were accounted for in EPA's baseline cost estimates in the proposed rule, meaning that EPA will recover a portion of these costs through fees. Under a plain reading of TSCA, EPA is not authorized to assign fees for CBI claims. EPA expects that the perceived issue of overclaiming CBI protections noted by the commenter will be mitigated to a certain extent by increased level of EPA scrutiny and new substantiation requirements in TSCA. As for risk management, EPA does not believe that a separate fee category is necessary to discourage use of dangerous chemicals; to the contrary, EPA believes that the new general requirements for prioritization and evaluation of existing chemicals may themselves be an incentive to manufacturing chemicals consider alternative chemistries.*

## Program Cost Estimates and Activity Assumptions

*In General*
Several commenters commented on their view that cost estimates were underestimated, and did not fully account for work under amended TSCA and that sufficient detail was not included

(0071, 0059). One commenter suggested that ORD costs were excluded and identified inconsistencies between the economic analysis and the technical background document (0059). One commenter suggested using Pesticide Registration Improvement Act costs to benchmark costs estimates (0052) and that cost estimates were unjustifiably high (0034)

*EPA Response:*
*EPA has made changes to correct certain errors and inconsistencies in the technical background document and economic analysis identified by commenters and appreciates these issues being brought to our attention. Some of these errors and inconsistencies are elaborated in the final section of this document under "Miscellaneous Issues and Requests for Clarification."*

*While some commenters felt that benchmarking risk evaluations costs to PRIA was not appropriate for TSCA risk evaluations, other commenters supported this approach. While EPA recognizes that the statutory authorities and approach are not identical, EPA generally agrees with the use of Pesticide Registration Improvement Act (PRIA) risk assessment costs as a baseline to benchmark estimated TSCA risk evaluation costs. EPA chose the costs of conducting reviews for new conventional food-use pesticide active ingredients under PRIA as the most relevant comparison 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%. EPA TSCA risk evaluation costs are roughly $1 million more than the PRIA costs due to several factors that EPA believes warrant the additional costs under TSCA. The scope of an existing chemical assessment and any risk management requirements TSCA are expected to be broader and therefore costlier than assessments under PRIA. TSCA risk evaluations will also generally include a broader set of scenarios use and exposure scenarios that must be assessed and uncertainties. EPA also considered the uncertainly associated with implementing a new evaluation program when estimating costs. Another pertinent factor is that risk management costs will be higher under TSCA, as risk management is implemented through notice and comment rulemaking. Under PRIA most risk mitigation for a pesticide can be achieved through negotiation of the registration for product labeling which requires less administrative cost.*

*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. Some commenters also indicated that the costs 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. EPA acknowledges that our experience undertaking risk evaluations under amended TSCA is very limited and we have not yet begun prioritizing chemicals for review or issuing test orders. Given this limited experience with novel obligations and authorities, our costs are by their very nature imprecise estimates. 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 of the costs new work under the amended statute.*

*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 our estimates by reviewing past staffing or non-pay budget needs for identical activities. However, EPA carefully took into account expanded requirements for risk evaluation, risk management, and new chemical review activities as well as the new test order authority. Furthermore, EPA believes that Congress understood the uncertainty in standing up a new chemical review and management program and required EPA to perform annual audits to determine the appropriateness of the fees to address this very concern. EPA is required to review and update the fees, if necessary, every three years to adjust for inflation and ensure that fees are approximately but not more than 25 percent of the costs to the Administrator of carrying out 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. The statutorily required annual review and three-year revisions process provided for in the statute demonstrates that Congress recognized the uncertain nature of cost estimates under amended TSCA and provided EPA with a process for evaluation and revising fees after gaining implementation experience.*

*Some commenters questioned whether EPA appropriately accounted for ORD costs in our estimates. EPA considered ORD costs related to section 4 and 5 in the overall ORD that are housed in section 6. ORD support is expected to be broadly applicable to all three sections of TSCA but EPA chose to include the costs in one place. EPA is considering ORD assistance with a wide range of activities including 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. See also Updated Technical Background Document.*

*Section 4 Activities*

Several commenters commented that costs were too low and did not take into account 4(h) requirements to identify non-animal alternatives (0071, 0059), EPA's new test order authority (0071), that the number of activities was underestimated and that EPA was not appropriately taking into account the new authorities under amended TSCA (0065, 0071, 0059, 0046) and that greater transparency in cost estimates should be provided (0070). One commenter pointed out discrepancies between the economic analysis and technical background document (0059). Another commenter suggested that EPA should begin work on all 2014 Work Plan chemicals (0068). One commenter supported "Alternative A" because they felt that section 4 costs should be more in line with section 5 and 6 (0071). Other comments felt that costs could be lowered by relying more on existing information and voluntary collection from industry (0050) or consolidation of orders to reduce costs (0060).

*EPA Response:*

*EPA's cost estimates for Section 4 activities presented in the Proposed Rule are unchanged in the Final Rule. Some commenters felt that cost estimates were too low in general and did not take into account section 4(h) requirements to identify non-animal alternatives. EPA is only in the very early stages of implementing the "Strategic Plan to Promote Development and Implementation of Alternative Test Methods" we therefore don't have experience with implementing this strategy or firm estimates of the costs of, for instance, validating the*

*equivalency of a non-animal test. EPA expects to include these costs in any updates to the fees rule during the next review cycle. EPA based Section 4 costs on our general experience with the rulemaking process, our experience with the developing an Enforceable Consent Agreement (ECA) for Octamethylcyclotetrasiloxane (D4) and costs associated with reviewing information received, and administration of the High Production Volume Voluntary Testing Program. EPA relied on this past experience, although limited in nature, and a thorough process of coordination with programmatic staff and management to estimate the section 4 costs. EPA included cost estimates for a full suite of activities related to developing and implementing the 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.*

*EPA cost estimates reflect the best estimates currently available, rely on past programmatic experience, and consider the information needs under amended TSCA for these new/more frequent section 4 activities. Therefore, EPA does not agree with commenters that felt that activity costs were too low. Further, the cost assumptions used in developing the section 4 estimates do not preclude the EPA from collecting data and information using additional Section 4 activities if needed. 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 reviews of fees.*

*Some commenters commented that the number of section 4 activities was too low. However, because section 4 actions are estimated to 7 chemicals each, EPA does not believe the activity levels are low. Therefore, testing under section 4 would provide information for up to 84 chemicals (7 x 12) per year. EPA believes that this is sufficient to supply EPA the information needed to prioritize and evaluate chemicals under TSCA.*

*EPA does not agree that Section 4 fees should be increased to recover a higher percent of EPA costs to develop, implement and review information from section 4 activities be more aligned with those in Section 5 and 6. Commenters suggested that the lower cost recovery and fee would disincentive EPA from undertaking these activities. EPA does not agree and will base decisions to undertake section 4 activities to provide the information needed to prioritize and evaluate chemicals under TSCA not for economic reasons. Some commenters felt that EPA recover a higher percentage of costs for section 4 activities. EPA does not agree, we strove to achieve this balance with careful consideration of early stakeholder comments that EPA should be take into account the costs that companies incur when developing test data and therefore consider relatively lower cost recovery, and therefore fees for section 4.*

*While EPA believes that the manner in which EPA gathers information on all the Work Plan chemicals is outside of the scope of this rule, EPA disagrees with comments suggesting that EPA immediately begin to simultaneously gather information on all Work Plan chemicals. However, EPA does plan to open a series of dockets for all of the work plan chemicals which will afford interested parties the opportunity to submit relevant information to the Agency.*

*Section 5 Activities*

Several commenters asked for more transparency (0070) and a more fulsome explanation of expected declines in new chemical submissions (0071, 0056). One commenter expressed concern that the estimated 20% decline in new chemical submissions would impact innovation (0049). Several commenters commented that EPA did not include all costs such as those related to Significant New Use Rules (SNURs) and Consent Orders, and existing chemical SNURs (0071, 0046), pre-notice consultation and public recordkeeping or were limited to "intended uses," and did not fully include costs associated with making the affirmative determination (0059). Another commenter felt that NOC costs should not be considered in setting fees (0061) and one commenter felt that SNUN costs were overestimated.

*EPA Response:*
*EPA's cost estimates for Section 5 activities presented in the Proposed Rule are unchanged in the Final Rule. EPA does not agree with commenters that suggested the costs related to SNUR and Consent Orders activities were "absurdly low." EPA relied on 40 years of experience under the previous statute and two years of experience under amended TSCA to estimate the costs for reviewing section 5 submissions. Estimates were also based on 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, section 5 costs are some the best understood in terms of anticipated activity level and per activity cost.*

*EPA also fully considered the costs of risk management associated with new chemical determinations in addition to estimates for reviewing new chemicals. This includes the cost of issuing consent orders and/or SNURs when needed. Because the bulk of consent orders and SNURs rely upon standard language, per activity costs are naturally relatively low. In addition, EPA frequently batches dozens of chemicals into one SNUR which significantly reduces the per chemical cost associated with issuing the SNUR.*

*One commenter felt that costs associated with processing Notices of Commencement (NOCs) should not be considered. While the fees rule does not include fees for NOCS, the Congressional authority to collect fees to defray 25% of the costs of administering Section 5 clearly allows EPA to consider the costs of NOCs in the total section 5 costs. EPA has included the costs associated with NOCs in setting the fees for PMNs, MCANs and SNUNs.*

*EPA's estimated 20% decline in new chemical submissions was based on the expectation that increased fee amounts would reduce submissions. Some commenters felt that increasing the fee would dampen innovation and that EPA was not taking this concern seriously. Consistent with the statute, EPA is committed to ensuring that implementation of TSCA does not impede unduly or create unnecessary economic barriers to technological innovation. EPA is aware that, historically, only approximately 57% of PMN submissions are followed by a Notice of Commencement (NOC) to bring the substance to market. Considering this, EPA does not expect fewer NOCs, and therefore does not expect an impact to getting new, innovative chemicals to market.*

*Section 6 Activities*

In general EPA received several comments that cost estimates in general were too high or were out of line with costs for private firms to undertake risk assessments (0064, 0050, 0057, 0046 0057), that EPA should narrow the scope of exposure scenarios to reduce risk evaluation costs (0050), and comments that costs were too low and incomplete, particularly for section risk evaluations (0071, 0059) and risk management (0059) or did not fully take into account the responsibilities under the amended law including pre-prioritization and consideration of vulnerable sub-populations (0059) development of data from downstream users (0068).

*EPA Response:*
*EPA's cost estimates for Section 6 EPA-initiated risk evaluations as presented in the Proposed Rule are unchanged in the Final Rule. However, for purposes of calculating economic burden and impact, EPA revised cost estimates for manufacturer-requested risk evaluations to be consistent with the costs of EPA-initiated risk evaluations. As described earlier, EPA is using an actual cost approach for calculating manufacturer-requested risk evaluation fees in the final rule to increase accountability and transparency. While the cost estimates for manufacturer-requested risk evaluations will be used in the economic analysis, the actual cost of the specific chemical review will form the basis for the fee amount.*

*Some commenters asserted because costs for private firms to undertake risk assessments are significantly lower than EPA's costs estimate for risk evaluations that EPA was over-estimating costs. EPA does not agree because costs for private firms are likely to undertake evaluations that are much narrower in scope. Therefore, risk evaluations undertaken by private firms will naturally be significantly less costly to undertake. Therefore, EPA does not believe that costs for private firms are relevant to risk evaluations under amended TSCA.*

*EPA also carefully considered comments that some risk evaluations may be less costly for the Agency to undertake. In consideration of these comments and to address these concerns that EPA might "overcharge" for some manufacturer-requested risk evaluations, EPA has revised the fee structure for manufacturer-requested risk evaluations and will collect an initial partial payment approximately equal to 50% or 100% of 2/3 of the total estimated cost of a risk evaluation or $1.25m or $2.5m respectively. EPA will then track actual costs and invoice for the remaining amount due after the conclusion of the risk evaluation. EPA estimates also fully consider the statutory requirements pertaining to conditions of use, consideration of susceptible subpopulations and include costs of prioritization, including the process of identifying potential candidates for the prioritization process.*

*Collecting, processing, reviewing, and providing access to and protecting from disclosure as appropriate under section 14*
EPA received several comments requesting more detail related to section 14 costs (0071, 0059) or suggesting costs were out of line with past EPA spending or budget requests (0071), did not include comprehensive CBI costs for developing actions and managing information under section 8 and 11 that support section 4 and 6 activities, and costs related to managing the inventory, and costs of upgrading systems (0071, 0059).

*EPA Response:*

*EPA's cost estimates for Section 14 TSCA CBI Review Program Activities presented in the Proposed Rule are unchanged in the Final Rule. In response to requests to better substantiate costs related to information management, EPA expanded upon the estimates from the proposed rule to better elaborate which activities were included in the costs estimates in the proposal. These estimates account for agency-wide recurring costs for all relevant information management activities, including: costs for CBI Claim Review for 100% of applicable Chemical Identity CBI Claims and 25% of all other applicable CBI Claims (Prescreen/Initial Review; Substantive Review and Making Final Determinations; Reviewing and Sanitizing Documents; Regulation Development; IT Support; Outreach/Communications), 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. While the overall estimate of costs is unchanged, EPA is providing a more detailed breakdown of the activity categories that underpin the overall Section 14 cost estimates.*

*Some commenters felt 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.*

## 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 as described in the sections that follow, and some more generally applicable. For example, one commenter (0067) suggested that EPA should set a maximum fee for scenarios where there are a small number of manufacturers subject to a large fee. Another commenter (0042) suggested that fee amounts should be adjustable based on the number of identified manufacturers for the particular chemical and activity. One commenter (0052) felt strongly that EPA proposed fee amounts and/or increases should be reconsidered in the absence of better explanation and support for the amounts. Finally, one commenter (0034) suggest that EPA create an alternative fee schedule that would more sensitive to small businesses.

*EPA Response:*

*EPA is not adjusting fee amounts for the final rule based on these general comments. First, EPA does not know in advance how many manufacturers will be identified for a particular chemical or 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. Second, 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. See Unit III of preamble to 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 anticipation of the next three-year fee cycle as required under TSCA. Finally, EPA believes that the fee structure already provides a significant accommodation for small businesses – fee amounts that are approximately 80% lower than the fee amounts for other businesses, and an adjustment to the standard that allows more companies to qualify as small businesses.*

*Fee Amounts for Section 4 Activities*

EPA proposed three different fee amounts for test orders, test rules and enforceable consent agreements (ECAs). These fees amounted to approximately 3.5% of the estimated activity cost. Several commenters (0070, 0043) expressed general support for the lower fee amounts for section 4 activities. Another commenter (0059) 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. Another commenter (0061) urged EPA to raise section 4 fees to offset a reduction in the proposed section 5 fees. One commenter (0042) suggested that EPA consider assigning lower fees when companies agree to collaborate and produce data.

*EPA Response:*

*EPA is not adjusting the section 4 fee amounts in the final rule. 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 fee amounts in the proposed rule. In addition, as described in the proposed rule, EPA believes that the section 4 fee amounts strike an appropriate balance of fee distribution amongst the activities in sections 4, 5 and 6. 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.*

*Fee Amounts for Section 5 Activities*

EPA proposed two fee levels – one for notices (PMNs, SNUNs and MCANs) at approximately 29% of the cost of the activities, and one for exemptions (LVEs, LoREX, TME, Tier II, TERA and film articles) at approximately 89% of the cost of the activities.

As a general matter, a large number of commenters (0070, 0065, 0046, 0049, 0043, 0048, 0061, 0053, 0052) indicated that the proposed 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. Others suggested that the proposed fees for section 5 activities were among the highest globally for similar programs. Some urged EPA to only adjust the old fees for inflation. One commenter (0060) suggested that EPA better balance fees between new and existing chemicals.

Other commenters had more specific comments or requests. For example, a few commenters (0059, 0061) expressed support for the proposed TME discount. A number of commenters (0070, 0057, 0061, 0046) suggested that EPA also apply a PMN discount for graduates of EPA's Sustainable Futures program. One commenter (0061) suggested reducing the fee for polymer exemption cases. Another commenter (0047) argued that SNUN fees should be lower than PMN fees as EPA is just evaluating one new use for a SNUN. One commenter (0042) suggested lower fees when a review is completed in less than 90 days, or when companies provide an enhanced data set. Another (0049) suggested lower fees for bio-based submissions, which they argue are disproportionately burdened by EPA policies. Another commenter (0048) suggested phasing any increase in section 5 fees over time. That same commenter suggested a reduced fee for submitting chemicals that are safer or more environmentally friendly. One commenter (0059) expressed concern that EPA based the proposed section 5 fees to minimize impact on innovation, arguing that there was no basis in TSCA to do so. This commenter also expressed concern regarding the same fee for consolidated PMNs and MCANs, even though EPA acknowledges that such consolidated submissions are costlier.

*EPA Response:*
*EPA appreciates commenters' concerns regarding increased section 5 fees and impacts to chemical innovation. First, amongst the fee categories for section 4, 5, and 6 activities, EPA proposed to collect the bulk of fees from manufacturers subject to section 6 EPA-initiated risk evaluations, in part, to minimize impacts to innovation and competitive standing for new chemical manufacturers. Second, the proposed fee amount for PMNs, MCANs and SNUNs was only moderately higher than the current fee adjusted for inflation. 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. As such, EPA is not changing section 5 fee amounts for the final rule. EPA disagrees with commenter on including considerations regarding impacts to innovation in the process for developing the proposed and final fee structure. Contrary to commenter's suggestion, TSCA requires EPA to implement TSCA in a manner that does not "impede" or create "unnecessary barriers to technological innovation." See TSCA section 2(b)(3).*

*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 cost the Agency less to review. With respect to polymer exemption cases (where a submitter seeks a full PMN review to get inventory status), bio-based submissions, or chemicals with a P2*

*(i.e., safer or more environmentally friendly) claim, there is similarly no evidence that such submissions are categorically any less complex or expensive to review. Further, EPA believes it would be inappropriate to provide a fee discount to a particular industry sector.*

*Commenter's point about SNUN review costs is well-taken, but TSCA does not impose limitations on EPA's development of the fee structure in this way. EPA chose to group PMN, MCAN and SNUN fees into a single category, with a single fee, for practical implementation reasons. The same is true with respect to comments that 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). While that may be the case, 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.*

*Fee Amounts for Section 6 Activities*

EPA proposed to set fee levels for EPA-initiated risk evaluations at approximately 35% of the estimated cost of the activity. At least one commenter expressed concern that high fees will result in manufacturers abandoning critical substances, placing more burden on downstream users. One commenter (0067) suggested that EPA should provide a discount when data/analytical needs were low, such as when a detailed review has already been conducted. Another commenter suggested reducing the risk evaluation fee when companies voluntarily submit additional data, or if a company would agree to voluntarily phase out manufacture of the substance. Another commenter (0045) suggested a reduced fee for chemicals on the TSCA Workplan, given that some amount of assessment has already taken place. One commenter requested certain clarifications. Commenter requested that EPA clarify that only one fee will be required for Risk Evaluations, 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.

With respect to manufacturer-requested risk evaluations, EPA set the fee levels at either 50% or 100% of the estimated costs of the activity, depending on whether the chemical was listed on the TSCA Work Plan. A number of commenters had suggestions in this area. For example, some commenters (0070, 0069) suggested that the fee should be a small, flat-rate down payment, followed by implementation of actual cost tracking limited to the uses requested and a final invoice reflecting those actual costs. One commenter (0057) indicated that EPA should try to leverage the resources of industry and incentivize manufacturers to make requests for risk evaluation, and that one way to do so would be to lower fees to encourage manufacturers to make more requests. One commenter (0061) asked EPA to clarify whether non-requesting manufacturers would be compelled to pay part of the fee.

*EPA Response:*

*EPA is not adjusting fee amounts for EPA-initiated risk evaluations, but as described earlier and in Unit III of the final rule, EPA is adopting an actual cost approach fee structure for manufacturer-requested risk evaluations. 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, or the availability of information. In assigning fees across activities in section 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. EPA does not believe that the prior process leading up to listing of the chemical on the TSCA Work Plan constitutes an assessment or risk evaluation, or that the costs of such a risk evaluation will be less expensive and therefore weigh in favor of a reduced fee.*

*EPA does not intend to charge multiple fees for a single risk evaluation, even if the unreasonable risk statements are communicated at different times as contemplated in the risk evaluation framework rule. Additionally, as indicated in the risk evaluation framework rule, only the manufacturer who requests a risk evaluation will be subject to the applicable fee, regardless of the scope of the risk evaluation as determined by EPA.*

## Payment / Collection of Fees

EPA generally proposed upfront collection of fees (prior to reviewing a section 5 notice, within 60 days of test order/rule effective, within 60 days of signing ECA, within 30 days of granting a manufacturer-requested risk evaluation, and within 60 days of publishing the final scope of a risk evaluations. A number of commenters (0067, 0043, 0069, 0070, 0055, 0043, 0047, 0057, 0052, 0060, 0058) encouraged EPA to allow for phased payments, particularly for section 6 activities. Some of these commenters that payment at specific milestones would better hold EPA accountable and assist with business planning efforts.

*EPA Response:*
*EPA is not modifying the final to rule to allow for phased collection of payments, with the exception of manufacturer-requested risk evaluations as described earlier. Fees collected under this rule are intended to defray TSCA implementation costs; collecting payments in advance is important to achieving this end. However, as already noted, EPA is moving to an actual cost approach for manufacturer-requested risk evaluations which will, in effect, allow for phased payments (e.g., initial flat payments followed by a final invoice at the end of the activity). Additionally, as described in Unit III of the final rule, 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 section 4 and 6 activities. EPA believes this additional time before payment is ultimately due, as well as the process for upfront identification of manufacturers subject to fee obligations in the final rule, will be useful for businesses to better financially plan for the additional expense.*

## Consortia

EPA proposed to allow formation of, and payment by, consortia for section 4 and 6 activities. Manufacturers are required to notify EPA of their intent to form a consortium within 30 days of the fee triggering event, determine amongst themselves about how to divide the fee, and then pay EPA within 60 days of the fee triggering event. A number of commenters (0060, 0051) suggested that EPA should do more to actively encourage formation of consortia, such as providing contact info for identified manufacturers. A significant number of commenters urged EPA to extend the time for consortia to form (0066, 0070, 0067, 0050, 0052, 0060) and pay

(0066, 0070, 0067, 0043, 0061). Commenters suggested anywhere from 90 to 180 days to form and pay. One commenter indicated that experience with consortia formation in the REACH context demonstrated that it generally took months to form.

Some commenters (0061, 0066, 0043, 0057) suggested that EPA should go further in prescribing fairness in consortia dealings, including dealings with small businesses. At least one commenter (0034) suggested that an expectation that consortia would assign lower fees to small businesses is unrealistic. Another commenter (0049) suggested EPA should require consortia to give small business discount. One commenter (0061) 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. 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 the final rule (0055, 0043, 0051, 0046, 0054).

Still other commenters (0070, 0058, 0066, 0060) asked EPA to clarify some of the complex scenarios, and how the division of costs would occur.

*EPA Response:*
*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. However, EPA must also balance the need to implement its statutory responsibilities in a timely manner (e.g., risk evaluations), and the expectation that fee payments will defray some of those implementation costs. As such, EPA is extending the dates for notification and payment each by 30 days for section 4 and 6 activities. 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.*

*TSCA section 26(b)(4)(A) clearly indicates Congress' intent that small business to be afforded lower fee payments. However, association with a consortium is a voluntary activity, and EPA does not believe it has the authority in TSCA to compel consortia managers to provide a discount to small businesses. Nevertheless, EPA strongly encouraged consortia to do so in the preamble to the proposed rule, and will do so again in the preamble to the final rule. EPA has included updated estimates of the administrative costs of consortia management in the supporting economic analysis for the final rule.*

*Finally, EPA is codifying some additional clarifications on the division of costs amongst consortia and individual manufacturers for certain complex scenarios identified by commenters. In short, in the absence of a single consortia of all manufacturers, EPA will tally the total number of manufacturers, apply the small business discount to individuals and small-business only consortia, and allocate the total fee accordingly.*

## Refunds

EPA proposed to issue refunds in certain circumstances related to section 5 activities: full refunds for submissions that are not new chemicals substance, new microorganism or significant new use, incomplete submissions, and when Agency fails to make a determination or deny an exemption request, unless the submitter unduly delayed the process; or partial refunds (i.e., 75% refund) if submission was withdrawn within 10 business days.

One commenter (0065) asked EPA for clarification as to whether bona fide submission would be subject to a fee. Another (0061) suggested that refunds would be provided if a chemical was determined not subject to TSCA jurisdiction, or if the case was "dropped" as they sometimes were under the previous law.

Several commenters had suggestions or requests for clarification with respect to partial section 5 refunds. One commenter (0065), for example, suggested that EPA consider granting partial refunds beyond the proposed 10 days window when little or no work has been done on the review. One commenter (0059) suggested shortening that window to 7 days, arguing that it's very possible EPA may have done a significant amount of work prior to Day 10. Another commenter (0061) argue the opposite – and encourage EPA to extend the 10-day to 15 days.

Several commenters (0065, 0057) asked EPA to describe the process/details on full refund based on failure to complete review within deadline. Others (0061, 0053, 0042) asked EPA to clarify what was meant by "undue delay" by the submitter – a circumstance which would prevent the submitter from receiving a full refund in the event the review is not completed within the statutory review period. A few commenters (0065, 0046) suggested that voluntary suspensions shouldn't stop the review period.

A number of commenters (0066, 0070, 0053, 0052, 0049) requested more generally that EPA clarify the circumstances under which refunds would be granted, and the associated process for doing so. For example, one commenter (0053) asked whether EPA would initiate refunds or if they need to be requested, and what the process would be for such requests.

A few commenters (0064, 0069) asked EPA to clarify the circumstances, if any, where EPA would issue refunds in the section 4 or section 6 context, such as when a manufacturer-requested risk evaluation fee exceeds the actual costs. Another commenter (0064) asked how EPA would handle refunds if the total fees collected exceed the statutory limit.

*EPA Response:*
*As indicated in the proposal, section 5 submissions provided in error are subject to full refund. Chemicals that are not subject to TSCA jurisdiction would not be subject to the section 5 notice requirements, and therefore not subject to section 5 fees. Additionally, the bona fide process allows manufacturers to determine whether or not a chemical is already on the TSCA Inventory, and such inquiries are not subject to fees. EPA will provide additional clarification in the final rule preamble. Chemicals can no longer be "dropped" as they were under the previous law. TSCA now requires EPA to make an affirmative finding under TSCA section 5(a)(3) in every case.*

*EPA is not adjusting the window for partial refunds in the final rule. The 10-day window was selected based on target dates for completing certain aspects of the new chemical review process. While it is possible that EPA may complete those specific steps faster or slower, EPA does not believe it would be practical to assess the merits of partial refunds on a case-by-case basis.*

*With respect to full refunds of section 5 fees, EPA has included additional clarification in the final rule. First, EPA is required to complete review 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 also agree to suspend the review period to allow the submitter to develop new information, or to provide EPA with time to review new information. A voluntary suspension tolls the applicable review period. Thus, if 90 calendar days had passed for a case under voluntary suspension with no determination, the submitter would not be entitled to a refund. EPA has also historically allowed the submitter to amend their submission at any time during the review period. EPA intends to continue these practices. "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 full refund if the TSCA review period expires. As a practical matter, this will likely be a rare scenario 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.*

*EPA is further including some additional clarification in the preamble to the final rule on the process for initiating refunds. EPA will initiate the refund process for those submissions withdrawn within the initial 10-day window, and for full refunds after the expiration of the TSCA review period. However, companies may also reach out to their program point of contact to make such a request.*

*Lastly, consistent with the proposal, EPA is not including any refund provisions for section 4 or section 6 activities. For both categories of fee-triggering events, EPA does not envision circumstances where refunds would be appropriate, including refunds based on late entrants, timing, or actual costs (except for manufacturer-requested risk evaluations). In the context of manufacturer-requested risk evaluations, EPA is finalizing an actual cost approach, so there would no longer be a circumstance where a manufacturer might be charged more than the cost of completing the activity.*

## Small Business Concerns

EPA received a significant number of comments related to small business concerns, small business standards and lower fees for small businesses. EPA specifically requested comment from stakeholders on these issues. The proposed rule set small business fees at an 80%-82.5% reduction compared to the base fee for each category. EPA also proposed to adjust the size standard used to identify businesses that can qualify as a "small business concern" from a current revenue threshold of $40 million to approximately $91 million. EPA also proposed to change

the time frame over which annual sales values calculated from one year, to average annual sales values over the three years preceding the submission.

Commenters provided mixed views on the size standards. A number of commenters (0066, 0057, 0052) expressed support for SBA's employee based definition. Other commenters (0070, 0034, 0065, 0046) suggested that EPA apply only the inflation-adjusted approach in proposal, or else risk over-identifying small business concerns. At least one commenter (0060) expressed support for a revenue-based definition, arguing that an employee-based metric is antiquated. A number of commenters (0061, 0052, 0049) supported an "either/or" approach, where a company could choose to certify as a small business under either a revenue or an employee-based approach. One commenter (0049) suggested that EPA consider an additional "micro business" category of 1-9 employees with an associated fee cap of $100.

Some commenters expressed concern regarding accommodations made to small businesses in the proposed rule. For example, a few commenters (0071,0024) 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 (0043) urged EPA to clarify and better support its proposed discount of 80%. One commenter (0059) noted that EPA would need to account for any shortfall in fee revenue when small businesses were afforded discounts in order to ensure the total of 25% of TSCA implementation costs. One commenter (0043) requested a related clarification as to who would cover the discount in fees for small businesses, between EPA or other businesses.

Finally, several commenters (0046, 0052) suggested that EPA take into account ability to pay and cash-flow issues for small businesses, and consider allowing installment payments for fees.

*EPA Response:*

*After further consideration, review of the public comments and consultation with SBA, EPA has determined to finalize an employee-based size standard modeled after SBA's standards. The standard provides that manufacturers and processors who have fewer than a certain number of employees identified in a table of North American Industry Classification System (NAICS) codes will be "small business concerns." For those not represented in the table, they must have 500 or fewer employees to be considered small. As a general matter, the reduction in revenue collection was minimal when applying employee-based standards versus revenue-based standards, and EPA deferred to the expertise of SBA in this area. 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 could potentially result in a significant increase to the number of small businesses identified overall, prompting a shortfall in EPA's overall fee revenue and the need to adjust the fee structure – either by providing small businesses with less of a discount, or increasing fees for other businesses. Adding a "micro-business" category could create similar issues with revenue shortfalls for EPA and likely create*

*a need to increase fee amounts elsewhere. Further, there is no precedent in the federal government for such a standard, including within SBA. Ultimately, EPA did not believe the TSCA fees rule was an appropriate venue to test a micro-business standard. As indicated in the proposed rule, EPA believes the ongoing TSCA 8(a) rulemaking will provide a venue for a more expansive consideration of appropriate size standards for industries subject to TSCA and offer the public with further opportunities to comment on the size standard, and EPA is committed to considering the results of that rulemaking when work begins to update the TSCA fees rule for the next three-year cycle.*

*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 light of the explicit statutory direction in TSCA and significant stakeholder input regarding the need to minimize impacts to small businesses. As noted earlier, EPA considered and is declining to finalize a process for phased collection of fee payments with the exception of the new manufacturer-requested risk evaluation approach. While EPA recognizes the concerns with small business cash-flow and ability to pay, EPA believes the 80% discount in fees should address most of those concerns.*

*Finally, when all manufacturers identified for a particular fee activity qualify as a small business, the discount in fees would be applied and EPA would not be able to collect the remaining 80%. While EPA recognizes that such a situation could potentially occur, EPA believes the frequency is likely to be rare. In scenarios where there are a mix of small and other manufacturers, the other manufacturers would be required to cover the shortfall. A number of these scenarios are explained in greater detail in Unit III of the preamble to final rule.*

## Enforcement

A number of commenters provided input or asked clarifying questions related to liability and enforcement issues. EPA indicated in the proposal - 700.45(e) - that a failure of the consortia to pay the fee or their portion of the fee would result in a violation by each consortium member. A few commenters (0066, 0041) indicated that liability should focus only on those members of the consortia who are at fault for non-payment. For example, commenter suggests that a consortium manager may determine not to allocate a fee to a particular member; if there is an issue with payment within the consortium, commenter believes that that the member with a $0 fee should not be subject to penalty.

*EPA Response:*
*EPA disagrees with commenters on these points. EPA is already providing an extended period of time (i.e., 120 days) for consortia to determine membership and resolve any payment issues before the payment is due. If the consortium is unable sort out these issues amongst their membership during that period, the final rule provides an opportunity for consortia to notify EPA and dissolve the consortia, triggering an additional period of time for individual manufacturers to submit individual payments. If the consortium is not dissolved prior to the payment due date, EPA has no choice but to hold each member liable for non-payment. EPA is not privy to discussions inside the consortia and would have no way of determining or verifying who within the group was at fault for non-payment.*

Another commenter (0061) suggested that EPA clarify joint and several liability in scenarios where consortia are or are not formed. The same commenter also suggested that EPA "decriminalize" fee disputes, and seek remedies in the form of late fees/interest. One commenter (0041) suggested that EPA develop an enforcement response policy for fees and failure to pay.

*EPA Response:*
*EPA is including some additional clarification regarding liability in different scenarios where multiple parties are obligated to pay a fee. EPA disagrees however, that penalty for failure to pay should just be a late fee and/or interest charge. Failure to pay a fee as required by this rule is a prohibited act under TSCA sec. 15(1) and therefore subject to a penalty under TSCA sec. 16. The Agency's ability to implement new responsibilities under TSCA in a timely manner is dependent upon timely collection of fees to defray the costs. Lesser consequences for failure to self-identify or failure to pay are likely to encourage non-payment issues in the future. 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.

## Miscellaneous Issues and Requests for Clarification

For manufacturer-requested risk evaluations, one commenter (0070) suggested EPA should clarify that a fee is not triggered unless request is submitted in accordance with final RE rule (0070).

*EPA Response:*
*Fees obligations are triggered when EPA grants such a request. The risk evaluation framework rule prescribes the circumstances under which the Agency will grant or deny requests for risk evaluations from manufacturers.*

A number of commenters (0071, 0055, 0043, 0051, 0059) requested clarity as to whether or not fees would apply to the first ten risk evaluations already underway; to notices and exemptions under review at the time the rule is finalized, and to ongoing section 6(h) activities related to PBT chemicals. One commenter (0059) strongly encouraged EPA to collect fees for the first ten chemicals, as it would be a significant source of revenue for EPA and the activities would be expected to continue during FY19 and FY20.

*EPA Response:*
*EPA will provide additional clarification on this point in the preamble to the final rule. As indicated in the proposed rule, EPA expects to begin requiring payment of fees for fee triggering events that occur on or after October 1, 2018, and will send invoices within 30 days of the effective date of the final rule. EPA is not collecting fees for fee-triggering events that started prior to October 1, 2018 such as the first ten risk evaluations, or any section 5 activities initiated before that date. There is no fee category associated with section 6(h) activities, and therefore no fees will be collected for those activities. However, the estimated costs of the remainder of*

*the risk evaluations for the first 10 chemicals including any potential section 6(h) activities were considered in developing the overall program cost estimates for section 6.*

One commenter (0060) asked EPA to clarify what would happen if no manufacturers are identified to pay.

*EPA Response:*
*If no manufacturers were identified for a section 4 or 6 activity, EPA would be required to cover the costs. As a practical matter, EPA believes that such a scenario would be extremely rare, particularly in this first three-year fee cycle. In the risk evaluation context, EPA's prioritization process will likely tend to identify as high-priority actively manufactured chemicals with greater potential for exposures.*

One commenter (0059) notes a number of inconsistencies or apparent errors in proposed rule and supporting documentation, and requested that EPA clarify or correct those issues.

- Section 4 activity reference in 700.45(a)(2)
- Inconsistent proposed fee amounts for orders, rules and ECAs
- Expected decrease in PMNs – conflicting reference to 10 and 20%
- Missing phrase on p.8234

*EPA Response:*
*EPA has clarified and/or corrected these inconsistencies and errors in the final rule and supporting materials. With respect to the reference to 700.45(a)(2) and (3), EPA has adjusted the regulatory text that fees apply to all section 4 activities, as well as test orders, rule and ECAs that arise out the section 5 review context. The error related to inconsistent fee amounts was simply an oversight. EPA has adjusted the supporting materials to ensure that fee amounts are consistent across all documents. The expected decrease in PMNs is 20%, and, again, EPA is adjusting all documents to ensure consistency. Any error in that regard was an oversight. Finally, EPA has corrected the error in the final regulatory text (p. 8234 in proposed rule) that suggested EPA would not initiate manufacturer-requested risk evaluations if the fee had not already been paid. Payment is due within 30 days after EPA grants a manufacturer-requested risk evaluation.*

One commenter (0057) that EPA's TSCA implementation efforts created a monopoly on risk assessments, as no risk evaluation work contemplated by 3rd parties.

*EPA Response:*
*EPA disagrees with this characterization. Congress imposed a mandatory duty for EPA to conduct risk evaluations under TSCA. However, there are plentiful opportunities built into both TSCA and EPA's framework rules for companies and other third parties to provide relevant information to EPA, including draft risk evaluations. In fact, EPA published guidance for persons interested in developing draft risk evaluations for EPA. This guidance is available on EPA's website here:* https://www.epa.gov/laws-regulations/significant-guidance-documents-chemical-safety-and-pollution-prevention. *As EPA gains experience with implementing TSCA, including conducting risk evaluations under section 6, EPA will consider adjusting the fees structure to better account for information submissions from third parties.*

A few commenters (0059, 0052, 0061) commented on the cap for consolidated section 5 submissions. One commenter (0059) suggested that EPA clarify that the cap is 6 submissions. Other (0061, 0052) suggested increasing the cap to some number greater than 6, such as 10.

*EPA Response:*
*When a potential chemical manufacturer wants to submit PMNs on several closely similar substances, there may be economies for the Agency in reviewing them together as opposed to individually. In recognition of these economies, and to encourage manufacturers to submit such PMNs together, the Agency will only charge a fee equal to that for a single submission for a consolidated submission of up to six chemical substances. EPA is not increasing the six-substance cap through this rulemaking.*

*Pre-approval before a PMN is submitted is required for a consolidated submission. Approval will be given if the substances are adequately similar chemically and toxicologically, if the planned uses are similar enough for combined review, and if intended volumes are not excessively different. Approved consolidations will be given a prenotice communication number, which must be entered on the Section 5 submission form. In some cases, a synthetic sequence can be consolidated, as well.*

One commenter (0052) expressed concern for disproportionate impact of fees on TSCA Work Plan chemical manufacturers.

*EPA Response:*
*EPA recognizes commenters' concern. TSCA required that the first 10 chemicals for risk evaluation be selected from the TSCA Work Plan, and, going forward, TSCA requires that at least 50% of all ongoing EPA-initiated risk evaluations are for TSCA Work Plan chemicals until that list is expired. The disproportionate impact to these manufacturers is driven in large part by requirements set in TSCA by Congress.*

One commenter (0041) urged EPA to stop referring to TSCA fees as "user fees," which have a specific meaning. "User fee" in the context of TSCA fees is inappropriate.

*EPA Response:*
*EPA appreciates the comment, and has updated the final rule to remove most references to a "user" fee.*

One commenter (0066) suggested that our economic analysis supporting the proposed rule needs revision. The employment impacts – underestimated; paperwork/hourly burdens – rule familiarization burden underestimated; cost impacts – EPA's estimate did not include cost to form/manage consortia.

*EPA Response:*
*Employment Impacts. EPA appreciates the comment on the estimate of employment impacts for the proposed rule. This is a rule for which EPA does not have information of the identity of the specific businesses that will subject to section 4, section 5 and section 6 activities. Rather, EPA*

*can only surmise as to the industry sectors that may be potentially impacted by the rule, as identified by three-digit NAICS codes in the final rule and six-digit NAICS codes in the economic analysis for the final rule. As a result, EPA is only able to conduct an employment impact analysis for the economy as a whole and not individual businesses for purposes of this rule. However, given the level of fees and the working assumption that any business would not be subject to a fee every year, EPA does not expect any significant long-term employment impacts from fee payment in accordance with this rule, as explained in the economic analysis.*

*Rule Familiarization Burden. EPA estimates that one technical or professional staff of an affected business will expend 0.5 hours to familiarize themselves with the rule. EPA's estimate of the time needed for rule familiarization for the TSCA Section 5(a)(2) Significant New Use Rules for Existing Chemicals, a more complicated rule, was 0.83 hours. As a result, EPA believes that 0.5 hours is sufficient average time for rule familiarization for this rule. EPA is aware that some affected entities may take more than 0.5 hours and others may take less, but on average, we expect 0.5 hours to be enough. EPA expects to apply lessons learned and feedback from fee payers for future iterations of this rule and any future revisions to the ICR burden estimates.*

*Cost to Form Consortia. EPA has considered the costs associated with forming and administering consortia and has included cost estimates in the economic analysis for the final rule, accordingly. However, EPA notes that businesses subject to TSCA section 4 activities already engage in consortia formation for purposes of conducting chemical testing and will, therefore, only expend minor additional costs associated with coordination of fee payment. For Risk Evaluations under TSCA section 6, EPA recognizes that consortia formation for purposes of coordinating fee payment is a new activity attributable to this rule and, as such, EPA will consider the costs associated with consortia in its economic analysis for the final rule, while noting that these costs will be substantially less than the cost to form and manage consortia for purposes of coordinating chemical testing under TSCA section 4.*

## Irrelevant

EPA received a number of comments (0030, 0029, 0027, 0028, 0025, 0031, 0032, 0033, 0040, 0063) that were not relevant to TSCA or TSCA fees. For example, these commenters provided song lyrics, concern about greenhouse gas emissions in China and India, wind energy markets, Russian influence on U.S. markets, and other topics without mention of TSCA or the TSCA fees rulemaking.

*EPA Response:*
*These comments do not warrant a response.*