Before the United States
Environmental Protection Agency
User Fees for the Administration of the Toxic Substances Control Act
83 Fed. Reg. 8,212 (February 26, 2018); Docket EPA-HQ-OPPT-2016-0401

Comments of the Chemical Users Coalition

The Chemical Users Coalition ("CUC") appreciates the opportunity to provide these comments addressing certain topics for which the U.S. Environmental Protection Agency ("EPA") requested public input in the context of the proposed User Fees Rule issued pursuant to Section 26 of the Toxic Substances Control Act ("TSCA").

CUC is an association of companies from diverse industries interested in chemical regulatory policy from the perspective of entities that typically acquire and use, rather than manufacture or import, chemical substances.[1] CUC encourages regulators seeking to develop and implement requirements to protect health and the environment to do so in a manner that enables the regulated community's ability to pursue technological innovation simultaneously with sustainable economic development in the United States. This is particularly important in the area of chemical regulatory policy, which necessarily addresses how core technologies and products can be adapted to address emerging information about health and environmental risk.

CUC supports the successful implementation of the 2016 amendments to TSCA in a manner that assures the various TSCA programs are both effective and efficient. CUC's comments regarding the TSCA Fees Rule support the Agency's decision as stated in the preamble to focus its fee collection efforts primarily on manufacturers and importers of chemical substances, and recommend ways in which EPA could revise or clarify portions of the proposed rule to ensure fair and efficient collection of fees for the administration of TSCA.

Entities Subject to Fee Requirements

CUC appreciates and encourages EPA's efforts in the rulemaking to focus its fee collection efforts on manufacturers (including importers) of chemical substances.[2] CUC agrees with EPA that it is most efficient for EPA to collect fees from manufacturers relating to TSCA Section 4 testing requirements, TSCA Section 5 notice requirements for new chemical substances, and TSCA Section 6(b) risk evaluations, and allow manufacturers to pass the costs of these fees along to purchasers and processors of affected chemicals. This is how manufacturers generally allocate the costs of the administrative burdens of chemical regulation and licensing requirements associated with regulated products. CUC does not believe the TSCA User Fees Rule is the proper vehicle to alter this scheme.

[1] The members of CUC are Airbus S.A.S., The Boeing Company, General Electric Company, HP Incorporated, IBM Company, Intel Corporation, Lockheed Martin Corporation, and United Technologies Corporation.
[2] 83 Fed. Reg. 8,212, 8,216.

EPA should consider a mechanism for exempting manufacturers and importers that import chemical substances in small quantities from fees relating to TSCA Section 6 risk evaluations, or allocating risk evaluation fees based on market share or the relative quantities of the specific chemical substance generated by manufacturers and importers. CUC understands that the current rule calls for the cost of a risk evaluation to be divided evenly among all non-small business manufacturers and importers of a chemical substance, regardless of the relative quantity of the substance they manufacture or import, unless the parties subject to fees for the risk evaluation form a consortium and come to a different arrangement. The proposed allocation of fees therefore puts non-small business entities at risk of paying a disproportionately high fee compared to their share of the market for a chemical substance subject to a risk evaluation. CUC suggests that this may be addressed by setting "tiers" of fees, and assigning manufacturers and importers of chemical substances to these tiers based on their annual production or import volumes or, alternatively, creating a *de minimis* exemption from the fee requirements for entities that manufacture or import a substance in volumes less than the CDR reporting thresholds.

Establish Fees More Closely Tied to Level of Effort Required of EPA

CUC supports the Agency's efforts to implement differences in the Section 5 notice submittal fees for those categories of Section 5 submittals that typically require less effort. Thus, it is appropriate that lower fees are being proposed for PMN exemption applications (which are reviewed in a shorter period of time) than for full PMN submissions.

CUC encourages EPA to consider adjusting the fee schedule across all categories of fees to more carefully reflect differences in the level of effort required of the Agency and its staff in processing the corresponding submittal. This would require the Agency to rethink its apparent decision not to impose fees that are "proportional to EPA's costs for undertaking" the activities covered by the TSCA Fees Rule.[3]

By way of example, the Agency should consider revising the fees imposed for the review of data under TSCA Section 4 to create categories of fees reflecting the burden placed on the Agency for review of particular types of data. The review of certain simpler studies, such as data generated during mutagenicity screening and physical-chemical properties data, does not require the same level of Agency resources required to review more complex studies and reports, such as those that accompany longer-term studies (e.g., oncogenicity and epidemiology studies). Thus, EPA could establish tiers of fees that will be assessed for TSCA Section 4 submittals which reflect the simplicity or complexity of the data submitted.

Similarly, with respect to the fee structure of EPA-initiated risk evaluations undertaken pursuant to Section 6, EPA could establish a sliding scale of fees which would be tied to factors including the number of separate uses (or conditions of use) that are within the scope of the risk evaluation to be conducted, the amount of data that the Agency must review in conducting the risk evaluation, and the quality of existing data that may be relied upon in the risk evaluation. For substances with multiple uses within the scope of the risk evaluation, the fee could be greater than for a substance with fewer uses within scope. Similarly, if adequate data exist for EPA to

[3] 82 Fed. Reg. at 8,215.

conduct a risk evaluation without conducting additional tests on a particular substance, the fee should be less than for a substance for which EPA must seek out or require the development of data to be relied upon in a risk evaluation.

The Agency might also consider the extent to which the number of entities that manufacture or import a substance will have a bearing on EPA workload for reviews of data submitted under Section 4 rules or orders, or risk evaluations under Section 6. If it is likely that a greater number of affected entities will increase EPA burdens, the Agency could establish a variable fee schedule which imposes a higher fee for Section 4 or 6 requirements when numerous entities are likely to be active participants.

Alternatively, EPA also may be able to ensure that the fees it collects are representative of the effort required of the Agency to complete particular tasks by collecting an initial at the commencement of the Risk Evaluation process from affected entities (e.g., following publication of the scoping document), and settling the final payment when the entire Risk Evaluation is complete. This would allow EPA to take into account the actual burden imposed on the Agency and more appropriately assess the costs incurred by EPA which should be shared among the regulated community.

Use Fees to Encourage/Achieve Policy Objectives for Certain Activities

CUC encourages EPA to consider reducing or eliminating fees for certain activities to encourage manufacturers and importers and processors to engage with the Agency in ways that further EPA's environmental objectives. For example, EPA has proposed to waive the Section 5 test market exemption application fee for graduates of the "Sustainable Futures" program to provide an economic benefit to entities that submit notices for substances EPA considers to be "safer" chemicals. CUC supports EPA's recognition of the effect that fees can have in the Section 5 program and the potential for fees to discourage innovation, and CUC encourages EPA to broaden its effort to minimize fees in the Section 5 PMN, SNUR, and biotechnology notifications requirements. Accordingly, EPA should look for similar ways to encourage cooperation and collaboration with the Agency in ways that also reduce burdens on EPA work load and review schedules. Some examples in the context of Section 5 submissions include:

- EPA could offer to issue a partial "rebate" of the User Fee paid for a substance reported in a PMN that ultimately does not require a full-90 day review (such as a substance that is "dropped" from further review at or prior to the "Focus" meeting).

- To encourage the submission of more robust information on the potential hazards associated with PMN substances, EPA could offer a reduced fee for the review of new chemical substances for which a basic set of test data is provided at the time of the PMN submission.

- The Agency could consider a program in which EPA agrees to return the User Fee if, in the course of reviewing a PMN, the Agency determines the substance can act as a "drop in" substitute for a chemical substance in a category of chemicals for which EPA has health or environmental concerns.

Examples in the Section 4 context include imposing significantly reduced fees when manufacturers and importers have agreed to collaborate to generate and provide data through a voluntary testing agreement (*e.g.*, an Enforceable Consent Agreement), in comparison to fees EPA would impose when the Agency must proceed to collect data through a Section 4 test rule or testing order.

For Section 6 risk evaluations, EPA could offer to reduce the required fee when a manufacturer or importer, or a consortium, voluntarily provides previously-unpublished data or risk evaluations for EPA consideration which are determined to meet certain basic standards. EPA also could establish a reduced fee or fee waiver process for entities that choose to voluntarily phase-out certain conditions of use of a substance about which EPA has raised concerns prior to EPA commencing the risk evaluation (such as when the Risk Evaluation scoping document is under consideration).

Clarifications Needed

CUC requests that EPA clarify or make express the following points in the proposed TSCA Fees Rule. CUC believes that these clarifications will help to ensure the efficient administration of the TSCA Fees Rule.

- EPA should make clear in the final TSCA Fees Rule that entities which only manufacture or import articles containing a chemical substance that is the subject of a TSCA Section 6 risk evaluation will not be subject to the requirements of the TSCA Fees Rule. As with processors, manufacturers and importers of chemical substances subject to the TSCA Fees Rule will likely pass along the costs of TSCA Section 6 risk evaluations to entities that purchase a chemical substance for use in articles or that purchase articles containing a chemical substance that is subject to a TSCA Section 6 risk evaluation. Thus, it would be inefficient for EPA to attempt to separately identify and impose fees on entities that manufacture or import articles containing a chemical substance that is the subject of a TSCA Section 6 risk evaluation.
- Second, CUC understands that EPA intends to begin assessing fees under the proposed TSCA Fees Rule as of October 1, 2018, and interprets this start date for the assessment of fees to mean that EPA will not assess fees for risk evaluations that began prior to October 1, 2018. To confirm this understanding, CUC requests that EPA expressly state that it does not intend to retroactively impose fees relating to the ongoing risk evaluations of the "First Ten" chemical substances.
- EPA should clarify that the TSCA Fees Rule will not impose fees for EPA actions taken pursuant to TSCA Section 6(h) (relating to chemical substances that are "persistent, bioaccumulative, and toxic"). EPA also should state it does not intend to impose fees relating to actions it must take pursuant to TSCA Section 6(h), such as the ongoing exposure assessments of these chemical substances, nor for regulatory actions it may impose (*e.g.*, limitations on use, phase down requirements, etc.).

Establish Process for Contesting Fees Imposed by EPA or for Seeking Exemptions

Finally, CUC requests that EPA consider developing a process by which entities could challenge fees imposed upon them by the Agency. The proposed TSCA Fees Rule does not appear to provide a mechanism by which an entity, designated by EPA as a manufacturer, importer, or processor of a chemical substance, could challenge this designation by EPA. The process should also allow companies to challenge EPA determinations that they are not eligible for a refund of PMN costs because the Agency determined that they "unduly delayed the process." CUC encourages EPA to outline the criteria by which the Agency would determine that a company "unduly delayed" the PMN process, and requests that EPA explicitly exclude "voluntary suspensions" from its definition of "unduly delayed".

Additionally, the Agency might want to establish a procedure for entities to seek exemptions from Fees on the basis of some unique hardship or special condition, or by submitting information and data demonstrating they do not, and have no intention to engage in, a condition of use which is within the scope of a Risk Evaluation. In doing so, EPA might seek to establish criteria that would be considered when evaluating a waiver request.

Conclusion

CUC appreciates the Agency's interest in soliciting public input on the proposed regulation and would be pleased to meet with EPA personnel to discuss these comments and related issues if doing so would assist in the development of the final rule.