Before the United States Environmental Protection Agency
Supplemental Notice of Proposed Rulemaking
Fees for the Administration of the Toxic Substances Control Act
87 Fed. Reg. 68647 (Nov. 16, 2022)
Docket EPA-HQ-OPPT-2020-04933

Comments of the Chemical Users Coalition

The Chemical Users Coalition ("CUC") appreciates the opportunity to provide these comments regarding the U.S. Environmental Protection Agency's ("EPA's" and "the Agency's") Supplemental Notice of Proposed Rulemaking for Fees for the Administration of the Toxic Substances Control Act ("TSCA") published in the Federal Register of November 16, 2023 (the "Supplemental Notice").

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, chemical substances and manufactured products (including articles). CUC encourages regulators, such as EPA, to develop a robust body of information concerning chemical substances and articles when such materials are under consideration for regulatory action, including a thorough understanding of the conditions of use for such substances and articles. When such information is sought, acquired, and considered carefully by regulators, they can more effectively develop and implement potential requirements when necessary to effectively and efficiently protect health and the environment in a manner that enables the regulated community to pursue technological innovation simultaneously with sustainable economic development in the United States. Such information also can have the benefit of providing EPA with a more robust appreciation of the supply chain with respect to chemicals, mixtures, and manufactured articles when instituting, and adjusting, user fees that are collected pursuant to Section 26 of the TSCA.

We appreciate EPA's efforts to take into consideration the unique perspectives of CUC's members as entities that acquire domestically and import for use and distribution various chemical mixtures and manufactured articles, as well as numerous article components, and highly complex durable equipment. With these important considerations in mind, our members wish to affirm our support for certain provisions of the proposed Fees Rule revisions and offer comments to clarify the importance of certain key features of the proposal.

CUC Members have been actively engaged on TSCA fees-related matters, including our timely comments submitted in response to the Agency's January 11, 2021 proposal to adjust the TSCA User Fees Rule, (the "2021 Fee Rule Proposal") which we reiterate and incorporate by reference here.[1]

[1] CUC's keen interest in and interactions with the Agency on Fees Rule related issues also date back to our January 29, 2020 submittals and follow-up meetings with the Agency concerning the importance of excluding from the Fees

I. CUC Members consider the proposed fee amounts to be too high and believe that additional analysis is needed.

When TSCA was amended in 2016, stakeholders shared goals that the amended law should provide EPA with the tools it needs to ensure the safe use of chemicals, enhance consumer confidence, and provide a more predictable regulatory environment enabling EPA to address unreasonable risks while allowing chemical innovation to maintain America's ability to compete in the global marketplace. Unfortunately, some of these goals are not being met, and the current methods by which the TSCA amendments are being implemented are actually preventing achievement of these goals. While EPA needs additional resources to fully and more efficiently implement the programs authorized under the amended TSCA, the Agency should strive for consistency in its TSCA decision-making practices, meet the statutory deadlines, and issue decisions in a timely and predictable fashion. With this in mind, CUC supports Agency efforts to adjust the TSCA fees when doing so will provide additional resources that are necessary to fully and more reliably implement the amended TSCA. However, justifications for increases should include an explanation of how fee payers will see demonstrable improvements throughout the TSCA programs for which fees are being increased.

In addition to the federal appropriations Congress provides the Agency to cover costs, EPA has the ability to impose fees for certain activities the Agency performs under TSCA. TSCA §26(b)(4)(F) requires EPA to review fees every three years and increase or decrease the fees as necessary to adjust for inflation and ensure that fees deposited in the TSCA Service Fee Fund are sufficient to defray the agency's costs as set forth in TSCA. In granting EPA the authority to collect fees under amended TSCA, Congress expected "EPA to act prudently with this new authority." See H.R. Rep No. 114-176 at 32 (2015).

However, the proposed revised fee amounts are very high. EPA provides a very high-level explanation for how it arrived at the proposed fee amounts. One important part of that equation is the total cost of carrying out the relevant activities. In order for stakeholders to better understand how EPA arrived at the fee amounts, EPA must provide a more detailed analysis of actual costs to justify these significant fee increases.

This is particularly true because the increased fees may frustrate the purpose and goals of the TSCA amendments. For example, the significant fee for a Manufacturer Requested Risk Evaluation makes it unlikely that manufacturers will avail themselves of this option. Even more troublesome are the fees for Section 5 activities. The fees for Premanufacture Notices are significant. That factor, combined with the slowness and inefficiencies of the current process, may drive manufacturers to introduce new chemicals outside of the United States. These factors together create a situation in which EPA is simply frustrating its own mission and goals and is stifling innovation and development of new chemistries that have a better safety and sustainability profile. Accordingly, EPA must carefully analyze its true resource needs, explain these needs in detail, and make a determination as to whether the increased fees are truly

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Rule's self-identification requirement the importers of articles containing certain chemical substances. Our prior comments are attached for reference.

warranted and beneficial. Such an analysis is lacking and must be performed prior to the finalization of the Fees Rule.

II. CUC supports removing the three fee categories proposed in 2021 and the maintenance of the original fee categories.

In the Supplemental Notice, EPA has proposed to not finalize the proposed fee categories for Bona Fide Notices, Notices of Commencement, and amended test orders. The CUC agrees with EPA that elimination of the proposed categories keeps the fee structure simple, and that costs associated with those activities can be captured via the fees associated with related activities.

III. CUC supports finalizing the six proposed exemptions to the Risk Evaluation provisions of the Fees Rule with certain clarifications.

In the 2021 Fee Rule Proposal, EPA proposed six fee exemptions for manufacturers of chemical substances undergoing EPA-initiated risk evaluation. These proposed exemptions would apply to: (1) Importers of articles containing a chemical substance; (2) Producers of a chemical substance as a byproduct; (3) Manufacturers (including importers) of a chemical substance as an impurity; (4) Producers of a chemical as a non-isolated intermediate; (5) Manufacturers (including importers) of small quantities of a chemical substance solely for research and development; and (6) Manufacturers (including importers) of chemical substances with production volume less than 2,500 lbs.

CUC generally supports finalizing each of the proposed exemptions to the Section 6/Risk Evaluation provisions of the Fees Rule. The exemption for imported articles is especially important to CUC members, who all are either users and/or producers of highly technical products that are comprised of numerous specialized components—many of which are imported for assembly in the US. These components constitute finished articles supplied by hundreds or thousands of different providers within multiple, global supply chains. Entities that manufacture and import numerous complex pieces of equipment would find it impossible to ascertain whether the components they receive and use are comprised of (or contain as impurities) certain chemical substances that are subject to EPA TSCA actions, especially test orders and risk evaluations. Thus, the proposed exemption from the Fees Rule for High Priority Substances in articles, and for the presence of such substances which might be present as unintentional (or unidentified) impurities in commercial products, are particularly important for CUC members.

CUC members also support the inclusion of these exemptions in the Section 6 Risk Evaluation fees context because these proposed provisions generally align with existing exemptions that have been consistently applied in TSCA reporting requirements (e.g., to the TSCA Section 5 rules and the Section 8 Chemical Data Reporting regulations). Codifying the proposed exemptions also is important because they are intended to make permanent the terms of the No Action Assurance that was issued for the first 20 High Priority chemical substances subject to fee assessments for TSCA Risk Evaluations. Reaching closure on this issue by codifying the exemptions is particularly of interest to those entities that relied on the terms of the

No Action Assurance when responding to the "self-identification" procedures for Fees imposed for the initial 20 High Priority Substance Risk Evaluations.

CUC believes, however, that a change is needed to maintain consistency. In the context of the "byproducts" exemption, EPA is proposing to limit the byproduct exemption to "producers of a chemical substance as a byproduct that is not later used for commercial purposes or distributed for commercial use." CUC believes that EPA should include importers in the byproduct exemption to be consistent with the other exemptions, such as the terms of the byproducts exemptions in the premanufacture notification rules at 40 CFR Part 720.

IV. CUC supports applying the EPA-initiated risk evaluation fee exemptions to fees for TSCA section 4 test rules. However, the production volume threshold should be made consistent with that in other exemptions and self-identification should not be required.

EPA is proposing to apply the categories of EPA-initiated Risk Evaluation fee exemptions to fees for TSCA Section 4 test rules as well. EPA believes that this change will reduce confusion and prevent challenges regarding the self-identification requirements which apply to fees for both EPA-initiated risk evaluations and test rules. However, being that the self-identification requirements do not apply to test orders or Enforceable Consent Agreements, EPA is not proposing to apply the exemptions to those actions.

EPA is proposing that Section 6 exemptions will remain the same for test rule and test order fees except the annual production volume threshold will change to 1,100 lbs. Manufacturers with an annual production volume of less than 1,100 lbs. will qualify for the exemption for the TSCA section 4 test rule fee.

CUC agrees with EPA that the proposed Section 6 exemptions should be incorporated into the fees provision related to Section 4 Test Rules and Testing Orders. Among the exemptions proposed, CUC recommends in particular that the proposed exemptions from the Section 6 Risk Evaluation Fees for importers of substances when present in articles, importers (and manufacturers) of substances present as impurities, and producers and importers of substances solely for R&D purposes should be carried over into the fees for test rules and test orders. Doing so would create a more reasonable and consistent regulatory structure in the Fees Rule and enable administrative ease as EPA implements fee assessments in both Section 4 (testing) and Section 6 (evaluation) contexts.

However, CUC believes that the production volume threshold should be 2,500 lbs. as opposed to 1,100 lbs. to maintain consistency with other exemptions, where the threshold is 2,500 lbs. The uniformity would reduce the chances of confusion. While it is true that the regulations concerning test rules at 40 CFR 790.42(a)(4) contain an exemption for applicability of test orders for those manufacturers with an annual production volume of less than 1,200 lbs., the exemptions for the Fees Rule are based on the role a particular manufacturer has with regard to the production of a specific substance and whether a fee for a TSCA related activity is therefore warranted. This rationale would still hold true for entities subject to a test order/rule with an annual production volume of under 2,500 lbs.. Accordingly, and for purposes of

consistency, the annual production volume exemption for Section 4 activities should be 2,500 lbs..

CUC supports a process for removing companies that qualify for the proposed exemptions, or those listed in error, from EPA's "preliminary list." CUC also appreciates that those entities who do not appear on the preliminary list and that qualify for an exemption may submit a certification statement if they wish. Of equal importance to CUC Members is that the requirements to utilize the exemption from the Fees Rules for low production volume should be the same as the procedure for the Chemical Data Reporting rule low-volume exemption, where no affirmative filing is required when an annual production or import volume of 2,500 lbs. is not exceeded. This would also create uniformity with the other exemptions, for which self-identification is not required to utilize the exemption. Requiring entities to notify EPA when they intend to take advantage of an exemption creates an unnecessary paperwork exercise. CUC Members recommend that EPA should not require an affirmative response on the part of manufacturers and importers when they manufacture or import the affected substances in quantities less than 2,500 lbs./year. For the purposes of allocating fees in an equitable manner, EPA should be able to capture the appropriate manufacturers as long as the self-identification requirement is applicable only to manufacturers that exceed that 2,500 lbs. threshold. If and when a scenario arises and EPA cannot identify a single entity that manufactures a substance in amounts greater than 2,500 lbs. per year, EPA can then require self-identification of those entities that have utilized the low production volume exemption.

V. Conclusion

CUC appreciates the opportunity to provide comment on the proposed amendments to the TSCA Fees Rule and supports the Agency's continued successful implementation of the TSCA rule and the proposed exemptions. Of utmost importance to fee payers is that EPA meets deadlines and issues determinations under TSCA in a consistent and timely fashion. While we acknowledge that additional resources could help EPA meet those goals, fees must be reasonable and balanced and not serve as a barrier to innovation. If fees do present a barrier, EPA will continue to be faced with resource challenges. The CUC would welcome the opportunity to discuss our comments.

ATTACHMENT 1

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.

ATTACHMENT 2

Before the United States Environmental Protection Agency
Proposed Revisions to TSCA Fees Rule
86 Fed. Reg. 18900 (Jan. 11, 2021)
Docket EPA-HQ-OPPT-2020-04933

Comments of the Chemical Users Coalition

The Chemical Users Coalition ("CUC") appreciates the opportunity to provide these comments regarding the U.S. Environmental Protection Agency's ("EPA's" and "the Agency's") Proposed Revisions to the Toxic Substances Control Act ("TSCA") Fees Rule published in the Federal Register of January 11, 2021.[1]

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, chemical substances and manufactured products (including articles).[2] CUC encourages regulators, such as EPA, to develop a robust body of information concerning chemical substances and articles when such materials are under consideration for regulatory action, including a thorough understanding of the conditions of use for such substances and articles. When such information is sought, acquired, and considered carefully by regulators, they can more effectively develop and implement potential requirements when necessary to effectively and efficiently protect health and the environment in a manner that enables the regulated community to pursue technological innovation simultaneously with sustainable economic development in the United States.

CUC member have been engaged constructively with EPA personnel on the myriad of issues that arose in the course of implementing the Fees Rule. We have appreciated and supported EPA's efforts to take into consideration the unique perspectives of CUC's members as importers, users, and distributors of manufactured articles, their components, and highly complex durable equipment.[3] With these important considerations in mind, our members wish to affirm our support for the proposed Fees Rule revisions generally and offer comments to clarify the importance of certain key features of the proposal.

1. The Exemptions Proposed to Fees for TSCA § 6 Risk Evaluation Fees are Critical

CUC supports finalizing each of the proposed exemptions to the Risk Evaluation provisions of the Fees Rule. The exemptions in proposed 40 CFR 700.45(a)(3)(i) (for imported articles) is especially important to CUC members who all are producers of highly technical products that are comprised of numerous specialized components—many of which are imported for assembly in the US. These components constitute finished articles supplied by hundreds or thousands of different providers within multiple, global supply chains. Entities that manufacture

[1] 86 Fed. Reg. 18900 (January 11, 2021).
[2] The members of CUC are Airbus S.A.S., The Boeing Company, HP Incorporated, IBM Company, Intel Corporation, Lockheed Martin Corporation, Raytheon Technologies Corporation, Sony Electronics, Inc. and TDK U.S.A. Corporation..
[3] http://www.chemicaluserscoalition.org/ckfinder/userfiles/files/CUC%20Comments%20to%20EPA%20061220.pdf

and import innumerable complex pieces of equipment would find it impossible to ascertain whether the components they receive and use are comprised of (or contain as impurities) certain high-priority chemical substances. Moreover, the process of chemically analyzing the composition of finished articles presents technical challenges that would make it impossible for CUC members to reasonably and responsibly ascertain whether articles they import contain a chemical undergoing a Risk Evaluation. Thus, the proposed exemption from the Fees Rule for High Priority Substances in articles, and for the presence of such substances which might be present as unintentional (or unidentified) impurities in commercial products (proposed § 700.45(a)(3)(iii)), are particularly important for CUC members.

CUC members also support the inclusion of these exemptions in the Section 6 Risk Evaluation Fees context because these proposed provisions generally align with existing exemptions that have been consistently applied in other TSCA reporting requirements (e.g., to the TSCA Section 5 rules and the Section 8 Chemical Data Reporting regulations). Codifying the proposed exemptions also is important because they are intended to make permanent the terms of the No Action Assurance that was issued for the first 20 High Priority chemical substances subject to fee assessments for TSCA Risk Evaluations. Reaching closure on this issue by codifying the exemptions is particularly of interest to those entities that relied on the terms of the No Action Assurance when responding to the "self-identification" procedures for Fees imposed for the initial 20 High Priority Substance Risk Evaluations,

In addition to the proposed exemptions discussed above, CUC wants to emphasize as well the importance of including in the final rule the exemption from fees for Risk Evaluations involving High Priority Substances when an entity produces, imports (or otherwise acquires), and supplies such substances for use solely for research and development purposes. *See* proposed Section 700.45(a)(3)(v). When chemicals are used solely in research and development efforts, exposures are minimal, and the uses undertaken are generally subject to the supervision of highly qualified engineers, scientists, and technicians who appreciate the nature of potential risks and the need to take precautions to preclude risks from chemical exposures. Moreover, the quantities involved are, by definition, finite, and (due to the limited quantities and practices involved) the opportunities for environmental releases minimal. Furthermore, R&D materials generally are not a significant source of revenue for the producers, importers, distributors, or users of such substances. Finally, entities that acquire and use chemical substances for R&D purposes generally do not purchase and track such materials in the same manner as commercial chemical products and formulations. Thus, the R&D exemption will avoid the unnecessary imposition in the Fees Rule context of new administrative requirements that are not necessary. Further, requiring entities that produce (including import), use and potentially distribute R&D substances to pay TSCA fees in equal measures with traditional chemical manufacturers would disproportionately allocate an unfair share of costs to those engaged solely in activities related to acquiring and using R&D substances. For these reasons, CUC endorses codifying the R&D exemption.

CUC members recommend that EPA clarify the language proposed in the exemption in Section 700.45(a)(3)(vi) for small quantity manufacturers (i.e., 2,500 lbs./year) prior to finalizing the proposed amendments. First, the use of the term "and/or" at the conclusion of the text proposed for the R&D exemption (Section 700.45(a)(3)(v)) and prior to the "low volume"

exemption (Section 700.45(a)(3)(vi)) creates unnecessary ambiguity. The use of this term unintentionally implies that the R&D exemption and the low-volume exemption are somehow linked or interdependent. The use of the term "or" between the exemptions listed should assist in removing this ambiguity and make clear that an entity might be eligible for any of the six exemptions being proposed if the criteria are met. Further clarification could be achieved by replacing the phrase "as *described* in § 700.43" in proposed Section 700.43(a)(3)(vi) (which is the same cross-citation in the R&D exemption) with "as *defined* in § 700.43…". This will clarify that the cross-citation pertains to the definition for the term "production volume" as it appears in proposed Section 700.43.

2. Exemptions Proposed for Section 6 Fees Should Pertain to Test Rules and Orders

CUC further recommends that when the amendments are issued in final form, the proposed exemptions also be incorporated into the fees provision related to Section 4 Test Rules and Testing Orders. Among the exemptions proposed, CUC recommends in particular that the proposed exemptions from the Section 6 Risk Evaluation Fees for importers of substances when present in articles, importers (and manufacturers) of substances present as impurities, and producers and importers of substances solely for R&D purposes should be carried over into the Fees for Test Rules and Test Orders. Doing so would create a more reasonable and consistent regulatory structure to the Fees Rule and enable administrative ease as EPA implements fee assessments in both Section 4 (testing) and Section 6 (evaluation) contexts.

3. Volume-Based Fees Allocations Should be Applied in Sections 4 and 6 Situations

CUC also supports EPA's proposal to allocate fees based on production volume shares for assessing costs of Section 6 Risk Evaluations. In addition, CUC recommends expanding this approach for use in Section 4 Test Rules and Testing Orders. Doing so will ensure greater fairness in the Fees Rule by distributing cost sharing on the basis of the comparative market share of the major producers and importers of an affected chemical. The current Fees Rule's allocation formula, based on per-capita division of the Risk Evaluation Fees results in an unfair economic burden being placed on businesses that produce comparatively smaller volumes of a substance. In addition, it is reasonable to apply the same allocation formulas for fees EPA imposes in the contexts of both Risk Evaluations and Test Rules and Test Orders.

Conclusion

CUC appreciates the opportunity to provide comment on the proposed amendments to the TSCA Fees Rule and supports the Agency's continued successful implementation of the TSCA rule and the proposed exemptions. Our members would be pleased to meet with EPA personnel to discuss these comments.