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Environmental Protection Agency (EPA)
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Washington, DC 20460-0001
Docket No. EPA-HQ-OPPT-2020-0493-0001

Via regulations.gov submission

RE: Fees for the Administration of the Toxic Substances Control Act (TSCA)

To whom it may concern:

The Society of Chemical Manufacturers & Affiliates (SOCMA) appreciates the opportunity to provide comment on the U.S. Environmental Protection Agency's proposed revisions to the TSCA user fees rule.[1]

SOCMA is the national trade association dedicated to the specialty and fine chemical industry. Founded in 1921, SOCMA represents a diverse membership of chemical companies who batch manufacture new and innovative chemistries used in a wide range of commercial, industrial, and consumer products. SOCMA maintains a strong record of member service through programs that maximize commercial opportunities, enhance regulatory and legal compliance, and promote industry stewardship.

SOCMA member companies are subject to TSCA and impacted by implementation of the amended statute. This includes proposed revisions to the TSCA user fees rule, which directly affect specialty chemical manufacturers' ability to respond to market demands, introduce new chemicals into commerce, and efficiently operate. SOCMA therefore has a vital stake in ensuring that TSCA fees are assessed in a manner that is fair and reasonable.

SOCMA welcomes EPA's proposed updates as part of its triennial reassessment of the TSCA fees under Section 26(b)(4)(F). The revisions, as proposed, would materially improve the fairness of the fees rule, minimize adverse impacts on chemical innovation, and better reflect users' ability to pay such assessments. In particular, SOCMA supports EPA's decisions to (i) not increase fees for new chemical submissions, (ii) exempt a variety of manufacture and import activities from fees for EPA-initiated risk

[1] 86 FR 1890 (January 11, 2021).

evaluations, and (iii) allocate risk evaluation fees volumetrically. SOCMA also recommends a number of further improvements to the rule, including provisions for managing late market entrants and reimbursing original payers. These revisions will establish a more balanced approach to fee collection while ensuring EPA can effectively offset the administrative costs of managing the TSCA program.

SOCMA offers the following comments for EPA's consideration:

I. TSCA Section 5 Fees

A. SOCMA Supports EPA's Decision to Forego Fee Increases for New Chemicals

EPA proposes to retain the Section 5 fee levels established under the 2018 TSCA User Fees Rule. The Agency cites two reasons for this decision: process efficiencies being implemented under the new chemicals program, and EPA's interest in not stifling economic development in the chemical industry. SOCMA strongly endorses both EPA's decision and its reasoning for not increasing Section 5 fees, and encourages the Agency to continue evaluating approaches that will improve the new chemicals program and support cost containment for submissions, because the specialty chemical industry thrives on innovation and additional costs create hurdles to bringing products to market.

SOCMA has long expressed concern regarding the cost prohibitiveness of new chemical submissions since the 2018 fees rule was first proposed. EPA then estimated that increasing the PMN/SNUN/MCAN fee by 540% would cause a 20% drop in submissions, while introducing a new fee for exemptions would cause an indeterminable number of reduced submissions. While some reduction in the number of submissions was an inevitable result of the statutorily mandated fee structure, Section 5 submissions dropped significantly more than EPA anticipated after the fees were implemented. EPA's current case number estimates under this rulemaking also represent a historically low number of new chemical applications compared to the program's historic experience.

Going forward, EPA should remain mindful of these adverse impacts and ensure its cost recovery efforts do not conflict with TSCA's statutory imperative that EPA not "impede unduly or create unnecessary economic barriers to technological innovation."[2] And since 1990, the Nation's policy under the Pollution Prevention Act has been to "[design[] chemical products to be less hazardous to human health and the environment."[3] TSCA Section 5 is the gate through which all new, greener chemicals have to pass. SOCMA believes the Agency's proposed decision to retain the current fee levels for Section 5 activities is an appropriate way to advance these two statutory directives and thus ensure that the TSCA program does not exhibit a bias toward existing chemistry.

SOCMA recommends that in future updates the Agency primarily scale its Section 5 fees to their predicted effect on the number of new cases to be received, rather than purely on the basis of program costs. This approach also aligns with the statute's requirement that EPA limit fees to those "that [are] sufficient and not more than reasonably necessary to defray the cost" related to the administration of the TSCA program.[4] This approach will, in the long term, ensure that overhead costs for developing new chemicals remain manageable and maximize the number of submissions the Agency can receive from the chemical industry.

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[2] 15 U.S.C. § 2601(b)(3).

[3] https://www.epa.gov/greenchemistry/basics-green-chemistry#definition.

[4] *Id.* § 2625(b)(1).

B. SOCMA Supports the Proposed Fee Categories for BFNs and NOCs

EPA proposes to add two new fees triggering events for Bona Fide Intent to Manufacture or Import Notices (BFNs) as well as of Notices of Commencement to Manufacture or Import (NOCs). The agency notes that the costs to review and process these submissions was not recovered under the 2018 user fees rule, and that adding fees for these categories will allow for more equitable accounting of costs for carrying out all relevant section 5 activities.[5]

SOCMA is supportive of EPA assessing fees for BFNs and NOC, but only if doing so avoids having to defray the cost of such submissions through higher fees on other Section 5 notices. Half of all PMNs ultimately never result in an NOC, and it is unfair to burden those submitters with the cost of an activity they may never impose on EPA. Likewise, the outcome of a BFN – determining the TSCA inventory status of a chemical substance – does not always lead to a decision by submitter to proceed with filing a PMN. These two categories are discrete activities in their own right, and like all other Section 5 submissions, should have discrete fee assessments that account for a portion of EPA's costs to review them.

II. Section 6 Fees

A. SOCMA Supports EPA's Proposed Exemptions for EPA-Initiated Risk Evaluations

EPA proposes a number of exemptions in this rulemaking to improve the manageability of the self-identification requirement for EPA-initiated risk evaluation fees and to minimize the significant burden of such fees on regulated entities – particularly those who are not significant manufacturers or importers of targeted chemicals. EPA proposes fee exemptions for the following categories of activity involving a High-Priority (HP) chemical substance subject to an EPA-initiated TSCA risk evaluation:

- Articles, Impurities, and Byproducts: EPA proposes to codify the enforcement policy[6] it adopted in March 2020 that exempts from risk evaluation fees any HP chemical substances that are imported in articles, manufactured or imported as impurities, or manufactured as byproducts.
- Non-isolated Intermediate: EPA proposes to exempt a company from risk evaluation fees if it only manufactured a chemical as a non-isolated intermediate.
- Research & Development: EPA proposes to exempt from the risk evaluation fees and any associated regulatory requirements for manufacturers and importers of small quantities of HP chemicals solely for research and development purposes.
- *De Minimis* Manufacture and Import: EPA proposes to exempt from the risk evaluation fees and associated regulatory requirements companies whose manufacture or import of an HP chemical substance did not exceed 2,500 lbs per year.

SOCMA strongly supports EPA's proposed exemptions of these categories of activity from the TSCA risk evaluation fees. These exemptions improve the fairness of the TSCA fees rule and ensure the rule accommodates the ability of users to pay such fees, as required under the statute. When setting its fees,

[5] 86 FR 1898.

[6] Guidance memorandum from Susan Parker Bodine, Assistant Administrator of the Office of Enforcement and Compliance Assurance (OECA), entitled, "No Action Assurance Regarding Self-Identification Requirement for Certain 'Manufacturers' Subject to the TSCA Fees Rule," (March 24, 2020).

EPA has a legal obligation to "take into account the ability to pay of the person required to pay such fee."[7] This statutory obligation is separate from, and thus in addition to, EPA's obligation to set lower fees for small businesses,[8] which further reinforces the imperative that the agency make appropriate accommodations for fees categories that are both significant and compulsory.

Experience with the most recent 20 risk evaluations demonstrated that, in most cases, fee apportionment under the original fees rule would have been highly unfair to many companies that only manufactured or imported miniscule volumes of a substance, or only produced such substances unintentionally. Indeed, but for EPA's wise adoption of its enforcement discretion policy, a majority of SOCMA member companies initially identified by EPA would have been liable for a fee that was extremely disproportionate to the commercial value of their past activity. For example, R&D activities tend to be non-commercial in nature and frequently involve very small quantities, while byproducts and impurities are produced incidentally and without a separate commercial intent from the chemical formulation of which they are a part.

The experience of the next 20 chemicals also showed that, in the majority of cases, multiple companies remained available to engage in cost-sharing after more tangentially-involved companies were exempted.[9] Implementing exemptions for such activities is therefore a reasonable and appropriate action on the part of EPA, and one that will not materially impact fee collection from companies, both large and small, who manufactured or imported HP substances in high volumes and who logically should be the responsible payers for EPA-initiated risk evaluations.

B. SOCMA Supports EPA's Revised Fee Allocation Approach

EPA proposes to implement a volume-based fee allocation methodology for EPA-initiated risk evaluation fees, replacing the current per capita approach. EPA proposes to base its volumetric allocations on a company's average annual production volume from four prior calendar years of data.

SOCMA supports this approach and agrees with EPA that it will result in a more equitable and representative distribution of fees. The per capita methodology originally endorsed by the agency, while straightforward to implement, did not adequately weigh the wide variation in production volume for each High Priority substance. Manufacturing activity from one company to another was ignored, leading to scenarios where widely disparate levels of production would result in identical fees. A volume-based approach should remedy such unfair fee distributions for EPA-initiated risk evaluations.

SOCMA also concurs with EPA's proposal to base its allocation on the average annual production volume from the four prior calendar years of commercial activity. Beyond the four-year window of commercial activity, there is a greater likelihood that EPA would identify companies that are no longer engaged in the manufacture or import of a HP substance. Such companies reap no present commercial benefits from the HP substance to justify the cost of the fee. A lookback period beyond four years would also penalize companies that have chosen to disengage from the market due to a HP substance's associated risks.

Separately, EPA should provide companies with confidentiality protection if they choose to certify their average annual production volume as confidential business information (CBI), as the agency has allowed when companies do not wish to publicly disclose their identity during the self-identification process.

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[7] 15 U.S.C. § 2625(b)(1).
[8] *Id.* § 2625(b)(4)(A).
[9] For 13 of the 20 chemicals, at least six companies shared in paying the fee.

SOCMA also strongly supports the added flexibility the Agency proposes regarding the fee payment process, under which the first payment of 50% would be due 180 days after EPA publishes the final scope of a chemical risk evaluation while the second payment for the remainder would be due no later than 545 days after EPA publishes the final scope of a chemical risk evaluation.

C. EPA Should Conform Eligibility Across its Risk Evaluation Fee Certifications for Exemptions, Cessations, and Cases of No Manufacture

EPA proposes that companies who wish to rely upon one of the new risk evaluation fee exemptions must have met the terms of the exemption for the five-year period preceding publication of the preliminary list of identified payers (similar to "certification of no manufacture" companies), and must promise to remain within the confines of the exemption during the successive five years (similar to "certification of cessation" companies). EPA does not explain why companies seeking to take advantage of the exemptions would, uniquely, have to meet both tests.

While SOCMA supports some regulatory limitations to ensure exemptions are not exploited to avoid fee responsibility, EPA should simplify the standards for its certifications, and make them as consistent as possible, to ensure entities properly understand their applicability. SOCMA proposes two specific changes:

1. *EPA should revise the certification period for the new exemptions so that it aligns with the certification of cessation*. Instead of having to meet a timed lookback period to qualify for an exemption, a manufacturer should only have to certify that it has stayed within the bounds of a given exemption since the certification cutoff date, and will not manufacture the substance outside of the limits of the exemption in the successive five years. There is no reason for EPA to subject the proposed exemptions to more burdensome gating requirements than instances where companies may use a cessation certification after importing or manufacturing even greater quantities of a HP substance. Aligning the requirements for exemptions and cessation certifications is ultimately a more practical, comprehensible, and fair approach, and would not materially affect the number of responsible fee payers.

If EPA elects to retain a timed lookback period to assess eligibility for the new exemptions, it should simply align the requirements for the exemption with those of the "no manufacture" certification, so that both involve the same lookback period and have no future certification requirement.

2. *EPA should shorten the lookback period for the "no manufacture" certification (and the new exemptions, if EPA retains that requirement) so that both commence at the outset of the four-calendar-year-period upon which EPA will determine production volume fees.* EPA proposes to base its volumetric fee allocations on a four-calendar-year lookback, which would create misalignment with the five-year lookback period of the "no manufacture" certification, as well as the proposed exemptions. There is no reason to create a discrepancy between the two periods that will inevitably lead to complex if not senseless results. (For example, if a company manufactured or imported a chemical within the five-year lookback period but not within the most recent four calendar years, it would seem to be subject to the fees rule, but have an allocation of zero.) Both periods should begin at the same time: the beginning of the four-calendar-year-period.

D. EPA Should Implement a Consistent and Fair Approach to Allow Companies to Enter or Re-enter the Market and Support Fee Reimbursement

The five-year forward-looking period currently applicable to "cessation of manufacture" certifications, and proposed to apply to the new exemptions, does not provide adequate flexibility for companies that wish to modify their commercial activity in the future. The five-year period is long from a commercial perspective, and companies may, in the future, wish to pay a fee to commence activities that are outside the limitations of their exemption or cessation certification. EPA should provide a mechanism in the TSCA fee regulations to allow companies to de-certify and pay an appropriate fee to manufacture or import the HP substance within the successive five-year period. EPA should offer this opportunity both to companies taking advantage of one of the newly-proposed exemptions and to companies making (or who have made) "cessation of manufacture" certifications.

Specialty chemical companies in particular need this provision because they are heavily engaged in contract and toll manufacturing, which relies upon sole-source contracts and responsiveness to ever-changing customer demands. When a contract or toll manufacturer is offered a new project, the company must conduct a suite of activities that typically include: analyzing the capabilities of its facilities; working with its suppliers to incorporate critical manufacturing equipment and raw materials; conducting applied research and development; updating manufacturing processes; providing applicable operational training to employees; constructing pre-production units; conducting pilot testing; completing customer approval processes; phasing in production; and completing final production within the specified timeframe. Contract and toll manufacturing is thus a highly dynamic segment of the chemical industry, and companies are often in circumstances where a chemistry they may have ceased using, or used within the narrow terms of an exemption, may be needed in a more significant capacity for a future project. A mechanism to allow such companies to alter their prior certifications is critical to ensure they can maintain agile and responsive operations and service key customer segments.

Companies who wish to nullify their exemption or cessation certification should be required to use the same self-identification process established under Section 6 to alert the Agency of their intent to engage in production of the HP substance. They should then be obligated to follow up with a one-time report of their average annual production volume over what remains of the successive five-year period. Once the forward-looking period concludes, EPA could then assess a late market entrant fee, with a reasonable rate of interest, proportionate to the company's average annual production volume over that period and the number of additional entrants into the market. Assessing a fee retrospectively in this way avoids the uncertainty and unfairness inherent in any attempt to estimate a "buy in" fee before the end of the five-year period. Ideally, the fees collected from such entrants would then be refunded to the original fee payers according to their original volumetric shares.[10]

This timed approach at the end of the forward-looking period would also make the reimbursement process a one-time event for EPA and avoid any need for repeated fee recalculations when compensating original payers, making it minimally burdensome to administer. This provision should also be applied to 'new market entrants'; i.e., companies that did not have any market presence beforehand and therefore did not have to utilize an exemption or cessation certification, but who nevertheless would be free riders by manufacturing or importing a HP substance during the forward-looking period.

[10] While it is SOCMA's preference that EPA reimburse original payers, that feature is not essential to the adoption of the market entry/reentry provision. EPA could still assess a fee for an entity's manufacture/import activity during the forward-looking period and use the surplus paid to the agency to reduce industry costs for successive risk evaluations during its next triennial review of the TSCA fees.

By implementing SOCMA's proposals, EPA will enhance market flexibility in the chemical sector while ensuring that original payers are treated fairly (and, ideally, can receive a commensurate reimbursement from EPA for their upfront contributions to the risk evaluation). This approach also aligns well with EPA's existing data compensation regulations (40 CFR § 791.48) for Section 4 test rules, which presume that an entity's fair share of the testing costs is proportionate to their share of the total production volume of the test chemical over a specified period of time.

E. EPA Should Exclude Export Only Activities from the Risk Evaluation Fees

EPA proposes that manufacturers that manufacture a risk evaluation chemical exclusively for export be subject to fees whenever any other entity manufactured, processed, or distributed in commerce such chemical substance for any domestic purpose. The Agency claims this decision is justified by the "ambiguity" of TSCA Section 12(a).

SOCMA disagrees with EPA's interpretation of the statute and its applicability to the TSCA fee requirements for EPA-initiated risk evaluations. TSCA Section 12(a), which was not materially changed by the 2016 Lautenberg amendments, has always been understood to exclude chemical substances, mixtures or articles manufactured, imported, processed or distributed solely for export from TSCA (except for the recordkeeping and reporting requirements of Section 8). This exclusion has always been applied to individual acts of manufacture, distribution, etc., by individual companies, and has not been dependent on broader commercial uses of the chemical substance in U.S. commerce by other entities. This interpretation is required by the repeated use of singular noun phrases and pronouns in Section 12(a) (e.g., "an article"; "any container in which it is enclosed").

For substances to qualify as export-only chemicals under Section 12(a), any given manufacture or importation activities must only end in the substance's exportation, and processing must also be limited to activities which do not involve domestic use. Processing must be performed at sites under the control of the processor; distribution in commerce is limited to purposes of export; and the processor may not use the chemical substance except in small quantities solely for research and development. These conditions all indicate that it is beyond EPA's authority to impose fees for EPA-initiated risk evaluations upon activities that technically are not in U.S. commerce.

Conclusion

Thank you very much for your willingness to seek feedback from stakeholders. SOCMA has appreciated the opportunity to provide advice and recommendations on improving the fairness and efficiency of the TSCA fees and would welcome further discussion with EPA on the proposal. If you have any questions about these comments, please contact me at jrothstein@socma.org or 571-348-5122.

Respectfully submitted,

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