1400 Crystal Drive, Suite 630, Arlington, VA 22202 571.348.5100 MAIN www.socma.com

SOCMA
Advancing the specialty chemical industry

May 24, 2018

Document Control Office (7407M)
Office of Pollution Prevention and Toxics (OPPT)
Environmental Protection Agency (EPA)
1200 Pennsylvania Avenue, NW
Washington, DC 20460-0001
Docket No. EPA-HQ-OPPT-2016-0401

Via regulations.gov submission

RE: User Fees for the Administration of the Toxic Substances Control Act

To whom it may concern:

The Society of Chemical Manufacturers & Affiliates (SOCMA) appreciates the opportunity to submit comments on the U.S. Environmental Protection Agency's proposed rule for user fees for the administration of the Toxic Substances Control Act (TSCA).[1]

SOCMA is the only U.S.-based trade association solely dedicated to the specialty and fine chemical industry. Our members play an indispensable role in the global chemical supply chain, providing specialty chemicals to companies in markets ranging from aerospace and electronics to pharmaceuticals and agriculture.

SOCMA member companies are subject to TSCA and are directly impacted by implementation of the amended statute. This includes EPA's proposed user fees, as they will directly affect the ability of specialty chemical manufacturers to meet market demands and to operate profitably. SOCMA has supported the expansion of EPA's authority under the Lautenberg amendments to collect user fees to help defray the costs of administering the Act. SOCMA has also supported the fundamental principle undergirding that authority that user fees should be implemented in a manner that keeps the United States in the forefront of new and innovative chemistries.

As noted below, SOCMA supports many aspects of the proposed rule, particularly:

[1] 83 FR 8212 (Feb. 26, 2018). On April 24, EPA noticed the availability of additional information, and extended the due date for comments until May 24. *See id*. at 17782.

- The alternative proposal to increase the PMN fee only by the rate of inflation;
- Not charging fees for CBI claims; and
- Updating the small business threshold for inflation.

But SOCMA also has a number of concerns regarding the proposal, and believes it is critical that EPA make improvements to ensure that TSCA fee revenue is assessed in a manner that is fair and reasonable. SOCMA urges EPA to be guided by the following considerations as it refines its approach for the administration of TSCA user fees:

I. EPA Should Minimize Fees for New Chemical Activities

A. EPA Should Take Into Account the Impact of Fees on Chemical Innovation

Section 26(b)(1) of amended TSCA authorizes EPA only to set fees "that [are] sufficient and not more than reasonably necessary to defray the cost" of administering Sections 4, 5, 6, and 14.[2] Amended TSCA also provides – as it did before amendment – that EPA's "authority over chemical substances and mixtures should be exercised in such a manner as not to impede unduly or create unnecessary economic barriers to technological innovation.[3] These two provisions imply that EPA should take into account all of the costs – both direct costs and the intangible efficiency costs – likely to be imposed by the fees program. To evaluate the reasonableness of its user fee program, other factors beyond historical experience and econometric projections must be considered, such as comparing the benefit to arise from the imposition of the proposed fee with the social cost created by its distortionary effect.

In its proposed rule, though, EPA does not adequately consider this approach. The Agency states that "although these user fees may be perceived by industry as direct private costs, from an economic perspective, they are transfer payments rather than real social costs."[4] This diminishes very real and serious concerns regarding innovation and the competitive standing of the American chemical industry. Specialty chemical manufacturers in particular produce thousands of highly specialized and innovative substances with unique functions and applications. It can take years of effort and expense, through extensive research and development, before a company is in a position to submit an exemption notice or a Premanufacture Notice (PMN). The additional cost of a submission fee will make some percentage of current new chemical projects no longer economically justifiable. That impact should be taken into account in judging what level of fee is "reasonably necessary."

EPA must not be indifferent to these concerns. In its estimate of the number of PMNs, MCANs and SNUNs to be processed after the establishment of the fees program, the Agency dispassionately notes that it expects to see a 20% drop in the typical number of submissions resulting from the impact of higher fees.[5] While some reduction is inevitable, EPA should be concerned about the lost social benefits of that reduction.

---

[2] 15 U.S.C. § 2625(b)(1).
[3] *Id*. § 2601(b)(3).
[4] 83 Fed. Reg. 8827.
[5] *Id*. at 8218.

EPA also neglects to account for the number of reduced submissions associated with exemption notices. Particularly given that EPA historically has not charged any fee for applications under the Test Market (TME), Low Volume Exemption (LVE), or Low Release-Low Exposure (LoREX) exemptions, it is undisputable that imposing new and substantial fees for these activities will reduce submissions significantly. EPA must adequately account for the presence of such negative externalities and make concomitant adjustments to its user fees (both in the aggregate and within each activity). Fees must not only be set in a manner that corresponds to the cost of the Agency's work but must also framed in a manner that does not unreasonably deter companies from introducing new chemicals into the marketplace. This will better justify the reasonableness of the fees that EPA finally imposes and ensure that the program does not stifle the global competitive advantage of the U.S. chemical industry.

B. EPA Should Only Increase the PMN Fee by Inflation

EPA's "Alternate Fee B" would set the fee for PMNs based on the inflation-adjusted amount of the current $2,500 fee. SOCMA strongly supports this proposal. It closely aligns with the fee structure SOCMA recommended in its 2016 comments, which stressed that, the higher the anticipated fee for Section 5 activities, the higher the risk for discouraging chemical innovation. The existing fees for EPA's new chemicals program has contributed to the United States being the preferred market for new, innovative, and greener chemistries, and has resulted in a greater number of new chemical submissions when compared to other regions.

By contrast, the proposed fee of $16,000 is too high. That fee would represent more than a six-fold increase in the current PMN fee, and would certainly impair this advantage, as EPA frankly recognized by projecting a 20% drop in PMN submissions. EPA may be in fact underestimating the decrease in PMN submissions, considering that the Agency has now also begun requiring expensive and time-consuming animal tests (e.g., 90-day inhalation studies and 2-generation reproductive toxicity tests) that PMNs traditionally have not been subject to. A (best-case) one-fifth drop in new chemical submissions is simply not consistent with the statute's requirement that "authority over chemical substances and mixtures should be exercised in such a manner as not to impede unduly or create unnecessary economic barriers to technological innovation."[6] As OPPT Director Jeffery Morris has emphasized: "New chemicals often have a better environmental footprint by cutting energy consumption, hazardous waste, water pollution or other environmental benefits when compared to the chemicals they replace."[7] PMN fees must promote, not discourage, innovation, and must be adjusted in alignment with inflation to ensure that they do not act as a market barrier. Increasing PMN fees only by the rate of inflation is the best approach to ensuring that PMN fees are fair and manageable to submitters. Updating $2,500 by the most recent annual average Producer Price Index (PPI) available – currently from 2017 – would appear to yield

[6] 15 U.S.C. § 2601(b)(3).

[7] Quoted in Pat Rizzutto, "EPA to Clear Backlog of New Chemical Approvals by July," Bloomberg BNA Energy & Environment Report (May 30, 2017), available at https://www.bna.com/epa-clear-backlog-n73014451641/; *see also* Charles Auer, "Old TSCA, New TSCA, And Chemical Testing," BNA Environment Reporter (Aug. 15, 2016).

$10,975.[8] SOCMA would support this fee for a PMN. Conversely, "Alternate Fee A" is even worse than the proposed fee structure and would be devastating to chemical innovation.[9]

SOCMA does not necessarily endorse the other aspects of Alternative Fee B, particularly the increase from 3% to 10% of the activity cost for Section 4 fees.

C. EPA Should Not Impose Fees on Section 5 Exemption Applications

As noted above, EPA has not historically imposed fees for applications under the TME, LVE, or LoREX exemptions. SOCMA believes that the amended statute does not authorize EPA to change its practice and start charging fees for exemption applications. The Senate-passed version of the Lautenberg amendments explicitly spoke of charging fees for "requesting an exemption under section 5,"[10] but the final bill dropped that language. EPA seems to recognize this in part by exempting Tier I microorganism and polymer exemption submissions from applicable fees, yet it does not go further and consider affording the other categories of exemptions the same treatment.

Rather than imposing fees on exemption applications, EPA should instead include the costs of reviewing those applications in the aggregate of overhead costs that TSCA fees are designed to recover. Activities qualifying for an exemption tend to be extremely restrictive in volume, manufacturing methods, and end use applications, and do not raise the same risk concerns that chemical substances manufactured in large volume notifications do. As a result, the review of these applications is substantially less burdensome on the Agency compared to the PMN review process. Additionally, EPA established in 1995 that LVE and LoREX exemption applications would only be granted on the basis of "affirmative[] find[ing]s" of no unreasonable risk (60 Fed. Reg. 16336, 16337). Neither this policy nor the process governing the review of exemptions has been significantly affected by the Lautenberg amendments.

It is also worth reiterating that the Agency did not account for the likely number of reduced exemption notice submissions if it proceeds with the user fees as they are currently proposed. The imposition of fees on an activity that has historically not had any fees will undoubtedly disrupt companies attempting to bring new and innovative substances to market.

For example, specialty chemical manufacturers often produce chemical products for research purposes, where LVEs are typically required by the customer before a research and development application can be considered. With no assurance that a commercial application will ultimately succeed, companies still must submit the LVE so as to not miss the opportunity of working with the potential customers. The paperwork process alone requires that companies commit significant resources to the effort, resources that would otherwise be utilized to conduct other research or production or marketing. If a specialty chemical

---

[8] To derive this value, we used data for the PPI values of Chemical and Allied Products found on the BLS website (http://data.bls.gov/cgi-bin/srgatet) under the Series ID WPU06. That was approach followed in "Supplemental Analysis of Alternative Small Business Size Standard Definitions and their Effect on TSCA User Fee Collection," EPA-HQ-OPPT-2016-0401; RIN 2070-AK27 (April 17, 2018), at 1.

[9] EPA needs to correct a typo in Table 7 that implies that LoREX and LVE notices would be charged PMN-level fees. (Compare Federal Register page 8223 with p. 40 of the prepublication version.) EPA needs to put a carriage return where the comma is after "MCAN" the second time it appears and move "LoREX, LVE" to next line down.

[10] *See* H.R. 2576, § 23 (new TSCA § 26(b)(1)(A)) (Dec. 17, 2015).

manufacturer also has to pay an exemption fee that may never be recouped, it is an additional burden that will dissuade experimentation. Additionally, specialty chemical manufacturers also submit a number of LVEs to the Agency just to formulate a single marketable chemical mixture, and would thus face duplicative costs on that single product. For these reasons, SOCMA urges EPA to reconsider the wisdom of imposing user fees for exemption applications to avoid creating harmful and unnecessary economic barriers to technological innovation.

II. SOCMA Strongly Supports Accounting for Section 14 Activities as an Overhead Cost

In its 2016 comments on fee issues, SOCMA strongly urged EPA not to follow the Canadian model of requiring fees for individual confidential business information (CBI) claims. SOCMA argued that setting any fees for asserting CBI claims would act as a market disincentive to innovative chemistry, as trade secrecy is typically the key to maintaining a competitive advantage, especially in the early life of a new commercial chemical. Chemical identity is often not patentable, and where it might be, time-to-market considerations and near-term revenues normally would not permit, respectively, the time and expense required to pursue a patent.

This argument has in fact been borne out in Canada, where U.S. manufacturers often offer a narrower range of products or formulations to minimize the expense and transaction costs associated with having to pay a fee for each CBI claim. In the proposed rule, EPA wisely elected not to assess greater fees on activities that include a CBI claim. Instead, the Agency accounted for such costs as overhead to be recovered via the other fee payment-triggering events outlined in the rule. SOCMA supports EPA's decision to not charge an additional fee for CBI-related activities and submissions.

III. SOCMA Supports EPA's Revision of the "Small Business Concern" Definition

A. SOCMA Supports EPA's Proposal

In its proposed rule, EPA proposes to increase the current revenue threshold for entities defined as small business concerns. The Agency suggests using the annual average PPI – using a base year of 1988 and inflating to 2015 dollars – resulting in a threshold change from $40 million to approximately $91 million. In its additional analysis for the small business definition[11], EPA also suggests that if such a revenue-based threshold is used to classify firms, it expects to employ the newly available 2017 PPI threshold of $96.5 million and to update the definition with the latest available annual average PPI value as part of the statutorily-required triennial reassessment of the TSCA fees (Section 26(b)((4)(F)). EPA also proposes to change the timeframe over which annual sales values are calculated when estimating business revenue. Instead of using just one year preceding the date of submission, the Agency has proposed averaging annual sales values over the three years preceding the submission.

SOCMA strongly supports updating the small business threshold, which has remained unchanged for literally three decades. SOCMA also supports the use of the PPI for this purpose. The PPI closely tracks the types of goods and services that chemical companies commonly purchase and represents an accurate measure of business output. Additionally, SOCMA supports updating the threshold every three years, as proposed. Finally, SOCMA supports measuring annual company sales values over a three-year period, as

[11] *See* "Supplemental Analysis," *supra* note 8, pp. 1-2.

it will provide a more accurate depiction of a company's financial performance over the business cycle. Specialty chemical companies in particular coordinate much of their business via sole-source contracts, producing chemical substances in relatively low volume yields for highly differentiated and functional end uses. The more fragmented nature of contract manufacturing for specialty chemicals can thus generate wider fluctuations in business revenue than would commodity chemicals, which are typically produced in continuous processes with relatively consistent feeds and yields.

B. EPA Should Also Institute an Employee-Based Standard for Small Businesses

The Agency has solicited input regarding whether to implement an employee-based size standard for small business entities, inquiring what an appropriate threshold should be for doing so and whether the need for such a standard varies across industry segments.

SOCMA recommends that the Agency establish two disjunctive size standards – one receipt-based and one employee-based – to ensure that the range of entities affected by user fees is accommodated. Under this approach, a business that triggered either standard would be considered a small business. EPA should utilize an employee threshold value that, based on the Agency's supplemental analysis, equates to the number of firms covered under the revenue threshold EPA ultimately adopts.[12] Keying the two approaches together according to an equivalent percentage of covered firms would allow EPA to functionally maintain revenue neutrality *ex ante* while providing additional relief to small businesses for whom the employee-based standard is beneficial.

This approach will allow EPA to better account for the unique characteristics of the specialty chemical market such as average firm size, start-up costs, entry barriers, and competitiveness within the industry. Specialty chemical manufacturers are more likely to face exclusion if only a receipts-based methodology is implemented. The production of unique batch-processed substances brings with it attendantly higher operational costs that a gross sales value approach does not adequately reflect. For each uniquely manufactured substance brought to market, a specialty chemical manufacturer must analyze the capabilities of its current facilities, work with its suppliers to incorporate critical manufacturing equipment and raw materials, conduct applied research and product development, update its manufacturing processes, provide applicable operational training to its employees, construct pre-production units, conduct pilot testing, complete customer approval processes, phase in production, manage stranded equipment costs, and complete final production within the timeframe specified in the contract.

Specialty chemical manufacturers thus face proportionately higher business costs as a segment within the chemical industry and face equivalent (or potentially lower) net revenues. Many such firms additionally concentrate their operations around one or a relatively small number of facilities since the customized nature of specialty chemistry is not afforded the benefits of scale enjoyed by bulk chemical manufacturers.

---

[12] SOCMA is conscious of the potential loss in TSCA fee revenue if an employee-based standard, using EPA's 500-employee threshold, is implemented. In the Agency's supplemental analysis, an additional 7% of firms would qualify for reduced fees under this approach, leading to a predicted gap of $211,000 in reduced fee revenue. SOCMA suggests that a lower threshold is appropriate to negate the projected revenue losses while still encompassing the equivalent number of firms that would qualify for reduced fees based on their average annual revenue. *See* "Supplemental Analysis of Alternative Small Business Size Standard Definitions and their Effect on TSCA User Fee Collection," *supra* note 8, at 9.

As such, a size standard based solely on revenue can result in labeling relatively very small operations (measured by number of employees) as "large," rather than small. Therefore, in addition to its receipts-based standard, the Agency should implement an alternative, employment-based option for the classification of small business entities. While EPA may be unable to determine the full revenue effects of these various thresholds until it conducts its first reassessment, the Agency will be able to adjust them at that point if the dual thresholds ultimately result in revenue losses versus these assumptions.

C. EPA Should Promptly Update the Section 8 "Small Manufacturer or Processor" Threshold

Finally, SOCMA urges EPA to promptly initiate a rulemaking to similarly update for inflation the test for what constitutes a "small manufacturer or processor" under Section 8(a). This spring's Regulatory Agenda has pushed a proposed rule on this topic back to September of this year, and now says only that EPA "may include updates" to the standards."[13] SOCMA is very disappointed by these developments, especially given EPA's preliminary determination that such an update is "indeed warranted."[14] Given all the work that the Agency has done on this issue for the fees rulemaking, it should be fairly straightforward to rely on that work to complete Section 8(a) rulemaking. That rulemaking must be concluded before the next CDR cycle, and so EPA should move quickly to initiate and conclude it. Consistent with the previous portion of these comments, SOCMA recommends that EPA set both revenue and employee-based cutoffs to entities for Section 8(a) data reporting purposes as well.

IV. EPA Should Modify its Section 5 Refund Provisions

A. Refunds for "No Substantial Work" Occurring

The statute requires EPA to "refund the fee or a portion of the fee [for a] notice submitted under Section 5 . . . if [the] notice . . . is not reviewed or . . . is withdrawn, . . . if no substantial work was performed on the notice."[15] Interpreting "no substantial work" in the case of a withdrawn notice, EPA notes that up to three significant milestones of a PMN review can occur within the first 10 days of a Section 5 notice, and therefore limits the entitlement to any refund for withdrawn notices to that number of days, without regard to whether any of those milestones had actually occurred. When such a withdrawal occurs within 10 days of the notice, EPA proposes refunding 75% of the fee that was remitted. However, the proposed rule does not interpret "no substantial work" in the "is not reviewed" context. SOCMA recommends that EPA modify this provision to provide a comparable refund any time that none of the three events (i.e., the Chemical Review / Search Strategy Meeting, the Structure Activity Team Meeting, and the Exposure / Release Assessments) has occurred within the first 10 days.

To the extent EPA ends up finalizing fees for exemption applications under Section 5, it should make the fee refund mechanism applicable to them, as that is the plain reading of the statutory language quoted above.

---

[13] *See* https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=201804&RIN=2070-AK33.
[14] 81 Fed. Reg. 90840 (Dec. 15, 2016).
[15] 42 U.S.C. § 2625(b)(4)(G).

SOCMA
Society of Chemical Manufacturers & Affiliates

B. EPA Failures to Make a Determination Within the Applicable Review Period

Under Section 5(a)(4) ("Failure to Render Determination"), amended TSCA obligates EPA to provide full refunds to submitters "[i]f the Administrator fails to make a determination on a notice under paragraph (3) by the end of the applicable review period and the notice has not been withdrawn by the submitter . . . ." The proposed rule text implements these requirements in proposed Section 700.45(g)(v)-(vi).[16]

However, the preamble to the proposed rule fails to note this requirement. It states that EPA is only obligated to provide refunds for submissions "whenever EPA determines that the notice or fee was not required," or for notices "that are later withdrawn and for which the Agency conducts no substantive work unless the Agency determines that the submitter unduly delayed the process."[17] The Agency goes on to say that it lacks the statutory authority to provide for refunds under any other circumstances.[18] This omission may have arisen because that preambular language only discusses Section 26(b)(4)(G), while the requirement to refund Section 5 fees when EPA's review exceeds the applicable review period arises under Section 5(a)(4). In any event, however, SOCMA recommends that the Agency clarify in the preamble to the final rule the full extent of EPA's refund obligations under Sections 5 and 26.

C. EPA Should Refund Section 5 Fees Whenever it Obtains a Suspension of the Applicable Review Period

Relatedly, as SOCMA emphasized in its comments on the New Chemicals Review Program[19], many of its members have been faced with the situation where EPA has obtained a voluntary suspension of the 90-day review period, but then has been unable to render a final determination on a PMN substance for a prolonged period of time. The Agency regularly requires submitters to suspend the statutory review deadlines, usually for two weeks at a time, or risk having their PMN denied, in order to give EPA more time to conduct its review (and, conveniently, also avoiding EPA's obligation to refund applicable fees). Once suspended, however, these review periods frequently drag on for months. For example, one SOCMA member was informed by the Agency in November 2017 that its proposed conditions of use for a PMN substance did not likely present an unreasonable risk, yet the Agency has still not formalized this determination because of delays in developing the accompanying "non-order" Significant New Use Rule (SNUR). In this instance, the Agency not only failed to make a determination on a notice by the end of the applicable review period, but it did so unilaterally -- the submitter did nothing to delay the process. By never invoking its authority to extend the 90-day review period by another 90 days and, instead, repeatedly asking submitters to suspend that period, the Agency appears to be complying with Section 5 requirements when it clearly is not.

In mandating that the Agency refund fees whenever it misses the 90-day PMN review period, Congress could not have been contemplating that EPA would continue its practice of uniformly coercing "voluntary" suspensions of that period. EPA in fact continued this practice immediately after enactment of the

---

[16] 83 FR 8234.
[17] *Id.* at 8225.
[18] *Id*. at 8226.
[19] Docket ID No. EPA-HQ-OPPT-2017-0585, New Chemicals Review Program under the Amended Toxic Substances Control Act; Notice of Public Meeting and Opportunity for Public Comment.

Lautenberg amendments, and PMN submitters are effectively powerless to resist. SOCMA is concerned that, as a result, Section 5(a)(4) will become effectively a dead letter. EPA is obligated to give effect to the words of the statute. In cases where EPA obtains a voluntary suspension of the 90-day review period, EPA must provide refunds to submitters -- as it is statutorily obligated to.

Considering that submitters are also expected to pay substantially higher fees for Section 5 applications under EPA's proposed fees, it is both reasonable and fair to expect that the increased expense will bring with it a commitment by the Agency both to meet the statutory review deadlines and to return the submitter's fees when those mandatory obligations are not met. Doing so will both improve the credibility of the New Chemicals Review Program and encourage EPA to meet its strategic goal of making final PMN determinations in accordance with the timelines set forth in the statute.

If the final rule ultimately requires fees for exemption applications, EPA should make the same refund available to submitters when EPA misses the applicable review period deadline.[20] Section 5(a)(4) does not technically apply to exemption applications, but then the statute also never states explicitly that exemption submitters should have to pay fees. If EPA is going to make exemption applicants pay fees, the Agency should also act consistently with the spirit of Section 5(a)(4) and refund fees if it asks the submitter to suspend the time limit.

D. EPA Should Clarify the Fee Status of Bona Fide Notices

The proposed fees rule notes that if a company filing a PMN is advised by EPA that the chemical is already on the confidential portion of the Inventory, the company will get its fee returned pursuant to Section 26(b)(4)(G).[21] While many companies, for a variety of reasons, will file a PMN on a proposed new chemical without regard to whether it is currently on the confidential Inventory, others will make a bona fide inquiry first to determine the answer to that question. Regardless of whether EPA does or does not confirm that a proposed new chemical is on the confidential Inventory, the fees rule currently does not list bona fide notices as filings that have to pay fees. This is appropriate, since the statute only authorizes EPA to impose fees on persons "required to submit . . . a notice or other information to be reviewed by the Administrator under Section 5 . . . ." – whereas a bona fide inquiry is an optional submission, not one required by Section 5.[22] SOCMA recommends that EPA clarify that bona fide notices would not be subject to fees.

V. Section 4 Fee Issues

A. The Number of Estimated Section 4 Activities Appears Low

The proposed rule says EPA expects to perform work on 10 test orders, one test rule, and one enforceable consent agreement (ECA). The proposal bases its cost estimates for Section 4 activities on prior experience developing ECAs and test rules and reviewing data submissions, but it does not provide specific reference

[20] *See* 40 C.F.R. §§ 720.38(d) (45-day review period for TME applications), 723.50(g) (30-day review period for LVE & LoREX applications).
[21] 83 FR 8225 ("EPA will continue to refund any fee paid for a section 5 notice whenever EPA determines that the notice or fee was not required. See, e.g., 40 CFR 720.62. This can happen, for example, when . . . the substance is already on the Inventory.").
[22] 15 U.S.C. 2625(b)(1).

points to validate its projections. The Lautenberg amendments made significant changes to Section 4, based on criticisms that the prior version of the statute crippled EPA's ability to compel testing. As a result, SOCMA would have assumed that EPA would anticipate a higher level of activity under Section 4.

During a March 30, 2018 Environmental Roundtable with the Small Business Administration, Mark Hartman, Acting EPA Deputy Director for Management at OPPT, indicated that the Agency's projections of various Section 4 activities were only predicated on historical experience, and were therefore "not a policy statement." While SOCMA appreciates this perspective, we also acknowledge that EPA should be exercising more of its authority under this section over time. SOCMA supports the recommendation of Charlie Auer that EPA should be using its Section 4 authority to gain information from existing chemicals about emerging health concerns, rather than burdening PMN submitters of similar molecules with such testing. By definition, existing chemicals have been in commerce for years or decades, and substantially greater evidence should be available about their health and environmental effects that should, through read-across and similar methods, be able to inform EPA's judgments regarding similar new chemicals. Existing chemicals also have markets that can support testing costs, whereas new chemicals by definition are generating no income.

For these reasons, SOCMA recommends that EPA rethink its predicted level of activity under Section 4. More Section 4 activities would, of course, allow EPA to assume that these could shoulder a greater percentage of the total fee burden without having to increase the relevant fees.

B. EPA Should Adjust its Fees for ECAs and Test Orders

Under Section 4, EPA proposes to set fees for Test Orders at $9,800 and enforceable consent agreements (ECAs) at $22,800. However, it would be appropriate for companies entering into ECAs to be allowed to pay lower fees than those subject to unilateral Section 4 orders because, by definition, the former are cooperating with EPA, while the latter are not. Instead, EPA has proposed to charge ECAs for more than twice as much as Test Orders. SOCMA suggests that EPA revise its fees here to make the former greater than the latter. Doing so will improve the fairness of the fee arrangement for Section 4.

VI. Section 6 Fee Issues

A. Fees for Risk Management Activities Should Be Separate from Risk Evaluation Fees

EPA has requested specific comments from stakeholders on the decision to not include a separate fee category for risk management activities under TSCA section 6(a).[23] The Agency also notes that it estimates risk management costs to comprise $6,584,000 out of the $43,618,000 annual costs of administering Section 6.[24] Because risk management represents a significant portion of these total administration costs, and because not all chemicals undergoing risk evaluation will receive a determination that they present an unreasonable risk to health or the environment, SOCMA recommends that EPA assess risk management fees separately, and only in connection with chemicals that proceed to risk management.

[23] *Id*. at 8227.
[24] *Id*. at 8219.

Not every risk evaluation will culminate in a risk management rulemaking. SOCMA believes it would be unfair to require manufacturers of chemicals that do not pose an unreasonable risk to pay part of the cost of risk management work for other chemicals – and, conversely, that it would be fair for manufacturers whose chemicals do pose unreasonable risk to pay for cost of developing the associated risk management rule. We anticipate that manufacturers will be engaged throughout the risk evaluation process, providing substantial resources to the Agency – both in respect to data generation and in validation of the scope of the assessment. In so doing, they will help ensure that the associated risk of a chemical substance is accurately determined, and that potential management of the substance is implemented properly. Charging separately for risk management activities would thus serve to reward those companies that have adequately demonstrated to the Agency that they manufacture chemicals of lower risk. They should therefore not be penalized by having to provide financially for the two to four years of risk management activities on other chemicals.

Additionally, the lengthy time periods specified in Section 6 for prioritization, risk evaluation, and risk management activities indicate that a chemical substance can occupy the attention of all interested stakeholders for upwards of 8.5 years. With the substantial time and resources devoted to any given chemical, it is appropriate that companies subject to a "no unreasonable risk" determination be able to fully exit the process. And, for those chemical substances ultimately subject to risk management, EPA would have already identified the appropriate companies subject to the Section 6 fees at the outset of the risk evaluation, so it should be a simple matter of assessing those same companies again when risk management procedures are initiated.

B. EPA Should Adopt an Explicit Process to Identify Companies Subject to Risk Evaluation Fees

EPA has requested specific comment on whether to adopt a process to develop the list of companies subject to risk evaluation fees before it finalizes the fee rulemaking.[25] The Agency identifies a number of reporting instruments that it could use to identify manufacturers and processors of a given chemical substance, such as Chemical Data Reporting (CDR) submissions, Toxic Release Inventory (TRI) data, and Notice of Commencement (NOC) submissions.

These reporting mechanisms, while useful, will only provide EPA with an incomplete list of users based on circumscribed conditions of production. The most effective way for the Agency to implement the fee obligation for risk evaluations would instead be for the rule to create two reporting obligations:

1. At the time that EPA designates a chemical substance as high priority, any entity manufacturing that chemical within the prescribed lookback period (discussed below) should have to submit an activity notification to EPA detailing their production volume and manufacturing history.

2. Any entity that commences manufacture of a chemical substance subject to a risk evaluation within the time period beginning on the date that the chemical is designated as high priority and

[25] *Id.* at 8216.

ending five years after the issuance of a final risk management rule for that chemical (or a finding that it does not present an unreasonable risk) has to notify EPA of that manufacture.

A formal notification system for high priority chemicals will discourage free-rider scenarios and ensure that EPA captures the full universe of manufacturers that have engaged (or will engage) in the manufacture of a risk evaluation chemical. Using such a system will also allow EPA to more accurately assess Section 6 fees when companies elect not to join a consortium, and it will provide companies with confidentiality protection if they choose to claim the fact that they manufacture the chemical substance as CBI (if, for example, they manufacture below the CDR threshold). A notification obligation also imposes a clear legal obligation on persons subject to Section 6 fees that will help promote participation in the system. Finally, such a system will also provide certainty for all concerned, including manufacturers that ceased manufacture before the lookback period.

It is critical that EPA also implement an open and transparent public participation process that allows for input on the accuracy of its list of identified users. It would be wise for the Agency to allow for sufficient time after the Risk Evaluation scope is made final to ensure that potentially affected companies have adequate time to respond to the notification request, associate with others as a consortium, and internally budget for their anticipated cost of the risk evaluation. To that end, EPA should present its list of affected companies in a new public docket after notification period has concluded. EPA should alert the public when that information has been made available in the docket and ensure that appropriate protections are in place for Confidential Business Information (CBI).

In its proposed rule, the Agency also notes that it "plans to include a limitation in the final regulatory text to ensure a manageable approach for the identification of manufacturers who are subject to a particular fee."[26] SOCMA concurs that EPA must delineate the scope and window of manufacturing activity applicable to the risk evaluation fees. SOCMA recommends that when the Agency identifies its list of affected companies, it establish a three-year lookback period from the point of the high-priority chemical designation. Beyond this window, there is an unacceptable likelihood that EPA would be identifying companies that are no longer engaged in the manufacture of a given substance. Such a long lookback would thus punish companies that have chosen to stop manufacturing or processing a chemical due to its associated risks. EPA should incentivize such behavior, not punish it.

The Risk Evaluation Rule also recognizes that EPA may, on a discretionary basis, exclude certain activities from risk evaluation (that it has otherwise determined to be conditions of use) such as *de minimis* exposures that occur in a closed system or uses as an intermediate. EPA should recognize similar practical boundaries regarding the scope of affected users subject to risk evaluation fees by providing for a *de minimis* production volume exemption that ensures that companies that have produced a risk evaluation substance in very low quantities are not impacted by the very costly section 6 fees. Such companies are analogous to the Boy Scout troops and churches that have been drawn into Superfund settlements for minuscule contributions of hazardous substances. Congress amended the Superfund statute to exempt such "de micromis" sources,[27] and EPA should do something comparable in the final rule.

C. EPA Should Assess Risk Evaluation Fees on Late Market Entrants

[26] *Id.*
[27] See 42 U.S.C. § 9607(o).

The Lautenberg Act neglected to address what is generically known as "data compensation" in Section 6, but TSCA has always had language in Section 4 to assure the "fair and equitable reimbursement" of data submitters by late market entrants. Under Section 4, those late entrants are required to provide "for a portion of the costs incurred by" the initial payors. The reimbursement obligation lasts for five years from the date the data was submitted. This language was retained by the LCSA without significant change (see TSCA § 4(c)). Under EPA's implementing rules (40 C.F.R. § 791.50), the original payors can be reimbursed for more than their direct out-of-pocket costs (e.g., they receive "a reasonable profit, and a reasonable rate of interest and depreciation on the tester's initial capital investment"). Original payers thus get a return they had to forego by their investment in the testing (a return that the late entrant was able to realize over those years by not having had to contribute to the testing).

Section 6 activities and externalities are similar to Section 4, in that manufacturers must collectively fund the evaluation of a given chemical in order to determine the potential risks associated with the substance's ongoing use in U.S. commerce. Late entrants who begin manufacture of a risk evaluation substance thus stand to benefit from the substantial financial contributions made by the original payors. SOCMA wishes to ensure that any TSCA fee program is both fair and easy to administer, and therefore suggests that EPA implement similar retroactive fee provisions for Section 6 activity.

EPA should provide in its final fees rule a provision that ensures fair and equitable reimbursement for fee-payers when late or new market entrants might potentially avoid section 6 fees after the scope of the risk evaluation is finalized. A late market entrant would be required to use the same notification process to alert the Agency of its intent to manufacture the risk evaluation substance (as described above), and would then be required to pay a fee directly to the relevant industry consortium that is based on the methodology previously established by the consortium for participating companies. Like the Section 4 testing provisions, EPA should provide for a five-year forward-looking reimbursement obligation and ensure that reimbursement takes into account a reasonable rate of interest. These provisions will improve the general affordability of Section 6 fees by allowing for a greater universe of fee payers, while also improving the fairness of the assessment.

D. EPA Should Adjust its Fee for Manufacturer-Requested Risk Evaluations of Work Plan Chemicals

EPA proposes that the user fee for an EPA-initiated risk evaluation be $1,350,000, while the fee for a manufacturer-requested risk evaluation of a Work Plan chemical is $1,300,000. SOCMA finds this arrangement to be odd. Certainly, the implicit goal of the 100% remittance requirement for manufacturer-requested risk evaluation fees of non-Work Plan chemicals was to ensure that manufacturers paid the full cost of those risk evaluations and did not receive a taxpayer-funded subsidy. Presumably, the 50% statutory requirement for manufacturer-requested risk evaluations of Work Plan chemicals was a compromise between the intent to avoid a subsidy and the reality that EPA would have to assess Work Plan chemicals in the near term anyway. Yet, one might also expect that the 50% cost would be a higher amount than the cost for chemicals where no manufacturer was requesting a risk evaluation, since requestors are ostensibly getting some benefit from requesting that the Work Plan chemical be assessed immediately.

The resulting effect is that manufacturers requesting a risk evaluation of a Work Plan chemical are apparently receiving a discount from the Agency versus manufacturers of other chemicals subject to an EPA-initiated risk evaluation, even though, as noted, requesting manufacturers are receiving some benefit from requesting the risk evaluation. This unfair arrangement conflicts with the apparent implication from the statutory text – namely, that EPA-initiated risk evaluations be the lowest cost assessment to manufacturers under Section 6. To correct this imbalance, SOCMA recommends that EPA adjust the user fees for both the EPA-initiated risk evaluation, and the manufacturer-requested risk evaluation of Work Plan chemicals, so as to make the fees for the former lower than those for the latter. This will improve the fairness of the Section 6 fee allotments and ensure compliance with the 50% statutory requirement. It will also minimize the potential negative impact on companies pulled into an EPA-initiated risk evaluation. It is critical that EPA consider that a company's ability to pay will have greater variability when the fee is assessed versus when the fee is volunteered upfront.

E. EPA Should Assist Manufacturers in the Formation of Consortia

EPA proposes that manufacturers be provided flexibility to apportion and pay risk evaluation fees via industry consortia in cases where multiple companies manufacture a chemical undergoing risk evaluation. The Agency also requests that consortia assign small businesses a lower risk evaluation fee than their larger counterparts. While manufacturers should indeed be provided flexibility in arranging their terms of remittance, SOCMA recommends that the Agency offer logistical support when challenges arise.

A number of practical concerns will likely arise when forming consortia. For instance, business confidentiality issues may make it difficult for companies to collectively apportion fees if they do so based on their market share of a given chemical substance. In such cases, a third-party fiduciary may be required to collect relevant market data from each company, aggregate that information, calculate fees by a presubscribed formula, and then individually assess the fees - all in a confidential manner as to avoid revealing competitive information between the various companies. Additionally, those companies in the consortia may prefer to assess user fees based on prior annual production volume, or average production volume over the prescribed lookback period of their manufacturing activity. Regardless, such information is competitive by nature and not readily available to the Agency. While industry trade associations will likely also provide support in such matters, they might not adequately capture the full universe of manufacturers in their membership. As such, EPA may need, on a discretionary basis, to provide direct assistance in calculating fees to the various companies it identifies for risk evaluation fees – or at least facilitate a process by which the companies can retain a third party, at their own expense, that would serve as an intermediary between the companies and EPA.

VII. EPA Must Take into Account the User's Ability to Pay Fees

When setting its fees, EPA has a statutory obligation to "take into account the ability to pay of the person required to pay such fee."[28] Notably, this obligation is separate from, and thus in addition to, EPA's obligation to set lower fees for small businesses.[29] In its rule, though, the Agency has not fully addressed circumstances where very few companies manufacture or process a substance, or where all or most of them are small businesses (or both). While many chemicals subject to risk evaluation will have many large

[28] 15 U.S.C. § 2625(b)(1).
[29] *Id.* § 2625(b)(4)(A).

entities available to form consortia and engage in cost-sharing arrangements, it is important not to assume that this will always be the case. The range of companies involved in an EPA-initiated risk evaluation will have a serious impact on the individual ability to afford the user fee.

At a minimum, EPA should allow for its Section 6 risk evaluation fees to be payable in installments over the course of the evaluation. The 60-day period proposed by EPA is insufficient. It should instead be used as the presumptive window for affected companies to form consortia, decide on cost apportionments, and provide the Agency with a proposed fee remittance schedule. Allowing for interim payments will provide greater flexibility to companies that may be shouldering a larger share of the fee burden, may not have readily available funds at the outset of the risk evaluation, may be experiencing other financial difficulties – or a combination of such factors. The consequences of failing to comply with fee payment requirements are also very costly and serious. Manufacturers should not be put in a position where they are incurring upwards of $38,114 in daily penalties because they were not provided sufficient opportunity to come up with a fee payment scheme that minimizes financial hardship on their companies.

VIII. SOCMA Supports the Exemption of Sustainable Futures Graduates from TME Fees

EPA has proposed that Sustainable Futures graduates can earn expedited review for pre-screened new chemical notices. In doing so, they must simultaneously submit both a Test Market Exemption (TME) and a PMN (or SNUN or MCAN), which will allow the submitter to receive a fee waiver for the TME submission. SOCMA supports affording credit for evaluations under the Sustainable Futures program, including the waiver for TME fees. Doing so will encourage industry engagement in the program and allow manufacturers to bring new chemicals to market more efficiently.

Because Sustainable Futures graduates also become eligible for an expedited EPA premanufacture review of their submission, SOCMA also recommends that the applicable PMN fee should be adjusted accordingly to reflect the expedited nature of the Agency's review. As EPA itself notes in the proposed rule, the review time-period is cut in half for graduates.[30] It makes reasonable sense that the proposed fee for PMNs should therefore be lower.

IX. EPA Has Not Justified the Reasonableness of its Proposed Fees

As noted above, Section 26(b)(1) limits fees to those "that [are] sufficient and not more than reasonably necessary to defray the cost" related to the administration of Sections 4, 5, 6, and 14. In SOCMA's view, this language imposes two obligations on the fees rulemaking, the first based on EPA's costs and the second based on the impact of the fees on industry. It is clear that, in calculating what fees to propose, EPA collected data on what its current costs ***are***. See 83 FR 8217-19. However, the statute's use of the phrase "reasonably necessary to defray the cost" means that EPA should instead be determining what it costs ***reasonably should be***. EPA's approach does nothing to restrain inefficiency or waste in these programs; indeed, it positively encourages them. EPA's current level of costs is certainly highly relevant, but it must be judged against a zero-based or bottom-up calculation of what its activities should cost. This would involve not just tabulation of the number of person-hours required for particular activities but an assessment of how many hours those activities should take. That latter assessment could be based on

[30] 83 FR 8222.

the costs experienced by private entities conducting or contracting for similar work, adjusted as necessary for any additional processes or inefficiencies that are inherent to government work. The cost of risk evaluations in particular ought to be pressure-tested in this way, as private companies commonly hire consulting firms to conduct evaluations analogous to those EPA will be conducting under TSCA. Our members advise us that they cannot imagine how an entity could spend $3.9 million on a risk evaluation, even using a 28% overhead rate. At a minimum, EPA should conduct some sort of review to demonstrate why it is unreasonable to expect that EPA's costs would be lower. Such a review would be consistent with the Administration's prominent initiative to "lean" its processes.[31] A commitment to seek to reduce EPA's costs over the coming 1-3 years would also be a welcome addition to the proposed rule package.

Conclusion

Thank you very much for your willingness to seek feedback from stakeholders. SOCMA has long supported modernization of TSCA and supports the Agency's ongoing efforts to implement the amended statute. SOCMA encourages EPA to modify its proposed fees for the administration of TSCA to ensure that they are not set at a level that would bring adverse harm to the competitive and innovative advantages of the American chemical industry. SOCMA has appreciated the opportunity to provide feedback on improving the fairness and efficiency of EPA's fees program and looks forward to continued collaboration with the Agency in the future.

Respectfully submitted,

Jared Rothstein
Senior Manager, Regulatory Affairs
Society of Chemical Manufacturers & Affiliates (SOCMA)
1400 Crystal Drive, Suite 630
Arlington, VA 22202

[31] *See* Eric Roston & John Lippert, "Pruitt's EPA Turns to 'Lean Manufacturing' to Speed Up Reviews," Bloomberg Politics (Dec. 18, 2017), available at https://www.bloomberg.com/news/articles/2017-12-18/pruitt-s-epa-turns-to-lean-manufacturing-to-speed-up-reviews.