UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Comments of Safer Chemicals Healthy Families, Natural Resources Defense Council and Earthjustice on EPA's Supplemental Proposed Fees Rule under the Amended Toxic Substances Control Act

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EPA-HQ-OPPT-2020-0493

INTRODUCTION AND SUMMARY

Safer Chemicals Healthy Families (the federal policy program of Toxic-Free Future), Natural Resources Defense Council and Earthjustice submit these comments on the November 16, 2022 supplemental proposed rule of the Environmental Protection Agency (EPA) requiring payment of fees by industry to support implementation of the Toxic Substances Control Act (TSCA) during fiscal years (FYs) 2023-2025.[1] Our organizations are committed to assuring the safety of chemicals used in our homes, workplaces and in the many products to which our families and children are exposed each day.

In amending TSCA in 2016, Congress recognized that strengthened protection of public health under the new law would require additional resources and that a significant portion of TSCA implementation costs should be defrayed by industry. To enable EPA to meet its expanded responsibilities, section 26(b) of amended TSCA authorizes EPA to collect fees from chemical manufacturers and processors. The goal of these provisions is to assure that fees account for approximately but no more than 25 percent of the direct and indirect costs EPA incurs in carrying out sections 4, 5 and 6 and collecting and managing information under other provisions of the Act. In section 26(b)(4)(E) of TSCA, Congress directed EPA to reexamine and adjust fees levels every three years to account for inflation and to assure that they continue to contribute sufficiently to the costs of TSCA implementation.

As described in these comments, the cost estimates in the supplemental rule better align with program realities and would increase resources for implementing the law. However, EPA is still foregoing many millions of dollars in fees that it has authority to collect under TSCA section 26(b). This shortfall in fee collection is due to flaws in the rule's design, continued underestimation of costs in critical areas and unnecessary exclusions of eligible activities from fee collection. EPA needs to fix these problems in the final rule in order to substantially increase

[1] 87 Fed. Reg. 68647 (November 16, 2022).

fee collection and assure that it has the resources necessary to accelerate progress on risk evaluations, risk management and other activities critical to the success of TSCA.

The American Chemistry Council (ACC) has expressed shock at the "astronomical" fee increases in the supplemental proposal. Yet ACC estimates that the industry's annual revenues are $517 billion, more than sufficient to absorb the modest fees payable under the supplemental proposal (or even much larger fees) without any financial impact. For industry to balk at paying its fair share of TSCA costs after receiving a virtual free pass under the current EPA fees rule – and after committing to Congress to contribute significantly to the costs of TSCA implementation -- is the height of irresponsibility.

TSCA and Resources: A Program in Crisis

Six years after Congress amended TSCA, the EPA chemicals program is suffering from a dramatic resource deficit. Without adequate resources, EPA has missed multiple goals and deadlines in the new law and struggled to achieve the increased health and the environment protection that Congress demanded. This crisis occurred because the Trump Administration cut corners on effective implementation of key TSCA provisions and failed to seek sufficient funding from Congress and industry to manage EPA's rapidly increasing workload and staffing needs.

EPA's risk evaluation and risk management work under section 6 – the centerpiece of the amended law – is well behind schedule, with some evaluations and rules expected to miss statutory deadlines by years. Testing under section 4 has been minimal despite EPA's new authority to issue testing orders, which Congress hoped would accelerate needed studies on chemical risks. And the review of new chemicals under section 5, which Congress sought to strengthen, has been weak and uneven because of both the Trump EPA's refusal to comply with the law and EPA's failure to conduct rigorous and protective assessments of new chemical risks.

Failed Fee Collection Efforts by the Trump EPA

Robust fee payments by industry could have partially compensated for EPA's resource deficit. However, EPA's initial TSCA fees rule, promulgated on October 17, 2018,[2] was a missed opportunity. In an egregious windfall to the multi-billion dollar chemical industry, the rule failed to require fee payments for EPA's first 10 TSCA risk evaluations, the major undertaking of the Agency between 2016 and 2021. As recently determined by the EPA Office of Inspector General (OIG), EPA ultimately collected fees of only $2.7 million and $3 million respectively in FYs 2019 and 2020, a small fraction of TSCA implementation costs eligible for fee recovery. As a result, tens of millions of dollars in fees were lost to the Agency (and taxpayers) during FY 2018-2022.

[2] 83 Fed. Reg. 52694 (October 17, 2018).

On January 17 2021, the Trump EPA proposed an update to the 2018 rule to govern fee collection for fiscal years (FYs) 2022-2024.[3] Unfortunately, the proposed rule was backward-looking and flawed, reflecting an approach that underutilized EPA's authorities and fell short of meeting statutory mandates. Like its predecessor, the proposed rule favored the bottom line of chemical manufacturers by greatly underestimating EPA's projected costs in carrying out the amended law and failing to impose fee obligations for categories of EPA activities eligible for fee payment under section 26(b).

In our comments on the 2021 proposal, our groups warned that its finalization would result in fee collections far below those authorized in section 26 and deny EPA the resources necessary for a higher-performing TSCA program that complied with the law and met public health needs. We recommended that the Biden EPA reexamine the proposal and publish a revised rule for comment based on a more comprehensive and credible analysis of anticipated TSCA resource needs for EPA activities eligible for fee collection under section 26(b).

The Supplemental Proposal's Significantly Improved Cost Estimates

The Biden EPA took this recommendation to heart and, recognizing the magnitude of the resource challenges it faced, initiated a comprehensive reanalysis in 2021 of TSCA implementation costs. This reanalysis led to a more defensible and realistic assessment of EPA's resource needs and ultimately to the current supplemental proposal, which is a welcome improvement on both the 2018 rule and 2021 proposal.

As we describe in these comments, the proposal estimates that full implementation of fee-eligible programs will cost the Agency approximately $181.9 million annually. This is more than double the cost estimates of $87.5 million in the 2021 proposal and $80.2 million in the 2018 rule. Since fees must account for approximately 25 percent of eligible TSCA implementation costs, EPA anticipates fee payments of $45.5 million each year under this higher cost estimate, more than twice the projected fee collections of $22 million under the 2021 proposal and $20 million under the 2018 rule.

According to EPA, the supplemental proposal boosts fees by basing cost estimates not on the current underperforming TSCA program but on projected resource needs for a more robust program that fulfills the vision of the 2016 law. Thus, instead of accepting the status quo, the new section 6 cost estimates assume that "EPA's workforce will be involved in at least 20 EPA-initiated chemical risk evaluations at all times, and that each risk evaluation will take three and a half years to complete." EPA maintains that these estimates also factor in actual costs of the initial 10 risk evaluations and the costs of ongoing risk management, which were not included in the 2021 proposal. The supplemental proposal similarly projects increased costs to require

[3] 86 Fed. Reg. 1890 (January 17, 2021).

testing under section 4, reflecting a long overdue push to develop needed data for prioritization and risk evaluations that anticipates issuance of 75 orders plus two test rules and two enforceable consent agreements (ECAs) between FY 2023 and FY 2025. Finally, EPA's higher cost estimates for new chemical reviews under section 5 may enhance the scientific rigor and thoroughness of its safety determinations and enable it to improve the protectiveness of its decisions.

Requiring Substantially Higher Fee Payments in EPA's Final Rule

Although EPA has improved its estimates of TSCA implementation costs and justified higher fees than it required under the 2018 rule and 2021 proposal, the supplemental proposal still fails to collect sizable additional fees to which EPA is entitled under section 26(a). We recommend the following fixes to boost fee payments:

Assuring that fees for the 20 ongoing risk evaluations and subsequent risk management rulemakings are based on the higher fee estimates in the supplemental proposal.

Under §700.45(g)(3)(iv) of the proposed rule, fees for risk evaluations will be paid in two stages: a 50 percent payment due 180 days after EPA publishes the final scope of an evaluation and a remaining payment due no later than 545 days after scope publication. Since final scopes for nearly all of the 20 high-priority substances were published in August 2020, these deadlines have now passed. Thus, fee payments have likely already been made in accordance with the lower fee levels in the 2018 rule, which was in effect when the scopes were published. That rule required fees for each evaluation of $1,350,000 ($2,560,000 when adjusted for inflation) as compared to per evaluation fees under the supplemental proposal of $5,081,000.[4] 87 Fed. Reg. at 68654. Thus, fees collected for the 20 evaluations would have been *nearly $50,000,000 less* than under the supplemental proposal (or nearly *$75,000,000* less without the inflation adjustment).

Since the 20 evaluations are at an early stage and will likely continue for years, the higher fee levels in the supplemental proposal should apply. For these ongoing evaluations, the final EPA rule should be revised to trigger fee payments 60 days after the rule's effective date and these payments should be based on the higher section 6 fees in the rule, reduced by any fee payments previously made under the 2018 rule.

[4] One explanation for the higher section 6 cost estimates is that, as EPA indicates in the preamble to the supplemental proposal, its section 6 cost estimates for both the 2018 rule and 2021 proposal did not account for risk management rulemaking triggered by completed risk evaluations. 87 Fed. Reg at 68654. In the supplemental proposal, EPA assigns to risk management rulemaking $24.5 million of the $88.7 million in annual section 6 costs it projects for high-priority substances. 87 Fed. Reg. at 68654.

Assuring that fees for the 20 risk evaluations reflect the costs necessary to remedy deficiencies in the 10 initial evaluations

As EPA explains, in contrast to both the 2018 fees rule and 2021 proposal, the supplemental proposal reflects the actual costs of conducting the first 10 evaluations. However, these evaluations had numerous flaws and, in the 20 ongoing evaluations, the Agency is planning several enhancements in methodology to address pathways of exposure and risk that were not considered. These include a full assessment of air emissions and other environmental release scenarios and their impacts on fenceline communities and environmental justice populations; cumulative and aggregate risks reflecting exposure to multiple exposure sources, chemicals and non-chemical stressors; higher levels of susceptibility by vulnerable subpopulations; and determinations of risk on a whole chemical basis. However, EPA has not demonstrated that the cost estimates in the supplemental proposal account for the resources necessary to implement these additional risk evaluation elements. EPA should clarify whether they are included in its cost estimates and increase those estimates if they are not.

Collecting fees for the 10 initial risk evaluations and ongoing risk management.

EPA's initial 10 risk evaluations (which were not completed until the end of 2020) and the resulting risk management rulemakings (which will continue at least through 2025 if not longer) were exempt from fee collection under the 2018 rule. This is because the triggering event under the rule for paying fees for section 6 costs was publication of final risk evaluation scopes, which occurred in June 2017 for the 10 initial evaluations, before the rule took effect. This "grandfathering" of the 10 substances from fee collection was contrary to the intent of Congress and provided the manufacturers of these substances a free ride with no possible legal or policy justification. EPA's supplemental proposal recognizes that the Trump EPA made a huge mistake but, without any explanation, says that the Agency is not seeking to recover these unpaid fees.

There is no reason why EPA is now barred from collecting fees for the section 6 costs incurred on the 10 chemicals merely because it failed to do so in the 2018 rule. EPA and taxpayers should not continue to bear the brunt of highly questionable legal and policy judgments made five years ago by a different Administration. Based on the estimates of section 6 costs in the supplemental proposal, fee revenues for the 10 chemicals would total *$50,810,000 ($5,081,000 X 10).* A revenue shortfall of this magnitude is simply unacceptable when EPA has the ability, authority and motivation to undo the unjustified exclusion of the 10 evaluations from fee collection.

Requiring fees for information collection and management under TSCA sections 8 and 11.

Like the 2021 proposal and the 2018 rule, the supplemental proposal would not collect fees for implementation of TSCA sections 8 and 11. This exclusion rests on a misreading of the plain language of the law. Section 26(b)(1) expressly covers the costs of "collecting, processing, reviewing and providing access to . . . information on chemical substances under this title." Clearly, developing a section 8 rule or section 11 subpoena is part of "collecting . . . information on chemical substances under this title" (a term that encompasses the entirely of TSCA and therefore includes both of these provisions). Reviewing, managing and publicly disclosing information after its collection under sections 8 and 11 are also within the express scope of section 26(b)(1). EPA's ongoing and planned information collection and management activities under section 8 are extensive and growing. Their costs – likely totaling millions of dollars per year – should be subject to fee collection.

Even if limited to protection of confidential business information (CBI) under section 14, EPA's cost estimate of $1, 873,433 is grossly understated and does not begin to reflect the resources required for timely review of CBI claims in accordance with section 14 and meeting disclosure obligations under the Freedom of Information Act (FOIA). EPA must significantly increase section 14 cost estimates in addition to including sections 8 and 11 in the scope of fee triggering activities.

Addressing Other Exclusions from Fee Collection

The supplemental proposal should also expand fee collection to include the costs of TSCA compliance and enforcement by the Office of Compliance Assurance and Enforcement (OECA) and development, validation and peer-review of non-animal test methodologies for use in the TSCA program by the Office of Research and Development (ORD).

Case-by-Case Exemptions from Fee Requirements

We agree it may be beneficial to narrow the range of manufacturers and importers required to pay fees for section 4 and 6 implementation in order to reduce EPA transaction costs, increase certainty and simplify allocation of fees among liable parties. However, exemptions from fee payment should not relieve firms that contribute significantly to exposure and risk from defraying the costs of risk evaluations, risk management rules and testing requirements. Nor should exemptions limit the universe of responsible entities to the point where EPA cannot recover industry's full share of the Agency's costs. Thus, while establishing across-the-board exemptions, EPA should reserve discretion to modify them as warranted on a chemical-by-chemical basis by adjusting the scope of fee exemptions where needed during the scoping process for each risk evaluation.

Application of Fee Requirements to Processors

The same considerations that warrant case-by-case exemptions from fee payments by manufacturers should apply to fee payments by processors. TSCA section 26(b)(4)(C) directs that EPA's fee rule must "reflect an appropriate balance in the assessment of fees between manufacturers and processors." As Congress recognized, there will be occasions where processing activities contribute significantly to the risks that EPA seeks to address under sections 4 and 6. In these cases, processors should not get a free ride on TSCA implementation costs. Thus, EPA should grant exemptions to processors on a case-by-case basis, determining at the scoping stage whether some, all or no processors should pay fees because of the exposure and risk profile of the chemical at hand or the need to prevent fee shortfalls because there are too few entities to assure full fee payment.

Preventing Manufacturers and Processors from Gaming the System

Principles of environmental accountability require that all manufacturers who are actively contributing to the risks that EPA is evaluating or managing bear an appropriate share of the Agency's section 6 costs, without regard to whether they previously produced the chemical and when that production occurred. Accordingly, 40 CFR §700.45(b)(5) must assure that all firms who start manufacture or importation within the five years following the initial assessment of fees must self-identify to EPA and then make fee payments.

I. EPA's Supplemental Proposal is Based on a More Defensible and Realistic Analysis of the Costs of Implementing TSCA's Goals and Deadlines

A. Current Resources for TSCA Implementation are Grossly Inadequate

As the Biden EPA has repeatedly emphasized, the Agency lacks the resources to carry out the mandates and meet the deadlines in the 2016 TSCA amendments. This is because Congress has failed to appropriate sufficient funding (initially as a result of inadequate budget requests by the Trump Administration) and fee collections from industry have fallen well below the amounts authorized in the law (again the result of the Trump EPA's underestimation of implementation costs). Making matters worse, EPA's resources have stagnated while its responsibilities and workload have grown substantially as additional requirements of the law have taken effect. As a result, EPA has fallen far behind schedule in meeting core TSCA milestones.

These crippling delays have taken a heavy toll on the new prioritization, risk evaluation and risk management process in section 6, the central driver in the amended law for determining the risks of chemicals of concern and strengthening protection of at-risk populations. For example, EPA listed 20 high priority substances in December 2019, triggering risk evaluations that were required to be completed in 3.5 years under section 6(b)(4). Yet all of these evaluations are still

underway, and EPA has indicated that only 7 will be finalized by the end of the first Biden term in January 2025.

Moreover, conducting these evaluations will likely require a higher commitment of resources than the first 10 evaluations. These evaluations had serious flaws and limitations that were highlighted by EPA's independent Science Advisory Committee on Chemicals (SACC) and our comments and must be remedied in ongoing and future evaluations.[5] These evaluations will also need to address "legacy" exposures from continuing use and disposal of products no longer distributed in commerce, as required by the Ninth Circuit decision in *Safer Chemicals, Healthy Families v. EPA*, 943 F.3d 397 (9th Cir. 2019). Meeting these requirements will require information collection, modeling and analysis in excess of EPA's work effort for the first 10 evaluations, adding to EPA's costs. EPA should not cut corners on necessary and legally required improvements to its risk evaluations because it failed to estimate their full costs.

Similarly, all of EPA's 10 initial risk evaluations made determinations of unreasonable risk, requiring promulgation of risk management rules under section 6(a). Yet to date, only one such rule – for asbestos -- has been proposed. Six of the remaining proposals are expected in 2023 and finalizing these proposals by the end of 2024 will be challenging. The substances subject to these rulemakings, such as methylene chloride, trichloroethylene and perchloroethylene, have widespread exposure and serious adverse effects, so rulemaking delays will have serious public health consequences. Again, the need to revise and strengthen the Trump EPA's risk evaluations before proceeding to risk management has both increased resource demands and slowed down rulemakings on the 10 substances. According to EPA's regulatory agenda, risk management rulemakings for 3 of the initial 10 substances will not be initiated until the next Presidential administration.

EPA's premanufacture notification (PMN) program under section 5 has also suffered from resource constraints. Congress expanded EPA's mission under section 5 in 2016 by requiring it to make safety determinations for all new substances. Under the law, EPA is directed to regulate all new substances under section 5(e) orders unless it finds that they are not likely to

[5] The omissions and flaws identified by the SACC and our comments included: (1) excluding environmental pathways from determinations of risk rather than accounting for the contribution of air, water, and waste contamination to total exposure and risk; (2) picking and choosing which conditions of use to address rather than determining risks for all conditions of use; (3) failing to aggregate risks across routes and pathways of exposure by adding together dermal and inhalation exposure and combining overlapping exposures in workplaces, homes and the ambient environment; (4) limiting evaluation of risks to consumers to acute exposure scenarios and excluding continuous use conditions that can cause chronic health effects; and (5) inadequately implementing the statutory requirement to identify and make unreasonable risk determinations for "potentially exposed or susceptible subpopulations," *i.e.* by identifying communities with elevated exposures or at greater risk because of preexisting conditions, health or economic status or other risk factors and meaningfully quantifying the degree of increased risk faced by these vulnerable groups.

present unreasonable risks. Under intense pressure from industry, the Trump EPA took legally questionable steps to circumvent these requirements after the Obama EPA had been complying with the law. Now, the Biden EPA has reversed course in several areas, reinstating interpretations of section 5 that conform to the law and increase protection of health and the environment. Although industry has complained about delays in completing PMN reviews, a much bigger concern is shortcomings in the quality and thoroughness of EPA risk assessments for new chemicals, particularly PFAS, that are resulting in under-protective restrictions and insufficient testing of new substances under section 5(e) orders.

Recognizing that original TSCA had failed to require significant testing of chemicals by industry, the new law also streamlined the process for chemical testing under section 4 to inform risk evaluation and management efforts. Congress expected that new authority to issue test orders in lieu of more cumbersome and time-consuming rules would result in significantly more health and environmental studies on substances lacking data for an informed understanding of risk. However, this authority went virtually unused by the Trump EPA. And while more testing orders have been issued by the Biden EPA, they have applied to a small universe of substances and called for a limited set of studies. Despite interest, EPA has been unable to launch a comprehensive effort to identify and fill data gaps on candidate substances for high-priority listing that would assure that needed studies are completed in advance of prioritization and risk evaluations.

B. <u>The 2018 Rule and 2021 Proposal Failed to Address Unmet EPA Resource Needs</u>

In light of EPA's inability to fully implement the 2016 law, it is deeply unfortunate that the fee collection efforts of the Trump EPA refused to recognize and address the Agency's unmet resource needs. EPA's 2018 fee rule estimated annual costs of $80.2 million to carry out TSCA provisions subject to fee collection and projected fee payments of $20 million per year. Our comments on the proposed rule expressed concern that these estimates greatly understated anticipated TSCA implementation costs and that a more realistic analysis based on the EPA resource levels necessary to meet TSCA requirements would require significantly larger fees.[6] We also emphasized that, as EPA's TSCA program expanded, its workload would increase rapidly and resource limitations would increasingly constrain its ability to deliver on TSCA's mandates. Two areas of particular concern we raised were the lack of any fee collection for the first 10 evaluations and for information collection and management under sections 8 and 11.

[6] Comments of Safer Chemicals Healthy Families, et. al. on Proposed User Fees for the Administration of the Amended Toxic Substances Control Act, Submitted via Regulations.gov (May 24, 2018) Docket ID EPA-HQ-OPPT-2016-0401.

However, despite these deficiencies, EPA's final rule made no adjustments in its estimate of TSCA resource needs and the size of industry fees.

EPA's 2021 proposal made negligible changes in the fee collection framework in the 2018 rule. Largely ignoring EPA's experience with TSCA implementation during the previous 3 years, it estimated eligible TSCA costs for FY 2022 through FY 2024 at $87.5 million and set industry fees at $22 million. While program costs and fee levels for section 6 implementation modestly increased compared to the 2018 rule, costs and fees for section 4 and section 5 implementation were unchanged despite the need for additional resources to realize the full benefits of these underperforming programs. As before, we cited as serious omissions the lack of fee collection for the initial 10 risk evaluations and risk management rulemakings and for information collection and management. And again, our comments expressed serious concern that EPA's estimates of TSCA implementation costs remained significantly understated and therefore fee levels would be inadequate.[7] We emphasized that low-balling TSCA costs and fees at a time when EPA needed substantially more resources for a higher performing program that would meet the goals of the amended law was a recipe for disaster.

As described by EPA, the reanalysis of TSCA implementation costs in support of EPA's supplemental fee proposal is informed by "a more accurate estimate of its anticipated costs to implement TSCA in the manner envisioned by Congress when it amended the law in 2016" and "includes what the Agency believes is a much more reliable estimate of the resources needed for the anticipated implementation efforts than the inaccurate cost estimate that was previously used." 87 Fed. Reg. at 68651. This forward-looking approach is more defensible because it determines fee levels based not on existing EPA costs for an underperforming program but on projected resource needs for a more robust program that fulfills the vision of the 2016 law and makes up for the previous shortfalls in funding and implementation. This is consistent with the directive in section 26(b)(1) to set fees at a level "sufficient . . . to defray the cost of . . . administering sections 4, 5, 6 and" TSCA information management activities.

Applying this improved approach, the supplemental proposal estimates the costs of carrying out fee-triggering TSCA authorities at approximately $181.9 million each year. 87 Fed. Reg. at 68651. This compares to EPA's cost estimates of $87.5 million in the 2021 proposal and $80.2 million in the 2018 rule. Based on the 25 percent target in the law, EPA anticipates collecting fees of $45.5 million each year under this higher cost estimate, over twice estimated annual fee collections of $22 million under the 2021 proposal and $20 million under the 2018 rule.[8] (These

[7] Comments of Safer Chemicals Healthy Families, et al on Proposed Fees for the Administration of the Amended Toxic Substances Control Act, EPA-HQ-OPPT-2020-0493, Submitted via Regulations.gov (March 27, 2021)
[8] Economic Analysis of the Supplemental Notice of Proposed Rulemaking for Fees for the Administration of the Toxic Substances Control Act, October 22, 2022, EPA-HQ-OPPT-2020-0493; RIN 2070-AK46)(Economic Analysis)

fee projections do not account for the costs of manufacturer-requested risk evaluations. Fees for these evaluations are estimated to yield nearly $6 million under the 2023 proposal).

The 2023 proposal explains in detail why the 2018 and 2021 cost estimates were roughly half of those in the 2023 proposal. The earlier estimates were calculated "using the costs for implementing TSCA before the law was amended and thus before EPA was required to carry out any of its new responsibilities." Thus, they did not consider "what it would cost the Agency to implement the revised law in the manner envisioned and directed by Congress." Consequently, EPA "did not conduct a comprehensive budget analysis designed to estimate the actual costs of implementing the amended law until the spring of 2021." 87 Fed. Reg. at 68648. In addition, the 2018 rule's "failure to collect any fees associated with any of the first 10 risk evaluations resulted in collection of roughly half of the (artificially-low) baseline costs EPA has the authority to collect." Id. at 68650. And EPA further excluded "any costs of section 6(a) risk management activities that are now required to be underway for the first 10 chemical substances or that will be required for any of the 20 High Priority Substances for which the Agency finds unreasonable risks." Id.

Another cause of EPA's under-estimation of TSCA implementation costs in 2018 and 2021 was identified in a December 29, 2022 report of the EPA Office of Inspector General (OIG).[9] The report found (p. 8) that EPA's "revised methodology did not adequately capture all expenses for carrying out sections 4, 5, 6, and 14 of TSCA, . . . [including] expenses funded prior to FY 2019, payroll expenses for employees working in direct-cost divisions, and additional indirect costs." The costs omitted totaled $24,565,454. At a 25 percent recovery rate, projected industry fees would have been $6 million higher had this sum been included in EPA's determination of costs eligible for fee recovery.

The OIG also found that, while EPA anticipated collecting approximately $20 million in fees in FYs 2019 and 2020, the fees it actually received were significantly less, totaling only $2.7 million and $3 million respectively. This shortfall occurred because EPA overestimated the number of PMN actions that would trigger fees under the 2018 fees rule[10] and the rule failed to capture any of the costs of the initial 10 risk evaluations, by far the biggest component of the TSCA program during these years. Thus, OIG concluded (p. 5) that the rule "did not meet the intent of TSCA to defray 25 percent of the specified costs of carrying out sections 4 and 5, parts of section 6, and section 14."

[9] EPA Office of Inspector General, *The EPA's Fiscal Years 2020 and 2019 Toxic Substances Control Act Service Fee Fund Financial Statements,* Report No. 23-F-0005

[10] In its 2018 rule, EPA assumed that it would receive 462 PMN/SNUN submissions and 560 exemption applications per year, nearly twice the estimate in the 2021 proposal. 83 Fed. Reg. 52704.

C. Estimated TSCA Implementation Costs in the Supplemental Proposal More Accurately Reflect EPA Resource Requirements

In estimating TSCA implementation costs twice as large as EPA estimated in 2018 and 2021, the supplemental proposal makes more supportable assumptions about the level of activity and associated workload necessary for a fully functioning TSCA program.

For example, Section 6(b) of TSCA required that EPA designate and initiate risk evaluations on at least 20 high-priority substances by December 2019 and complete these evaluations in three years, with a six-month extension if necessary. Completion of each evaluation triggers an obligation to designate another high-priority substance, for which a risk evaluation must also be completed in 3-3.5 years. However, recent delays in performing evaluations have shown that "at current funding and staffing levels, 20 risk evaluations will not be completed within the statutory timeframe." 87 Fed. Reg. at 68650. Instead of accepting the current unacceptable rate of progress, the section 6 cost estimates in the supplemental proposal are based on an assumption that "EPA's workforce will be involved in at least 20 EPA-initiated chemical risk evaluations at all times, and that each risk evaluation will take three and a half years to complete."[11] Maximizing fee collection in support of the section 6 program will "enable EPA to significantly improve on-time performance and quality," even though more funding from Congress is necessary to fully meet the statutory deadlines. 87 Fed. Reg. at 68650.[12]

Another example is the supplemental proposal's projection of substantially increased costs to implement section 4 testing requirements. The 2018 rule and 2021 proposal assumed that EPA would initiate work on 10 testing orders each year and one test rule and testing consent agreement every two years.[13] By contrast, the supplemental proposal estimates issuance of 75 orders plus two test rules and two testing consent agreements between FY 2023 and FY 2025. This dramatic increase in testing activity will be considerably more effective in filing data gaps on chemicals of concern, better reflecting the 2016 law's commitment to accelerating health and environmental effects testing by manufacturers. According to EPA, it "intends to expand the use of Section 4 authorities significantly moving forward to inform prioritization of substances for risk evaluation and develop the most scientifically-sound risk evaluations of those chemical substances." 87 Fed. Reg. at 68652. More testing orders will also "advance additional information development activities through TSCA section 4, such as the issuance of test orders for certain PFAS, as informed by the National PFAS Testing Strategy." Id. at 68650. These are important goals that received short shrift by the Trump EPA; additional resources for

[11] Technical Support Document Supplemental Notice of Proposed Rulemaking; Fees for the Administration of the Toxic Substances Control Act (TSCA) (RIN 2070-AK46), at 5.

[12] It appears that EPA has also failed to collect fees for other section 6 activities, such as development and implementation of the rules reducing exposure to five PBTs required under section 6(h), which were promulgated in early 2020, and rulemaking and related activities on PCBs under section 6(e) of TSCA. These activities are not mentioned in the supplemental proposal.

[13] 86 Fed. Reg. 1893.

testing orders will greatly enhance EPA's ability to make risk judgments on chemicals informed by the best available science.[14]

EPA has also recognized that previous cost estimates for the section 5 PMN program greatly understated the resources required to implement the more comprehensive approach to new chemical review required in the 2016 amendments. Under section 5(a)(3), EPA must now make determinations of safety for all new substances. This requires an in-depth assessment of exposure and risk for many more chemicals than under the old law. Along with enhancing the rigor and depth of analysis of its PMN reviews and obtaining more reliable and complete information from submitters, additional resources will help address these issues. As EPA explains:

> The updated estimate provides a more comprehensive accounting of program implementation, which includes, but is not limited to: (1) costs incurred by EPA for multiple rounds of revisions to the risk assessment due to late submission of information or rebuttals by companies, (2) multiple rounds of risk management actions, redactions and posting of final reports to meet transparency commitments while safeguarding CBI, (3) IT infrastructure maintenance and enhancement to ensure the quality and safeguard of data collection, storage and reporting, staffing and contractor support from supporting offices such as the Office of General Counsel (OGC), the Office of Enforcement and Compliance Assurance (OECA), and the Office of Research and Development (ORD), among others, and (4) other operational costs that were not previously captured or fully itemized.

87 Fed. Reg. at 68651. Under EPA's new estimates, PMN program costs have increased to $54,162,600 annually from $41,998,820 in the 2021 proposal. 86 Fed. Reg. at 1893. This will result in higher fees per submission but the additional resources devoted to each new chemical and significant new use review will enable EPA to enhance the scientific rigor and completeness of its safety determinations and improve the quality of its decisions.

II. Despite Improvements, the Supplemental Proposal Falls Significantly Short of Requiring the Full Amount of Fees that TSCA Authorizes EPA to Collect

Although EPA's estimates of its costs under TSCA better correspond to program realities and provide additional resources for implementing the law, the proposal would still fail to collect

[14] Our comments on EPA's draft risk evaluations and proposed high-priority listings have demonstrated significant data gaps which should be filled to assure high-quality, health-protective determinations of unreasonable risk. The test orders EPA has issued to date are both too few and too narrow in scope to fill this need. Along with other groups, we have also advocated a pre-prioritization process that would screen candidate chemicals for data-gaps before formal prioritization – an approach EPA included in its 2017 proposed prioritization rule but did not pursue during the Trump years. Were EPA to reinstate this approach, there would be significantly more testing orders, rules and consent agreements, resulting in a considerably larger workload under section 4 and greater costs to EPA.

the full amount of fees that are authorized under section 26(b). **Because of flaws in the rule's design, continued underestimation of costs in certain areas and unnecessary exclusions of eligible activities from fee collection, EPA is foregoing many millions of dollars in fees that it has authority to require industry to pay. This is a missed opportunity to obtain desperately needed funding for the TSCA program.** We recommend below several steps EPA should take in the final rule to increase fee payments.

A. Fee Collections for Ongoing Section 6 Activities for the 20 High Priority Chemicals Would Be Based on the 2018 Rule Rather than Updated Cost Estimates in the Supplemental Proposal

Despite more robust and realistic estimates of section 6 costs, we are concerned that the supplemental proposal's higher fees for section 6 activities *will not* govern fee collection for ongoing risk evaluations and anticipated risk management rulemakings on the 20 chemicals designated high-priority in December 2019. As described below, fee collection on these activities was likely accomplished under the 2018 rule, with fee payments for the section 6 program much smaller than warranted by the most current and reliable estimates of EPA's costs.

As EPA explains in the preamble, proposed §700.45(g)(3)(iv) provides that fees for risk evaluations will be paid in two stages: "the first payment of 50 percent [will be] due 180 days after EPA publishes the final scope of a chemical risk evaluation and the second payment [will be] due not later than 545 days after EPA publishes the final scope of a chemical risk evaluation." 87 Fed. Reg. at 68655. According to the EPA Website, final scopes were published in August 2020 for nearly all of the 20 high-priority substances. Thus, deadlines for making fee payments for the ongoing evaluations have already passed.

This would mean that fees for these evaluations would be governed by the 2018 rule, not the supplemental proposal. Since that rule required payment within 120 days of publication of the final risk evaluation scope, these fees likely have already been paid. The amounts collected would have necessarily been based on the fee levels in the 2018 rule. Under that rule, fees per risk evaluation were set at $1,350,000 ($2,560,000 under EPA's 2022 adjustment for inflation). By contrast, per evaluation fees under the supplemental proposal are $5,081,000.[15] 87 Fed. Reg. at 68654. This means that EPA has likely collected *nearly $50,000,000 less* in fees than called for by the supplemental proposal based on EPA's current projections of risk evaluation

[15] One explanation for the higher section 6 cost estimates is that, as EPA indicates in the preamble to the supplemental proposal, its section 6 cost estimates for both the 2018 rule and 2021 proposal did not account for risk management rulemaking triggered by completed risk evaluations. 87 Fed. Reg at 68653. In the supplemental proposal, EPA assigns $24.5 million of the $88.7 million in annual section 6 costs to risk management. 87 Fed. Reg. at 68654.

and risk management costs. (Without the inflation adjustment, the fees shortfall would be nearly $75,000,000).

Since the bulk of the work on the 20 evaluations has not yet begun and risk management rulemakings are years off, most of EPA's costs have not yet been incurred. It makes no sense to base industry fees for these future activities on a methodology that dramatically underestimates how much they will actually cost the Agency. This would only compound the resource shortages that are now making it more difficult for EPA to complete the 20 evaluations by the statutory deadlines and delaying risk management by several years.

We strongly recommend that, for the 20 ongoing risk evaluations, the rule should be revised so that fee payments are no longer trigged by publication of the scopes in August 2020. Instead, payments should be triggered 60 days after the rule's effective date. These payments should be based on the per evaluation fee amounts in the rule, reduced by any fee payments previously made under the 2018 rule. Going forward, as EPA resets and updates fee amounts in future rule iterations, it should likewise trigger payments for ongoing evaluations at the new fee levels, after crediting previous payments. This will assure that current estimates of implementation costs are the basis for determining fees for ongoing section 6 activities. Otherwise, EPA will continue to collect smaller fees than current cost estimates warrant, reducing fee collections below the statutory target for years to come and adding to resource constraints and program delays.

B. <u>EPA Has Not Shown That Its Revised Cost Estimates Are Sufficient to Cover the Costs of Planned Improvements in Risk Evaluation Methodology</u>

EPA has recognized that both the 2018 fees rule and the 2021 proposal substantially underestimated the costs of the first 10 evaluations. The supplemental proposal increases these estimates based on the actual costs of the 10 evaluations. However, the Agency recognizes that they had numerous flaws and, in the 20 ongoing evaluations, is planning several enhancements in methodology to better determine unreasonable risks under the law.

For instance, the Biden Administration's FY2023 Budget Request stated that EPA "is conducting aggregate exposure and cumulative risk approaches to characterizing chemical exposure and risk in risk evaluations under TSCA."[16] EPA is also preparing two new guidance documents on the consideration of cumulative risk in evaluations under TSCA, which it expects to release for public comment and peer review next month. But EPA's supplemental fees proposal and its underlying economic analysis and technical support document do not mention aggregate or cumulative risk assessment, raising questions as to whether EPA has adequately accounted for the costs associated with those critical activities.

[16] EPA FY2023 Budget Justification at 495.

Similarly, EPA has stated its intent to "consider[] … exposure pathways (i.e., air, water, disposal) that were originally omitted from the scopes of the [EPA-initiated] and [manufacturer requested] risk evaluations, and to address 'fenceline' risk (risks to exposed populations in communities adjacent to the perimeter of manufacturing facilities, often vulnerable and underserved populations . . ."[17] EPA's 2022 *Legal Tools to Advance Environmental Justice* similarly advises that "in estimating the agency's costs [when setting fees], the Agency could incorporate relevant environmental justice work, such as characterizing fenceline communities for TSCA § 6 risk evaluations, into [its] underlying costs."[18] Achieving those objectives – both of which are required by TSCA – will require increased information gathering about fenceline community exposures and previously-excluded exposure pathways, and will also entail additional work at the risk evaluation and risk management stage to evaluate and address any unreasonable risks associated with those exposures. EPA's supplemental fees rule and supporting documents are silent on those necessary activities as well.

TSCA requires EPA to consider unreasonable risks to potentially exposed and susceptible subpopulations (PESS), including fenceline communities and groups that experience greater susceptibility because of their cumulative exposures to multiple chemicals and non-chemical stressors. EPA has indicated that its assessment of unreasonable risks to PESSs will be more robust and inclusive in the ongoing 20 evaluations than in the first 10, responding to recommendations of the SACC and public commenters as well as the requirements of the law.

In order to assure that its "TSCA section 6 cost estimates have been informed by the Agency's experience conducting evaluations for the first 10 chemical substances," 87 Fed. Reg. 68652, EPA must account for the added costs of implementing improvements in methodology that address deficiencies in these evaluations. Thus, the cost estimates for the ongoing risk evaluations should factor in the resources necessary to address environmental exposure pathways, fenceline community risks, and aggregate and cumulative exposures. EPA should clarify whether such costs have been included in the supplemental rule, and if not, should adjust its cost estimates to account for them.

C. <u>EPA Must Revise Its Rule to Require Manufacturers and Importers of the 10 Risk Evaluation Chemicals to Contribute to the Costs of these Evaluations and Risk Management Rulemakings</u>

As EPA emphasizes in the supplemental proposal, the failure of the 2018 rule to cover the first 10 risk evaluations was a mistake that deprived EPA of fee revenues for its principal area of activity during the initial years of TSCA implementation. 87 Fed. Reg. at 68650. In our comments on the 2018 proposed rule and on the 2021 proposal, we highlighted this basic flaw

[17] Id. at 490.
[18] EPA, Legal Tools to Advance Environmental Justice at 124.

in EPA's approach and the unnecessary loss of funds critical to meeting the Agency's resource needs. Our comments recommended changes to the proposed rules that would expand fee collection to include the 10 evaluations and follow-up risk management rulemakings. EPA rejected this recommendation in the final 2018 rule preamble but did not meaningfully explain its rationale. 83 Fed. Reg. at 52708. Now, in the supplemental proposal, EPA reiterates that it "will not be collecting fees for the first 10 risk evaluations" but again fails to justify foregoing millions of dollars in fees to which it was entitled under the law. 87 Fed. Reg. at 68649.

The "grandfathering" of the 10 risk evaluations under the 2018 rule resulted from the same flaw in design (discussed above) that will preclude recovery of fees for the 20 ongoing evaluations at the higher fee levels in the supplemental proposal. The 2018 final rule took effect on October 18, 2018 and generally imposed fee obligations on industry for TSCA implementation activities occurring after October 1, 2018. However, like the supplemental proposal, the rule provided that the triggering event for fee payments for EPA-initiated risk evaluations was the publication of final risk evaluation scopes. 40 CFR ¶700.45(g)(3)(iv)(A). Since scopes for the 10 chemicals were published in June 2017, the 10 risk evaluations were therefore exempt from fee collection under section 26(b).

In the preamble to the final 2018 rule, EPA defended this exemption as follows:

> A number of commenters requested that EPA explicitly state whether fees will apply to certain ongoing activities, such as the first 10 chemical risk evaluations and TSCA section 5 submissions under review at the time the rule is finalized. To be clear, EPA will not collect fees for events that started prior to October 1, 2018 such as the first ten risk evaluations, or any TSCA section 5 activities initiated before that date. In these cases, the fee event is already ongoing, and EPA has determined not to retroactively apply fee obligations on these manufacturers.

83 Fed. Reg. 52708. Despite EPA's 2018 position, neither TSCA nor any other law dictates that EPA cannot collect fees for ongoing activities under section 6 merely because they had already been initiated before the 2018 rule took effect. While EPA had completed scoping documents and other preliminary risk evaluation tasks by this date, its work on the evaluations continued until the end of 2020. Moreover, risk management rulemakings for the 10 chemicals are still at an early stage and will extend until the end of 2024 for some chemicals and even later for others. To collect fees for this work plainly does not impose "retroactive" liability on industry since the bulk of the fee-triggering activities would have occurred *after* the 2018 rule took effect.

Moreover, section 26(b)(4)(B) underscores that the purpose of fee collection is to "provide a sustainable source of funds to annually defray . . . 25 percent of the costs to the Administrator of carrying out sections 4,5 and 6" of TSCA. There is no indication in the statute that Congress

wanted only a portion of EPA's costs under section 6 to be subject to fees or intended to exempt ongoing activities initiated before the fee rule took effect even though they would continue for several more years. As the preamble to the final 2018 rule itself acknowledges, "EPA believes it was Congress' intent for EPA to be able to start assessing fees as quickly as possible after the enactment of the fee provisions and that fees would already be in place by October 1, 2018." 83 Fed. Reg. 52707. To preclude fee recovery for the initial 10 evaluations and risk management rulemakings – by far the biggest EPA priority in the initial years of implementing amended TSCA and an effort spanning several years – would be contrary to these clear expectations and undermine the Congressional goal of assuring that industry contributes its fair share of the costs of implementing TSCA.

D. EPA Misreads the Plain Statutory Language By Excluding the Costs of Information Collection and Management from Fee Collection and Underestimates CBI Costs

TSCA section 26(b)(1) directs EPA to collect fees to defray the costs of "collecting, processing, reviewing and providing access to and protecting from disclosure under section 14 information on chemical substances under this title." EPA's 2021 proposal estimated that the annual cost of these activities for FY 2022-24 will be $1, 873,433 – a surprising (and unexplained) reduction from the $4,346,000 estimate in the 2018 rule. (Compare 86 Fed. Reg. 1895 to 83 Fed. Reg. at 52703). The supplemental proposal nonetheless uses the 2021 estimates, explaining that "EPA is making minimal changes to estimates of program costs of collecting, processing, reviewing, and providing access to and protecting from disclosure as appropriate under TSCA section 14 information on chemical substances that were previously described in the 2021 Proposal." 87 Fed. Reg at 68653.

EPA's approach excludes information collection and management activities under TSCA sections 8 and 11 that are subject to fee recovery under the plain language of section 26. It also underestimates the resource commitment required to implement CBI protections in accordance with the law. Effectively addressing these two concerns will enable EPA to collect significantly greater fees than under the supplemental proposal.

In the 2021 proposal, EPA explained why it excluded information collection and management under TSCA sections 8 and 11 from the scope of fee recovery:

> EPA does not believe that Congress intended EPA to offset costs associated with administering authorities under these other sections. The statutory text clearly points to the authorities of TSCA sections 4, 5, 6 and14. If the costs of administering activities under TSCA sections 8 and 11 were intended to be defrayed with fees, Congress would have specifically included those authorities in the statutory text.

86 Fed. Reg. 1894-95. However, although section 26(b)(1) does not mention sections 8 and 11 specifically, it expressly covers the costs of "collecting, processing, reviewing and providing access to . . . information on chemical substances under this title." Clearly, developing a section

8 rule or section 11 subpoena is part of "collecting . . . information on chemical substances under this title" (a term that encompasses the entirely of TSCA and therefore includes both of these provisions). Reviewing, managing and publicly disclosing information after its collection under sections 8 and 11 is within the express scope of section 26(b)(1) as well. While the statutory language also includes "protecting [information] from disclosure under section 14," this is only one of several covered activities eligible for fee collection. If Congress had wanted to require fees only for the cost of CBI protection under section 14, it would have drafted section 26(b)(1) very narrowly instead of including all components of information collection and management under the law.

In sum, TSCA directs EPA to imposes fees to recover the costs of section 8 rulemaking and section 11 subpoena development as well as related activities such as webinars, guidance documents and other efforts to educate the regulated community about reporting obligations. EPA is also required to collect fees for the costs of designing electronic reporting systems and processing, organizing, reviewing and disclosing submitted information along with protecting CBI consistent with section 14.

Information collection and management have been, and continue to be, high priorities for EPA under TSCA. For example, in August 2017, EPA promulgated a reporting rule requiring industry to identify active and inactive substances listed in the TSCA Inventory as required by section 8(a)(4). 82 Federal Register 37520 (August 11, 2017) After reports were submitted on October 5, 2018, EPA overhauled the Inventory so it differentiated between active or inactive substances in U.S. commerce. Starting on August 5, 2019, manufacturers and processors were required to notify EPA before reintroducing inactive substances into U.S. commerce.

In 2020, EPA updated Chemical Data Reporting (CDR) requirements (40 CFR Part 711) in advance of the 2020 reporting cycle and the reporting period ended on January 29, 2021 after considerable outreach and guidance to the regulated community. EPA received thousands of reports providing information on the production and use of chemicals in commerce. EPA then embarked on the resource-intensive phase of compiling, reviewing and analyzing these reports. The next CDR update will occur in 2024 and EPA will need to complete all these steps again.

On June 28, 2021, EPA also proposed new section 8(a)(7) reporting requirements for Per- and Polyfluoroalkyl Substances (PFAS) as directed by the 2019 National Defense Authorization Act (NDAA). 86 Fed. Reg. 33926. These rules, expected to be finalized early in 2023, will require reporting of extensive information on hundreds if not thousands of PFAS. Both administering the reporting process and managing and analyzing the voluminous information submitted will be highly resource-intensive. EPA is also planning to propose expanded "tiered" section 8 reporting requirements for chemicals listed and/or under consideration for listing as high-priority substances under section 6(b). These rules would augment CDR reporting by requiring reporting of more comprehensive use and exposure information on substances that are likely to receive close scrutiny in risk evaluations. Finally, EPA will need to devote continuing resources to managing ongoing reporting programs like health and safety study submission

under section 8(d) and substantial risk reporting under section 8(e), both of which trigger regular transmittal of study reports and other information to the Agency.[19]

In sum, the demands on EPA resources from both completed and anticipated section 8 rulemakings are obviously substantial and likely account for millions of dollars in costs to the Agency annually. Exclusion of these costs from fee collection both is contrary to TSCA and will deprive EPA of revenues that are critical for successful implementation of the law.

Moreover, for the section 14 CBI protection activities that EPA considers eligible for fee recovery under section 26(b), the Agency's estimated costs are disturbingly low. EPA says that "[i]ncreased resources will ensure EPA continues to establish improved processes, systems, and procedures to enable submitters to provide the information required when making CBI claims and to facilitate EPA's review, whenever applicable under TSCA section 14." 87 Fed. Reg. 68650. Yet both the 2021 and supplemental proposals actually lowered estimated CBI costs by nearly 60 percent from its 2018 estimates, a reduction hardly conducive to building increased capacity for timely processing and review of CBI claims.

The CBI protection framework established by the 2016 TSCA amendments is unusually complex and elaborate. Under section 14, EPA must now require information submitters to substantiate most of their CBI claims. Thus, it must identify the elements that substantiation must contain, review industry submissions to assure that it is complete, and determine whether the submitters have demonstrated that they meet the criteria for CBI protection. For the first time, all CBI claims for chemical identity and 25 percent of all other claims must be evaluated within 90 days and accepted or denied. There are several exemptions from CBI protection that must be applied on a case-by-case basis.

As detailed in the 2018 rule and the 2021 proposal (83 Fed. Reg. 52703; 86 Fed. Reg. at 1895), meeting these obligations requires numerous tasks that have added significantly to EPA's workload:

> Specific activities considered . . . under section 14 include: Prescreening/ initial review; substantive review and making final determinations; documents review and sanitization; regulation development; IT systems development; and transparency/communications.
>
> Estimates also include Office of General Counsel costs associated with coordinating, reviewing, issuing, and defending TSCA CBI claim final determinations, and supporting guidance, policy and regulation development for TSCA section 14 activities, *e.g.,* implementing the unique identifier provisions, ensuring access to TSCA CBI for emergency personnel, states, tribes and local governments, and developing the TSCA CBI sunset provisions, among others.

[19] For an extended period, EPA failed to include substantial risk notices under section 8(e) in its internal data-bases or disclose them to the public because of claimed resource limitations.

Other chemical information management activities included in the analysis are: Costs for implementing the requirements in TSCA section 14(d); costs for implementing the CBI sunset requirements; costs for Notice of Activity chemical identity CBI claim reviews; costs for Freedom of Information Act-Related CBI claim reviews; costs for providing public access to Non-CBI Data; and IT costs for operating and maintaining the CBI Local Area Network (LAN).

The heavy workload created by these tasks has steadily grown as the TSCA program has expanded. New information collection requirements will only increase the volume of CBI claims and the resources necessary to process them. For example, the 2024 CDR update will require EPA to process thousands of CBI claims with accompanying substantiation; reports under the upcoming section rule 8 for PFAS will likewise include extensive CBI claims requiring EPA review; the anticipated tiered reporting rule for prioritization candidates will be another source of CBI claims; PMN, SNUN, LVE and LoREX submissions under section 5 will continue to redact extensive information claimed CBI; the confidentiality of toxicological data on risk evaluation chemicals will continue to raise CBI issues as EPA proceeds with the ongoing 20 evaluations; and a growing number of CBI claims for data developed under section 4 can be expected as EPA ramps up testing orders.

It is hard to fathom how EPA can efficiently manage this burgeoning workload with a budget of $1,873,433 and only 8.6 FTE.

Right now, the perception of CBI claimants and FOIA requestors is that the TSCA CBI system is plagued by lengthy and frustrating delays caused by lack of resources and overburdened EPA staff. Waiting times for FOIA responses typically are many months and even years. In addition, reviewing CBI substantiation and determining the validity of CBI claims are extending far beyond TSCA deadlines, causing unwarranted CBI claims to be upheld by default. Although the carefully crafted CBI provisions of the 2016 TSCA amendments aspired to increase transparency, EPA's dysfunctional CBI and FOIA review processes have had the opposite effect.

Given EPA's commitment to transparency, it should be boosting the fees it collects under section 26(b) so it can better fund the increased investment in staff expertise and workflow efficiency required for a functional and responsive CBI process and speedy action on FOIA requests. Continued underestimation of the size of this investment will worsen the staff shortages and underfunding of information management systems that are causing unacceptable logjams in public information access. Accordingly, we urge EPA to significantly increase the costs it estimates for information collection and processing and CBI protection under TSCA so that fees that reflect the true challenges EPA is facing.

E. Estimates of the Costs of Administering TSCA Should Account for the Compliance and Enforcement Activities Necessary to Assure Compliance with the Law

Neither the 2018 final fees rule nor the 2021 or supplemental proposals include compliance monitoring, assistance and enforcement in determining industry fee obligations under TSCA.

Yet these activities are critical in assuring the successful implementation of the law. Without full compliance with EPA rules and orders under sections 4, 5, 6, 8 and 14, the goals of these programs cannot be achieved. Thus, the resources necessary to assure compliance clearly comprise a cost of "carrying out" and "administering" TSCA under section 26(b)(1). EPA's final rule should revise its cost estimates for sections 4,5, 6, 8, 11 and 14 so costs incurred by the Office of Enforcement and Compliance Assistance (OECA) to enforce these provisions are eligible for fee collection.

F. Recovering the Costs of Reducing Animal Testing

Under section 4(h) of TSCA, EPA has significant new responsibilities for reducing vertebrate animal testing where non-animal methods that provide equal or better information are identified. The Agency is expending considerable time and effort on animal testing issues and its work will only expand. Part of the cost of testing orders, rules and ECAs under section 4 is the development, evaluation, validation, peer-review and application of non-animal test methods where justified in lieu of animal studies for required testing. In addition, the section 4 program is supported by broader activities required under section 4(h)(2), including issuing and updating a strategic plan to promote the development and implementation of alternative test methods and research and assessment efforts to support validation of alternative test methods. These are "costs to the Administrator of carrying out section 4" and as such are recoverable through payment of fees under section 26(b)(4)(F)(i). Since the Office of Research and Development (ORD) is contributing heavily to OCSPP's work on non-animal test methodologies for use under TSCA, its costs along with OCSPP's should be eligible for fee recovery under TSCA.

III. The Proposed Exemptions from Section 6 Fee Requirements Should be Applicable on a Case-by-Case Basis

After listing 20 chemicals as high-priority in late 2019, EPA triggered the process in its 2018 rule for identifying manufacturers and importers of these chemicals so that they could be required to pay fees. However, as implemented, this process proved inefficient and confusing because of the large universe of entities subject to fee obligations and the complexity and effort of identifying them. To streamline the process and reduce transaction costs, the 2021 proposal and now the supplemental proposal would provide several exemptions from section 6 fee requirements. These exemptions would be for (1) importers of articles containing high-priority chemicals, (2) manufacturers of these chemicals as byproducts, impurities or non-isolated intermediates, (3) producers of the chemicals for R&D purposes and (4) low volume producers and importers (i.e., in amounts of 2500 pounds or less). Under the supplemental proposal, similar exemptions from fee payment would be provided for testing orders, rules and ECAs under section 4, with a low-volume cutoff of 1,100 pounds.

In general, narrowing the range of manufacturers and importers required to pay fees for section 4 and 6 implementation can reduce transaction costs, increase certainty and simplify allocation of fees among liable parties. However, this should not be accomplished in a way that relieves firms that contribute significantly to exposure and risk from any responsibility for the costs of sections 4 and 6 implementation. Nor should exemptions from fee requirements limit the universe of responsible entities to the point where EPA is unable to recover industry's full share of section 4 and 6 costs. As EPA recognized in the 2021 proposal, "there may be chemicals [designated high-priority] where the chemical's condition of use is covered under one of the five exemptions . . ., resulting in little to no manufacturers obligated to pay the fee. This could result in higher fees for entities that do not meet the exemption or no fee payments for a chemical substance risk evaluation." 86 Fed. Reg. at 1900.

EPA's first 10 risk evaluations illustrate how the proposed exemptions may have these undesirable consequences. For example, a primary focus of EPA's risk evaluation for 1,4-dioxane was consumer products containing this chemical as a byproduct of the manufacture of ethoxylated substances used to formulate detergents, soaps and other common household cleaners.[20] Under the proposed fee exemptions, however, producers of these products would have had no fee obligations because 1,4-dioxane is formed solely as a byproduct in their manufacturing process.[21] The cleaning product manufacturers would likewise be off the hook because they do not produce 1,4-dioxane but formulate mixtures containing it as an impurity and, as processors, are not subject to section 6 fee requirements under the 2018 rule. Thus, fees for EPA's risk evaluation would be paid solely by on-purpose manufacturers of 1,4-dioxane who do not make the component chemicals of cleaning products or these products themselves. This would violate basic principles of product stewardship because the companies most directly causing the consumer exposure to 1,4-dioxane addressed in EPA's risk evaluation would bear none of the evaluation's costs while companies engaged in unrelated activities would be liable for all the fees.

Another example is the EPA Part 1 "chrysotile-only" asbestos risk evaluation[22] and proposed risk management rule.[23] Asbestos is no longer mined in the United States so there are no domestic manufacturers who would be responsible for paying fees under TSCA section 26(b). The chlor-alkali industry is the only importer of raw asbestos and uses it in the manufacture of chlorine and caustic soda. In addition to finding that asbestos exposure within this sector

[20] 86 Fed. Reg. 1495 (January 8, 2021).
[21] The supplemental proposal would narrow the byproduct exemption to exclude byproducts "later used for commercial purposes or distributed for commercial use." 87 Fed. Reg. at 68658. This is a positive change generally but would not apply to manufacture of 1,4-dioxane as a byproduct in cleaning products because its formation has no separate commercial purpose.
[22] 86 Fed. Reg. 89 (January 4, 2021).
[23] 87 Fed. Reg. 21706 (April 12, 2022).

presents an unreasonable risk, the EPA evaluation also addressed several asbestos-containing products (such as sheet gaskets or aftermarket automotive asbestos-containing brakes/linings) and determined that they too present unreasonable risks. These products are all imported articles and therefore would be exempt from fee requirements under the supplemental proposal. In this event, no entity responsible for unsafe asbestos exposure during importation and use of these articles would contribute to the costs of determining and managing their risks. Instead, importers of raw asbestos for use in chlor-alkali production would be required to pay all the fees attributable to these activities.

Because each chemical has its own conditions of use and exposure, "one size fits all" exemptions from fee obligations are overly rigid and will produce perverse and counterproductive apportionments of fees in particular cases. Thus, while establishing exemptions, EPA's fees rule should reserve the Agency's discretion to determine their application on a chemical-by-chemical basis. The rule should direct EPA to make these determinations during the scoping process for each risk evaluation. Self-identification of responsible entities should then be tailored to the particular exemptions that EPA decides to apply.

We support EPA's proposal to "include self-identification requirements for manufacturers (including importers) of chemical substances with production volume less than 2,500 lbs" so it can then make the low volume exemption inapplicable "when all manufacturers of that chemical substance manufacture in quantities below 2,500 lbs." 87 Fed. Reg. 68658. We recommend expanding this mechanism to both section 4 and 6 and applying it where (as discussed above) low volume manufacturers are significant contributors to exposure even though there are also high-volume manufacturers.

IV. EPA Should Not Exempt All Processors from Fees but Provide Such Exemptions on a Case-by-Case Basis

EPA's 2018 rule limits fee obligations under sections 4 and 6 to manufacturers/importers and exempts all processors. In the preamble to the 2021 proposal, EPA maintained that "limiting fee obligations to manufacturers is the simplest and most straightforward way to assess fees for conducting risk evaluations under TSCA section 6 and most TSCA section 4 testing activities." 86 Fed. Reg. 1901. The supplemental proposal retains this approach for section 6 fee collection. However, "EPA is proposing and requesting comment on modifying the fee payment obligations in 40 CFR 700.45(a) to require payment by processors identified in the TSCA section 4 test orders and ECAs who submit information." As EPA explains, "[i]n the event that there are no manufacturers receiving a test order or ECA, requiring fee payments by processors would allow EPA to recoup the costs of administering such test orders and ECAs." 87 Fed. Reg. at 68660

In general, we believe that an across-the-board exemption of processors from fee payments under sections 4 and 6 is unjustified. TSCA section 26(b)(4)(C) directs that EPA's fee rule must "reflect an appropriate balance in the assessment of fees between manufacturers and processors." As Congress recognized, there will be occasions where processing activities contribute significantly to the risks that EPA seeks to address under sections 4 and 6. Examples include formulated products that were put into the stream of commerce by processors and are significant sources of worker and consumer exposure. Upcoming risk management rulemakings for several solvents (e.g. methylene chloride, trichloroethylene, perchloroethylene) will likely ban or severely restrict such products and it would be unwise to exempt the processors directly responsible for their manufacture and distribution in commerce from any fee payment obligation. Another example, cited above, is the 1,4-dioxane risk evaluation, where EPA's major focus was on formulated cleaning products manufactured by processors. In these cases, processors should not get a free ride on EPA risk evaluation, management and testing costs that are directly attributable to the contribution of their products to exposure and risk.

In addition, categorically excluding all processors from fee payments may in some cases deprive EPA of the full fees it is entitled to recover because there are no manufacturers or they are too few to cover the substantial fee payments required for risk evaluations and risk management rules. A mechanism for identifying processors where needed to avoid fee shortfalls should thus be available on a case-by-case basis. Since the same exemptions would apply to processors as to manufacturers, the number of processors required to self-identify could be limited to a manageable universe. Including this mechanism in its final rule would assure that EPA is not without recourse in those cases where processor fee payments are warranted for reasons of equity and environmental responsibility or to assure full recovery of the industry share of EPA's costs.

We agree with EPA that where an industry consortium is formed to assume responsibility for paying the full fees for section 4 or section 6 activities, there would be no need for the Agency to require fee payments directly by processors. But if no consortium is formed or if a chemical's manufacturers are unwilling to cover required fees in their entirety and cannot reach a fee sharing agreement with processors, EPA should have the ability to assess fees on processors.

V. Fee Obligations Should Apply to Firms Resuming or Initiating Production After the Initial Assessment of Fees

Consistent with the 2018 rule, proposed 40 §CFR 700.45 (b)(5)(ii) provides that firms who manufactured a risk evaluation chemical in the five-year period preceding identification of liable parties will have no fee obligation if they certify that they have ceased manufacture and will not resume it in the subsequent five year period. We support this provision and would

oppose any attempt to weaken it, as suggested in the preamble to the 2021 proposal. See 86 Fed. Reg. at 1901. While there may be some burden associated with reallocating fee obligations to account for new entrants, it is more than outweighed by the undesirable consequences of allowing firms to time their exit from production to avoid fees and then to restart production shortly thereafter. This would mean that firms which contribute to exposure and risk but cease production for a brief period could shift the burden of fees to their competitors. This "gaming" of the fee collection system would undermine the goal of Congress to impose equitable and uniform fee payment responsibilities on industry commensurate with the time and effort expended by EPA to determine the risks of their manufacturing activities.

We are, however, concerned that proposed 40 §CFR 700.45 (b)(5)(iii) would provide a safe harbor to firms that certify that they did not manufacture a substance during the preceding five years without also certifying that they will not begin production in the next five years. Principles of environmental accountability require that all current manufacturers who are contributing to the risks EPA is evaluating and managing under section 6 bear an appropriate share of the Agency's costs, even if they did not previously produce the chemical. Accordingly, EPA should revise 40 CFR §700.45(b)(5) so that all firms who start manufacture or importation within the five years following the initial assessment of fees must self-identify to EPA and then make fee payments. While some added effort may be required to reallocate fees to new entrants, this cost is more than justified by the need to assure the integrity of the fee collection process.

CONCLUSION

We appreciate the opportunity to comment on EPA's supplemental proposed fee rule under section 26(b) of TSCA. Our organizations commend EPA for reexamining and re-estimating the true costs of TSCA implementation and significantly increasing fee payments by industry based on this analysis. However, as EPA well knows, the TSCA program is severely strapped for resources and there is an acute need to fund its growing workload and legal obligations at higher levels. Our comments demonstrate that, under TSCA section 26(a), EPA has the authority to increase fees significantly above the levels called for by the supplemental proposal, netting millions of additional dollars for TSCA implementation. We urge EPA to follow these recommendations and strengthen its final rule so industry pays the full share of the costs of TSCA implementation as Congress directed.

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