UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Comments of Safer Chemicals Healthy Families, BlueGreen Alliance, Defend Our Health, Earthjustice, and Natural Resources Defense Council on Proposed Fees for the Administration of the Amended Toxic Substances Control Act

Submitted via Regulations.gov (March 26, 2021)

EPA-HQ-OPPT-2020-0493

INTRODUCTION AND SUMMARY

Safer Chemicals Healthy Families, BlueGreen Alliance, Defend Our Health, Earthjustice, and Natural Resources Defense Council submit these comments on the proposed rule of the Environmental Protection Agency (EPA) requiring payment of fees to support implementation of the Toxic Substances Control Act (TSCA).[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. After disappointing progress in addressing chemical risks in the Trump Administration, we call on EPA's new leadership under President Biden to greatly strengthen the evaluation, testing and regulation of chemicals that may pose unreasonable risks to human health and the environment, as Congress directed in the 2016 Frank R. Lautenberg Chemical Safety for the 21st Century Act (LCSA) amending TSCA.

In enacting LCSA, Congress recognized that strengthened protection of public health under the new law would require additional resources and that a significant portion of the increased costs incurred by EPA should be contributed by industry. Section 26(b) of amended TSCA reflects this Congressional determination by creating broad new requirements for the payment of fees by chemical manufacturers and processors to support EPA's activities. The goal of these requirements is to assure that fees account for 25 percent of the 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 assure that they continue to contribute sufficiently to the costs of implementing the Act.

EPA promulgated an initial TSCA fee collection rule on October 17, 2018.[2] The recent proposal updates and modifies the 2018 rule and sets TSCA fee levels for fiscal years (FYs) 2022-2024. Although these fees will support implementation of TSCA by the Biden EPA, the proposed rule is backward-looking and flawed and retains the shortcomings of the 2018 rule. Like that earlier rule, the proposal reflects approaches to TSCA implementation under President Trump that failed to protect public health, underutilized TSCA authorities and fell short of meeting statutory requirements. The proposed rule also continues to greatly underestimate EPA's costs in carrying out the amended law and fails to

[1] 86 Federal Register 1890 (January 17, 2021).
[2] 83 Federal Register 52694 (October 17, 2018).

impose fee obligations for categories of EPA activities that are subject to fee payment under section 26(b). Finalization of the proposal in its current form will deprive EPA of industry funding for TSCA implementation at the levels required by Congress and hamstring the Agency in investing the resources necessary for a higher-performing TSCA program that implements the Biden Administration's priorities.

We recommend that EPA reexamine this disappointing proposal and publish a revised rule for comment after reviewing the scope and level of fee obligations in light of a more realistic assessment of TSCA resource needs and the range of EPA activities for which fee collection is required under section 26(b). In addition, the record for the current proposal provides virtually no documentation of how EPA has determined the costs of TSCA implementation and this lack of transparency has frustrated informed public comment. A re-proposal should be accompanied by a detailed explanation of the components of EPA's cost estimates so the public can meaningfully evaluate whether they realistically reflect the anticipated costs of implementing TSCA over the next four years.

As we discuss in these comments:

Accurately Estimating the Costs of TSCA Implementation

- The 2018 proposal estimated that the costs of TSCA implementation subject to fee recovery are in the range of $80 million per year and therefore required industry to pay annual fees of approximately $20 million. The 2021 proposal modestly increases these cost estimates and would require annual fees from industry of $22 million. We believe the proposal's cost estimates and fee levels are greatly understated. A more realistic and defensible projection of likely TSCA implementation costs would be at least $100 million and probably much more, resulting in greater fee revenues to support the program. Low-balling TSCA costs and fees when EPA is transitioning to a higher performing program would needlessly tie the hands of the new EPA leadership.

- In addition to making unrealistically low estimates of the costs of implementing section 4, 5, 6 and 14, both the 2018 rule and the 2021 proposal preclude fee recovery of the costs of developing information collection requirements under sections 8 and 11 of TSCA and of compliance assurance and enforcement activities under section 4, 5 and 6. These exclusions are not justified under the broad mandate in section 26(b) for payment of fees to defray the costs of "carrying out" and "administering" TSCA and should be eliminated.

Requiring Fees for the Initial 10 Risk Evaluations and Risk Management Rulemakings

- EPA's 2018 final rule took effect on October 18, 2018 and imposes fee obligations on industry for TSCA implementation activities occurring after October 1, 2018. Remarkably, however, 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 2022 if not longer) are exempt from fee collection under the rule. This is because the triggering event

under the rule for paying fees to cover costs under section 6 is the publication of final risk evaluation scopes, which occurred in June 2017 for the 10 initial evaluations. This "grandfathering" of the 10 substances from fee collection under section 26(b) is contrary to the intent of Congress to implement the fee requirements as soon as possible after enactment of the new law and gives the manufacturers of these substances a free ride which has no possible legal or policy justification.

- At a time when EPA's responsibilities are expanding and resources are constrained, EPA's failure to collect fees for its previous and ongoing work on the 10 chemicals represents a substantial revenue loss it can ill-afford. The 2021 fee proposal estimates that per chemical section 6 costs are $5,671,000. For the 10 chemicals, this would represent a total cost of $56,710,000. With industry contributing 35 percent of these costs as required in the 2021 proposal*, EPA would collect $19,848,500 in fees.* It is essential that EPA revise the 2018 rule so that these fees are paid.

Case-by-Case Exemptions from Fee Requirements Based on Principles of Environmental Responsibility

- Because of the large universe of entities potentially subject to fee obligations and the complexity of identifying all these entities and allocating fees among them, EPA is now proposing to establish exemptions from section 6 fee requirements 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).

- We agree it may be beneficial to narrow the range of manufacturers and importers required to pay fees for section 6 implementation in order to reduce EPA 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 defraying the costs of risk evaluations and risk management. Nor should exemptions from fee requirements limit the universe of responsible entities to the point where EPA may be unable to recover industry's full share of the Agency's costs under section 6.

- 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. The application of the proposed exemptions should thus be determined on a chemical-by-chemical basis. The fee rule should direct EPA to make exemption determinations during the scoping process for each risk evaluation and requirements for self-identification of responsible entities should be tailored to the particular exemptions that EPA decides to apply.

Case-by-Case Application of Fee Requirements to Processors

- EPA's 2018 rule limits fee obligations under sections 4 and 6 to manufacturers and importers and exempts all processors. An across-the-board exemption of processors from fee payment responsibility 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 section 4 and 6. In these cases, processors should not get a free ride on TSCA risk evaluation and management costs that are directly attributable to the contribution of their products to exposure and risk. Thus, EPA should grant exemptions to processors on a case-by-case basis, determining at the scoping stage whether some or all processors should pay fees because of the exposure and risk profile of the chemical at hand.

Preventing Manufacturers from Gaming the System by Exiting and Resuming Production

- EPA should revise provisions in the 2018 rule which provide protection from fees to firms who did not manufacture a risk evaluation chemical during the preceding five years but commence production of the chemical after the initial assessment of fees. Principles of environmental accountability require that all manufacturers who are actively contributing to the risks EPA is evaluating 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, 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 pay their appropriate share of fees. 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.

I. EPA's Proposal Underestimates Costs of Implementing TSCA Programs Subject to Fee Collection

EPA's 2018 fee rule estimated that EPA's annual costs to carry out TSCA provisions subject to section 26(b) would be $80,178,000 and on this this basis set annual fee payments under the rule at $20 million. Our comments on EPA's 2018 proposal underscored that, to assure effective implementation of TSCA, the fees rule must be designed to produce the maximum amount of revenue allowable under the law and establish an efficient and effective collection mechanism that prevents a shortfall in payments.[3] We expressed concern that the rule as proposed underestimated anticipated TSCA

[3] 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 (SCHF et al 2018 Comments).

implementation costs and that a more realistic analysis based on the necessary EPA resources to meet TSCA requirements would result in significantly larger industry fees. 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. However, despite these concerns, EPA's final rule made no adjustments in its estimate of TSCA resource needs and the size of industry fees.

EPA's latest proposal purports to bring to bear its experience with TSCA over the last two years in determining fee levels. However, the changes in these levels are negligible. Under the proposal, EPA's annual TSCA costs for FY 2022 through FY 2024 are estimated at $87.5 million and industry fees are set at $22 million. While program costs and fee levels for section 6 implementation have modestly increased compared to the 2018 rule, levels for section 4 and section 5 implementation are unchanged.

EPA has not provided a detailed breakdown of the specific components of its cost estimates. Instead, these estimates are only presented in aggregate form in the preamble to the proposed rule and support documents in the record. The lack of specificity has made it impossible to fully understand and analyze how EPA's cost estimates were derived. Based on the general information in the proposal, however, we have major concerns that EPA's estimates of TSCA implementation costs remain significantly understated and therefore fee levels are inadequate.

The proposal was developed before the change in administrations and is based on the Trump EPA's approach to TSCA implementation, which our groups and others have faulted as falling well short of TSCA requirements. We are optimistic that, under new leadership, EPA will revisit the shortcomings in the Trump approach, commit to following the law and implement TSCA more expansively as intended by Congress. This will raise the level of activity in the program and increase resource requirements. To avoid revenue shortfalls, the fee rule should be reworked to reflect the increased costs and higher fees required by a more robust approach to TSCA implementation. A more realistic and defensible projection of likely TSCA implementation costs under the Biden EPA would be at least $100 million and probably much more, resulting in greater fee revenues to support the program. Low-balling TSCA costs and fees when EPA is transitioning to a higher performing program would needlessly tie the hands of the new EPA leadership.

Earlier this month, the General Accounting Office (GAO) released its biennial report on "federal programs and operations that are vulnerable to waste, fraud, abuse, and mismanagement, or that need broad reform," also known as the "High Risk List."[4] The GAO not only identified EPA's TSCA implementation as a "high risk" program, but it was one of only five such programs the GAO identified as having "regressed" since the last high risk report in 2019.

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[4] General Accounting Office, *High-Risk Series: Dedicated Leadership Needed to Address Limited Progress in Most High-Risk Areas,* March 2, 2021, https://www.gao.gov/products/gao-21-119sp.

In its latest report, the GAO singled out EPA's goal of building capacity to implement the 2016 TSCA amendments as "not met," in part because "EPA had not implemented the recommendation we made in 2013 regarding TSCA's ability to identify resources needed to conduct risk assessments. Specifically, EPA program offices have not identified workforce needs for budget justification purposes since 1987 ..." Moreover, while EPA has announced plans to hire additional staff to work on TSCA, GAO reported that EPA "had not conducted a workforce and workload analysis to demonstrate that, even with 50 additional staff, it would have the capacity to successfully implement the TSCA requirements by the statutory deadlines." These findings are consistent with an August 2020 report by the EPA Inspector General, which concluded that "the Agency is at risk of missing future [TSCA] deadlines due to a lack of staff and resource planning."[5]

Independent investigators and auditors have thus confirmed the need for both increased funding and enhanced financial planning within OCSPP. A revised fee rule based on more realistic assumptions about the costs of TSCA implementation is a critical first step towards addressing those recommendations.

Below we discuss several examples of EPA's underestimation of likely TSCA implementation costs.

A. Costs of Implementing Section 5

According to the proposed rule, EPA's cost estimates assume that it will annually receive 301 PMNs, SNUNs and MCANS and 320 exemption applications. 86 Fed. Reg. 1894. While these assumptions may reflect section 5 submission activity for the last two fiscal years, they understate the level of submissions over the longer period since the TSCA amendments took effect. The Agency's PMN statistics indicate that section 5 submissions between June 2016 and March 2021 totaled 3622 – or an average of 732 per year.[6] This is 18 percent higher than the projection of future submissions in EPA's proposal. Since submission levels over the last two years may have been artificially depressed by COVID-19 and other factors, the five-year average is more representative of overall trends and should be the basis for EPA's estimates of future costs under section 5. Given EPA's projected cost of $55,343 per submission, this would increase section 5 costs by $5,867,730.[7]

Equally important, EPA has not revealed its assumptions about how many section 5 submissions are expected to result in section 5(e) orders and significant new use rules (SNURs) in the next three years. Initially, EPA issued section 5(e) orders for 75 percent of the PMNs reviewed under the new law.

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[5] EPA Office of Inspector General, *Lack of Planning Risks EPA's Ability to Meet Toxic Substances Control Act Deadlines,* Report #20-P-0247, August 17, 2020, https://www.epa.gov/office-inspector-general/report-lack-planning-risks-epas-ability-meet-toxic-substances-control-act.

[6] https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/statistics-new-chemicals-review.

[7] In fact, 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. Why EPA's estimates are dramatically lower 2.5 years later is not explained.

However, based on highly debatable changes in EPA's interpretation of the 2016 amendments, this percentage has now declined dramatically. To assume that issuance of orders will continue at this low level into the future is to ignore the real possibility that the new EPA leadership will reinstate an interpretation of section 5 that conforms to the statute, increasing use of the order and SNUR authority to previous levels and requiring increased testing of new chemicals.

In this event, the costs associated with drafting and negotiating orders and reviewing test data and other submissions would be substantially larger than under the Trump EPA. For example, in its 2018 fees rulemaking, EPA estimated it would incur total annual costs of $1,648,162 for 5(e) order development and implementation.[8] However. assuming that EPA receives 366 PMNs per year and 75 percent result in section 5(e) orders, this would mean an outlay of only $5993.00 per order, which plainly is well below the level of effort each order would entail. Moreover, under section 5(f)(4) of amended TSCA, EPA must promulgate SNURs for all 5(e) chemicals or justify its decision not to do. If EPA increases use of the order authority to previous levels, the number of SNURs would increase proportionately. For example, in the 2018 rulemaking, EPA estimated that total annual SNUR development costs would be $1,552,609,[9] but this estimate would be far too low if SNURs were promulgated for 75 percent of PMN substances.

B. Costs of Implementing Section 4

As in the 2018 rule, EPA's calculation of section 4 costs assumes that it will initiate work on 10 testing orders each year and one test rule and testing consent agreement every two years.[10] In overhauling and streamlining section 4's mechanisms for requiring testing in 2016, Congress intended to substantially increase the amount of testing conducted under TSCA. However, EPA's assumed activity level under section 4 continues the "business as usual" approach of old TSCA and is far too low to meet Congressional expectations for a ramp up in data development under the amended law.

Our comments on EPA's draft risk evaluations and proposed high-priority listings have demonstrated significant data gaps that should be filled to assure high-quality, health-protective determinations of unreasonable risk.[11] In peer reviewing the draft evaluations, the EPA Scientific Advisory Committee on Chemicals (SACC) likewise raised concern about data gaps. 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 Administration. Were EPA to reinstate this approach, there would be

[8] EPA Technical Background Document for TSCA Fees, December 2017, at 7.
[9] Id.
[10] 86 Fed. Reg. 1893.
[11] *Comments of Safer Chemicals Healthy Families, Natural Resources Defense Council, and Environmental Health Strategy Center on Proposed High-Priority Substance Designations Under the Toxic Substances Control Act (TSCA)* (November 21, 2019), at 5-8.

significantly more testing orders, rules and consent agreements, resulting in a considerably larger workload under section 4 and greater costs to EPA.

Consistent with the 2018 rule, EPA's preamble to the proposal indicates that the "estimated cost to the Agency of each test order under the proposal is approximately $279,000," including the effort required to develop the order, oversee testing and review test results.[12] This modest estimate seems to assume that future test orders will follow the model of the few orders issued in 2020 for Pigment Violet 29 and 10 substances listed as high-priority.[13] For example, EPA "assumes that testing required by test orders is likely to be completed in under a year."[14] Future orders, however, may not be limited to a narrow group of workplace monitoring, ecotoxicity and physical-chemical properties studies but include chronic and subchronic *in vivo* studies for health effects that take several years to complete. In this event, designing the requirements in the order, overseeing testing and evaluating test findings and raw data will be a significantly larger task requiring a multi-year commitment of time and resources. This greater resource burden should be factored into EPA's estimates of section 4 costs.

Finally, EPA has significant new responsibilities for reducing animal testing under section 4(h). The Agency is expending considerable time and effort developing and promoting non-animal test methods and its work in this area will only expand. EPA's estimates of the costs of testing orders, rules and consent agreements may include the resources necessary to evaluate the availability of validated non-animal test methods in lieu of animal studies for required testing. However, these estimates do not include the costs of 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 conducting 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).

C. Costs of Implementing Section 6

EPA's estimates of section 6 costs assume that it will be conducting 20 EPA-initiated risk evaluations in any given year and that total per chemical costs for section 6 activities will be $5,671,000.[15] This is an increase over the $3.9 million estimate in the 2018 rule and, according to EPA, has been informed by "the Agency's experience conducting and in some cases completing risk evaluations for the first 10 risk evaluations under amended TSCA . . .; by the Agency's experience developing the scope of the risk evaluations of the 20 chemicals designated as high-priority in December 2019; and by the Agency's

[12] 86 Fed. Reg. 1893.
[13] TSCA Section 4 Test Orders https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/tsca-section-4-test-orders#list | Assessing and Managing Chemicals under TSCA | US EPA
[14] 86 Fed. Reg. 1893.
[15] Id at 1896. EPA appears to assume that risk evaluation costs will be spread over three years although the preamble does not make this explicit.

experience with risk management actions addressing unreasonable risks from particular chemical activities."[16]

Neither the proposed rule nor materials in the docket provide a cost breakdown for the specific steps in section 6 implementation – prioritization, risk evaluation and risk management – or the activities EPA undertakes during each step.[17] Because this breakdown is unavailable, it is impossible to critically examine how and why EPA has modified its 2018 estimates. Nonetheless, we believe that EPA's new estimates are still too low and significantly understate the level of activity under section 6 as it will likely be implemented by the Biden EPA.

Costs of Risk Evaluations. The first 10 risk evaluations are not an accurate measure of the level of effort that will likely be required to complete future risk evaluations, including those underway on the 20 high-priority chemicals. EPA's independent Science Advisory Committee on Chemicals (SACC) found that the first 10 TSCA risk evaluations were inadequate and flawed. In comments on the draft evaluations, our groups expressed similar concerns, emphasizing gaps and limitations in these evaluations that violated TSCA requirements.

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.

Ongoing and future risk 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). For asbestos alone, EPA has already announced a Part 2 risk evaluation to assess legacy exposure pathways, a challenging task because of the prevalence of legacy asbestos in tens of thousands of buildings across the country. Risk evaluations for the 20 high-priority substances may raise similar legacy issues.

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[16] Id at 1894.

[17] The economic analysis for the proposed rule, cited in the preamble as a basis for the cost estimates, provides the same general summary of these estimates as the preamble itself. *Economic Analysis of the Proposed Rule for Fees for the Administration of the Toxic Substances Control Act,* https://www.regulations.gov/document/EPA-HQ-OPPT-2020-0493-0025

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.[18] The Biden EPA should not have to cut corners on necessary and legally required improvements to its risk evaluations because the Trump EPA declined to recover the full amount of anticipated costs as authorized by Congress.[19]

Risk Management Costs. Although EPA's proposal does not break out risk management costs under section 6, EPA is likely underestimating these costs as well. The preamble to the proposal explains that:

> Cost estimates for risk management activities have been informed, in part, by EPA's recent risk management actions on several chemicals, including development of the proposed rules regarding the use of N-methylpyrrolidone and methylene chloride in paint and coating removal, and the use of trichloroethylene in both commercial vapor and aerosol degreasing and for spot cleaning in dry cleaning facilities, and the development of the final rule regarding methylene chloride in consumer paint and coating removal.

86 Fed. Reg. 1894. These rulemakings are not indicative of current and anticipated risk management costs under section 6. With the exception of the ban on consumer uses of methylene chloride paint strippers, they did not progress beyond the proposal stage and were withdrawn by the Trump EPA in January of this year.[20] Moreover, they targeted a small number of conditions of use (COUs) and were based on a subset of health end-points. By contrast, the 10 recently completed TSCA risk evaluations encompass a far larger range of COUs and address all end-points. All 10 evaluations contain determinations of unreasonable risk and thus have triggered TSCA risk management rulemaking. For several evaluations, these determinations apply to dozens of COUs, all of which must now be regulated under section 6(a) in order to eliminate the unreasonable risk. The 20 rulemakings now underway must include resource-intensive analyses of costs, benefits, economic effects and availability of substitutes under TSCA section 6(c). Either in the rulemaking or subsequently, EPA may also need to review and act on numerous applications for use exemptions under section 6(g). As Acting Assistant Administrator Freedhoff recently announced, in parallel with the risk management rulemakings, EPA also intends to rework portions of the initial 10 evaluations that do not fully comply with TSCA, adding to the costs of section 6 implementation.[21] In sum, the 10 rulemakings and further work on the 10 evaluations will be complex and costly and require a substantial commitment of resources.

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[18] While EPA's proposal cites its "experience developing the scope of the risk evaluations of the 20 chemicals designated as high-priority in December 2019" as a basis for its cost estimates, these scope documents were cursory and uninformative, as our groups commented, and their costs are not indicative of the level of effort necessary to comply with the scoping requirements in section 6(b)(4)(D) of TSCA.

[20] 86 Fed. Reg. 3932 (Jan. 15, 2021)

[21] March 25 keynote address to Chemical Watch conference on U.S. and international toxics policy. https://insideepa.com/sites/insideepa.com/files/documents/2021/mar/epa2021_0627.pdf

We have not seen any explanation of how the proposed fees rule accounts for risk management costs. However, the 2018 final rule indicated that EPA anticipated total annual risk management costs of $6,584,000. 83 Fed. Reg. 52702. Apportioned across the 10 risk evaluation chemicals, this would result in per substance costs of $658,400 to propose and finalize section 6(a) rules. Based on the considerations discussed above, these estimated costs would likely be far below EPA's actual costs for risk management on the 10 chemicals.[22] For risk management on the 20 high-priority chemicals now undergoing risk evaluations, the disparity would be even greater because estimated per chemical costs would be 50 percent lower than for the 10 chemicals.

Prioritization Costs. While EPA's proposal does not break out the costs of the priority-setting process under section 6(b)(1), the 2018 rule projected prioritization costs of $2,573,000 annually. 83 Fed. Reg. 52702.[23] This estimate likely understates the actual costs of the prioritization process. To identify priority listing candidates, EPA must screen a large number of chemicals. Once chemicals are selected for proposed listing, section 6(b)(1)(C) requires a 9-12 month prioritization process with two rounds of public comment. Before and during this process, EPA must conduct a comprehensive analysis of hazard and exposure data. Section 6(b)(2)(B) directed EPA to designate at least 20 high-priority chemicals and 20 low-priority chemicals by the end of 2019. The proposed low-priority listings elicited extensive comments and triggered additional analysis by EPA. For both high and low priority listings, EPA responded to public comments. It is inconceivable that this large undertaking cost EPA only $64,000 per chemical ($2,573,000 ÷ 40) or that future rounds of prioritization can be accomplished for this modest sum. EPA must therefore reconsider and increase its estimates of the costs of prioritization under section 6.[24]

Industry-Requested Risk Evaluations. In its 2018 rule, EPA determined that fees for conducting manufacturer-requested risk evaluations will be based on the Agency's actual (not estimated) costs and that, consistent with TSCA, manufacturers will cover 50 percent of these costs for Workplan chemicals and 100 percent for other substances.[25] The proposal retains this approach, which we believe correctly interprets section 26(b)(4)(D). However, EPA should clarify that industry fees will include not just the actual costs of conducting risk evaluations but the costs of reviewing and seeking comment on industry evaluation requests and conducting risk management rulemakings should the Agency make a determination of unreasonable risk. It is likely that the section 6 costs of industry-requested evaluations will approximate those of EPA-initiated evaluations and if EPA increases its

[22] It does not appear that EPA's cost estimates have considered 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, or further rulemaking and related activities on PCBs under section 6(e) of TSCA.

[23] Presumably, EPA's fee assessments for the 20 high-priority and 20 low-priority chemicals designated in late 2019 will include the costs of prioritization.

[24] Given resource constraints and shortfalls in fees resulting from underestimation of EPA costs, the Agency should consider postponing further low-priority listings and using its resources for activities that directly enhance health and environmental protection.

[25] 83 Fed. Reg. 52705.

section 6 cost estimates as we recommend above, its estimates for industry-requested evaluations should be adjusted proportionately

D. Costs of Information Collection and Management

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 proposal estimates 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 for FY 2019-21. (Compare 86 Fed. Reg. 1895 to 83 Fed. Reg. at 52703). We have significant concerns about both the scope of the information management activities that EPA deems recoverable through fees and the accuracy of its cost estimates for covered activities.

In its 2018 final rule and now in its proposal, EPA has excluded from fee collection the development of information collection requirements under sections 8 and 11 of TSCA:

> EPA's cost estimates include the costs of information management for sections 4, 5, 6 and 14 but do not include the costs of administering other authorities for collection such as those in TSCA section 8 and 11. 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. Cost estimates in the proposed rule consider costs associated with managing information that, for instance, was received pursuant to a TSCA section 8 rule but not the costs of developing the TSCA section 8 rule.

86 Fed. Reg. 1894-95. Although section 26(b)(1) does not mention sections 8 and 11 specifically, the plain language of the statute covers the costs of "collecting . . . information on chemical substances under this title." Clearly, developing a section 8 rule or section 11 subpoena is an integral part of "collecting . . . information on chemical substances under this title" (a term which includes both of these TSCA provisions). Thus, recoverable information management costs include 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. Also included are the costs of designing electronic reporting systems and processing, organizing and reviewing reports as they are received by the Agency.

EPA earlier completed an extensive reporting effort to identify active and inactive substances listed in the TSCA Inventory under section 8(a)(4). In 2020, EPA updated Chemical Data Reporting (CDR) requirements in advance of the 2020 reporting cycle and the 2020 reporting period closed

on January 29, 2021 after considerable outreach to the regulated community. EPA is now in the resource-intensive phase of compiling, reviewing and analyzing CDR reports. EPA is also developing new section 8 requirements for Per- and Polyfluoroalkyl Substances (PFAS) as directed by the Fiscal Year 2020 National Defense Authorization Act (NDAA) and is considering expanded section 8 reporting requirements for chemicals listed and/or under consideration for listing as high-priority. The costs of completed and anticipated section 8 rulemaking are clearly significant and should not be excluded from EPA's fee collection rule.

Moreover, for the information management activities that EPA does consider recoverable under section 26(b), the surprising reduction of over 50 percent in EPA's cost estimates from the 2018 rule is not credible and calls into question how EPA is calculating these costs and what activities are included. Under the 2016 TSCA amendments, EPA must now require information submitters to substantiate most of their Confidential Business Information (CBI) claims. Thus, it must address what elements this substantiation must contain and review industry submissions to assure that it is provided. 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. CBI information can now be shared with states and health professionals.

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 greatly increased 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.
>
> 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).

Looking forward, the heavy workload imposed by these tasks should remain constant and likely will increase. For example, recently submitted CDR reports almost certainly contain numerous CBI

claims with accompanying substantiation that EPA will need to review and accept or reject under section 14(f) of TSCA; reports under the upcoming section rule 8 for PFAS will likewise include numerous CBI claims requiring EPA review; and PMN, SNUN, LVE and LoREX submissions under section 5 will continue to redact extensive information claimed CBI. EPA needs to explain why anticipated costs for these information collection activities will only total $1,873,433 as estimated in its proposal.

Freedom of Information Act (FOIA) requestors seeking access to TSCA information uniformly report lengthy delays in disclosure attributable to lack of resources and overburdened EPA staff. Waiting times for FOIA responses typically are many months and even years. As a result, EPA has failed to realize the increased transparency which the TSCA 2016 amendments sought to achieve. EPA's cost estimates for information management under section 26(b) should reflect the full investment in staff expertise and workflow efficiency required for a functional and responsive FOIA process. Underestimating these costs will not only frustrate fee recovery but lead to continued underinvestment in staff and data systems that is causing frustrating logjams in public information access.

E. Costs of Compliance Assurance and Enforcement

Neither the 2018 final fees rule nor the 2021 proposed revisions include EPA compliance monitoring, assistance and enforcement activities in cost estimates for determining fee payments under section 26(b). These activities are critical in assuring the successful implementation of TSCA; the goals of the law cannot be achieved without full compliance with EPA rules and orders under sections 4, 5, 6, 8 and 14. The resources necessary for effective compliance and enforcement clearly comprise a cost of "carrying out" and "administering" these TSCA provisions as described in section 26(b)(1). EPA's final rule should revise its cost estimates so this cost is recoverable through fee collection.

II. 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

EPA's 2018 final rule took effect on October 18, 2018 and imposes fee obligations on industry for TSCA implementation activities occurring after October 1, 2018. However, the rule provides that the triggering event for fee payments for EPA-initiated risk evaluations is the publication of final risk evaluation scopes. 40 CFR 700.45(g)(3)(iv)(A). Since scoping documents for the 10 chemicals were published in June 2017, the 10 risk evaluations are therefore exempt from fee collection under section 26(b).

In our comments on the proposed rule, we argued that the 10 ongoing risk evaluations and subsequent risk management rulemakings would continue for several years and that exempting them entirely

from fee collection would deprive EPA of cost recovery for resource-intensive activities that are plainly within the scope of TSCA section 26(b)(1).[26] We recommended that, to avoid unnecessary loss of fee revenues, EPA should revise the final rule so that it requires payment of fees for risk evaluations underway on October 1, 2018, notwithstanding the timing of final scoping documents. However, EPA rejected this recommendation in the preamble to the final rule:

> 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. EPA offers no legal or policy basis for this approach. Indeed, 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. As the preamble to the final 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 now 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 – would be contrary to these clear expectations.

The preamble to the 2018 rule claims that "the costs of completing [the 10] risk evaluations ha[ve] been included in the overall program cost estimates for TSCA section 6 activities, and EPA expects to recover 25% of these costs through implementation of this rule." 83 Fed. Reg. 52708. This is plainly incorrect. It is clear from the 2021 proposal that EPA's annual cost estimates for section 6 implementation are for evaluations of the 20 high-priority substances listed in 2019 and do *not* incorporate past costs for the 10 initial evaluations. Indeed, manufacturers of the 20 chemicals would be surprised and concerned to learn that they were defraying costs relating not to these chemicals but to ten different chemicals previously evaluated by EPA.

At a time when EPA's responsibilities are expanding and resources are constrained, EPA's failure to collect fees for its previous and ongoing work on the 10 chemicals represents a substantial revenue loss it can ill-afford. The 2021 fee proposal estimates that per chemical section 6 costs are $5,671,000. 86 Fed. Reg. 1896. For the 10 chemicals, this would represent a total cost of $56,710,000. With

[26] SCHF et al 2018 Comments, at 9-10.

industry contributing 35 percent of these costs as required in the 2021 proposal, *EPA would collect $19,848,500 in fees*. A revenue shortfall of this magnitude is simply unacceptable.

The final 2021 rule should modify the 2018 rule to require fee payments for all section 6 activities on the 10 chemicals (or at a minimum activities subsequent to October 1, 2018). This can be accomplished by revising 40 CFR 700.45(b) so that manufacturers and importers of the 10 chemicals must self-identify to EPA 30 days after the final rule takes effect and make fee payments 90 days later.

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

In early 2020, 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 to be inefficient and confusing because of the large universe of entities subject to fee obligations and the complexity of identifying them. To streamline the process, EPA is now proposing to establish 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).

In general, narrowing the range of manufacturers and importers required to pay fees for section 6 implementation may conserve EPA resources by reducing transaction costs and simplifying 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 defraying the costs of risk evaluations and risk management. Nor should exemptions from fee requirements limit the universe of responsible entities to the point where EPA may be unable to recover industry's full share of the Agency's costs under section 6. As EPA itself acknowledges, "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. 1900.

EPA's first 10 risk evaluations illustrate how the proposed exemptions may have these undesirable consequences for particular chemicals. 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.[27] Under the proposed exemptions, however, producers of these chemicals would have no fee

[27] 86 Fed. Reg. 1495 (January 8, 2021).

obligations because 1,4-dioxane is formed as a byproduct in the manufacture of other substances. 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 such, are processors not subject to fee requirements under the 2018 rule. Thus, fees for EPA's risk evaluation would solely be the responsibility of 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 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.[28] 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 risks of asbestos exposure within this sector present 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 of injury to health. These products are all imported articles and therefore would be exempt from fee requirements under the proposed rule. In this event, no entity responsible for unsafe asbestos exposure during importation and use of these articles would contribute to the costs of determining their risks. Instead, importers of raw asbestos for use in chlor-alkali production would be required to pay all the fees attributable to the EPA risk evaluation.

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. The application of the proposed exemptions should thus be determined on a chemical-by-chemical basis. The fee rule should direct EPA to make exemption determinations during the scoping process for each risk evaluation and requirements for self-identification of responsible entities should then be tailored to the particular exemptions that EPA decides to apply.

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 indicates that that it has further evaluated this exemption but continues to believe 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.

[28] 86 Fed. Reg. 89 (January 4, 2021).

We believe that this across-the-board exemption of processors from fee payment responsibility 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 section 4 and 6. Examples include the proposed section 6(a) rules for methylene chloride and N-methylpyrrolidone paint removers, which are formulated products that were put into the stream of commerce by processors. 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 TSCA risk evaluation and management costs that are directly attributable to the contribution of their products to exposure and risk.

We agree with EPA that where a 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 where appropriate. We recommend that the fees rule include a mechanism by which EPA can determine whether processors are subject to fees on a case-by-case for section 4 and 6 activities. This mechanism 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.

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

The 2018 rule 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 to the cessation of manufacture and do not resume production in the subsequent five year period. 40 CFR 700.45 (b)(5)(ii). However, the preamble to the 2021 proposal indicates that EPA is considering modifying this provisions so that former manufacturers may restart production at any time after the initial identification of liable parties without any fee obligation. 86 Fed. Reg. 1901. We strongly oppose this change. 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 for the time and effort expended by EPA to determine the risks of their manufacturing activities.

For similar reasons, we request that EPA reexamine and revise provisions in the 2018 rule which provide protection from fees to firms who at any time commence production of a risk evaluation chemical but did not manufacture it during the preceding five years. Principles of environmental accountability require that **all** manufacturers who are actively contributing to the risks EPA is evaluating 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, 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 pay their appropriate share of fees. 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 proposed fee rule under section 26(b) of TSCA. Our organizations urge EPA to reexamine, revise and repropose this flawed rule so it reflects EPA resource needs and priorities under TSCA and requires industry to pay the full share of the costs of TSCA implementation that Congress required.

Please contact Bob Sussman, SCHF counsel, with any questions or feedback at bobsussman1@comcast.net.

Respectfully submitted,

El'gin Avila
Director of Occupational and Environmental Health and Equity
BlueGreen Alliance

Patrick MacRoy
Deputy Director
Defend Our Health

Jonathan Kalmuss-Katz
Staff Attorney
Earthjustice

Daniel Rosenberg
Senior Attorney & Director of Federal Toxics Policy
Natural Resources Defense Council

Liz Hitchcock
Director
Safer Chemicals Healthy Families