Environmental Defense Fund

Comments on Fees for the Administration of the Toxic Substances Control Act

Docket ID: EPA-HQ-OPPT-2020-0493; 87 Fed. Reg. 68647 (November 16, 2022)

Submitted: January 17, 2023

Introduction

EDF supports EPA's November 2022 supplemental proposal on "Fees for the Administration of the Toxic Substances Control Act (TSCA)" ("the Supplemental Proposal"). EPA's proposal to increase the anticipated collection of TSCA fees, from $22 million to $45.5 million, is a critical and long overdue step to better resource EPA to carry out its responsibility for protecting public health and the environment under TSCA. There are some areas where improvements are needed, including full consideration of the cost of "collecting, processing and reviewing information under TSCA", collection of fees on the first 10 chemicals and adjusted fees for the 20 high-priority chemicals, a less lenient fee schedule, and removal of fee exemptions. We encourage the Agency to move expeditiously to finalize the rule, with the needed adjustments, to ensure that the Agency is appropriately resourced to do its job.

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1. EPA's Supplemental Proposal is critical to address major TSCA resource and capacity gaps.

EPA's TSCA program is severely underfunded, which hinders EPA's ability to faithfully implement the law and protect public health. EPA's proposal to considerably increase TSCA fees is a critical – and overdue – step to address years of lowballing both the true cost to implement TSCA and the fees needed to recoup industry's share. TSCA mandates that companies pay 25% of the cost of implementing TSCA. Yet industry has not paid anywhere near its fair share – leaving the taxpayer subsidizing the industry and EPA struggling to get its work done. In the Supplemental Proposal, EPA has proposed fees that are commensurate with the Agency's revised cost estimates to administer the law and are appropriately designed to recoup the required 25% from industry.

The 2016 TSCA amendments dramatically increased EPA's responsibilities to review and manage chemicals. Yet the previous Administration failed to seek the needed funds and staff to stand up a strong, new program. Developing cost and workload accounting that is reflective of EPA's actual resource needs is critical to EPA's ability to manage chemical safety under TSCA. A 2020 report by EPA's Office of Inspector General ("OIG") noted that EPA lacked the workforce and workload assessment needed to plan for and meet TSCA deadlines (EPA is "at risk of missing future deadlines due to a lack of staff and resource planning"). [1] Likewise, a 2021 Government Accountability Office ("GAO") report found that EPA had not met its capacity needs, resulting in missed statutory deadlines, and that the Agency's ability to assess and manage chemicals regressed due to failures to complete workforce and workload planning to ensure that the Agency could carry out its duties. [2] Both OIG and GAO recognized that EPA's scope of work greatly increased under amended TSCA, and that EPA had failed to translate that into needed additional staff and resources.

A robust regulatory framework for collecting industry fees is critical to fully resource the TSCA program. TSCA mandates that companies pay 25% of the cost of "carrying out sections 4, 5, and 6, and of collecting, processing, reviewing, and providing access to and protecting from disclosure as appropriate under section 14 information on chemical substances under [TSCA]."[3] However, according to EPA, the Agency has collected an average of only 13% of the previous Administration's artificially low estimate of the costs to implement TSCA.[4] Further, a January

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[1] EPA, Office of Inspector General, "Lack of Planning Risks EPA's Ability to Meet Toxic Substances Control Act Deadlines," August 17, 2020, https://www.epa.gov/sites/default/files/2020-08/documents/_epaoig_20200817-20-p-0247.pdf, at 3.

[2] Government Accountability Office, Report to Congressional Committees, "High Risk Series: Dedicated Leadership Needed to Address Limited Progress in Most High-Risk Areas," March 2021, https://www.gao.gov/assets/gao-21-119sp.pdf.

[3] 15 U.S.C. § 2625(b)(4)(B)(i)(I) ("TSCA section 26(b)(4)(B)(i)(I)").

[4] EPA, "EPA Announces Supplemental Proposed Rule to Modify Toxic Substances Control Act Fees Rule," November 16, 2022, https://www.epa.gov/newsreleases/epa-announces-supplemental-proposed-rule-modify-toxic-substances-control-act-fees-rule.

2023 EPA OIG report found that EPA collected only approximately $2.7 million and $3 million in FY 2019 and FY 2020, respectively, a mere 3-4% of this low baseline.[5] These fee collection percentages would be much lower still using EPA's more recent cost estimates.

Developing an estimate of the Agency's costs to implement TSCA that is reflective of the actual workload is critical to establishing industry fees that actually represent 25% of the cost of implementing TSCA. In 2021, as EPA reports, the Agency conducted its first-ever workforce and budget analysis to develop a more realistic estimate of its anticipated costs to implement TSCA.[6] As evidenced by the current proposal, it appears that EPA has improved its assessment of the work required under TSCA. Under the previous Administration, EPA had ignored or underestimated the cost of swaths of Agency activities, including section 4 testing, evaluation of new chemicals under section 5, and section 6 chemical prioritization and risk management. As described in detail in Section 2 below, EPA has addressed many of these shortcomings in the current proposal. EPA has more than doubled its estimated cost to administer fee-eligible programs of TSCA – from $87.5 million to $181.9 million – a necessary and appropriate step to address the previously ignored and underestimated activities.

Commensurate with the Agency's revised cost estimates, EPA has proposed to increase the anticipated collection of TSCA fees, from $22 million to $45.5 million, to recoup the required 25% of costs from industry.

Finally, over the last 15 years the GAO has provided guidance about best practices in setting, collecting, using, and reviewing federal user fees.[7] For example, the GAO poses questions for Agency decision makers to implement and evaluate their user fee collections.[8] EDF encourages EPA to review the GAO's guidance.

2. EPA appropriately revised its cost estimates and fees for sections 4, 5, and 6.

The 2021 Proposal released by the previous Administration dramatically underestimated the costs to administer key provisions of TSCA. Under the current rule, EPA has appropriately revised its cost estimates to better reflect the resources required to administer section 4, 5, and 6 of TSCA, resulting in revised fees designed to recoup the required 25% of costs from industry. Such increased fees are vital to better resource the Agency to carry out its responsibility for protecting public health and the environment under TSCA.

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[5] EPA Office of Inspector General, "The EPA's Fiscal Years 2020 and 2019 Toxic Substances Control Act Service Fee Fund Financial Statements," December 29, 2022, https://www.epa.gov/office-inspector-general/report-epas-fiscal-years-2020-and-2019-toxic-substances-control-act.

[6] We note that EPA has not made this document available to the public, which we urge it to do.

[7] GAO, "Federal User Fees; Key Considerations for Designing and Implementing Regulatory Fees," September 2015, GAO-15-718; GAO, "Federal User Fees: Fee Design Options and Implications for Managing Revenue Instability," September 2013, GAO-13-820; GAO, "Federal User Fees: A Design Guide, May 2008, GAO-08-386SP.

[8] GAO, "Federal User Fees; Key Considerations for Designing and Implementing Regulatory Fees," September 2015, GAO-15-718, at 34.

A. EDF supports increased section 4 costs and fees.

i. EPA expanded its anticipated testing under section 4 and its cost estimate.

The 2016 reform to TSCA (the "Lautenberg Act") enhanced EPA's authority to require testing of chemicals, giving it broader latitude under section 4 to issue test orders, test rules, and enforceable consent agreements (ECA).[9] Despite this expanded authority, EPA to date has taken little action to require testing of chemicals to inform risk evaluation and risk management decisions.

We commend EPA for committing to expand use of its section 4 authorities through this rule. EPA specifically states, "EPA 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."[10] Such action is critical to fill significant information gaps on chemicals; these gaps were a constant criticism of EPA's draft risk evaluations for the first 10 chemicals from stakeholders such as the EPA's Scientific Advisory Committee on Chemicals (SACC) and advocacy organizations alike.[11]

Commensurate with this statement, EPA has estimated that it will issue 75 test orders a year (45 of which are to be for PFAS, to fulfill the PFAS Testing Strategy obligations), which is a considerable increase from the 10 and 11 test orders a year EPA estimated in its 2018 Final Rule and 2021 Proposal, respectively. This increase in testing will provide more of the data necessary to conduct robust risk evaluations. Along with this planned increase in test orders, the overall cost estimate for section 4 has significantly increased and will enable fees to acquire needed resources to facilitate the expanded use of section 4 testing authorities. However, we note that the roughly doubling of cost compared to the 2021 proposal (from $3,543,000 to $7,383,300 annually) does not appear to be consistent with the more than seven-fold increase in anticipated test orders. EPA has not provided sufficient public information to determine the source of this discrepancy, and the Agency should provide a fuller accounting when finalizing the rule.

In addition, EPA has not accounted for any use of section 4 testing authorities for the New Chemicals program in its cost estimates. EPA should do so in promulgating its final rule. See section 3.F. below for further detail.

Nonetheless, we are optimistic that EPA's proposal reflects an Agency plan to increase required testing and move away from overreliance on voluntary information collection by companies. As EDF has commented on extensively to EPA, EPA's past reliance on voluntary methods of data

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[9] *See* 15 U.S.C. § 2603(a)(2) ("TSCA section 4(a)(2)").

[10] EPA, "Fees for the Administration of the Toxic Substances Control Act (TSCA)," 87 Fed. Reg. 68647, 68652, November 16, 2022, https://www.govinfo.gov/content/pkg/FR-2022-11-16/pdf/2022-24137.pdf.

[11] *See* EDF, "Comments on Fees for the Administration of the Toxic Substances Control Act," March 30, 2021, https://www.regulations.gov/comment/EPA-HQ-OPPT-2020-0493-0061, at 17-19.

collection has proven consistently ineffective.[12] Given the burden (whether heavy or light) that industry incurs through testing, EPA must anticipate that those burdens will discourage many industry stakeholders from producing and submitting such information voluntarily. And where industry does voluntarily submit information, there is the potential for significant problems, including selective reporting, bias, and the appearance of partiality.

ii. EPA appropriately adjusted its section 4 fees.

EPA is proposing section 4 fees at approximately $1,942,000 a year, intended to defray 26.3% of the section 4 program costs. This is a significant improvement over the 2021 proposal, where EPA proposed to collect only 4.1% of its section 4 program costs. In our comments on the 2021 proposal, we explained why the disproportionately low fee was inconsistent with the intent of the statute, and we are encouraged to see this issue resolved in the current proposal. [13] However, EDF notes that EPA should not have removed the 2021 proposed fee category for amended test orders, as these orders incur extra costs to the Agency from reviewing resubmitted data, which could be recovered by the Agency, and that it should have provided greater explanation for its decision to remove the fee category.[14]

We also support EPA's proposal to expand the fee requirement to manufacturers required to submit information rather than only applying the requirement to manufacturers "request to test" under 40 CFR § 700.45(a)(2). This change is important to ensure that companies that fulfill a section 4 testing obligation by collecting and submitting existing information are appropriately held accountable for the cost in the same way as companies who conduct new testing. Developing a test order is a resource-intensive process for EPA, regardless of how the company acquires the relevant information, and the costs to the Agency should be partially borne by all relevant companies.

B. EDF supports increased section 5 costs and fees.

EPA has increased its section 5 cost estimate from $34 million to $54 million annually.[15] EDF supports this increase, which reflects the additional workload the Agency faces under the Lautenberg Act. The 2016 statute mandates that EPA's health reviews of new chemicals be more rigorous and health-protective, which means that the Agency faces additional costs to comply with the greater requirements. EDF supports EPA's decision to account for the extra section 5

[12] EDF, "Comments on § 6(h) PBTs under the Toxic Substances Control Act," January 19, 2018, https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0730-0014, at 12-13.

[13] EDF, "Comments on Fees for the Administration of the Toxic Substances Control Act," March 30, 2021, https://www.regulations.gov/comment/EPA-HQ-OPPT-2020-0493-0061, at 22-23.

[14] 87 Fed. Reg. at 68656.

[15] EPA, "Fees for the Administration of the Toxic Substances Control Act (TSCA)," 86 Fed. Reg. 1890, 1896 (January 11, 2021); EPA, "Technical Support Document," Supplemental Notice of Proposed Rulemaking; Fees for the Administration of the Toxic Substances Control Act (TSCA)," November 18, 2022, https://www.regulations.gov/document/EPA-HQ-OPPT-2020-0493-0084, at 4. [Hereafter "Technical Support Document"]

costs incurred from companies submitting information during the Agency's risk assessment process, often in an attempt to refute EPA's initial risk determination, resulting in resource-draining "rework" by EPA scientists. EDF outlines its support for this accounting, and for the increased fees, below in Section 2.B. However, EPA should not allow for such "rework" in the first place, and Section 3.E. outlines EDF's opposition to this practice.

i. EPA is correct that it should account for the extra section 5 costs it incurs from late submissions and back and forth with industry, and it should incorporate such costs.

EDF supports EPA's revision of its TSCA section 5 cost estimates to account for the costs that are associated with conducting "rework" during new chemical risk assessment and risk management activities. What EPA refers to as "rework" are cases where EPA must redo its analysis based on companies' belated provision of information that they failed to include when they submitted their new chemical pre-manufacture notice or exemption request, as well as back and forth with industry regarding information that EPA may include in its analysis. Each time that EPA receives late information from companies, or has to engage in back-and-forth over the revisions to the risk assessment with submitters, the Agency expends additional resources beyond what is already required to conduct a new chemical evaluation. EPA's 2022 analysis of rework under Section 5 stated that "the frequency and amount of information submitted after EPA has started its evaluation causes substantial rework and delays in completing the analysis."[16] It further stated that "in many cases, the same types of information were submitted multiple times by a submitter because they were not accepted by EPA due to a lack of supporting data or documentation" which "can result in several rounds of EPA review and rework."[17] The proposed rule explicitly highlights the "costs incurred by EPA for multiple rounds of revision to the risk assessment due to late submission of information or rebuttals by companies" and the resulting "multiple rounds of risk management actions, redactions and posting of final reports to meet transparency commitments while safeguarding CBI."[18] In estimating EPA's costs and workload, it is important that the Agency include these costs. However, we note that there are insufficient details provided to the public to discern whether EPA has sufficiently incorporated the full extent of the substantial "rework" it conducts in its cost estimate.

In Section 3.E., below, we discuss the fact that this rework caused by companies' submission of information throughout the risk assessment process, and by industry's additional interference in the new chemicals process, is not authorized by TSCA, and that EPA should require companies to submit all information with their new chemical notice.

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[16] EPA, "TSCA New Chemical Engineering Initiative to Increase Transparency and Reduce Rework: Analysis of New Chemicals Rework Issues," July 22, 2022, https://www.epa.gov/system/files/documents/2022-06/Engineering%20Initiative%20Analysis.pdf, at 8.

[17] *Id*. at 8-9.

[18] 87 Fed. Reg. at 68651.

ii. Fees are appropriately proposed to be increased to better reflect the full cost to administer section 5 activities and better balance fees across TSCA programs.

EPA's proposal to increase fees for section 5 activities from $16,000 for PMNs/SNUNs/MCANs and $4,700 for exemptions to $45,000 and $13,000, respectively, is appropriate.[19] These fee modifications better reflect EPA's additional workload under revised TSCA and should better enable it to meet that workload by providing additional resources. The Agency's proposal acknowledges its backlog for section 5 activities and the greater duties – including conducting more health-protective and comprehensive risk reviews of new chemicals – it faces under the Lautenberg Act.[20] For example, EPA states that the reform law requires risk assessment activities for 100 percent of new chemical submissions, while the Agency previously only completed risk assessment activities for 20 percent of new chemical submissions.[21] Increased fees under section 5 will help EPA to adequately fund such substantially increased work, as its anticipated annual collections will increase from $4.3 million to $9.6 million. [22]

Further, even under its proposal to shift fees to be greater for section 5 activities, the Agency still anticipates collecting proportionally more fees for section 6 activities compared to section 5 activities. EPA anticipates collecting fees sufficient to offset 18% of its section 5 costs, versus 38% of its section 6 costs.[23] It is appropriate for the agency to shift its fees towards collecting a larger proportion of fees from section 5 fees than it has in the past. Over time, however, we encourage the Agency to collect 25% of its costs to administer section 5 from section 5 fees. Further, the Agency should not have removed the 2021 proposed fee categories for NOCs and Bona Fide Notices, because reviewing and responding to these submissions imposes costs on EPA, and it has failed to adequately explain why it does intend to finalize those categories.[24]

iii. EPA appropriately proposes to retain fees for reviews of section 5 exemption applications.

EPA appropriately proposes to maintain fees to offset its costs for review of section 5 exemption applications. EPA projects that exemption applications are likely to be the majority of section 5 submissions it will receive. The Agency estimates that it will annually receive 290 exemption notices and applications, but only 210 Premanufacture Notices (PMNs) and Significant New Use

[19] 87 Fed. Reg. at 68654.

[20] 87 Fed. Reg. at 68652, 68655.

[21] 87 Fed. Reg. at 68655.

[22] EPA, "Economic Analysis of the Supplemental Notice of Proposed Rulemaking for Fees for the Administration of the Toxic Substances Control Act," October 2022, https://www.regulations.gov/document/EPA-HQ-OPPT-2020-0493-0078, at ES-4. [Hereafter, "Economic Analysis"]

[23] 87 Fed. Reg. at 68655.

[24] 87 Fed. Reg. at 68655.

Notices (SNUNs).[25] Further, exemption notices and applications have been the majority of section 5 submissions since at least fiscal year 2019. In fiscal year 2019 the Agency received 278 exemption notices and applications but only 167 PMNs and SNUNs, and in fiscal year 2020 it received 266 exemption notices and applications but only 168 PMNs and SNUNs.[26] Reviewing and responding to each exemption notice and application requires agency resources and TSCA authorizes EPA to collect fees to provide resources to review these submissions.[27] There is therefore no reason that EPA should not account for these costs in setting its fees.

C. EDF supports increased section 6 costs and fees.

i. EPA addressed major gaps in section 6 cost estimates from its 2021 Proposal.

EDF supports the fact that EPA has increased the cost estimates to administer section 6 of TSCA. EPA's cost estimate increased from the 2021 proposal from $46,190,973 to $88,251,500 (excluding manufacturer-requested risk evaluations). This increase represents an improved accounting of the workload to conduct a TSCA risk evaluation, as well as the incorporation of the cost of risk management and increased prioritization costs.

EPA's 2021 proposal underestimated the true cost of conducting the comprehensive risk evaluations required under the law. At the time, the Agency estimated the cost of conducting risk evaluations based on internal tracking of the hours that staff reported working on the first 10 risk evaluations. However, as stakeholders like EDF and EPA's own Scientific Advisory Committee on Chemicals (SACC)[28] repeatedly pointed out, those risk evaluations excluded or omitted certain conditions of use and major known sources of exposure to the chemicals. Therefore, the hours spent on the first 10 risk evaluations were not an accurate reflection of the hours that should be spent on appropriately comprehensive risk evaluations. A November 2019 Ninth Circuit Court of Appeals ruling in *Safer Chems. v. United States EPA* affirmed that TSCA requires comprehensive risk evaluations,[29] and both the 2021 GAO and 2020 OIG reports

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[25] 87 Fed. Reg. at 68652.

[26] EPA, Office of the Inspector General, "The EPA's Fiscal Years 2020 and 2019 Toxic Substances Control Act Service Fee Fund Financial Statements," December 29, 2022, https://www.epa.gov/office-inspector-general/report-epas-fiscal-years-2020-and-2019-toxic-substances-control-act, at 6.

[27] 15 U.S.C. § 2625(b)(1) ("TSCA section 26(b)(1)").

[28] *See*, *e.g.*, Science Advisory Committee on Chemicals, "Peer review report on methylene chloride draft risk evaluation," March 2, 2020, https://www.regulations.gov/document?D=EPA-HQ-OPPT-2019-0437-0080; Science Advisory Committee on Chemicals, "Peer review report on 1-bromopropane draft risk evaluation," December 16, 2019 https://www.regulations.gov/document?D=EPA-HQ-OPPT-2019-0235-0061; Science Advisory Committee on Chemicals, "Peer review report on the 1,4-dioxane and HBCD draft risk evaluations," November 1, 2019, https://www.regulations.gov/document?D=EPA-HQ-OPPT-2019-0238-0063.

[29] *Safer Chems. v. United States EPA*, 943 F.3d 397 (9th Cir. 2019).

recognized the implications of the court ruling on TSCA risk evaluations: more staffing and resources are required to address the expanded, appropriate scope of the evaluations.[30]

In the current rule, EPA has increased the estimated cost to conduct EPA-initiated risk evaluations from $41,998,820 to $54,877,100 annually.[31] This increase will help to address at least some of the resources needed to perform appropriately comprehensive risk evaluations.

However, EPA's May 2022 *Legal Tools for Environmental Justice* document states that the 2016 TSCA amendments:

> gave EPA broad authority to 'ensure that funds sufficient to defray a substantial portion of EPA expenses in information collection and processing, prioritization, safety assessment and determination, and regulation under the Act are provided [to EPA]. … *In estimating the agency's costs under these sections, the Agency could incorporate relevant environmental justice work, such as characterizing fenceline communities for TSCA § 6 risk evaluations, into those underlying costs.*"[32]

It is unclear based on the available public documentation whether EPA has in fact considered the costs of fenceline assessments and other 'relevant environmental justice work,' which EPA did not include in the first 10 TSCA risk evaluations (nor in its new chemical reviews). EPA should use its TSCA authority to include such costs in its estimates.

As we commented on in detail, EPA's 2021 proposal also dramatically underestimated the section 6 costs of TSCA by excluding the costs of risk management and prioritization,[33] and of

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[30] GAO, Report to Congressional Committees, "High Risk Series: Dedicated Leadership Needed to Address Limited Progress in Most High-Risk Areas," March 2021, https://www.gao.gov/assets/gao-21-119sp.pdf, at 205 ("In addition to the challenges of meeting existing deadlines, EPA has to incorporate a recent court ruling into its ongoing risk evaluations. Under this ruling, EPA must evaluate the risks associated with the use and disposal of chemicals that are not being, and are not expected to be, manufactured, processed, or distributed—called legacy uses. For example, polychlorinated biphenyls (PCBs) were produced until the late 1970s, when their production was banned in the United States. But older products such as fluorescent lights, caulking, and paints may contain PCBs, and remain a concern for workers and consumers. According to EPA's OIG, the resulting expansion of the scope of EPA's risk evaluation process will require the Agency to devote more staffing and resources to existing chemical risk evaluations."). *See also* OIG report: EPA, Office of Inspector General, "Lack of Planning Risks EPA's Ability to Meet Toxic Substances Control Act Deadlines," August 17, 2020, https://www.epa.gov/sites/default/files/2020-08/documents/_epaoig_20200817-20-p-0247.pdf.

[31] Technical Support Document at 4.

[32] EPA, "Legal Tools to Advance Environmental Justice," May 2022, https://www.epa.gov/system/files/documents/2022-05/EJ%20Legal%20Tools%20May%202022%20FINAL.pdf, at 124 (emphasis added).

[33] We note that while the current rule acknowledges that EPA failed to include risk management in the 2021 Proposal ("EPA's estimates did not include any costs of TSCA section 6(a) risk management activities for the first 10 chemical substances or 20 High Priority Substances in the proposal which resulted in EPA underestimating TSCA section 6 Agency costs." 87 Fed. Reg. at 68653), it does not make

the scientific assistance provided by EPA's Office of Research and Development (ORD).[34] At the time, when we inquired with EPA staff, we were informed that a discrepancy in numbers that we identified – at $4,192,152 a year – was intended to represent the section 6 costs for these activities (i.e., prioritization, risk management, and assistance from ORD). As we commented extensively on the 2021 proposal, $4 million is an impossibly low cost to cover the extensive work required under risk management and prioritization.[35]

In the current proposal, EPA acknowledged its failure to include the cost for risk management in the 2021 proposal and has rectified this by providing a cost estimate for risk management in this rule. The Agency has estimated $24,553,500 and 77.3 FTE a year for this category of activity. While detailed accounting is not provided, EPA indicates that the cost estimate has been informed both by the recent risk management actions for the first 10 chemicals that are broad in scope, in addition to more discrete and resource-limited risk management actions (on trichloroethylene, N-methyl pyrrolidone, and dichloromethane). It is important that EPA base its risk management cost estimates on full risk management actions going forward. Furthermore, while the details are scant, EPA has provided an estimate of the cost of prioritization at $8,820,900 annually, or 35.9 FTE.

As for support from ORD, it appears that EPA has spread out the costs across programmatic areas.[36] However, we note that the exact estimates are not transparent. In our comments on the 2021 proposal, we detailed the critical support role that ORD plays in TSCA administration.[37] And we can expect that critical role to increase moving forward, given the new multi-year collaborative research program partnership with ORD, focused on approaches for performing risk assessments on new chemical substances.[38]

Finally, EPA should consider the costs of TSCA compliance and enforcement by the Office of Compliance Assurance and Enforcement (OECA). While the Supplemental Proposal notes

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the same acknowledgment for prioritization. As described in detail in our previous comments, there was an un-accounted for $4.5 million in the previous rule. It is possible this was intended to cover prioritization costs, although we cannot be sure.

[34] EDF, "Comments on Fees for the Administration of the Toxic Substances Control Act," March 30, 2021, https://www.regulations.gov/comment/EPA-HQ-OPPT-2020-0493-0061, at 32-37.

[35] *Id*. at 34-37.

[36] 87 Fed. Reg. at 68653 ("Some of the direct program costs included in the estimates for TSCA sections 4, 5, and 6 and collecting, processing, reviewing, and providing access to and protecting from disclosure as appropriate under TSCA section 14 information on chemical substances are for work performed in other Agency offices (e.g., the Office of Research and Development and the Office of General Counsel").

[37] EDF, "Comments on Fees for the Administration of the Toxic Substances Control Act," March 30, 2021, https://www.regulations.gov/comment/EPA-HQ-OPPT-2020-0493-0061, at 36-37.

[38] EPA, "New Chemicals Collaborative Research Program," April 27, 2022, https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/new-chemicals-collaborative.

OECA's support for section 5 new chemical submissions, the Agency does not make an analogous statement regarding section 6 risk management. As EPA moves forward to finalize risk management rules in the near future, it will have associated enforcement costs for which it should be accounting.

ii. EPA appropriately increased section 6 risk evaluation fees.

EPA has significantly increased the fees for risk evaluations – nearly doubling the fee for EPA-initiated risk evaluations. Increased fees are critical to help defray the costs of administering section 6 of TSCA, which EPA estimates to be the most resource-intensive section of the law to implement.

We note, however, that EPA is missing an opportunity to recoup costs for the first 10 chemicals and adjusted fees for the 20 high-priority chemicals currently being assessed. See additional detail in Section 3.B, below.

D. EPA's proposal to require processor payment under sections 4 and 5 is sound.

EDF supports EPA's proposal to require payment by processors subject to test orders and enforceable consent agreements (ECAs). TSCA empowers EPA to structure fees so that they "reflect an appropriate balance in the assessment of fees between manufacturers and processors."[39] However, under the current regulations, only manufacturers are obligated to pay for the administration of test orders and ECAs.[40] As the Agency explains, in cases where only processors are responsible for submitting information, EPA would be responsible for all of its costs to administer the orders or ECAs if only manufacturers are required to pay.[41]

This is not just a theoretical issue: it has already happened. The Agency was unable to collect any payments for its 2021 test order to processors of o-dichlorobenzene; because the existing regulations only required payment from manufacturers, EPA received no payment from the test order recipients.[42] Expanding the payment requirement to processors will allow EPA to ensure that it can recoup the costs of administering test orders and ECAs. This modification appropriately balances fee assessments between manufacturers and processors and will ensure EPA does not issue test orders or ECAs that are unsupported by fees.[43]

[39] 15 U.S.C. § 2625(b)(4)(C) ("TSCA section 26(b)(4)(C)").

[40] 40 C.F.R. § 700.45(a)(2).

[41] 87 Fed. Reg. at 68660.

[42] *Id*.

[43] 15 U.S.C. § 2625(b)(4)(C) ("TSCA section 26(b)(4)(C)").

3. In promulgating the final rule, EPA should make several improvements.

While the current rule better reflects the Agency's resource needs to administer TSCA in a health-protective manner, there are a number of shortcomings and missed opportunities that we urge the Agency to resolve in promulgating the final fee rule. First, EPA has continued to underestimate the cost of "collecting, processing and reviewing information under TSCA" and is missing the opportunity to collect fees for the first 10 chemicals and adequate fees for the 20 high-priority chemicals currently undergoing risk assessment (Subsections A and B). The result is that EPA will continue to forgo millions of dollars in fees that it has the authority to collect from industry. Second, EPA has proposed a lenient fee collection schedule for section 6 risk evaluations that will hamper staffing and resource planning (Subsection C). Third, EPA has retained fee exemptions proposed by the previous Administration that are broad, sweeping, and unsupported by the law (Subsection D). Fourth, EPA's proposal to allow a partial refund for new chemical submissions withdrawals is likely to drain more resources and invite more industry interference in the review process (Subsection E). Finally, we encourage EPA to consider section 4 testing in the context of new chemicals reviews (Subsection F), address the "free rider" issue for late company entrants (Subsection G), and take public comment on future fee rule updates regardless of their scope (Subsection H).

A. EPA has not estimated its full cost of collecting, processing and reviewing information under TSCA.

EPA continues to grossly underestimate the true costs of carrying its expanded duties under the reformed law, relating to "collecting, processing, reviewing, and providing access to and protecting from disclosure as appropriate under section 14 information on chemical substances under [TSCA]."[44] As detailed below, EPA has significantly underestimated the cost of administering section 14, and has entirely ignored relevant costs from other sections of TSCA to collect, process, and review information.

i. EPA has underestimated its costs associated with confidential business information under section 14.

In the current proposal, EPA estimated its section 14 costs at just $1.78 million, slashing by more than half the woefully inadequate $4.3 million estimated in the 2018 final rule. We again note that in 2016, the White House Budget for fiscal year 2017 estimated that the cost of managing CBI under TSCA, *before* the passage of the Lautenberg Act, was *$20,000,000.*[45] EPA's costs under section 14 should be significantly higher than this now, since the Lautenberg Act passed,

[44] 15 U.S.C. § 2625(b)(4)(B)(i)(I).

[45] The White House proposed annual fees at 40% of the Agency's estimated cost of reviewing and managing TSCA CBI under the pre-Lautenberg law, and stated it would yield an annual fee revenue of $8,000,000, which indicates an estimated annual budget of $20,000,000. GPO, "Analytical Perspectives: Budget of the United States FY 2017," 2016, https://www.gpo.gov/fdsys/pkg/BUDGET-2017-PER/pdf/BUDGET-2017-PER.pdf, at 218, 223.

because EPA now has significantly broader duties to carry out under section 14.[46] Yet EPA provides no justification for its assumption in the Supplemental Proposal that its CBI-related costs are less than 10% of its own 2016, pre-Lautenberg Act estimate. Ironically, EPA refers to an "increased workload" on CBI, while simultaneously decreasing its cost estimates.[47]
It is unclear how EPA developed its estimate for costs under section 14. EPA's proposal provides just a single point estimate of $1,783,800 and 8.6 FTE. EPA refers the reader to the 2021 Proposal for further detail on how the CBI estimates were developed[48] which itself is devoid of detail (see our comments on the 2021 Proposal).[49] EPA's referral to the previous proposal begs that question whether EPA's 2021 workforce and budget analysis addressed the costs for CBI. Nevertheless, the Technical Support Document for the current rule does include the Agency's costs under section 14; yet there is just a single sentence with a list of activities considered (which is nearly identical to a sentence from the 2021 Proposal).[50] There are problems with this list. First, EPA has made no attempt to delineate costs for each activity, e.g., by describing how many CBI claims it receives each year, estimating how many of those would require review, how many would be expected to be challenged, how many would be expected to be approved and would need to be tracked against sunset dates, etc.

Second, EPA fails to include in the Technical Support Document many of its required section 14 activities. For example, EPA's primary focus from its listed activities appears to be on reviewing CBI, but makes little mention of its duties to provide access to both non-confidential information to the public and CBI to authorized entities under sections 14(d)(4), (5), and (6) and section 14(g)(3). While EPA briefly mentions "ensuring access to TSCA CBI for emergency personnel, states, tribes and local governments," EPA omits mandated disclosures to health and environmental professionals in response to an environmental release or to assist in diagnosis under section 14(d)(5), and fails to acknowledge its responsibility to establish and maintain a

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[46] Under reformed TSCA, EPA must now proactively review CBI claims and their substantiations for all claims related to chemical identity (with one exception) and for at least 25% of all other CBI claims. 15 U.S.C. § 2613(g)(1)(A), (C) ("TSCA section 14(g)(1)(A)"). EPA also needs to make all determinations regarding CBI claim reviews public. 15 U.S.C. §§ 2613(g)(1), 2625(j)(1) ("TSCA section 14(g)(1)"). EPA must develop and apply a system of unique identifiers for chemical identities kept confidential. *Id.* § 2613(g)(4) ("TSCA section 14(g)(4)"). EPA must monitor the duration of CBI claims, given that most claims sunset after 10 years unless they are renewed, resubstantiated, and reviewed by EPA. *Id.* § 2613(e). EPA has other, additional new duties under section 14. *See*, *e.g.*, *id.* § 2613(d)(4)-(6) and (g)(3) (requiring EPA to provide access to CBI by certain government employees and other individuals). All of these activities involve processing, reviewing, providing access to, and protecting from disclosure information under TSCA, and thus EPA must include these costs in estimating the total costs to be used in establishing the level of fees under TSCA section 26(b)(4)(F))(i). 15 U.S.C. § 2625(b)(4)(F)(i) ("TSCA section 26(b)(4)(F)(i)").

[47] Technical Support Document at 7.

[48] 87 Fed. Reg. at 68653.

[49] EDF, "Comments on Fees for the Administration of the Toxic Substances Control Act," March 30, 2021, https://www.regulations.gov/comment/EPA-HQ-OPPT-2020-0493-0061, at 37-38.

[50] Technical Support Document at 7; 86 Fed. Reg. at 1895.

"request and notification system" in consultation with CDC to facilitate disclosure, as required under TSCA section 14(g)(3).[51] Indeed, there is no indication EPA has made any progress toward meeting this requirement, over six years after it was enacted. Yet the required system is vital to ensuring that government-associated health and environmental professionals, medical personnel, and first responders can gain access to confidential information they need to do their jobs.

Despite its new responsibilities under reformed TSCA, EPA has provided little public accounting of the types of CBI claims it has received, or how many or what specific claims have been asserted in the various kinds of submissions it receives (for example: a new chemical submission or a section 8(e) submission). EPA also lacks any system for informing the public whether, when, and how information found not to warrant CBI protection from disclosure has been or will be made public. EPA has not mentioned or assigned costs to any of the minimal public documentation that it presently provides of CBI claims and its review of CBI claims, much less the cost of the full public documentation that it should be providing.

EDF commented extensively on EPA's failure to appropriately estimate the true cost of handling CBI under section 4 in our comments on the 2021 Proposal. We incorporate those comments by reference.[52]

ii. EPA continues to misread TSCA in asserting that its baseline costs of collecting, processing, and reviewing information "under this title" are limited to section 14 activities.

EPA continues to exclude from its cost estimates the costs associated with collecting, processing, and reviewing information under other sections of TSCA. EDF has previously commented on EPA's failure to include these costs and incorporates those comments by reference here.[53]

The text of TSCA section 26(b)(1) states that EPA may collect fees from any person to defray costs related to "collecting, processing, reviewing, and providing access to and protecting from disclosure as appropriate under Section 14 information on chemical substances under this title."[54] It seems that EPA interprets this provision to allow only accounting for costs activities under Section 14, but this interpretation of the statute is improper.

First, the plain meaning of the words "collect," "process," and "review" encompass EPA's activities beyond just section 14, particularly actions under sections 8 and 11. For example, EPA

[51] *Id.*

[52] EDF, "Comments on Fees for the Administration of the Toxic Substances Control Act," March 30, 2021, https://www.regulations.gov/comment/EPA-HQ-OPPT-2020-0493-0061, at 37-38 and 45-49.

[53] EDF, "Comments on Fees for the Administration of the Toxic Substances Control Act," March 30, 2021, https://www.regulations.gov/comment/EPA-HQ-OPPT-2020-0493-0061, at 38-41.

[54] 15 U.S.C. § 2625(b)(1) ("TSCA section 26(b)(1)").

develops reporting rules under sections 8(a) and 8(d) under which it *collects* information.[55] Further, section 8(b)(4)(C) requires EPA to *review* claims to protect specific chemical identities and under section 8(b)(5) it is required to *review* CBI claims included in notices to change the status of chemicals from inactive to active.[56] These activities, and others not listed as examples, fall within the plain meaning of "collect," "process," and "review" and therefore should be included in EPA's cost calculations.

Under section 8(b)(4)(C), EPA must develop and implement a rule establishing "a plan to review all claims to protect the specific chemical identities of chemical substances on the confidential portion of the [Inventory]."[57] EPA must also manage and review CBI claims asserted in notices submitted by manufacturers or processors to change the status of chemicals from inactive to active pursuant to section 8(b)(5).[58] Additionally, under sections 8(c) and 8(e), EPA has authority to *collect* and *review* records of significant adverse reactions to health or the environment and notices of substantial risk, respectively.[59] These activities under section 8 all squarely fall within the plain text of section 26(b)(4)(B)(i)(I), so EPA must consider these costs in its baseline. EPA should also defray other costs of collecting, processing, and reviewing information under TSCA, such as the costs of collecting, processing, and reviewing information through subpoenas under TSCA section 11(c).[60]

Furthermore, many section 8 activities are inextricably intertwined with section 14 activities and those activities must be included in EPA's costs. For example, sections 8(b)(4)(B)(ii) and (iii) require EPA to *collect* from manufacturers notices and substantiation of confidentiality claims submitted pursuant to section 14.[61] Further, section 8(b)(4)(D) lays out the requirements for EPA's *review* of CBI claims, which must be "in accordance with section 14."[62] EPA is also required to provide the public with access and information under sections 8(b)(4)(B)(i) and 8(b)(7) consistent with and subject to section 14.[63] Section 14 is inextricably a part of these section 8 activities and EPA must therefore include the cost of these "section 8 activities" as part of its costs for administering section 14.

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[55] 15 U.S.C. § 2607(a), (d).

[56] 15 U.S.C. § 2607(b)(4)(C), (b)(5).

[57] 15 U.S.C. § 2607(b)(4)(C) (emphasis added).

[58] *See* 15 U.S.C. § 2607(b)(5).

[59] *See* 15 U.S.C. § 2607(c), (e).

[60] *See* 15 U.S.C. § 2610(c).

[61] 15 U.S.C. § 2607(b)(4)(B)(ii), (iii).

[62] 15 U.S.C. § 2607(b)(4)(D).

[63] 15 U.S.C. § 2607(b)(4)(B)(i), (b)(7).

Second, the structure of section 26(b)(4)(B)(i)(I) does not support EPA's interpretation. If it intended only to allow for fees to defray costs under section 14, then Congress could have stated that EPA may charge a fee at a "level that will annually defray "25 percent of the costs to the Administrator of carrying out sections 4, 5, [ ] 6, [and 14]."[64] Congress did not enact this language, however, and the Supreme Court has stated that where Congress has not adopted alternative language "the natural implication is that [it] did not intend" to.[65]

Applying the "rule of the last antecedent" to the structure of the section further supports EDF's interpretation.[66] Under this approach, "a limiting clause or phrase … should ordinarily be read as modifying only the noun or phrase that it immediately follows."[67] In *Barnhart v. Thomas*, the Court held that the phrase "which exists in the national economy" could only be read to modify the phrase "any other kind of substantial gainful work" in a statutory provision which read: "An individual shall be determined to be under a disability only if his physical or mental impairment or impairments are of such severity that he is not only unable to do his previous work but cannot, considering his age, education, and work experience, engage in any other kind of substantial gainful work which exists in the national economy."[68]

Applying the Supreme Court's approach to Section 26(b)(1) clearly shows that EPA should account for its costs and could collect fees for relevant activities under other sections of TSCA. Here, the limiting phrase is "as appropriate under Section 14."[69] Applying the rule of the last antecedent, "as appropriate under Section 14" should only modify the phrase "protecting from disclosure."[70] Thus, under the rule of the last antecedent, EPA may collect fees for collecting information under any section of TSCA, processing information under any section of TSCA, reviewing information under any section of TSCA, and providing access to information under any section of TSCA.

Third, the list of activities for which EPA may collect fees ends with the phrase "under this title" modifying the object "information," meaning that the statute requires that EPA consider all the costs of "collecting, processing, reviewing, … information on chemical substances *under this title*."[71] EPA's interpretation limiting activities to section 14 contradicts the plain language that it encompasses all of these activities "under this title," i.e., under TSCA as a whole. In addition,

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[64] 15 U.S.C. § 2625(b)(4)(B)(i)(I).

[65] *See Lozano v. Montoya Alvarez*, 572 U.S. 1, 16, (2014) ("Given that the drafters did not adopt that alternative, the natural implication is that they did not intend" to do so).

[66] 540 U.S. 20 (2003); *see also* Lockhart *v. United States*, 577 U.S. 347, 351 (2016).

[67] *Barnhart* at 26.

[68] *Id*.; 42 U.S.C. § 423(d)(2)(A).

[69] 15 U.S.C. § 2625(b)(1) ("TSCA section 26(b)(1)").

[70] *See Barnhart*, 540 U.S. at 26.

[71] 15 U.S.C. § 2625(b)(4)(B)(i)(I) ("TSCA section 26(b)(4)(B)(i)(I)") (emphasis added).

EPA's interpretation gives this phrase no meaning whatsoever. EPA's interpretation thus "runs aground on the so-called surplusage canon—the presumption that each word Congress uses is there for a reason."[72] Since EPA only considered the costs related to "collecting, processing, reviewing, *** information" under section 14, EPA has failed to give any meaning to the phrase "under this title." In essence, EPA "treat[s] those words as stray marks on a page—notations that Congress regrettably made but did not really intend."[73] But a correct interpretation should "give effect, if possible, to every clause and word of a statute."[74]

Finally, comments in the legislative history suggest that section 26(b)(4)(B)(i)(I) was not restricted to section 14. Four lead negotiators stated three times in the record, without reference to section 14, that "[f]ees under section 26(b) *** are authorized to be collected so that 25% of EPA's overall costs to carry out section 4, 5, and 6, and to collect, process, review, provide access to and protect from disclosure information, are defrayed ***." [75] That language indicates that Congress intended for EPA to defray the costs of collecting, processing, and reviewing information, without limitation to doing so under section 14.

In incorrectly interpreting this provision so that only the costs under section 14 of "collecting, processing, and reviewing" information are included, EPA's baseline cost estimate fails to include many of the costs of collecting, processing, and reviewing information that EPA must consider under section 26(b)(4)(B)(i)(I).[76]

iii. The cost of administering sections 4 and 6 includes costs of collecting, processing, and reviewing information under sections 8 and 11(c).

Even if EPA unlawfully limits its baseline cost of "collecting, reviewing, [and] processing" information to section 14, the costs of administering sections 4 and 6 include costs of collecting, processing, and reviewing information under sections 8 and 11(c). EPA's actions under sections 4 and 6 regarding testing, risk evaluation, and risk management rely on EPA's authority under sections 8 and 11. Under section 8, EPA has authority to require submission of reports on information including chemical uses and environmental and health information under section 8(a), to require submission of records regarding adverse environmental impacts under section 8(c), to collect health and safety studies under 8(d), and to receive information on chemicals that present a substantial risk of injury to health and the environment under 8(e). Further, EPA has authority to subpoena information under section 11(c). All of these provisions provide information which should be used to fill information gaps during the prioritization process under section 6 and during the course of evaluating the risks chemicals pose under section 4. EPA is required to consider "reasonably available information" under section 26(k) when carrying out

[72] *Advocate Health Care Network v. Stapleton*, 137 S. Ct. 1652, 1659 (2017).

[73] *Id*.

[74] *Id*. (quoting *Williams v. Taylor*, 529 U. S. 362, 404 (2000)).

[75] 114 Cong. Rec. S3518 (daily ed. June 7, 2016).

[76] 15 U.S.C. § 2625(b)(4)(B)(i)(I).

section 6, and EPA's regulations define "reasonably available information" as "information that EPA possesses or can reasonably generate, obtain and synthesize for use, *** considering the deadlines."[77] Under this language, information generated through EPA's authority under sections 8 and 11 is reasonably available information. Thus, EPA should include the cost of the above section 8 and 11 actions in its estimation of the costs of implementing sections 4 and 6. EDF commented on this issue in detail in our comments on the 2021 Proposal, which we incorporate by reference here.[78]

B. EPA has failed to collect appropriate fees for the first 10 chemicals and ongoing 20 high-priority chemicals.

i. EPA has missed an opportunity to collect fees on the first 10 chemical risk evaluations and should at a minimum collect associated risk management fees.

EPA has failed to recoup a tremendous amount of money by not collecting fees on the first 10 chemicals to undergo risk evaluation. In its announcement on the Supplemental Proposal, EPA calls out that the 2018 Final Rule "excluded all the costs for the first ten risk evaluations, which are the highest-cost activities for TSCA implementation." Despite this, EPA has made no attempt in the current proposal to recoup the cost of conducting these risk evaluations or, where EPA identifies unreasonable risk, the cost of the following risk management.

While we understand the potential complications of collecting fees now for the first ten chemical risk evaluations, at the minimum we encourage EPA to collect fees moving forward for the risk management – a time consuming and costly process – of the first 10 chemicals. To do this, EPA could create a temporary fee triggering category for the risk management of the first 10 chemicals. Risk management as a separate fee triggering category is not a new concept. In its 2018 rule, EPA sought comment on whether risk management actions should constitute its own fee triggering category,[79] and EDF has twice provided comments on this approach.[80]

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[77] EPA, "Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act," 82 Fed. Reg. 33726, 33748, July 20, 2017, https://www.govinfo.gov/content/pkg/FR-2017-07-20/pdf/2017-14337.pdf (promulgating 40 C.F.R. § 702.33).

[78] EDF, "Comments on Fees for the Administration of the Toxic Substances Control Act," March 30, 2021, https://www.regulations.gov/comment/EPA-HQ-OPPT-2020-0493-0061, at 43-44.

[79] EPA, "User Fees for the Administration of the Toxic Substances Control Act," 83 Fed. Reg. 8212, 8227, February 26, 2018, https://www.govinfo.gov/content/pkg/FR-2018-02-26/pdf/2018-02928.pdf.

[80] EDF, "Comments on Fees for the Administration of the Toxic Substances Control Act," March 30, 2021, https://www.regulations.gov/comment/EPA-HQ-OPPT-2020-0493-0061 and EDF, "Comments on User Fees for the Administration of the Toxic Substances Control Act," May 24, 2018, https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0401-0059.

ii. EPA should collect the adjusted fees for the ongoing 20 high-priority chemicals.

In its Supplemental Proposal, EPA has missed an opportunity to collect sufficient fees for the 20 high-priority chemicals currently being evaluated under TSCA. Under the Final 2018 Rule, we can expect that EPA has already collected fees for these 20 EPA-initiated risk evaluations at the rate of $1,350,000.[81] Therefore, companies were charged just a fraction of the fee proposed in the current proposal, $5,081,000, and EPA has so far missed the opportunity to collect $74.6 million.[82] The higher fee in the current proposal is far more reflective of the work that EPA must conduct under section 6; therefore, if EPA proceeds to not collect the proper fees for each risk evaluation, it will lack resources needed to conduct these ongoing risk evaluations and associated future risk management rules.

This example is illustrative of an ongoing issue EPA can expect to face with its fee rule framework: as the Agency better understands the work entailed in a particular activity, it may already be operating under a fee rule that has underestimated the cost of its ongoing activities and, thus, their associated fees. To resolve this issue, we recommend that for activities that span multiple fee rules, EPA should collect the difference between old fee rates and new fee rates. In the case of the next 20 chemicals, doing so would enable EPA to retroactively collect $3,731,000 for each ongoing risk evaluation, providing much-needed resources for the evaluation and risk management.

C. EPA's proposed schedule for collecting fees is too lenient.

Unchanged from its 2021 proposal, EPA has proposed an extremely lenient fee collection schedule for section 6 risk evaluation fees that would delay and spread out fee payments over nearly the entire period during which they are to be conducted. Specifically, under the current proposal, the full fee for risk evaluations would not be due for 545 days after the final scope is published – years after the risk evaluation work begins. This is a dramatic change from the 2018 final rule, which requires the full payment for EPA-initiated evaluations to be paid within 120 days of EPA publishing the final scope of a chemical risk evaluation. EPA's collection of manufacturer-requested risk evaluations fees has also been shifted to later in the process as compared to the 2018 final rule.[83]

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[81] Under the 2018 Final Rule, the full fee is due within 120 days of the final scope being published. The final scopes for the next 20 chemicals were finalized in August 2020. EPA, "Chemicals Undergoing Risk Evaluation under TSCA," August 19, 2022, https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/chemicals-undergoing-risk-evaluation-under-tsca.

[82] ($5,081,000 - $1,350,000) * 20 = $74,620,000.

[83] Specifically, in the 2018 final rule, the first payment for manufacturer-requested risk evaluations was due within 30 days of granting the request (an estimated two thirds of the cost), with the remainder of the fee due upon finalization of the risk evaluation to adjust for actual cost. In the current proposal, EPA has spread out the fee payment to three installments: the first 180 days after granting the request, the second 545 after granting the request, and the final to adjust for actual cost within 30 days after finalization of the risk evaluation.

As we described further in our 2021 proposed fee rule comments,[84] this drawn-out fee collection schedule, if implemented, will impede staffing and resource planning, compromising both the quality and timeliness of EPA's TSCA work. For example, a 2015 GAO report on Federal User Fees concluded that "timing of fee collections can sometimes cause agencies to experience revenue instability. Specifically, collections that come in small increments on a rolling basis or late in the fiscal year may inhibit an agency's ability to identify overall patterns and fluctuations, or may create cash flow challenges."[85]

However, EPA's rationale for this extended, and counterproductive, fee collection schedule, laid out in its the 2021 proposal, favors avoiding impact on industry without any acknowledgement of the resulting impact on EPA:

> EPA is proposing modifications to the time allowed for payment established under the 2018 Fee Rule for EPA-initiated risk evaluation fees, enabling the fee payer to pay in installments. This proposed change includes a two-payment process—first payment of 50% to be due 180 days after EPA publishes the final scope of a chemical risk evaluation and the second payment for the remainder no later than 545 days after EPA publishes the final scope of a chemical risk evaluation. *EPA believes that a two-payment process will reduce the burden on fee payers and allow them to have more money on hand for operating and other expenses that are incurred between payments*.[86]

In the current proposal, EPA has not only failed again to acknowledge the negative impact on EPA's work of the extended collection schedule, but has now also proposed to expand this approach to the collection of section 4 fees. Specifically, EPA is proposing to extend the timeframe to collect fees 180 days after the effective date of the test order or rules as "[t]his timeframe aligns with the proposed timeframe for the initial fee payment associated with EPA-initiated risk evaluations under section 6, which is also 180 days."[87] While in this case the change is only an additional 40 days (from the original 120 days), EPA's rationale for extending the timeframe continues to fail to acknowledge and describe the impact that extending the fee schedule will have on its own planning and resourcing needs.

We continue to support the approach taken in the 2018 final rule, whereby EPA requires payment of fees before or soon after initiating the activities triggering the fees. This is because EPA's ability to develop and sustain capacity to conduct its activities under TSCA depends on the payment of fees up front.

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[84] EDF, "Comments on Fees for the Administration of the Toxic Substances Control Act," March 30, 2021, https://www.regulations.gov/comment/EPA-HQ-OPPT-2020-0493-0061, at 54.

[85] GAO, Report to Congressional Addresses, "Federal User Fees: Key Considerations for Designing and Implementing Regulatory Fees," September 2015, https://www.gao.gov/products/gao-15-718.

[86] 86 Fed. Reg. 1890, 1902 (emphasis added).

[87] 87 Fed. Reg. 68660.

D. EPA's proposed exemptions from paying fees are inappropriate.

i. EPA should not finalize the proposed fee exemption for risk evaluations.

EDF continues to disagree with EPA's proposed six fee exemptions to EPA-initiated risk evaluations. The activities EPA has proposed to exempt are:

(1) importing the chemical in an article;
(2) producing the chemical as a byproduct;
(3) producing or importing the chemical as an impurity;
(4) research and development activities;
(5) manufacturing less than 2,500 pounds annually of the chemical; and
(6) manufacturing a chemical as a non-isolated intermediate.

We incorporate by reference our 2021 comments outlining our objections to these exemptions.[88] The activities that EPA would fail to collect fees for under EPA's proposed exemptions all constitute commercial activities, and should not be exempt from risk evaluation fees both because TSCA provides no basis for the exemptions and because EPA incurs costs for evaluating risks associated with all of these activities.

EPA is authorized under TSCA section 26(b)(4)(F) to "increase or decrease the fees … as necessary to adjust for inflation and to ensure that funds deposited in the Fund are sufficient to defray," but Congress did not provide EPA the authority to exempt categories of manufacturers from fees as EPA proposes to do here.[89]

Further, EPA's 2018 final fee rule did not include these exemptions and even explicitly rejected manufacturers' proposals to include exemptions like those for byproducts.[90] EPA stated: "TSCA requires EPA to evaluate chemicals under their conditions of use, and conditions of use evaluated may involve manufacture of impurities or byproducts, or chemicals used in niche market applications. As such, EPA does not believe it would be appropriate to exclude these manufacturers from fee obligations for TSCA section 6 activities."[91] The Agency has never rebutted this 2018 statement, and since that time Congress has not modified EPA's risk evaluation requirements under TSCA.

EPA's rationales for these exemptions are unsupported and are not allowed as a justification for exempting fees under TSCA. In its 2021 proposal, EPA outlined the six proposed exemptions and stated that the exemptions for importers of articles, production of a chemical as a byproduct, producing or importing the chemical as an impurity, and manufacturing less than 2,500 pounds annually of a chemical were needed because without them industry faced "significant burdens"

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[88] EDF, "Comments on Fees for the Administration of the Toxic Substances Control Act," March 30, 2021, https://www.regulations.gov/comment/EPA-HQ-OPPT-2020-0493-0061, at 49-53.

[89] 15 U.S.C § 2625(b)(4)(F).

[90] 83 Fed. Reg. at 52699.

[91] *Id*.

associated with self-identification.[92] The Agency's proposal did not provide any quantitative analysis or substantive reporting that such a burden would exist without the exemptions, and instead cited only industry complaints and a theoretical burden.[93] Further, even if burdens do exist, TSCA's fee provisions do not authorize EPA to exempt categories of manufacturers from paying a fee based on burden.[94]

EPA also argued that the exemption for non-isolated intermediates was justified because it would achieve consistency with other regulatory regimes, but no language in the statute permits EPA to grant an exemption solely on the basis of consistency with other regulatory schemes.[95] While non-isolated intermediates are exempt from review under section 5, that section is a distinct part of TSCA and EPA cites no other justification for applying an exemption from another section to fees for section 6, other than consistency of regulations. TSCA does not give EPA authority to create exemptions for fees simply for consistency, and the Agency has not provided an adequate independent justification for the proposed exemption in section 6.

Finally, EPA argued that the exemption for research and development was justified because industry faced "burdensome costs," but the Agency failed to outline these costs or show that regulated entities were unable to pay the fees. EPA is only authorized to consider a fee payer's ability to pay when setting fees, not to exempt a whole category of regulated entities on the assertion that the costs are burdensome generally.[96] In addition to the fact that EPA's 2021 justification for the exemptions are unsupported factually and legally, the current proposal does not provide any justification for these previously proposed fee exemptions.

In addition, EPA's proposal to narrow the byproduct exemption for risk evaluation fees is insufficient. EPA proposes to narrow the exemption to only "producers of a chemical substance that is not later used for commercial purposes or distributed for commercial use" and again cites issues regarding self-identification challenges.[97] The Agency states that this narrowing will ensure that fees are paid by producers who use a substance for other commercial purposes.[98] However, it fails to acknowledge the fact that EPA is still required to evaluate the risks associated with production of a byproduct not used for commercial purposes and the risks associated with the subsequent disposal or other waste treatment of the chemical. EPA incurs costs when it completes such an evaluation, and EPA is entitled to collect fees to offset those costs. Narrowing the exemption is an inadequate solution. EPA should not provide the byproduct exemption.

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[92] 86 Fed. Reg. at 1899-1900.

[93] *Id*.

[94] 15 U.S.C. § 2625(b) ("TSCA section 26(b)").

[95] *Id*; 86 Fed Reg. at 1899-1900.

[96] 15 U.S.C. § 2625(b)(1) ("TSCA section 26(b)(1)").

[97] 87 Fed. Reg. at 68658.

[98] *Id*.

In sum, EPA should not finalize any of the proposed exemptions because TSCA does not allow them, because EPA has not rebutted its own argument against them, and because EPA cannot support them with hypothetical industry burdens.

ii. EPA should not extend the proposed fee exemptions to test rule fees.

EDF further disagrees with EPA's proposal to extend the exemptions to section 4 test rule fees. EPA's proposed exemptions are not authorized under TSCA section 4, just as they are not authorized under TSCA section 6.[99] There is no statutory language that gives EPA power to grant these exemptions for section 4 activities.[100]

Further, EPA's stated justification for the exemptions – that they will "provide greater consistency and fairness" between section 4 and section 6 fees – is inadequate.[101] If the exemptions that are the source of unfairness are themselves not justified under TSCA, the proper approach to achieving fairness is not to also apply the unjustified exemptions to section 4. The exemptions should not exist for section 6 and fairness requires that the exemptions also not exist for section 4.

E. EPA's proposal to notify companies of its new chemicals risk assessments and allow a partial refund for withdrawal is likely to drain more resources and invite more industry interference in the review process.

EPA has proposed to allow a 20 percent refund of the user fee to companies that choose to withdraw their new chemical notices[102] up to five days after the agency gives the companies notice of its completion of its risk assessment of the new chemical. We are concerned that such an allowance will only increase industry's attempts to interfere in the evaluation and regulation of new chemicals. If EPA does finalize this approach, the Agency should first modify it to include safeguards against industry interference, and provide for simultaneous public access to the risk assessments along with the companies.

[99] 15 U.S.C. § 2625(b) ("TSCA section 26(b)").

[100] *Id*.

[101] 87 Fed. Reg. at 68659.

[102] The Supplemental Proposal preamble appears to limit this provision to PMN, SNUN, and MCANs. 87 Fed. Reg. at 68656. The proposed regulatory text refers to "section 5 notices." 87 Fed. Reg. at 68667.

i. The New Chemicals program is severely hampered by industry interference and resource-draining "rework" imposed by industry on Agency scientists.

EPA has recognized the significant problems posed by industry submitting information during the new chemicals review process, which engenders what the Agency calls "rework."[103]

> Intake, review, and inclusion of new data and information takes time. When additional information is submitted, EPA reviews it in order to determine whether it is relevant, adequately documented, and well-supported and whether the Agency needs to revise its risk assessment to incorporate it. Revision(s) to risk assessments (known as 'rework') take additional time, causing delays in the new chemical review for the submitter as well as other companies whose new chemical reviews are also delayed.[104]

In 2022, EPA analyzed nearly 100 new chemical reviews and found that, due to industry actions, risk assessments "may be **reworked anywhere from one to five times**, with each rework being the result of an additional information submission, and the reworks could add at least several months to the case review."[105] The Agency determined that companies submit additional information, resulting in rework, in approximately 30 percent of all new chemical submissions.[106]

EPA reports that companies may submit such information, triggering rework, in order "to refute EPA's initial risk determination."[107] Indeed, there is ample evidence that industry has used the opportunity that EPA provides during the new chemicals review process for companies to revise

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[103] One definition that EPA provides of "rework" is "intake, review, and revision(s) to risk assessments when additional information is submitted" by companies seeking a new chemical review. EPA, "TSCA New Chemical Engineering Outreach Initiative to Increase Transparency and Reduce Rework, Webinar 2," October 18, 2022, https://www.epa.gov/system/files/documents/2022-10/TSCA%20Engineering%20Outreach%20Webinar%20-%20Info%20Evaluation%20Consideration%202022-10-12%20508.pdf, at 3.

[104] EPA, "TSCA New Chemical Engineering Initiative to Increase Transparency and Reduce Rework," October 18, 2022, https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/tsca-new-chemical-engineering.

[105] EPA, "Analysis of Engineering Information Submitted for TSCA Section 5 New Chemicals Submissions," https://www.epa.gov/system/files/documents/2022-06/Engineering%20Initiative%20Analysis.pdf, at 3 (emphasis in original).

[106] *Id*. at 4.

[107] EPA, "TSCA New Chemical Engineering Outreach Initiative to Increase Transparency and Reduce Rework, Kickoff Meeting," July 27, 2022, https://www.epa.gov/system/files/documents/2022-07/TSCA%20New%20Chemical%20Engineering%20Initiative%2C%20Kick%20Off%20Meeting%20Materials.pdf, at 4.

and add to their submissions, and to engage in back and forth with the Agency, in an attempt to influence the scientific outcome.[108]

TSCA does not authorize such back and forth between industry and EPA as EPA reviews new chemicals, nor does the statute authorize companies to add and revise information about their chemicals throughout the scientific assessment. Numerous problems stem from EPA permitting these industry practices. Those issues include the substantial delays and resource drain of "rework," described vividly by EPA; the potential to draw undue agency attention to company submitters' concerns to the exclusion of the public's concerns; the appearance of or actual conflicts of interest; and the subjection of EPA scientists to pressure and distraction from their mission to thoroughly review the safety of new chemicals.

Given these pervasive problems, EDF calls for EPA to minimize the influence industry can exert during the new chemicals review process. Industry should submit robust new chemical notices that do not need to be supplemented during the new chemical review process. After a new chemical notice has been submitted and deemed administratively complete, EPA should conduct its review of the notice. This should not require going back and forth with the company. Based on the information provided in the new chemical notice, EPA should proceed to make its statutory determination and take appropriate risk management action. EPA has provided ample guidance to companies about what they need to submit in their new chemical notices, and companies should be expected to use those tools in preparing new chemical submissions so that they do not need to be supplemented during the review period. EPA's risk review and determination should be based on the information provided with the submission. EDF urges the Agency to make this necessary change, aligning its New Chemicals program with TSCA, and to take the opportunity this year to codify these changes in updating the TSCA new chemicals regulations.[109]

ii. The 20 percent fee refund proposal risks increasing industry interference and rework in new chemical reviews.

EPA has proposed to give companies notice when its risk assessments of their new chemicals have concluded, and then to refund a portion of the fee if companies withdraw their new chemical applications within five days.[110] Presuming that this notice will inform the company of

[108] *See* EDF, "Loosening Industry's Grip on the New Chemicals Program," September 22, 2021, https://blogs.edf.org/health/2021/09/22/loosening-industrys-grip-on-epas-new-chemicals-program/; Sharon Lerner, "EPA Exposed," *Intercept* series, July 2, 2021-August 1, 2022, https://theintercept.com/series/epa-exposed/.

[109] "Updates to New Chemicals Regulations Under the Toxic Substances Control Act (TSCA)," RIN 2070-AK65, https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=202210&RIN=2070-AK65.

[110] "(2) If a TSCA section 5 notice is withdrawn during the period beginning 10 business days after the beginning of the applicable review period under § 720.75(a) of this chapter and ending 5 business days after EPA has provided the submitter notice that the risk assessment on the chemical substance(s) has concluded, the Agency will refund all but 80% of the fee as soon as practicable." 87 Fed. Reg. at 68667.

the Agency's risk determination,[111] and based on EPA's own analysis, this is highly likely to result in many submitters attempting to proffer new information and engage in back and forth with the Agency in a bid to change any risk assessment they do not like. For example, the Agency pointed out in a presentation that industry's "additional information submissions" may be made "to refute EPA's initial risk determination."[112] Under the Agency's current practices, a system that allows bids by industry to change the risk assessment not only provides industry with undue access and influence not afforded other stakeholders; it also, as EPA reports, has "contributed to delays in EPA's review of these chemicals and stretched already limited resources."[113] In fact, in the Supplemental Proposal EPA appears to concede that it could well end up doing "rework" of its risk assessments after issuing these proposed risk assessment notices to submitters. ("Withdrawals [per a refund] would prevent **the need for EPA to conduct risk assessment rework** and execut[e] unneeded risk management actions"[114].

We are concerned that the proposed risk assessment notice period could impose even more burden on the Agency than it is already subjected to by industry-prompted "rework," and EPA must not invite this additional set of problems.[115] The Agency should also limit any refund-for-withdrawal opportunity to what current EPA regulations provide: a 75% refund if a company withdraws its new chemical notice within the first 10 days after its submission.[116]

However, if EPA does proceed with its proposal to notify companies of the completion of the risk assessment, and to allow a partial refund up to five days after providing this notice, the Agency should make clear in the final fee regulations that the risk assessment notice is for a final risk assessment and does not provide opportunity for the submitter to challenge the risk assessment. EPA should specify that the notice of the risk assessment will be done only for the purpose of allowing five days for the company to withdraw and receive a partial refund. It is

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[111] The proposed regulatory language does not make clear what is to be included in the "notice that the risk assessment on the chemical substance(s) has concluded," but the Agency's preamble indicates that it may include "the Agency's determination and risk management actions." 87 Fed. Reg. at 68656. *See also id.* ("Based on the cases withdrawn during FY 2020 and 2021, EPA estimates that approximately 23 percent of cases are withdrawn during review. However, EPA anticipates this percentage could be much higher if submitters had the opportunity to obtain a partial refund when risk assessment results and likely risk management actions are known.").

[112] EPA, "TSCA New Chemical Engineering Outreach Initiative to Increase Transparency and Reduce Rework, Kickoff Meeting," July 27, 2022, https://www.epa.gov/system/files/documents/2022-07/TSCA%20New%20Chemical%20Engineering%20Initiative%2C%20Kick%20Off%20Meeting%20Materials.pdf, at 4.

[113] EPA, "TSCA New Chemical Engineering Initiative to Increase Transparency and Reduce Rework," December 15, 2022, https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/tsca-new-chemical-engineering.

[114] 87 Fed. Reg. at 68656 (emphasis added).

[115] Instead, as we recommend above, EPA's risk review and determination should be based on the information provided with companies' new chemical submission.

[116] 40 C.F.R. § 700.45(i).

critical that the fee rule not create or provide the appearance of any opportunity for the reopening of such final risk assessments – either during or after the five-day period.

In addition, if EPA communicates about the risk assessment to companies, it must provide the same information to the public simultaneously. Any communication to a company of its risk assessment determination is information that the public is entitled to in order to be fully informed about the agency's health and safety assessment of the new chemical, and to ensure public accountability in the new chemical review process.

F. EPA should consider section 4 testing in the context of new chemical reviews.

It appears EPA has not considered the potential to rely on section 4 testing in reviewing new chemicals under section 5. Even beyond EPA's expansive information needs under section 6, EPA has separate authority under section 4 to "require the development of new information *** to review a notice under section 5 ***."[117] Even though EPA also has broad authority under section 5 to issue orders that require testing,[118] there are instances where EPA may want to rely on its section 4 authority to require testing to aid it in making determinations under section 5, such as for categories or groups of chemicals that are routinely included in section 5 notices. It appears that EPA assumes it will never rely on its section 4 authority when reviewing new chemicals, which is problematic considering that EPA expects to receive and review hundreds of section 5 notices a year. EPA should reconsider this assumption, and appropriately adjust the cost estimate to account for these additional expected test orders.

G. EPA should address the "free rider" issue for late company entrants.

Several representatives from industry have articulated a "free rider" issue with the risk evaluation fee consortia framework, such that those companies entering the market later would not have to pay. We agree that EPA should establish a mechanism by which late market entrants would need to pay into the risk evaluation fee. Not only would this be more equitable, but it would also serve as a monetary disincentive for getting into the market of a chemical which has already been designated a High Priority chemical (or as posing an unreasonable risk, depending on the timing of desired market entry).

H. EPA should take public comment on future updates to its fee rule even if it intends only to make an adjustment for inflation.

EPA has not proposed to change section 700.45(d)(3) of the fee rule, which states:

> (3) The Agency will initiate public consultation through notice-and comment rulemaking *prior to making fee adjustments beyond inflation*. If it is determined that no additional adjustment is necessary beyond for inflation, EPA will provide public notice of the inflation-adjusted fee amounts most likely through posting to the Agency's web page by the beginning of each three-year fee adjustment cycle (October 1, 2024, October 1, 2027,

[117] 15 U.S.C § 2603(a)(2)(A)(i) ("TSCA section 4(a)(2)(A)(i)").

[118] *See, e.g.*, 15 U.S.C. § 2604(e)(1)(A) ("TSCA section 5(e)(1)(A)").

> etc.). If the Agency determines that adjustments beyond inflation are necessary, EPA will provide public notice of that determination and the process to be followed to make those adjustments[119]

As EDF made the case in our comments on the 2021 proposed rule, this provision unacceptably precludes any opportunity for the public to comment on a decision by EPA not to adjust fees beyond accounting for inflation. The public should have an opportunity to comment on such an EPA decision, and EPA should be required to consider those comments before making such a decision. Members of the public may have information or strong arguments for why they believe the fees should be adjusted for more than just inflation. We reincorporate our previous comments by reference.[120]

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EDF appreciates EPA's consideration of these comments.

[119] 40 C.F.R. § 700.45(d)(3) (emphasis added).

[120] EDF, "Comments on Fees for the Administration of the Toxic Substances Control Act," March 30, 2021, https://www.regulations.gov/comment/EPA-HQ-OPPT-2020-0493-0061, at 59.