Environmental Defense Fund Comments on

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

Docket # EPA-HQ-OPPT-2020-0493

Submitted March 26, 2021

Summary

Environmental Defense Fund (EDF) appreciates the opportunity to provide these comments on the Environmental Protection Agency's (EPA) 2021 proposal to amend EPA's TSCA fee rule, authorized under section 26(b)(1) of the Toxic Substances Control Act (TSCA), as amended by the Lautenberg Act in 2016. 86 Fed. Reg. 1890 (Jan. 11, 2021). The proposed rule addresses EPA's collection of fees to help defray the costs of EPA's "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]." 15 U.S.C. § 2625(b)(4)(B)(i)(I). The Appendix to these comments provides a summary of the amendments made to TSCA's fee authority and the expanded authorities and duties under TSCA that EPA must account for in setting fees.

Major concerns

EDF is concerned that EPA has lost sight of the purpose of its authority to collect fees from industry under TSCA as the means to help defray its costs in implementing the law. Instead, it has metamorphosed into a new purpose entirely divorced from TSCA: to reduce asserted burdens

on industry – without regard to the impacts that will have on EPA's implementation of the law or health and environmental protection from chemical exposures. See section 1 of these comments.

EPA can collect fees in excess of $25 million and must do so as necessary to ensure it recoups 25% of program costs. See section 2.

EDF supports or partially supports several specific EPA proposals; see section 3. However, as detailed in section 4, EDF believes that EPA continues to significantly underestimate the baseline costs to the agency 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]." 15 U.S.C. § 2625(b)(4)(B)(i)(I). For example:

- TSCA Section 4: EPA has significantly underestimated the amount of testing EPA needs to conduct robust risk evaluations and instead still intends to over-rely on voluntary information submissions.
- TSCA Section 5: EPA estimates its costs for new chemicals based on an illegal review approach limited to intended uses and fails to adequately address costs of developing consent orders and Significant New Use Rules (SNURs).
- TSCA Section 6: EPA fails to include *any* explicit estimate or cost breakdown for several core section 6 activities and needs, including: identifying potential candidates for prioritization and prioritization itself; risk management, and scientific assistance provided by EPA's Office of Research and Development (ORD).
- TSCA Section 8: EPA has ignored the costs associated with developing reporting rules under this section, which are vital to inform section 4 testing actions and section 6 prioritization, risk evaluation, and risk management activities.
- TSCA Section 14: EPA's estimate for activities under this section has dropped by more than half relative to that in its 2018 final rule – a clear indication that EPA continues to grossly underestimate the true costs of carrying out its duties under TSCA.

As a result of these underestimates and omissions, EPA has set the fees below the levels required by TSCA section 26(b)(4)(B), and the proposed fees will not recoup the allowable costs under TSCA. *See* 15 U.S.C. § 2625(b)(4)(B). Recent reports by the Government Accountability Office (GAO) and EPA's Office of Inspector General (OIG) found that EPA's ability to assess and manage chemicals has regressed due to lack of workforce or workload planning to ensure the agency can meet carry out its duties. To fulfill its obligations under TSCA section 26(b)(4)(B), EPA must more fully, accurately and transparently calculate the costs of "administering 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]" to ensure EPA receives the fees necessary to support implementation of TSCA. 15 U.S.C. § 2625(b)(1).

EDF is also deeply concerned over EPA's proposal to exempt many manufacturers from TSCA's obligation that companies making a chemical substance that is undergoing a risk evaluation under section 6(b) be subject to fees. Neither TSCA nor EPA's Final 2018 Fee Rule provides any basis for establishing such exemptions. We detail our concerns in section 5 of these comments.

EPA has provided insufficient basis for its proposal to delay and spread out fee payments (see section 6), has undercounted the number of manufacturer-requested risk evaluations it must conduct (see section 7), and has failed to account for inflation in adjusting fees (see section 9). EPA must take public comment on any future adjustment of fees, including where EPA proposes only an adjustment based on inflation (see section 10).

EDF continues to believe EPA should establish a separate fee category for risk management, and that it should charge fees to recover a portion of its costs for the risk management rules it is developing for the first 10 chemicals that underwent risk evaluations; see section 8.

EDF submitted extensive comments on EPA's 2018 proposed TSCA fees rule. Because EPA's final 2018 rule failed to account for many of these comments and many are still relevant to the 2021 proposal, EDF incorporates those comments in full herein by reference.[1]

EDF has included its own table below (Table 1) that summarizes EDF's understanding of the agency's estimates for the number of actions per year, the costs per action, the cost per year, the actual (2018) or proposed (2021) fee, and the projected fee revenue for each category of actions. The table compares what EPA projected at the time of the Final 2018 Fee Rule to what it now projects in the Proposed 2021 Fee Rule.

[1] Environmental Defense Fund Comments on User Fees for the Administration of the Toxic Substances Control Act, submitted May 24, 2018, available at https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0401-0059.

Table 1: Summary of EPA's Program Cost Estimates and Proposed Fees

TSCA Provision	EPA Program Area	No. of Actions per year		Cost per activity		Cost per year		Fee Structure (fee per action)		Total Annual Fees EPA expects to collect (in dollars, assuming 3% discount rate[2])	
		2018 final	*2021 proposal*	*2018 final*	*2021 proposal*	*2018 final*	*2021 proposal*	*2018 final*	*2021 proposal*	*2018 final*	*2021 proposal*
Section 4	Test Order	10	10	279,000	279,000	2,795,000	2,795,000[3]	9,800	9,800	98,000	107, 800
	Amended Test Order	N/A[4]	1[5]	N/A		N/A		N/A	9,800	N/A	
	Test Rule	1 every 2 years	1 every 2 years	844,100	844,000	422,000	422,000	29,500	29,500	19,670	19,670
	Enforceable Consent Agreement (ECA)	1 every 2 years	1 every 2 years	652,000	652,000	326,000	326,000	22,800	22,800	15,202	15,202
Section 5[6]	PMN/MCAN/ SNUN	462	301	55,200	NP[7]	25,500,000	NP	16,000	16,000	6,256,800[13]	3,430,000
	All Exemptions[8]	560	320	5,600	NP	3,149,000	NP	4,700	2,700	2,240,960[13]	1,082,880
	Bona Fide Notice	N/A	207	N/A	NP	N/A	NP	N/A	500	N/A	62,490

[2] Figures come from Table 3-5 in the Economic Analysis for the Final 2018 Fee Rule and Table ES-4 in the Economic Analysis for the Proposed 2021 Fee Rule. While we use the figures for a 3% discount rate, each of those tables also provides figures assuming a 7% discount rate.
[3] Table 2 of the 2021 proposal indicates the cost for test orders is $2,795,000, but this appears to omit the cost of the amended test order. See section 4.A.vii. for further detail.
[4] N/A is "not applicable," as the item was not included in the 2018 fee rule.
[5] Note that Table 2 and the preamble language (p. 1893) of the 2021 proposal present only 10 test orders, and do not mention the amended test order. However, the 2021 Economic Analysis (e.g., Table 3-4) present EPA's estimate of one amended test order per year.
[6] Under section 5 EPA has assumed that a number of notices will come from small businesses and be subject to reduced fees. While the number of small businesses and reduced fee amounts are not shown in the table, the total annual fees EPA expects to collect includes those reductions.
[7] "NP" is "not provided," and is used in this table because EPA did not provide individualized (i.e., per-activity) estimates for these actions.
[8] Characterized in the 2021 proposal as "LoREX, LVE, TME, Tier II exemption, TERA, Film Article."

TSCA Provision	EPA Program Area	No. of Actions per year		Cost per activity		Cost per year		Fee Structure (fee per action)		Total Annual Fees EPA expects to collect (in dollars, assuming 3% discount rate[2])	
		2018 final	*2021 proposal*	*2018 final*	*2021 proposal*	*2018 final*	*2021 proposal*	*2018 final*	*2021 proposal*	*2018 final*	*2021 proposal*
	Notice of Commence-ment	N/A	175	N/A	NP	N/A	NP	N/A	500	N/A	73,980
Section 6 Risk Evaluation	EPA-Initiated Risk Evaluation	25 every 3 years	20 every 3 years	3,884,000	5,671,000	32,370,000	41,998,820	1,350,000	2,560,000	11,250,000[13]	17,066,667
	Manufacturer-Requested Risk Evaluation (Work Plan)	2 every 3 years	2 every 3 years	3,884,000	5,671,000	2,370,000	3,783,000	1,942,000	2,835,500	N/A	1,890.333
	Manufacturer-Requested Risk Evaluation (Non-Work Plan)	3 every 3 years	3 every 3 years	3,884,000	5,671,000	3,884,000	5,671,000	3,884,000	5,671,000	N/A	5,671,000
Section 6 Other	Office of Research and Development	NP	NP	NP	NP	2,091,000	4,192,153[9]	0	NP	0	0
	Risk Management	7.5[10]	NP	877,867[11]	NP	6,584,000		0		0	
	Prioritization	NP	NP	NP	NP	2,573,000		0		0	

[9] Based on direct communication with EPA staff; see section 4.C.ii.

[10] This is EPA's estimate for the annual number of ongoing risk management actions, which we found in the TSCA Fees Costing Spreadsheet in the docket. *See* TSCA Fees Costing Spreadsheet Submitted to OMB for Proposed 2018 Fee Rule, https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0401-0021. No comparable figure was provided in the 2021 proposal.

[11] This cost-per-activity estimate was not calculated by EPA, i.e., it is not included in any of the tables in its proposed or final 2018 rule, but was calculated by EDF using the same formula EPA used for other activities to calculate the cost per year (# of actions per year x cost per activity = cost per year). No comparable figure was provided in the 2021 proposal.

TSCA Provision	EPA Program Area	No. of Actions per year		Cost per activity		Cost per year		Fee Structure (fee per action)		Total Annual Fees EPA expects to collect (in dollars, assuming 3% discount rate[2])	
		2018 final	*2021 proposal*	*2018 final*	*2021 proposal*	*2018 final*	*2021 proposal*	*2018 final*	*2021 proposal*	*2018 final*	*2021 proposal*
Section 14	CBI Review & CBI LAN[12]	NP	NP	NP	NP	4,345,000	1,873,443	0	0	0	0
TOTAL COSTS						**80,178,000**	**87,536,000**				
TOTAL FEES										**19,880,632[13]**	**$21,858,688**

Data sources for table:

- Final 2018 Fee Rule: https://www.regulations.gov/document/EPA-HQ-OPPT-2016-0401-0072.
- Economic Analysis of the Final 2018 Fee Rule: https://www.regulations.gov/document/EPA-HQ-OPPT-2016-0401-0084.
- Proposed 2021 Fee Rule: https://www.regulations.gov/document/EPA-HQ-OPPT-2020-0493-0001.
- Economic Analysis of the Proposed 2021 Fee Rule: https://www.regulations.gov/document/EPA-HQ-OPPT-2020-0493-0025.

[12] The CBI LAN, according to the CBI Manual, is a "physically isolated Local Area Network located at EPA headquarters dedicated exclusively to TSCA CBI." U.S. EPA, OPPT, TSCA CBI Protection Manual at p. 6 (Oct. 2003), https://www.regulations.gov/document?D=EPA-HQ-OPPT-2017-0318-0005.

[13] These figures are those reported in the Economic Analysis for the Final 2018 Fee Rule. The corresponding amounts for 2018 (identified as "baseline") reported in Table ES-4 of the Economic Analysis for the 2021 proposed rule differ considerably. The 2018 figures for PMN//MCAN/ SNUN were reduced in the 2021 Economic Analysis from $6,256,800 (462 actions) to $3,430,000 (301 actions); those for Exemptions were reduced from $2,240,960 (560 actions) to $1,082,880 (320 actions); and those for EPA-initiated risk evaluations were reduced from $11,250,000 (25 actions) to $9,000,000 (20 actions). Overall, the projected fees to be recouped dropped from $19,880,632 to $13,645,752. EPA did not acknowledge or explain why these figures were changed from those in the Final 2018 Fee Rule documents.

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1. EPA has lost sight of the purpose of its authority to collect fees from industry under TSCA.

Among the key reforms made to TSCA in 2016 was the expansion of EPA's authority to collect fees from industry to help defray its costs in implementing the law. There was widespread agreement, including by industry at the time, that EPA needed significantly more resources to faithfully execute TSCA and that industry should significantly contribute financially.

Unfortunately, that purpose has disappeared almost entirely from the current proposal, and has metamorphosed into a new purpose entirely divorced from TSCA: to reduce asserted burdens on industry – without regard to the impacts that will have on EPA's implementation of the law or health and environmental protection from chemical exposures. EPA repeatedly invokes industry burden reduction as justification for many of its proposed changes to the risk evaluation fees relative to the Final 2018 Fee Rule:

- allowing payment of fees for risk evaluations in installments, with the final payment not being required until 725 days – two full years – after initiation of the risk evaluation (p. 1898);
- providing exemptions from fees for risk evaluations for (1) Importers of articles containing a chemical substance subject to an EPA-initiated risk evaluation; (2) manufacturers of a substance subject to an EPA-initiated risk evaluation that is produced as a byproduct; and (3) manufacturers (including importers) of a substance subject to an EPA-initiated risk evaluation that is produced or imported as an impurity (p. 1899);

- providing further exemptions from fees for risk evaluations for manufacturers of small quantities of a chemical for research and development (p. 1900); and for manufacturers of a chemical substance in quantities at or below 2,500 lbs (p. 1900).

Notably, EPA has cited no evidence other than industry complaints to demonstrate that the fees actually impose any undue burdens on industry.

EPA's discussion of the proposed changes fails even to acknowledge, let alone assess, the effects of the reduced or delayed fees that would result from its proposed changes on EPA's ability to carry out its duties under TSCA. Indeed, EPA asserts without basis that "EPA will incur no additional burden, relative to the 2018 TSCA Fees Rule as a result of the proposed Fee Rule amendments" (p. 1904). It is exceedingly difficult to see how reduced or delayed fees would not significantly adversely affect EPA's ability to plan ahead and budget; take timely actions to collect or require development of needed information; hire and train sufficient staff; engage contractors for needed work; and other activities it must undertake to conduct risk evaluations and meet its statutory deadlines.

EPA has provided insufficient basis, and no basis is provided in TSCA, for EPA to elevate asserted industry burden above Congress' clear intent in enhancing EPA's fee authority to ensure the agency has adequate resources to implement TSCA.

2. EPA can collect fees in excess of $25 million and must do so as necessary to ensure it recoups 25% of program costs.

In setting the level of fees EPA could collect initially, TSCA stated that "the Administrator shall ***

> (B) set the fees *** at levels such that the fees will, in aggregate, provide a sustainable source of funds to annually defray—
> (i) the lower of—
> > (I) 25 percent of the costs to the Administrator 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 this title, other than the costs to conduct and complete risk evaluations under section 6(b); or
> > (II) $25,000,000 (subject to adjustment pursuant to subparagraph (F))[.]"

Id. at § 2625(b)(4)(B). Notwithstanding that provision, for chemical substances for which EPA has granted a manufacturer request to prepare a risk evaluation, EPA shall "establish the fee at a level sufficient to defray the full costs to the Administrator of conducting the risk evaluation" or

sufficient to defray 50% of the costs if the granted request pertains to a chemical substance on the 2014 update to the TSCA Work Plan. *Id.* at § 2625(b)(4)(D).

TSCA section 26(b)(4)(F) authorizes EPA to modify the fees every 3 years in order 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" the specified portion of EPA's costs. This provision mandates that, in updates made to the initial rule promulgated in 2018, EPA is to adjust fees so as to continue to defray 25 percent of the specified costs, without regard to the initial annual fee cap of $25,000,000. The proviso in section 26(b)(4)(B)(i)(II) that the initial cap is "subject to adjustment" when updates to the initial fee rule are made makes clear that annual fees can and must exceed the initial cap when necessary to ensure EPA collects fees sufficient to defray 25% of the costs specified in section 26(b)(4)(B)(i)(I). 15 U.S.C. § 2625(b)(4)(B)(i)(I).

3. EDF supports or partially supports several specific EPA proposals.

A. Three new fee categories

EDF supports the proposal's introduction of three new fee categories, specifically:

- a Bona Fide Intent to Manufacture or Import Notice,
- a Notice of Commencement (NOC) of Manufacture or Import, and
- an additional fee associated with companies redoing testing to comply with test orders.

Each of these activities takes EPA time and resources, and, therefore, should be included both in EPA's baseline costs for administering TSCA and as fee categories. EPA's review of bona-fide requests, NOCs, and test orders are part of "carrying out" section 5 and section 4 of TSCA, so EPA should include those costs in its baseline costs used to determine the level of fees under section 26(b)(4). *See* 15 U.S.C. § 2625(b)(B) (requiring that fees be set at a level to annually defray "25 percent of the costs to [EPA] of carrying out sections 4, 5, and 6"). In addition, EPA may charge a fee to "*any person* required to submit *** a notice *or other information* to be reviewed by the Administrator under section 5." 15 U.S.C. § 2625(b)(1) (emphases added). A person submitting a notice of bona fide intent or a NOC clearly fits within that language. See EDF's comments on the proposed 2018 Fee Rule for more detail.[14]

With regards to the additional fee for test orders, it is wholly warranted for EPA to charge an additional fee to companies that fail to follow terms or conditions in the order, resulting in redoing and resubmitting data for review. EPA should not bear the brunt of the cost to review

[14] Environmental Defense Fund Comments on User Fees for the Administration of the Toxic Substances Control Act, submitted May 24, 2018, sections II.C.i. and V.C., available at https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0401-0059.

test order data multiple times due to the company's failure to comply with the order. Beyond a fee, such failures to comply with a test order constitutes a violation of TSCA under section 15 and should be accompanied by a penalty under section 16.

In its proposal EPA states that it "requests public comment on whether this new fee will incentivize companies to correctly follow section 4 test order guidelines." (p. 1898) Instead of suggesting it needs to provide incentives to companies to comply with binding orders issued the law, EPA should be making absolutely clear that enforcement actions will be taken when companies fail to comply with a test order. Unfortunately, failure to comply has already occurred despite the small number of test orders EPA has issued. EPA noted in its final risk evaluation for Pigment Violet 29 (p. 44):

> The occupational inhalation exposure report did not meet the terms set out in the approved study plan (EPA-HQ-OPPT-2020-0070-0006) but was given a high quality rating following a review for data quality. Despite this rating, EPA maintains that there are several critical deficiencies in the study that result in a determination of low confidence in the results.

It is not clear what if anything EPA has done to date to enforce its test order in light of this failure of the company to comply. But this excerpt makes clear one of the consequences: that EPA lacks the needed data the test order was intended to provide for use in its risk evaluation. While we support the additional fee, it is also essential that EPA send a clear signal to companies that EPA will enforce against their failures to comply with test orders and not simply rely on an additional fee to provide companies an incentive to comply.

B. Increased risk evaluation cost estimate and fee

EPA has increased its estimated cost for risk evaluations from $3,884,000 to $5,671,000, better reflecting its actual cost to conduct a risk evaluation, and resulting in an increased risk evaluation fee as compared to the 2018 Final Rule. EDF supports this increase. However, as we discuss in section 4.C., EPA continues to underestimate the true cost of comprehensive risk evaluations and has obscured the costs of other section 6 activities.

C. Applying fee requirements for manufacturers that exclusively export

EDF also supports the proposed application of fee requirements for manufacturers that exclusively export chemicals subject to EPA-initiated risk evaluations. We agree with EPA's rationale that the activities of manufacturers that exclusively export High-Priority Substances still need to be included in risk evaluations and should, therefore, share in defraying the cost of EPA-initiated risk evaluations.

D. Rejection of a fee cap

EPA considered, and appropriately rejected, the regulatory option of a fee cap. EDF strongly supports EPA's position that creating such fee caps would put the agency at risk of not collecting the full amount of fees ("EPA believes imposing a cap on fees for individual entities could result in EPA not collecting the full cost associated with that risk evaluation," p. 1898). It is not in the public interest to push an undue portion of the cost of conducting the risk evaluation – a portion of which should be covered by chemical manufacturers – back onto the taxpayer. Further, such a cap could result in EPA not recouping the required 25% of EPA's costs.

E. Five-year prohibition on manufacture for those certifying cessation

EDF supports EPA's proposed five-year prohibition on manufacture of a substance for which a manufacturer has certified cessation to opt out of fee payment. EPA indicates it is considering a regulatory alternative that would allow manufacturers that had previously certified cessation to begin manufacturing or importing the substances within the successive five-year period and pay their portion of the fee after initial invoicing. We strongly oppose the regulatory alternative and support EPA's rationale for not pursuing this approach, including that it would result in an unnecessary increased burden to EPA and could create inequities between manufacturers paying the fees upfront versus those opting back in.

We also support EPA's preamble text indicating that resuming manufacture or import during the five-year period would be a prohibited act under TSCA section 15(1) and subject to a penalty under TSCA section 16 (p. 1901); however, we do not see this language reflected in the regulatory text. EPA should rectify this in promulgating the final rule.

4. EPA continues to significantly underestimate its annual budget.

As with the Final 2018 Fee Rule, EPA is continuing to underestimate the agency's baseline costs to administer TSCA, which will ultimately result in recouping less funds through fees than warranted. In the current proposal, EPA has both underestimated the agency's costs for many of the activities it did include, and omitted altogether the costs of other activities it must undertake and which the fees it collects are to help defray.

Based on EDF's review of the proposed rule and the other materials EPA has provided in the docket, it appears that EPA has failed to fully account for the costs of numerous activities EPA must undertake in carrying out under sections 4, 5, and 6, and in collecting, processing, reviewing, and of providing access to and protecting from disclosure as appropriate under section 14 information under TSCA.

In revising the fee rule, EPA must set fees at a level that will annually defray "approximately but not more than 25 percent of the costs to the Administrator 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 this title" 15 U.S.C. § 2625(b)(4)(F)(i). For manufacturer-requested risk evaluations, EPA must retain the fees "at a level sufficient to defray the full costs to the Administrator of conducting the risk evaluation under section 6(b)," unless the chemical appears on the 2014 Work Plan in which case the fees must defray 50 percent of the costs. *See id.* § 2625(b)(4)(F)(ii), invoking § 2625(b)(4)(D). Thus, EPA must accurately estimate the costs of "carrying out" these various activities to ensure that EPA establishes fees at the legally mandated levels.

EDF's comments address each of the statutory sections in turn, identifying areas where EDF believes EPA has underestimated its budget for its activities under that section. Specifically, in the comments below, we address the following:

- When estimating costs under section 4, EPA has significantly underestimated the amount of testing EPA needs to conduct robust risk evaluations and instead still intends to over-rely on voluntary information submissions – as demonstrated by its recent proposed section 4 and voluntary Information Collection Requests (ICRs).
- When estimating costs under section 5:
    - EPA estimates its costs based on an illegal review limited to intended uses and fails to adequately address costs of developing consent orders and Significant New Use Rules (SNURs).
    - EPA fails to transparently and accurately account for its new obligations under the Lautenberg Act.
- With respect to section 6:
    - EPA relies on the costs of the first 10 chemical risk evaluations, despite the agency's obligation to broaden the scope of these evaluations based on the Ninth Circuit Court of Appeals 2019 decision.
    - EPA fails to include *any* explicit estimate or cost breakdown for several core section 6 activities and needs, including: identifying potential candidates for prioritization and prioritization itself; risk management, and scientific assistance provided by EPA's Office of Research and Development (ORD). EPA's apparent estimate (which was not explicitly stated and we had to derive from other estimates) for the combination of all of these activities appears to be well below what is needed.
    - EPA's proposed estimated cost for administering section 6 has been reduced by nearly $2 million since the Final 2018 Fee Rule, which is highly questionable given EPA's increased risk evaluation and risk management workload.

- With respect to the costs of collecting, processing, and reviewing information under TSCA, EPA has failed to include any estimates beyond the cost of reviewing confidential business information (CBI) claims under section 14 (and possibly section 8). As a result:
    - EPA has ignored the costs associated with activities such as the following:
        - developing reporting rules under section 8(a) and (8)(d), which may be critical in providing information needed to meet section 4 testing requirements and inform section 6 prioritization, risk evaluation, and risk management activities; and
        - providing access to CBI by authorized entities under section 14(d)(4), (5), and (6) and section 14(g)(3).
    - In addition, it is not clear whether EPA has included costs for implementing the CBI claim review plan called for under section 8(b)(4)(C); EPA's line item for section 8 provides no indication of what activities it includes.
- Finally, EPA's estimated costs under section 14 are unreasonably low:
    - They are as much as five-fold lower than EPA's prior (2016) budget estimates for these activities under TSCA *prior* to its reform.
    - Despite the fact that EPA is well behind in meeting its obligations with regard to information access and cites resource constraints as the reason, EPA's estimate for such activities has dropped by more than half relative to that in its 2018 final rule – a clear indication that EPA continues to grossly underestimate the true costs of carrying out its duties in these areas under TSCA.

Furthermore, by relying heavily upon EPA's past experience and internal tracking of staff hours, EPA fails to recognize the dramatically increased workload (and therefore cost) needed to faithfully comport with the requirements of amended TSCA. In March 2021, the Government Accountability Office (GAO) released its annual High Risk report,[15] finding that EPA's ability to assess and manage chemicals has regressed. The GAO report highlights that EPA has failed to complete workforce or workload planning to ensure the agency can meet TSCA deadlines, and reiterates findings from an August 2020 Office of Inspector General (OIG) report[16] noting that OPPT has failed to identify workforce needs for budget justification since 1987. Both reports recognize the greatly increased scope of work under amended TSCA, and EPA's failure to translate that into additional staff and resources needs.

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

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

A. EPA has underestimated its costs for administering Section 4.

As discussed in the Appendix, 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). *See* 15 U.S.C. § 2603(a)(2). Yet EPA's proposed rule indicates that it only anticipates annually working on 10 test orders, one amended test order, one test rule, and one ECA. 86 Fed. Reg. 1890; Economic Analysis at 3-10. For test rules and ECAs, EPA only expects to initiate each of these activities about every other year and take two years to complete them. *Id.* EPA has made no change (with the exception of the addition of one amended test order a year) to these estimates since the 2018 final rule. As explained below, these estimates are very low given EPA's broad duties and the acknowledged information gaps that exist for many chemicals.

These low estimates raise concerns that EPA will continue not to require sufficient testing to provide the information needed to fulfill its obligations, especially for prioritization, risk evaluation, and risk management under section 6. If EPA underestimates its true data needs here, EPA will also not charge sufficient fees to help defray the costs of lawful implementation of TSCA, including meeting the science standards of sections 26(h) and (i). *See* 15 U.S.C. § 2625(h), (i). The concerns raised by these low estimates for testing activities are compounded by EPA's underlying assumptions that each section 4 activity will only involve a small number of chemicals, tests, and companies.

EPA's low estimates for testing actions suggest that the agency believes there are few or no information gaps to be filled to inform EPA's ongoing and anticipated activities under sections 6 and 5. In fact, EPA has only issued 10 test orders on chemicals undergoing section 6 risk evaluations since the law was reformed in 2016.[17] But in reality, there are significant data gaps that are crucial to fill in order to appropriately conduct section 6 prioritization and risk evaluation. EDF, among other stakeholders, has been calling on EPA to mandate information submission or development under TSCA § 4 (as well as § 8) for years, including on the first 10 chemicals, the 20 chemicals currently undergoing EPA-initiated risk evaluations, the additional chemicals undergoing manufacturer-requested risk evaluations, and the remaining TSCA Work Plan chemicals. Below we provide additional detail on these data gaps – and EPA's continual failure to require testing under section 4 to fill them.

[17] See: https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/tsca-section-4-test-orders.

i. EPA failed to use its information authorities to fill data gaps for the first 10 chemicals.

A constant criticism of EPA's draft risk evaluations for the first 10 chemicals was the dearth of information on which EPA has relied to draw firm risk conclusions. Stakeholders like EDF[18] and EPA's own SACC[19] repeatedly pointed to the lack of sufficient, reliable information on the chemicals' presence in and releases into various environmental media; their presence in and releases from industrial, commercial, and consumer products and materials; the extent and magnitude of workplace exposure levels; key human hazard endpoints; and ecological hazards to sediment- and soil-dwelling and terrestrial as well as aquatic organisms. Concerns were also repeatedly raised about EPA's over-reliance on models and on modeled vs. measured physical-chemical and environment fate data, especially in the absence of rigorous uncertainty analyses and incorporation of uncertainty into EPA's risk conclusions.

ii. EPA has not accounted for the information gaps for the chemicals currently undergoing risk evaluation and other TSCA Work Plan chemicals.

The agency has only recently and in a limited way used its authorities to require the generation and submission of data for the 20-plus chemicals now undergoing risk evaluation, despite clear data gaps. While EPA did recently issue test orders for nine of these chemicals, they require relatively narrow testing.[20] Notably, none of EPA's 20 scope documents makes even a single

[18] See, for example: Environmental Defense Fund Comments on the Draft Risk Evaluation of 1-Bromopropane, (Oct. 11, 2019), https://www.regulations.gov/document?D=EPA-HQ-OPPT-2019-0235-0047; EDF Comments on Draft Risk Evaluation of Trichloroethylene (Apr. 27, 2020), https://www.regulations.gov/document?D=EPA-HQ-OPPT-2019-0500-0108; EDF Comment on the 1,4-Dioxane Draft Risk Evaluation (Aug. 30, 2019), https://www.regulations.gov/document?D=EPA-HQ-OPPT-2019-0238-0058; EDF Comments on Draft Risk Evaluation of Methylene Chloride (December 30, 2019), https://www.regulations.gov/document?D=EPA-HQ-OPPT-2019-0437-0073.

[19] See, for example: SACC peer review report on the methylene chloride draft risk evaluation, https://www.regulations.gov/document?D=EPA-HQ-OPPT-2019-0437-0080; SACC peer review report on 1-bromopropane draft risk evaluation, https://www.regulations.gov/document?D=EPA-HQ-OPPT-2019-0235-0061; SACC peer review report on the 1,4-dioxane and HBCD draft risk evaluations, https://www.regulations.gov/document?D=EPA-HQ-OPPT-2019-0238-0063.

[20] See: https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/tsca-section-4-test-orders. As an example, the test order for *p*-Dichlorobenzene requires testing only for two narrow ecotoxicity endpoints and for workplace exposure data, despite far greater data needs; EPA proposes instead to use the same approaches for which it was heavily criticized when used for the first 10 risk evaluations (see subsection A.i. above).

mention of EPA ever using the enhanced information authorities under amended TSCA to address data gaps and needs.[21]

As a specific example, EPA has left data gaps identified years ago for the flame retardants TCEP and TBBPA unaddressed for more than five years. In 2015, EPA released TSCA Work Plan Initial Problem Formulations for three clusters of flame retardant chemicals, including the "Chlorinated Phosphate Ester (CPE) Cluster" – which included the current high-priority chemical TCEP – and the "Tetrabromobisphenol A (TBBPA) and Related Chemicals Cluster" – which included the current high-priority chemical TBBPA. At the time, EDF recommended that EPA should develop and present a plan to fill major data gaps, specifically by promulgating § 4 test rules (although the test order authority added by the 2016 TSCA amendments could now be used instead) and/or §§ 8(a) or 8(d) rules, as well as issuing other data call-ins for the chemicals in these three flame retardant clusters. We specifically recommended the following regulatory actions be taken to address identified data gaps:[22]

Chlorinated Phosphate Ester (CPE) Cluster (includes TCEP)

- Section 4 test rule and/or section 8(d) data call-in for inhalation and dermal route-specific toxicity data (identified in assessment as a critical data need).
- Section 4 test rule for exposure monitoring studies of U.S.-based industrial workers.
- Section 8(a) reporting rule on the number of individuals exposed in their place of employment and the duration of exposure.

Tetrabromobisphenol A (TBBPA) and Related Chemicals Cluster:

- Air/dust exposure monitoring studies at U.S.-based recycling facilities and reporting on the number of recycling workers exposed. EPA may need to use other authorities to obtain this information.
- U.S. data on recycling and disposal of discarded electronics. EPA may need to use other authorities to obtain this information.
- Section 4 test rule and/or section 8(d) data call-in for dose response data on exposure to TBBPA and incidence of hepatoblastomas.

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[21] See EDF Comments, "Draft Scopes of the Risk Evaluation to Be Conducted for Seven Chemical Substances Under the Toxic Substances Control Act," June 8, 2020, at p. 41. Available: https://www.regulations.gov/comment/EPA-HQ-OPPT-2019-0131-0047.

[22] See EDF Comments, "TSCA Work Plan Chemical Problem Formulation and Initial Assessment: Chlorinated Phosphate Ester Cluster Flame Retardants," November 18, 2015, at p. p.17. Available: https://www.regulations.gov/document?D=EPA-HQ-OPPT-2015-0068-0015, and "TSCA Work Plan Chemical Problem Formulation and Initial Assessment: Tetrabromobisphenol A and Related Chemicals Cluster Flame Retardants," November 18, 2015, at p. 17. Available: https://www.regulations.gov/document?D=EPA-HQ-OPPT-2014-0730-0022.

Based on our review of the TSCA scopes for these chemicals and EPA's ChemView database, it does not appear that EPA has acted to fill any of these data gaps in the subsequent five years. More recently, EPA's Children's Health Protection Advisory Committee (CHPAC) sent a letter to Acting Administrator Jane Nishida in January recommending that the agency fill significant data gaps for the TSCA Work Plan chemicals that will be needed to conduct both prioritization and subsequent risk evaluations. Specifically, CHPAC recommended that EPA utilize its section 4 authorities (as well as those under section 8) to fill hazard and exposure data gaps ranging from reproductive and developmental toxicity to the presence of the chemical in drinking water, breast milk, child care/school settings, and more.[23]

Nowhere in the docket has EPA attempted to reconcile the extensive information needs for the ongoing and future section 6 prioritization and risk evaluation activities with its low projections of the number of section 4 testing actions to be taken.

iii. EPA has not considered the potential to rely on section 4 testing in reviewing notices 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 ***." 15 U.S.C § 2603(a)(2)(A)(i). Even though EPA also has broad authority under section 5 to issue orders that require testing, *see, e.g.*, 15 U.S.C. § 2604(e)(1)(A), there are instances where EPA may want to rely on its section 4 authority to require testing prior to making a determination under section 5. It appears that EPA assumes it will never rely on its section 4 authority when reviewing section 5 notices, which is problematic considering that EPA expects to receive and review hundreds of section 5 notices a year. *See 86* Fed. Reg. at 1893-4. In developing the estimates for the fee rule, EPA must acknowledge this authority and indicate whether EPA intends to use it to assist with its ongoing section 5 reviews of new chemicals.

iv. EPA cannot reasonably assume that voluntary approaches to information collection will suffice.

It appears that EPA is basing its low projections for section 4 actions, in part, on its plan to continue relying on voluntary information collection. See subsection A.v. below. As EDF has previously commented to EPA, however, EPA's past reliance on voluntary methods of data collection has regularly proven ineffective.[24] Given the burden (whether heavy or light) industry

[23] CHPAC Letter to Acting Administrator Jane Nishida, January 26, 2021. Available at: https://www.epa.gov/sites/production/files/2021-02/documents/2021.01.26_chpac_tsca_charge_response_letter.pdf.

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

incurs through testing, EPA must anticipate that those burdens will discourage many industry stakeholders from producing and submitting the information voluntarily. And voluntary approaches do not address potential selective reporting, bias or the appearance of partiality. Thus, EPA should not base its projections for exercising its testing authority on the questionable assumption that stakeholders will meet all or most of the agency's information needs through voluntary testing and submissions.

v. EPA's Information Collection Requests (ICRs) provide evidence that EPA is over-relying on voluntary submissions and underestimating its section 4 testing needs.

Since TSCA was amended in 2016, EPA has continually scaled back the extent of section 4 testing it includes in its Information Collection Requests (ICRs), and it recently proposed new voluntary ICRs that demonstrate the agency's intent to over-rely on voluntary industry submissions.

In EPA's 2013 ICR on section 4 – issued well before Congress enacted the reforms expanding EPA's testing authority under TSCA – EPA estimated that it would promulgate "six rules annually, each involving an average of 15 chemicals (90 responses)."[25] Subsequently, EPA's 2017 ICR renewal for section 4 indicated that it would promulgate only "two rules annually, each involving an average of five chemicals."[26] In 2020, EPA proposed a revision to its existing TSCA section 4 ICR[27] that projects the same number of section 4 actions as projected in the current proposed fee rule (with the exception of one amended test order): 10 test orders annually, and one test rule and one enforceable consent agreement every two years. (Notably, however, the 2020 proposed ICR assumes each section 4 action covers seven chemicals (see Table C-1, p. 56 of ICR supporting statement),[28] while the fee rule assumes each action would address only a single chemical (see Table ES-8, p. xv, of the Economic Analysis supporting the 2021 fee rule proposal).) While the latest section 4 ICR proposal is a slight increase over the existing ICR, EPA has not explained why its estimates under the *amended* law – which eased the evidentiary findings EPA must make in order to require testing and increased its needs for robust information on chemicals to inform required actions – are *lower* than what it projected under the old TSCA.

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[25] U.S. EPA, TSCA Section 4 Test Rules, Enforceable Consent Agreements (ECAs), Voluntary Testing Agreements (VTAs), Voluntary Data Submissions, and Exemptions from Testing Requirement at p.37 (2017), https://www.reginfo.gov/public/do/PRAViewDocument?ref_nbr=201712-2070-004.

[26] *Id.*

[27] 85 Fed. Reg. 33,151 (June 1, 2020), available at: https://www.regulations.gov/document?D=EPA-HQ-OPPT-2015-0436-0015. EDF's comments on this proposed ICR are available at https://www.regulations.gov/document/EPA-HQ-OPPT-2015-0436-0033.

[28] Available at: https://www.regulations.gov/document?D=EPA-HQ-OPPT-2015-0436-0018.

Further, EPA's 2020 proposed revision of the section 4 ICR drastically reduces and alters the battery of tests it indicates would be considered in requiring companies to conduct under any section 4 action it undertakes over the next three years. EPA's supporting statement indicates that for the ICR currently in effect, the following 10-test battery would be used (see Table A-1, p. 51 of the ICR supporting statement):[29]

- Algal Acute Toxicity
- Daphnid Acute Toxicity
- Fish Acute Toxicity
- Gene Mutations in Somatic Cells
- Subchronic Oral Toxicity
- Prenatal Developmental Toxicity (2 species)
- Reproduction/Fertility Effects
- Salmonella Reverse Mutation Assay
- In vivo Bone Marrow Cytogenetics
- Developmental Neurotoxicity

Three of these tests are deemed "long-duration" tests: Prenatal Developmental Toxicity (2 species); Reproduction/Fertility Effects; and Developmental Neurotoxicity.

This battery is quite similar to the test battery developed by the Chemicals Program of the Organization for Economic Cooperation and Development (OECD) known as the Screening Information Data Set (SIDS),[30] which was expressly developed as the *minimum* information necessary to conduct a *screening-level* risk assessment, and is well short of what would be needed to inform a full risk evaluation under TSCA.

Contrast this with the radically reduced and different 7-test battery that EPA is proposing to use under its revised section 4 ICR (Table A-2, p. 52 of ICR supporting statement):

- Melting Point
- Boiling Point
- Vapor Pressure
- log Kow
- Water Solubility
- Ready Biodegradation

[29] Available at https://www.regulations.gov/document?D=EPA-HQ-OPPT-2015-0436-0018.
[30] OECD, *Chapter 2. Data Gathering and Testing: SIDS, the SIDS Plan and the SIDS Dossier* in MANUAL FOR THE ASSESSMENT OF CHEMICALS (2012), http://www.oecd.org/env/ehs/risk-assessment/chapter2datagatheringandtestingsidsthesidsplanandthesidsdossier.htm.

- Acute Toxicity to Daphnia

This battery includes no mammalian toxicity tests, and no tests for chronic or even subchronic toxicity to any type of organism. It consists of only a single toxicity test of any sort – for acute toxicity to an aquatic invertebrate (Daphnia) – with the remaining six tests limited to physical-chemical and environment fate parameters measured in a laboratory setting.

Consistent with the proposed section 4 ICR, the proposed rule states that "EPA assumes that testing required by test orders is likely to be completed in under a year" (p. 1893) – in other words, EPA assumes that test orders will not be used for longer-term testing. EPA indicates that the Agency's work on each test rule and ECA is "likely to take two years to complete" (p. 1893), and hence EPA will only pursue such actions once every other year. This is clearly insufficient to fill the major data gaps needed to conduct robust risk evaluations for the 20-plus chemical undergoing them at present.

Furthermore, EPA recently proposed two voluntary ICRs, one on its proposed use of interviews and focus groups, and the other on its proposed use of surveys.[31] EDF submitted comments on both of these proposals, noting their failure to consider the many limitations and deficiencies of relying on voluntary information submissions under TSCA.[32]

Absent more testing, EPA appears intent on continuing to conduct risk evaluations that are ill-informed by actual data and instead will rely on the kinds of questionable voluntary submissions and assumptions and extrapolations from whatever physical-chemical and environment fate data EPA happens to already have in hand —approaches that have been heavily criticized.

vi. EPA's rationale for providing that only a low percentage of section 4 costs would be charged in fees is inappropriate.

EPA's proposed fees for section 4 cover a mere 4.1% of the total estimated agency cost to administer section 4 activities -- far lower than the average 25% of its costs EPA is to recoup through fees. This is compared to 13% for section 5 and 35% for section 6.

EPA's reason for charging disproportionately low fees for Section 4 is not consistent with the intent of the statute. The only reason EPA gives is that industry already pays for the costs of testing itself: "The lower fee relative to program costs takes into account that manufacturers will be responsible for paying to develop the test information in addition to paying the TSCA fee and is reflected in assigning lower proposed fee amounts. 86 Fed. Reg. at 1902. This is not sufficient

[31] See https://www.regulations.gov/docket?D=EPA-HQ-OPPT-2018-0611 and https://www.regulations.gov/docket?D=EPA-HQ-OPPT-2018-0612, respectively.
[32] See https://www.regulations.gov/document?D=EPA-HQ-OPPT-2018-0611-0016.

justification for setting the fees on industry contrary to EPA's own costs and the intent of the law.

First, EPA has real costs arising from implementing section 4, including costs of developing rules or orders, negotiating enforceable consent agreements, and collecting, managing, and providing access to information received pursuant to required testing.

Second, the argument that, because industry pays the costs of testing, it should bear little or no responsibility to pay fees to defray EPA's real costs of requiring that testing is specious. TSCA is not unique in requiring industry to pay for the costs of testing, and nothing in the text of TSCA supports giving industry a discount on this basis.[33] In fact, Congress made clear in TSCA that companies that manufacture and process chemicals *should* bear the responsibility of developing information needed to assess the safety of their chemicals. Section 2(b)(1) of TSCA states:

> It is the policy of the United States that *** adequate information should be developed with respect to the effect of chemical substances and mixtures on health and the environment and that *the development of such information should be the responsibility of those who manufacture and those who process such chemical substances and mixtures* ***.

15 U.S.C. § 2601(b)(1) (emphasis added). Congress anticipated that the development of information on chemicals would be resource-intensive, and as a matter of national policy placed that responsibility on the industry. Congress then also gave EPA authority to assess fees for EPA's actions to require the development of that information where it was not made available, by allowing EPA to "require *** payment from any person required to submit information under section 4." 15 U.S.C. § 2625(b)(1). Congress adopted a system where EPA would recover fees to defray its costs for section 4 activities; EPA should honor that choice by allocating fees to these activities that are more proportional to their costs. Not to do so could have the perverse effect of shifting more of the cost burden for section 4 actions onto the public than Congress intended.

vii. EPA appears to have miscalculated its section 4 costs for test orders.

The preamble of the proposal states: "EPA estimated that 10 test orders will be issued annually with one being amended" (p. 1898). Yet it appears that EPA's estimated annual cost of $2,795,000 for test orders in the proposed rule is calculated based on 10 test orders, omitting the

[33] *See, e.g.*, PRESCRIPTION DRUG USER FEE ACT, https://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ (last visited May 20, 2018); PESTICIDE REGISTRATION FEES AND FEE WAIVERS, https://www.epa.gov/pesticide-registration/pesticide-registration-fees-and-fee-waivers (last visited May 20, 2018).

cost of one amended test order. Table 2 in the proposal only includes a line item for 10 test orders (annual cost of $2,795,000 to agency), with no line item for the amended test order. Further, when one adds up all of the line items under Table 2, it equals the total cost of section 4 listed in Table 1 ($3,543,000).

While the Economic Analysis does include 11 test order actions per year (see, e.g., Table 3-4), we are unable to locate a resulting total section 4 cost in that document.

This oversight on EPA's part is inconsistent with its addition of a new fee category associated with an amended test order. EPA's rationale for adding this new fee category is that the agency "would incur extra costs from reviewing this resubmitted data, costs that would not be accounted for via the original fee payment by the recipient of the test order" (p. 1898). EPA must include this cost in its baseline costs to the agency to implement TSCA section 4.

*** * * * ***

In sum, EPA's fee rule must reflect that there will be greater, not fewer, information needs to be met over the next three years to address the ongoing prioritization, risk evaluation, and risk management activities that EPA is required to undertake. By underestimating the amount of testing that will be required and discounting the percentage of its testing-related costs to be covered by fees, EPA is not only unnecessarily and unreasonably limiting its ability to collect the amount of fees Congress authorized, it is also threatening to undermine the quality and reliability of its actions under TSCA.[34]

B. EPA has underestimated or failed to sufficiently document its costs for administering Section 5.

i. EPA's operation of the new chemicals program under an illegal and insufficiently protective scheme almost certainly underestimates the true costs of conducting new chemicals reviews that meet TSCA's requirements.

Under the Lautenberg Act, EPA must assess the potential risks of a new chemical under its "conditions of use," which are defined as "the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of." 15 U.S.C.

[34] Notably, section 26(k) requires that in carrying out section 6, EPA must consider "[r]easonably available information," 15 U.S.C. § 2625(k), and EPA regulations now define "reasonably available information" to mean "information that EPA possesses or can reasonably generate, obtain and synthesize for use, considering the deadlines." 40 C.F.R. §§ 702.3, 702.33. Under this definition, information that EPA can reasonably generate, develop, or obtain through the exercise of its information authorities under section 4 is "reasonably available information."

§ 2602(4). For the past several years EPA has been conducting such reviews under its "Working Approach," which fails to result in reviews meeting TSCA's requirements. EDF has commented extensively on the many ways this Working Approach is illegal and insufficiently protective scheme. EDF incorporates these comments herein by reference.[35]

In its proposed rule, EPA fails to make any mention of the costs associated with developing consent orders or SNURs, or of imposing testing requirements on new chemicals. The reduction in such actions that has taken place may explain why such activities are not addressed in the current proposed rule, but EPA's failure to conduct the reviews and take the actions TSCA requires does not negate the need to accurately account for the costs of full, legal implementation of TSCA's new chemical review requirements. See subsection B.v. below for more detail on the understating of these costs.

Reliance on the Working Approach strongly suggests that EPA estimated its costs based on a limited review only of intended uses, and not of intended, known, and reasonably foreseen uses as required under the law. EPA must clarify how it calculated the costs of these new chemical reviews. Looking at only *intended* uses would not only be unlawful, it would severely underestimate EPA's costs under section 5. EPA should base its cost estimates for reviews under section 5 on the assumption that EPA will comply with the law and review all intended, known, and reasonably foreseen activities.

EPA has also not explained or documented at all how its section 5 cost estimate covers EPA's additional duties under the Lautenberg Act. The Lautenberg Act revamped TSCA section 5 in numerous, significant ways, and EPA now has many additional obligations under the statute.

For example:

1. EPA must review each new chemical and make an affirmative finding as to its safety, 15 U.S.C. § 2604(a)(3);
2. If EPA lacks sufficient information on a new chemical or finds it may present an unreasonable risk, it must issue an order prohibiting or regulating the chemical in order to mitigate any unreasonable risk, 15 U.S.C. § 2604(a)(3), (e);
3. EPA must consider issuing a Significant New Use Rule after it issues an order under TSCA § 5(e) or a rule or order under § 5(f), 15 U.S.C. § 2604(f)(4);
4. EPA must analyze and eliminate unreasonable risks presented by "reasonably foreseen" circumstances of production, processing, distribution, use or disposal, as well as those

[35] Environmental Defense Fund Comments on Updated Working Approach To Making New Chemical Determinations Under the Toxic Substances Control Act (TSCA) Docket ID: EPA–HQ–OPPT–2019–0684 Submitted February 18, 2020, available at: https://www.regulations.gov/document/EPA-HQ-OPPT-2019-0684-0013.

intended by the company providing the new chemical notice to EPA, 15 U.S.C. §§ 2602(4), 2604(a)(3); and

5. EPA must protect against potential risks to "potentially exposed or susceptible subpopulations," including workers. 15 U.S.C. §§ 2602(12); 2604(a)(3).

EPA's cost estimates for activities under section 5 need to account for and provide specific estimates for costs associated with each of these additional duties and obligations under the statute. EPA has failed to transparently explain how its cost estimate includes these additional costs.

Lastly, the proposed rule provides estimates of the number of PMNs/MCANs/SNUNs EPA expects to receive annually, but EPA then failed to identify how many orders and significant new use rules (SNURs) it expects would be issued in response to its reviews of those submissions. In addition to not indicating how many orders or SNURs would be issued annually, it is not clear whether EPA accounted for both order SNURs (those that follow issuance of a section 5(e) order) and non-order SNURs (those that follow issuance of a "not likely to present unreasonable risk" determination). Costs for both types of SNUR promulgation include the costs of developing the rule, publication in the Federal Register, taking and addressing public comments, and finalizing the rule. While SNURs that follow orders are likely less resource-intensive because EPA will have already developed the conditions and circumstances for the order, non-order SNURs will be significantly more resource-intensive.

ii. EPA's invoking of "economic development in the chemical industry" as a basis for not raising fees for new chemical reviews is highly inappropriate.

EDF takes strong issue with this statement in the proposed rule (p. 1902):

> Since EPA does not want to stifle economic development in the chemical industry, EPA is not proposing changes to the section 5 fees established under the 2018 Fees Rule at this time.

There is no basis in the statute for EPA considering factors such as "economic development in the chemical industry" in setting fees. *See* 15 U.S.C. § 2625(b). Nor is it the, or even a, mission of the agency to promote the industry's economic standing. Those who have tried to make such arguments rely on the only reference to innovation in all of TSCA, in the law's policy intentions in section 2(b)(3). Such persons typically paraphrase this provision as stating that, under TSCA, EPA should not act in a manner that impedes innovation. But that is a selective reading of the actual provision, which in its entirety reads as follows:

> (b) POLICY.—It is the policy of the United States that— ***

> (3) authority over chemical substances and mixtures should be exercised in such a manner as not to impede unduly or create unnecessary economic barriers to technological innovation *while fulfilling the primary purpose of this Act to assure that such innovation and commerce in such chemical substances and mixtures do not present an unreasonable risk of injury to health or the environment*.

15 U.S.C. § 2601(b)(3) (emphasis added). Rather than seeking to use TSCA to promote companies' or the chemical industry's economic development or standing, EPA should be establishing the level of fees for section 5 activities aimed at achieving that primary purpose of TSCA – providing an assurance that innovation and commerce in new (as well as exiting) chemicals do not present unreasonable risk.

iii. EPA fails to transparently and accurately account for its new obligations under the Lautenberg Act when estimating its costs under section 5.

In its Final 2018 Fee Rule, while EPA failed to provide a sufficient basis for its cost estimate for implementing section 5, it at least provided some granularity by estimating its per-activity costs for some specific activities it undertakes. In contrast, the only dollar figure EPA provided in its 2021 proposal is an overall cost for the entirety of section 5.

More specifically, while Table 3 (p. 1896) of the proposed rule indicates the number of each of four activities undertaken under section 5, it provides no unit cost for any of them and its only cost estimate is for section 5 implementation as a whole. Only a very general and vague explanation and no quantitative basis is provided for how that estimate was derived. A table note merely notes that "costs were not broken out and therefore are not shown." No further detail is provided in the Economic Analysis.

This is unacceptably generalized and provides no ability for the public to evaluate the reasonableness of EPA's cost estimate.

EPA provided even less information about other activities that are or should have been included in its section 5 costs estimates. These are described below.

iv. EPA failed to include or delineate in its estimates the costs it incurs for activities it undertakes during the initial stages of the section 5 review process.

In estimating its costs of carrying out section 5, EPA failed to account for certain activities that undoubtedly create costs that EPA needs to include in establishing the level of fees for new chemical reviews. Even for the activities it indicates are included, it has provided no breakdown of those costs and insufficient documentation to afford any confidence in the accuracy of its cost estimates.

First, relevant activities not included in Table 3 are merely mentioned as somehow included in the overall section 5 estimate with absolutely no indication even as to their frequency or the magnitude of their costs and how they were estimated. For example, EPA acknowledges it conducts pre-notice consultations it with companies *before* they submit new chemical notices (p. 1894). But it provides no indication of how many such consultations it conducts annually, how much staff time is required, etc. Engaging in potentially hundreds of pre-notice consultations annually clearly requires time and resources that need to be delineated in EPA's cost estimates for EPA's section 5 activities. Considering the importance EPA has placed on these pre-notice consultations, EPA must provide a specific estimate of the number and costs of such consultations, and ensure its associated fees reflect this activity.

Second, EPA failed to include the costs of maintaining an accurate and timely accounting of its section 5 activities in the Federal Register and the costs of maintaining *electronic* public files and databases on the new chemical review process. *See* 40 C.F.R. §§ 720.95, 700.17(b)(1). As EDF has repeatedly noted, EPA has fallen far short of complying with its own procedural regulations and providing timely access to information on new chemicals.[36] Given the serious delays and deficiencies in EPA's execution of these activities, EPA will need to expend considerably more resources than it has been to create and maintain these electronic public files, and EPA should include those costs in estimating the costs to the Administrator of carrying out section 5.

v. EPA's cost estimates under section 5 seem especially low for cases where a PMN or SNUN review results in an order or SNUR, given EPA's much higher unit cost estimates for similar activities under section 4.

In the 2018 proposed rule, EPA estimated the average total cost of processing a PMN or SNUN, and asserted without providing any detail that it included the costs for cases where that review leads to development of an order or a SNUR. 83 Fed. Reg. at 8217-18. In our comments on that proposal EDF argued EPA's costs estimate of $55,200 per PMN/SNUN – the figure retained in the Final 2018 Fee Rule – appeared much too low, given that EPA estimated then and continues now to estimate that developing orders and rules under section 4 costs far more: $279,000 and $844,000 each, respectively. Even if one unrealistically assumed the full cost of a PMN review could be allocated to the order or SNUR, these estimates suggest that section 5 orders and rules are massively less expensive than similar activities under section 4. EPA has never provided an explanation for these differences. In fact, in the current proposal EPA fails altogether even to mention the need to issue orders and SNURs as an outcome of its PMN/SNUN reviews: The terms "consent order" and "SNUR" do not appear even once in the proposal, despite the fact that

[36] Environmental Defense Fund Comments on Needed Improvements to EPA's CBI Claim Reviews and Public Access to Information (Jan. 24, 2020), https://www.regulations.gov/document/EPA-HQ-OPPT-2019-0637-0007.

many PMN/SNUN reviews it has undertaken have led to order or SNURs (see subsection B.i. above for more on this issue).

EPA should re-examine its estimated costs and increase its estimates for section 5 activities to account for cases where issuance of orders or SNURs occurs. Unless EPA has and presents convincing evidence that the costs of developing orders and rules under section 5 are truly many times lower than the costs of similar activities under section 4, it must assign significantly higher costs to these cases.

vi. Consolidated submissions cost more than regular submissions and EPA's estimates should reflect that fact.

Under section 5, in certain cases multiple new chemical notices may be consolidated into a single notice for submission. EPA stated in the 2018 proposed rule that consolidations require "a *substantially* increased amount of effort over the assessment of a single submission." 83 Fed. Reg. at 8220 (emphasis added). Yet EPA did not include this increased workload in its estimate for the cost of reviewing section 5 notices, and in the final rule EPA decided not to charge a higher fee for consolidated submissions (83 Fed. Reg. at 52705). EPA needs to account for those higher costs when setting the fee level for new chemical reviews, regardless of whether or not it sets a higher fee specifically for such consolidated submissions. As no mention is made of this issue in the new proposal it is not at all clear that EPA did account for such higher costs. EPA has still not provided any estimate of the number of such submissions it receives. EPA needs to address these issues in revising the fee rule. We reiterate our call for EPA to establish a higher fee or separate fee category that charges more for consolidated submissions.

C. EPA has underestimated and failed to document the full extent of section 6 costs.

EPA has grossly underestimated the full extent of section 6 costs in the proposal, and thus, has proposed an insufficient fee. Remarkably, EPA's estimated cost for administering section 6 has actually *gone down* by nearly $2 million since the 2018 rule,[37] which is highly questionable given EPA's greatly increased risk evaluation and risk management workload.

i. EPA underestimates the costs of risk evaluations under section 6 by basing its estimates on the illegally narrow and scientifically flawed risk evaluations conducted under the Trump administration.

EPA has increased its estimated cost for conducting a risk evaluation from $3,884,000 to $5,671,000, better reflecting its actual cost and resulting in an increased risk evaluation fee compared to the 2018 Final Fee Rule. EDF supports this increase. Nonetheless, EPA continues to

[37] The overall estimated cost for administering section 6 in the 2018 Final rule was $43,618,000. EPA's estimate in the current proposal is $41,998,820.

underestimate the true cost of conducting the comprehensive risk evaluations required under the law and should rectify this in promulgating its update to the fee rule.

EPA indicates it estimated the cost of conducting risk evaluations based on internal tracking of staff hours reported working on the first 10 risk evaluations. However, as stakeholders like EDF[38] and EPA's own SACC[39] repeatedly pointed out, those risk evaluations excluded or omitted certain conditions of use and major known sources of exposure to the chemicals. Hence, there is little doubt that EPA's estimates significantly understate the actual costs of conducting the comprehensive evaluations TSCA and sound science require.

TSCA calls for comprehensive assessments. Risks of chemicals are to be both evaluated with respect to their "conditions of use," which is defined by TSCA as (emphasis added): "the circumstances, as determined by the Administrator, under which a chemical substance is *intended, known, or reasonably foreseen* to be *manufactured, processed, distributed in commerce, used, or disposed of*" 15 U.S.C. § 2602(4). This expansive definition means that EPA must include exposures from activities that span the entire lifecycle of a chemical in evaluating its risks. EPA must also examine how such activities extend beyond those intended by the chemical's manufacturers, processors, and users to encompass ways the chemical is known or can be reasonably anticipated to be handled. However, the Trump Administration's EPA flouted these requirements in its risk evaluations for the first 10 chemicals. As just one example, the agency ignored the risks arising from the tens of millions of pounds of these chemicals released to air, water, and land every year.[40] The agency also set out to ignore legacy uses and associated disposal of a chemical no longer actively manufactured for such use but still in active use and disposal.

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[38] See, for example: Environmental Defense Fund Comments on the Draft Risk Evaluation of 1-Bromopropane, (Oct. 11, 2019), https://www.regulations.gov/document?D=EPA-HQ-OPPT-2019-0235-0047; EDF Comments on Draft Risk Evaluation of Trichloroethylene (Apr. 27, 2020), https://www.regulations.gov/document?D=EPA-HQ-OPPT-2019-0500-0108; EDF Comment on the 1,4-Dioxane Draft Risk Evaluation (Aug. 30, 2019), https://www.regulations.gov/document?D=EPA-HQ-OPPT-2019-0238-0058; EDF Comments on Draft Risk Evaluation of Methylene Chloride (December 30, 2019), https://www.regulations.gov/document?D=EPA-HQ-OPPT-2019-0437-0073.

[39] See, for example: SACC peer review report on the methylene chloride draft risk evaluation, https://www.regulations.gov/document?D=EPA-HQ-OPPT-2019-0437-0080; SACC peer review report on 1-bromopropane draft risk evaluation, https://www.regulations.gov/document?D=EPA-HQ-OPPT-2019-0235-0061; SACC peer review report on the 1,4-dioxane and HBCD draft risk evaluations, https://www.regulations.gov/document?D=EPA-HQ-OPPT-2019-0238-0063.

[40] EDF, 2019. "Toxic Consequences," at p. 7. Available at: http://blogs.edf.org/health/files/2019/06/EDF_Toxic_Consequences_Report.pdf.

A November 2019 Ninth Circuit Court of Appeals ruling in *Safer Chems. v. United States EPA* affirmed that TSCA requires comprehensive risk evaluations.[41] As described in detail in our April 2020 comments on the draft trichloroethylene risk evaluation, the ruling makes clear that EPA's Risk Evaluation Rule does not grant EPA discretion to exclude conditions of use (including legacy uses) or any hazards or exposures under the conditions of use. We incorporate those comments here by reference.[42]

The Court's decision and the need for EPA to conduct more comprehensive risk evaluations than it has to date were highlighted in both an August 2020 report of EPA Office of Inspector General (OIG)[43] and a March 2021 report of the Government Accountability Office (GAO).[44] Each report recognized the greatly increased scope of work under amended TSCA and EPA's failure to translate that into needed additional staff and resources. The GAO report states:

> 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. (p. 205)

The OIG report – which is titled "Lack of Planning Risks EPA's Ability to Meet Toxic Substances Control Act Deadlines" – reached similar conclusions, noting that "OPPT cannot demonstrate that it has the capacity to successfully implement the TSCA amendments within the required time frames." (p. 9)

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[41] *Safer Chemicals v. United States EPA*, 2019 U.S. App. LEXIS 33976. Available at: http://cdn.ca9.uscourts.gov/datastore/opinions/2019/11/14/17-72260.pdf.

[42] EDF Comments on Draft Risk Evaluation of Trichloroethylene, at pp. 141-144 (Apr. 27, 2020), https://www.regulations.gov/document?D=EPA-HQ-OPPT-2019-0500-0108.

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

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

Instead of only relying on hours worked on the first 10 risk evaluations, EPA must detail and cost out all of the activities required to conduct comprehensively risk evaluations in order to accurately estimate the cost that will be needed moving forward. (Table 2 in EPA's Final 2018 Fee Rule provided such a breakdown, although EPA provided insufficient detail then as to how the individual costs were estimated.)

ii. EPA failed to explicitly include section 6 costs for prioritization, risk management, and support from the Office of Research and Development and underestimated their costs.

Despite EPA's claim that it did so, it is far from clear whether or how EPA included the costs of prioritization, risk management, and support from the Office of Research and Development (ORD) in its estimate of section 6 costs. EPA has provided no line-item cost for any of these activities – let alone a breakdown for the component steps each activity entails – in either the proposed rule or the draft Economic Analysis.

EPA acknowledges that these activities entail costs to the program in the preamble:

> Note that the costs presented in Tables 2, 3, and 4 include only the costs of fee-triggering events and so do not include costs associated with activities such as CBI reviews, *alternative testing methods development, risk management for existing chemicals, or prioritization of existing chemicals*. Costs associated with those activities are part of the overall costs of administering relevant activities under TSCA sections 4, 5, and 6 and relevant information management activities and, as such, *are included in the overall cost estimates provided previously in Table 1*. (p. 1895, emphases added)

However, despite the excerpt above, when one adds up the line items in Tables 2, 3, and 4, detailing costs for sections 4, 5, and 6, respectively, they total exactly to the costs for the corresponding sections in Table 1. That is, contrary to EPA's statement, there are not costs in Table 1 that are not included Tables 2, 3, and 4 – raising the question as to whether or how the costs of the three additional activities EPA notes are being accounted for. We suspect, but have not been able to definitively confirm, that the discrepancy between EPA's statements and its Tables resides in an "extra" $4,192,153 of estimated annual cost to the agency attributed to EPA-initiated risk evaluations.

In Table 4, the manufacturer-requested line totals appear to have been calculated simply by multiplying the number of actions/year (i.e., 2 and 3) by the estimated cost to the agency per action (i.e., $5,671,000) and then dividing by the 3 years over which they will occur. However, when this same arithmetic is applied to the line in Table 4 for the EPA-initiated risk evaluations, the resulting value differs from the line total that appears in that line of Table 4: (20 x

$5,671,000) / 3 = $37,806,667 instead of the $41,998,820 shown as the line total. The difference in these two values is $4,192,153.

When we inquired with EPA about these discrepancies, we were informed via email that the difference of $4,192,153 per year represents the additional section 6 costs noted in the excerpt above and further detailed on page 1894 (i.e., "risk management efforts; support from the Office of Research and Development (ORD) for alternative animal testing and methods development and enhancement, data integration, meta-analysis of studies, and providing access to other models, tools and information already developed by ORD; and the process of prioritizing chemical substances").

In other words, it appears that EPA has effectively hidden the costs for three major areas of its section 6 work. EPA then bases its fees on its estimated cost of a risk evaluation, which excludes these additional section 6 costs. But while subjection of a chemical to a risk evaluation is the fee-triggering event, the resulting fee must be set based on EPA's total section 6 costs, not just its costs for conducting risk evaluations. TSCA section 26(b)(4)(F)(i) requires that fees defray a portion of EPA costs "of carrying out … section 6," not just its costs of carrying out the fee-triggering event of subjecting a chemical to a risk evaluation. We are concerned that EPA may have set its fees for risk evaluations without including these relevant section 6 costs, and hence that EPA may be assessing lower fees than warranted.

Moreover, EPA's estimated annual cost of $4,192,153 for the additional section 6 activities appears to dramatically underestimate the actual costs of these activities. Each of these areas is discussed in more detail below. But just taking risk management to illustrate our concern, it is difficult to see how even the full $4,192,153 annual cost estimate will be sufficient to cover EPA's development and completion of risk management rules for all of the first 10 chemicals, which it now must do, let alone any modifications to the risk management rules it issued in January for the five PBT chemicals it has reopened for public comment.

EPA has provided so little information on its costs for these critical activities that our ability to provide meaningful public comment is severely compromised. These activities clearly constitute activities central to administering section 6, and hence their associated costs must be included and detailed in EPA's baseline costs to be used to establish fees under section 26(b)(4)(B)(i)(I).

Below we briefly describe the effort involved in each of these ignored areas of work – prioritization, risk management, and support from ORD. In promulgating the final rule, EPA should include realistic cost estimates for these activities, and adjust the fees to reach 25% of the overall cost as necessary.

a. Prioritization

As required under the section 6(b)(1)(A) of the Lautenberg Act, EPA promulgated a final rule establishing its process for prioritizing chemicals under TSCA.[45] That rule established extensive procedures EPA will use and regulatory requirements it must meet in conducting prioritization so as to ensure it is conducting EPA-initiated risk evaluations on at least 20 chemicals at any given time. Because the prioritization process must by law play out over a period of time, EPA should be in the process on an ongoing basis of identifying candidates for prioritization and prioritizing chemicals, so that at least one new high-priority chemical enters risk evaluation every time a risk evaluation on a chemical is completed. This is not a trivial amount of work. In fact, EPA's new "Prioritization and Informatics" branch, created through the Fall 2020 OPPT reorganization, was set up to focus in large part on prioritizing chemicals for risk evaluation, including gathering relevant data.

b. Risk Management

EPA is currently undergoing the process – for the first time – of promulgating 10 comprehensive risk management rules under amended TSCA. In addition to developing the rules and underlying analyses, EPA is conducting outreach on each chemical with the public and a variety of stakeholders.[46] This is a major undertaking yet is largely ignored in the fee rule proposal.

In addition to EPA's failure to explicitly include the cost for risk management in its proposal, EPA inappropriately relied on narrow, partially completed risk management actions to inform the cost of its current and future risk management actions:

> 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. (p. 1894)

[45] EPA's final rule, Procedures for Prioritization of Chemicals for Risk Evaluation Under the Toxic Substances Control Act, is available at https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0636-0074. EPA's docket that includes the many public comments it received concerning this rule is available at https://www.regulations.gov/docket?D=EPA-HQ-OPPT-2016-0636. EDF submitted extensive comments on the proposed rule, available at https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0636-0060.

[46] See, for example: https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-management-existing-chemicals-under-tsca.

However, EPA fails to note or account for the fact that these prior risk management proposals were extremely narrow, requiring far fewer resources than current and future risk management actions under the Lautenberg Act will require. These risk management actions addressed only a narrow subset of uses of the chemicals, whereas current and future risk management will need to address many more conditions of use.[47] For example, compared to the single paint stripper condition of use addressed in the prior methylene chloride risk management proposals,[48] EPA's June 2020 final methylene chloride risk evaluation found dozens of conditions of use to present unreasonable risk[49] – each of which will require risk management. Thus, risk management actions under the Lautenberg Act will undoubtedly be more expansive and require more EPA resources as a result.

Further, with the exception of consumer uses of methylene chloride, these actions were never finalized. Therefore, their costs do not reflect the costs of *completing* a risk management action.[50] In order to finalize the risk management actions proposed, EPA would need, among other things, to consider and develop and provide a written response to public comments, revise the rules and associated analyses, shepherd them through internal review and address comments and concerns that arise in that process, and then subject them to OMB/inter-agency review and address comments and concerns that arise in that process. None of the costs associated with these activities could have been included in any cost estimates derived based on these incomplete risk management actions.

Finally, even the costs of those narrow, incomplete actions indicate EPA has seriously underestimated its risk management costs in the current fee rule proposal. In EPA's Technical Background Document for the 2018 Proposed Rule, EPA stated that, up until that date, each of the proposed risk management actions for TCE, DCM, and NMP had taken two years, cost EPA

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[47] Even under EPA's illegal approach to the first 10 risk evaluations, which limited the conditions of use EPA considered, *see* 82 Fed. Reg. 33726, 33729-30 (Jul. 20, 2017), the scope of the risk evaluations and risk management actions under the Lautenberg are nevertheless broader than under the old law. *See, e.g.*, U.S. EPA, OCSPP, Scope of the Risk Evaluation for Trichloroethylene (June 2017), https://www.epa.gov/sites/production/files/2017-06/documents/tce_scope_06-22-17.pdf.

[48] Methylene Chloride and N-Methylpyrrolidone; Regulation of Certain Uses Under TSCA Section 6(a), 82 Fed. Reg. 7464 (Jan. 19, 2017); and Methylene Chloride; Regulation of Paint and Coating Removal for Consumer Use Under TSCA Section 6(a), 84 Fed. Reg. 11420 (March 27, 2019).

[49] U.S. EPA, 2020. Risk Evaluation for Methylene Chloride. June 2020. Available at: https://www.epa.gov/sites/production/files/2020-06/documents/1_mecl_risk_evaluation_final.pdf.

[50] *See, e.g.*, RISK MANAGEMENT FOR N-METHYLPYRROLIDONE (NMP), https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-management-n-methylpyrrolidone-nmp (last visited May 14, 2018) (indicating that EPA has not yet finalized the rule for NMP).

$2,485,000, and required an average of 8 FTE.[51] In our previous comments on the 2018 proposed fee rule, we commented on the agency's inappropriate assumption that risk management under the Lautenberg Act would cost far less – on the order of 65% less ($877,867 as calculated by EDF) – than the still-incomplete, much narrower risk management actions proposed in December 2016 and January 2017. Yet in the current proposal, EPA has taken this flawed assumption a step further. While EPA did not even include an explicit estimated cost for risk management, even assuming that all of the $4,192,153 per year in extra costs (discussed above) were attributed to risk management (leaving no funds for prioritization and support from ORD), and with 10 rulemakings currently underway, that would only provide $419,000 a year per rule – even less than assumed under the 2018 Final Rule.

EPA has clearly dramatically underestimated its costs for risk management and must rectify this situation in finalizing the amended fee rule.

c. Support from ORD

First, EPA anticipates relying on ORD staff to support a variety of section 6 activities under TSCA. In the preamble, EPA indicates that these include "alternative animal testing and methods development and enhancement, data integration, meta-analysis of studies, and providing access to other models, tools and information already developed by ORD." (p. 1894)

Furthermore, ORD resources are likely to be utilized by OPPT for activities under TSCA sections 4 and 5, not just section 6. For example, ORD has provided significant support for implementing TSCA Section 4(h). EPA needs to appropriately account for the ORD staff resources it intends to rely upon in estimating its costs for all of these sections.

Second, especially if the ORD estimate in the proposed fee rule applies across all three sections, EPA appears to continue to severely underestimate OPPT's utilization of ORD under TSCA. EPA has provided no detail whatsoever either in the fee rule proposal or its Economic Analysis as to the extent of ORD staff and resource support it expects to rely on. In its 2018 rulemaking, EDF's comments noted that EPA's estimate of only a single FTE could not be reconciled with EPA's draft Strategic Plan for the Development of Alternative Test Methods, which envisioned the development of a multi-office "TSCA NAM Team" (TNT) to take advantage of expertise and resources within the Agency. The TNT would oversee the implementation of the Strategic Plan, and would include experts in ORD.[52] The responsibilities of the TNT were to include, but not be limited to, developing appropriate communication materials and collaborating with external

[51] Technical Background Document, TSCA User Fees NPRM, at p. 3. Available at: https://www.regulations.gov/document/EPA-HQ-OPPT-2016-0401-0020.
[52] Response to Comments, at 33 (March 2018), https://www.regulations.gov/document?D=EPA-HQ-OPPT-2017-0559-0583.

parties, working more with academics, and partnering with journals to encourage the publication of negative results. While it is not clear how many of these efforts were actually undertaken or initiated or how many experts from ORD took part, implementing anything like what was envisioned in the Strategic Plan would take more than one FTE from ORD. Thus, just this one activity could well require more ORD resources than the $4 million per year EPA has estimated for these activities plus prioritization and risk management.

EPA will likely rely on ORD for numerous other activities as well. For example, ORD was already involved in the development of a method for identifying chemicals for prioritization under section 6. At the December 2017 public meeting on prioritization, ORD gave a presentation on an approach "to identify potential candidate chemicals for prioritization: integration of traditional and new approach methods."[53] The estimated costs for section 6 must reflect these efforts by ORD to assist with prioritization of chemicals.

EPA will almost certainly rely on ORD for assistance beyond the two examples provided above. EPA should reassess its estimate for ORD costs and update its cost estimates for sections 4, 5, and 6 to provide more realistic estimates for ORD contributions to TSCA implementation.

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

i. EPA fails to transparently account for the many CBI claims it must review and the additional duties EPA has under section 14.

EPA's section 14 costs in the proposed rule is a single point estimate of $1,873,443, which matches the figure in the Economic Analysis (Table 3-1, p. 3-7) for "TSCA Chemical Information Management." It is wholly unclear how EPA developed that estimate. In presenting the agency's costs under section 14, EPA made no attempt to describe how many CBI claims it receives each year, or estimate 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.

As described at length in our comments on EPA's 2018 Fee Rule proposal, EPA receives tens of thousands of CBI claims each year. It is unclear how EPA can accurately estimate its costs for CBI review when EPA has failed to describe and account for how many CBI claims it annually receives, and for what types of information and in which submissions, that it must review. Especially considering the often excessive and erroneous manner in which industry has

[53] U.S. ORD, Integration of Traditional and New Approach Methods (Dec. 2017), https://www.epa.gov/sites/production/files/2017-12/documents/session_6_-_tsca_preprioritization_tool_public_meeting_dec_2017_final2.pdf.

historically claimed information CBI under TSCA,[54] EPA must provide a much more detailed accounting for its receipt and review of CBI claims in estimating its baseline costs.

In addition, as discussed in subsection D.vi., the section 14 baseline cost estimate fails to transparently account for a number of EPA's responsibilities under section 14, such as: 1) providing for disclosure to authorized persons under sections 14(d)(4), (5), and (6); 2) creating an electronic database to facilitate that disclosure; 3) developing a system for tracking and notification relating to reassertion of claims; and 4) maintaining or updating clearance/security activities. EPA must make clear not only what activities it has included, but the costs for each, in its baseline estimates for section 14.

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.

Section 26(b)(1) states that EPA may "require the payment from any person *** of a fee that is sufficient and not more than reasonably necessary to defray the cost related to such chemical substance of *** collecting, processing, reviewing, and providing access to and protecting from disclosure as appropriate under section 14 information on chemical substances under this title ***." 15 U.S.C. § 2625(b)(1). Similarly, EPA must set fees at a level that will annually defray "25 percent of the costs to the Administrator 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 this title*." 15 U.S.C. § 2625(b)(4)(B)(I) (emphasis added). In other words, the user fees EPA collects must recoup a portion of EPA's costs of "collecting, processing, [and] reviewing" information on chemicals substances *under Title I of TSCA. Id.*

EPA continues to incorrectly interpret this provision so that only the costs under section 14 of "collecting, processing, and reviewing" information are included in its baseline costs. EPA states (pp. 1894-95):

> 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 and

[54] Hampshire Research Associates, Inc., Influence of CBI Requirements on TSCA Implementation at p.41 (March 1992), https://www.regulations.gov/document?D=EPA-HQ-OPPT-2002-0054-0074.

14. 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.

In doing so, 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). 15 U.S.C. § 2625(b)(4)(B)(I). EPA's reading of this TSCA provision is simply incorrect, as we indicated in our comments on the 2018 Fee Rule proposal and reiterate again below.

First, the plain meaning of the words "collect," "process," and "review" clearly encompass EPA's activities outside of section 14, particularly under section 8. For instance, under sections 8(a) and 8(d), EPA develops reporting rules under which EPA *collects* information on chemicals. *See* U.S.C. § 2607(a), (d). Bizarrely, EPA says it has included costs of managing information collected under section 8 rules, but not the costs of developing those rules. But the costs of collecting information under section 8 clearly entails the costs of developing the rules that require submission of the information. EPA's statement that it includes information management costs – which entail "processing" and "reviewing" information received through section 8 – but excludes development of section 8 rules that are the means of "collecting" that information, draws a distinction between "collecting" vs. "processing" and "reviewing" information that cannot be supported by the statutory language and is arbitrary.

EPA's exclusion of the costs of developing TSCA section 8 rules is especially ironic, given that EPA is actually in the process of developing one at this moment to aid in its carrying out its responsibilities under TSCA section 6. In its Fall 2020 regulatory agenda, EPA indicated it is developing a section 8(d) rule – which it indicates was supposed to have been promulgated this month – on 20 high-priority substances under TSCA, as well as 30 organohalogen flame retardants requested by the Consumer Product Safety Commission.[55]

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]." 15 U.S.C. § 2607(b)(4)(C) (emphasis added). 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). *See* 15 U.S.C. § 2607(b)(5). Here, EPA says it has included "costs for Notice of Activity chemical identity CBI claim reviews" (p. 1895) which is appropriate but is inconsistent with its assertion that it need not include other section 8-related costs.

[55] See: https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=202010&RIN=2070-AK69.

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. *See* 15 U.S.C. § 2607(c), (e). These activities under section 8 all squarely fall within the plain text of section 26(b)(4)(B)(I), so EPA must consider these costs in its baseline. To be sure, 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), *see* 15 U.S.C. § 2610(c).

Second, if Congress had intended for section 26(b)(4)(B)(I) to only include the costs of administering section 14, Congress could have easily done so with a much more concise and precise formulation. For instance, the provision could have alternatively stated 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]." 15 U.S.C. § 2625(b)(4)(B)(I). Congress did not enact this language, however. See *Lozano v. Montoya Alvarez*, 134 S. Ct. 1224, 1235 (2014) ("Given that the drafters did not adopt that alternative, the natural implication is that they did not intend" to do so).

Consistent with this plain language reading, under the rule of the last antecedent, the phrase "under section 14" modifies only the phrase "providing access to and protecting from disclosure as appropriate." *Lockhart v. United States*, 136 S. Ct. 958, 963 (2016) ("The rule provides that 'a limiting clause or phrase *** should ordinarily be read as modifying only the noun or phrase that it immediately follows.'"); *see also* A. Scalia & B. Garner, Reading Law: The Interpretation of Legal Texts 144 (2012). In other words, because the modifier, "under section 14," appears at the end of a list, it applies only to the item that immediately precedes it. *Lockhart*, 136 S. Ct. at 963. The structure of the list supports this interpretation because it contains two "ands," suggesting that the final two verbs are distinct from the three proceeding verbs: "collecting, processing, reviewing, *and* providing access to *and* protecting from disclosure as appropriate." 15 U.S.C. § 2625(b)(4)(B)(I) (emphases added). In addition, these last two verbs align well with EPA's duties under section 14.[56]

[56] While EPA's proposed rule at least accurately quotes this TSCA provision, its Economic Analysis repeatedly rewrites the provision so as to alter its meaning. The first of many such instances is on p. xii, where EPA states: "The fees to be paid by industry would defray the cost for EPA to administer TSCA sections 4, 5, 6, and collecting, processing, reviewing, and providing access to and protecting information about chemical substances from disclosure as appropriate under TSCA section 14." EPA has rearranged the provision, physically moving "information about chemical substances" to precede rather than follow the reference to section 14, making it appear that section 14 modifies all listed activities when in fact it only modifies "providing access to and protecting from disclosure as appropriate." While in a few places it accurately cites TSCA's language, the Economic Analysis repeatedly uses variants of the incorrect formulation. For example, on p. 3-6 it refers to "[t]he annual cost estimate of

Third, the whole list ends with the phrase "under this title" modifying the object "information," making it clear that the statute requires that EPA consider all the costs of "collecting, processing, reviewing, *** information on chemical substances *under this title*." 15 U.S.C. § 2625(b)(4)(B)(I) (emphasis added). EPA's interpretation limiting this language 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, 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." *Advocate Health Care Network v. Stapleton*, 137 S. Ct. 1652, 1659 (2017). 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." *Id.* But a correct interpretation should "give effect, if possible, to every clause and word of a statute." *Id.* (quoting *Williams v. Taylor*, 529 U. S. 362, 404 (2000)).

Additionally, comments in the legislative history suggest that section 26(b)(4)(B)(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 ***." 114 Cong. Rec. S3518 (daily ed. June 7, 2016). 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.

iii. Even if EPA's cost of collecting, processing, and reviewing information were limited to section 14, EPA should still defray the section 8 costs that are inextricably intertwined with section 14 activities.

Even if the baseline information costs were limited to activities under section 14 (which they are not, as explained above), EPA must include the costs of implementing much of section 8 into its baseline estimates for the costs under section 14 because a number of the section 8 provisions are inextricably intertwined with the section 14 provisions. Congress clearly intended that EPA's actions under section 8, specifically the requirements under section 8 to collect, process, review, provide access to and protect from disclosure CBI claims and substantiations, must be done pursuant to section 14. For example:

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collecting, processing, reviewing, and providing access to and protecting from disclosure as appropriate information on chemical substances under section 14 of TSCA."

- Section 8(b)(4)(B)(i) sets requirements that manufacturers and processors notify EPA of active and inactive chemicals, and EPA must *provide public access* to a list of those substances "consistent with *** *section 14*;"
- Section 8(b)(4)(B)(ii) and (iii) require that EPA *collect* notices and substantiations from manufacturers and processors that submit claims of confidentiality pursuant to *section 14*;
- Section 8(b)(4)(D) sets the requirements for EPA's *review* of the CBI claims, which must be "in accordance with *section 14*;"
- Section 8(b)(5) states that if any person intends to manufacture or process a chemical on the inactive list, and wants to maintain it on the confidential list, the person must submit and EPA must *collect* a notice and substantiation "consistent with the requirements of *section 14*;" and
- Section 8(b)(7) states that EPA "shall *make available to the public*" certain information "subject to this subsection and *section 14*." 15 U.S.C. § 2607(b)(7) (emphases added).

The invocation of section 14 throughout section 8 makes it impossible for EPA to estimate accurately the costs of "collecting, processing, [and] reviewing" information under section 14 without also estimating the costs of these activities under section 8. For this reason, EPA must include these "section 8" costs in the baseline costs for section 14. Yet it appears EPA has only included costs of some of these activities, specifically "costs for Notice of Activity chemical identity CBI claim reviews" (p. 1895).

EPA needs to carefully estimate its costs for the review plan required by TSCA section 8(b)(4)(C)-(E). 15 U.S.C. § 2607(b)(4)(C)-(E). In the review plan, EPA must "require *** all manufacturers or processors asserting [confidentiality] claims *** to substantiate the claim[s], in accordance with section 14," and EPA must "in accordance with section 14—review each substantiation." *Id.* § 2607(b)(4)(D)(i), (ii). As of now, EPA has to review confidentiality claims for over 8,200 chemicals;[57] EPA will undoubtedly incur significant costs in performing these reviews, which EPA indicates must be completed by February 19, 2024;[58] hence a significant portion of these reviews will take place during the FY2022-2024 period.

[57] This count is based on the latest version of the TSCA Inventory posted by EPA on its website at https://www.epa.gov/tsca-inventory/how-access-tsca-inventory#download. The Inventory file named "PMNACC_022021" lists chemicals with confidential chemical identities using their generic names and accession numbers. The number of such chemicals tagged as "active" in this file is 8,257. That count is expected to increase because EPA recently reopened reporting under its TSCA Inventory Notification (Active-Inactive) Rule. *See* https://www.epa.gov/chemicals-under-tsca/epa-reopens-reporting-period-tsca-active-inactive-rule.

[58] See: https://www.epa.gov/tsca-inventory/procedures-review-cbi-claims-active-chemicals-tsca-inventory.

Despite these clear requirements and EPA's indication it has included such costs, it has provided no detail whatsoever as to the magnitude of the costs, the number of claims to be reviewed annually, or other critical details – which provides no confidence that it has accurately determined the associated costs with this significant duty EPA has under TSCA. While EPA includes a line item in Table 1 for section 8, indicating annual costs of $3,974,522, neither the proposed rule nor the Economic Analysis provides any specific indication of what these costs actually are. Presumably they are the costs of reviewing the CBI claims associated with Notices of Activity under the review plan required by TSCA section 8(b)(4)(C)-(E). If so, that needs to be specified and much more detail about how the estimate was derived needs to be provided. If other section 8 costs are included, those need to be specified and cost estimates broken out for them.

iv. The cost of administering sections 4 and 6 include some of the cost 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, much of EPA's costs under sections 8 and 11(c) should nevertheless be included in the baseline because those activities are relevant to "carrying out sections 4 *** and 6." 15 U.S.C. § 2625(b)(4)(B)(I). EPA's activities under sections 8 and 11(c) directly inform testing under section 4, and section 6 prioritization,[59] risk evaluation,[60] and risk management decisions. Specifically, in carrying out sections 4 and 6, EPA should rely on, in part:

- Section 8(a), which gives EPA authority to require by rule the submission of reports that may include, but are not limited to, information on chemical uses, environmental and health information, and the number of individuals exposed to a chemical, 15 U.S.C. § 2607(a)(2);
- Section 8(d), which allows EPA to collect health and safety studies, 15 U.S.C. § 2607(d);
- Section 8(c), which gives EPA authority to require the submission of records detailing instances of significant adverse reactions to health or the environment, 15 U.S.C. § 2607(c);
- Section 8(e), under which EPA receives information on chemicals that present a substantial risk of injury to health or the environment, 15 U.S.C. § 2607(e); and

[59] EDF Comments on Prioritization at p. 9 (submitted Mar. 2017), https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0636-0060 (urging EPA to "directly incorporate its TSCA section 8(a) and 8(d) authorities into that rule, to allow EPA to require, by notice in the Federal Register, manufacturers with relevant information to submit that information to EPA.").
[60] EDF Comments on Risk Evaluation at pp. 18-20 (submitted Mar. 2017), https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0654-0074.

- EPA's subpoena authority under section 11(c), 15 U.S.C. § 2610(c).

Each of these provisions generates information about chemical exposures and hazards, which are critical to filling the information gaps that will need to be addressed before, during and after the prioritization process" under section 6. These provisions also generate information important to the administration of section 4, because the information could support findings that a chemical substance or mixture "may present an unreasonable risk" or has high production and high release or exposure under section 4(a)(1), or would identify a need for new information under section 4(a)(2).

Not only do these provisions provide EPA with potentially relevant information, EPA needs to aggressively make use of these authorities both prior to and during its prioritization and risk evaluation processes. TSCA section 26(k) requires that in carrying out section 6, EPA must consider "[r]easonably available information," which includes existing information, such as scientific literature, government assessments, and industry studies. But it also includes any information that EPA can reasonably require to be developed or submitted under its broad information authorities. EPA regulations now define "reasonably available information" to mean "information that EPA possesses or can reasonably generate, obtain and synthesize for use, *** considering the deadlines." 82 Fed. Reg. 33726, 33748 (Jul. 20, 2017) (40 C.F.R. § 702.33). Under this definition, information that EPA can reasonably generate, develop or obtain through the exercise of its information authorities under sections 8 and 11 is "reasonably available information." Since EPA must consider "reasonably available information," EPA must exercise those information authorities to inform the prioritization and risk evaluation processes or provide an explanation, supported by evidence, that EPA's alternative approach will otherwise obtain that reasonably available information.

In addition, EPA should not exclude from its prioritization and risk evaluation processes chemical substances that could present significant risk merely because EPA lacks or cannot ensure timely development of information needed to conduct a full risk evaluation within the allotted timeframes. Because EPA will likely have to exercise its information authorities under sections 8 and 11 to fulfill its duties under section 6, EPA should include those costs when estimating the costs of carrying out section 6.

In sum, considering this crucial role that EPA's section 8 and 11(c) authorities play in the timely administration of sections 4 and 6, EPA should include the costs of these activities in its baseline costs for carrying out sections 4 and 6.

v. *Despite evidence that EPA is not meeting its obligations under section 14, EPA's cost estimate inexplicably dropped by more than half relative to that in its Final 2018 Fee Rule.*

In its Final 2018 Fee Rule EPA estimated its annual costs for "TSCA Chemical Information Management" to be $4,345,000 (83 Fed. Reg. 52699, Table 1). This is the same estimate that the 2018 proposed rule identified for Section 14 (83 Fed. Reg. 8217, Table 1).

Yet in the 2021 proposal, the section 14 cost estimate reported in Table 1 (p. 1893) is only $1,873,443, an amount that is only 43% of the 2018 estimate for the same activities. This dramatic drop is never acknowledged or explained, and it is difficult to see how such a reduction could possibly be justified.

We noted above that EPA includes a new line item in Table 1 for section 8 but does not indicate what these activities these costs are intended to cover. If they are the costs of reviewing the CBI claims associated with Notices of Activity under the review plan required by TSCA section 8(b)(4)(C)-(E), that is entirely separate from the many other ongoing obligations EPA has under section 14.

First, EPA appears to have only included the cost of reviewing confidential business information (CBI) claims under section 14 (and possibly section 8). EPA makes no mention of its many duties to provide access to both non-confidential information by the public and (CBI by authorized entities under section 14(d)(4),(5), and (6) and section 14(g)(3). While EPA recently began reporting statistics on its review of CBI claims under TSCA,[61] EPA has provided little public accounting of the CBI claims it has received, with no indication of how many claims it has received in the various types of submissions it receives; for what types of information (other than chemical identity); how many claims it has reviewed within what timeframe; and so on. EPA also lacks any system for informing the public whether and when 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 these activities.

EPA provides no costs for establishing and maintaining the "request and notification system" required under TSCA section 14(g)(3), and indeed there is no indication EPA has made any progress toward meeting this requirement, almost five years after it was enacted. That 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.

[61] See: https://www.epa.gov/tsca-cbi/statistics-tsca-cbi-review-program.

Second, there is clear evidence EPA is not meeting its obligations to conduct timely reviews of CBI claims and execute required actions in response to those reviews. For example:

- *Lag in assigning unique identifiers to chemicals claimed CBI in Notices of Commencement (NOCs)*: EPA is required under TSCA section 14(g)(1)(C)(i) to review 100% of claims it receives in NOCs to maintain chemical identities as CBI (15 U.S.C. § (g)(1)(C)(i)), and per TSCA section 14(g)(1)(A) to do so within 90 days of receipt (15 U.S.C. § 2613(g)(1)(A)). Under TSCA section 14(g)(4), EPA must also assign a "unique identifier" to each such claim it approves (15 U.S.C. § 2613(g)(4). Yet based on EPA's public data on the extent and outcomes of its CBI reviews through early February 2021,[62] EPA has not taken these steps for at least 30% (141 of 467) NOCs it reported receiving through October 2020,[63] despite more than 90 days having passed.

  For other types of submission EPA receives it is far more difficult to track EPA's review of CBI claims but we suspect it is failing to keep up with other types of submissions as well.

- *Excessive delays in responding to FOIA requests*: EDF has submitted a number of requests under the Freedom of Information Act (FOIA) for information that is subject to CBI claims made by submitters of the information. Some of these requests have languished for more than a year. Two examples follow:
  - Request #EPA-2020-000867: We submitted this request for a group of NOCs on November 5, 2019, 18 months ago. After an initial release in September 2020 was limited only to the records that contained no CBI claims, EDF successfully appealed EPA's failure to disclose the additional records, with a full grant of our appeal issued in December 2020. We are still waiting for the additional records, having learned from EPA that the CBI claim reviews mandated under TSCA section 14(f)(2)(A) had not been conducted for the great majority of the claims. That review has only now just been initiated.[64]

[62] See: https://www.epa.gov/tsca-cbi/statistics-tsca-cbi-review-program#reviews.

[63] These reports of NOCs received are in Federal Register notices reporting NOCs received in a given month. This analysis was based on our tracking of these notices through October 2020, https://www.federalregister.gov/documents/2020/12/15/2020-27540/certain-new-chemicals-receipt-and-status-information-for-october-2020.

[64] EDF has also learned from EPA staff that another reason for delay in providing public access to NOCs is that, unlike for most other submissions entailing CBI claims, EPA does not require companies to submit "sanitized copies" of NOCs that redact information claimed CBI. That means that either EPA must redact such claims or request submitters to do so, or manually transfer the NOC information into a spreadsheet to share, which we indicated was an acceptable alternative in the case of this specific FOIA request. EPA should require companies to submit sanitized copies of their NOCs.

- Request #EPA-2019-004827: We submitted this request for public files on a group of PMNs on April 5, 2019, 2 years ago. After an initial partial release of documents in June 2019, we were told that release of the remaining records required further review including of information claimed or withheld as CBI. We are still awaiting the remaining records, reviews of which were mandated under TSCA section 14(f)(2)(A).

- *Missing consent orders for new chemicals*: Until about a year ago, EPA's website listing decisions made in its reviews of PMNs indicated that, for any cases yielding a consent order, that order would be posted to EPA's ChemView database within approximately two weeks of its effective date. In the middle of last year EDF noted that recent consent orders had not been posted. EPA then quietly removed its reference to posting within two weeks. The last consent order posted to ChemView by EPA was one covering two chemicals that became effective in April of last year. Since that one, EPA has actually finalized 50 consent orders – but not a single one of them is publicly available, whether through its tables listing final decisions on PMNs or ChemView. On a recent call with EPA staff EDF was told that the delay has been because EPA has stopped producing public versions of the consent orders for posting where information deemed CBI has been redacted.

When we have raised concerns such as these with staff, the response has consistently been that this part of the TSCA program lacks sufficient resources to carry out its duties and to do so in a timely manner.

EPA must fully account for the costs necessary to actually meet its obligations, and not simply those it may currently be expending, which are clearly insufficient. Reducing its projected cost estimate for the next three years for these and related activities to only 43% of that for the past three years simply cannot be justified.

vi. EPA underestimates the costs of its obligations under section 14 by estimating the costs at less than 10% of its prior proposed budget and failing to account for its numerous additional obligations under the Lautenberg Act.

With almost no explanation, EPA assumes that carrying out *all* of its section 14 activities will cost about $1.87 million per year, about 2% of its estimate for total program costs.[65] It is impossible to parse EPA's estimates for section 14 because EPA made no attempt to itemize its costs under section 14. As noted above, despite the absence of an accounting, there is every reason to believe EPA's estimate is far too low. This is further reinforced by earlier budget estimates EPA made for these activities predating the Lautenberg Act.

[65] EPA's total program cost estimate is $87,536,000; see Table 1, p. 1893.

In 2016, the White House Budget for FY 2017 estimated that the cost of managing TSCA CBI, under TSCA *prior to passage of the Lautenberg Act*, was $20,000,000.[66] That earlier estimate seems like a reasonable place to begin forming an estimate for the costs of activities under section 14 as amended by the Lautenberg Act. EPA provides no justification for its assumption in the proposed fee rule that its CBI-related costs are *less than 10%* of its prior estimate. Neither the proposed rule, nor any of the documents in the docket, grapple with the discrepancy between the estimate of the cost under the old law and EPA's current, far lower estimate.[67]

EPA should estimate its costs under section 14 to be significantly higher since the Lautenberg Act passed, because EPA now has significantly broader duties to carry out under section 14. EPA's activities regarding CBI under the old law were limited in scope, only including the maintenance of CBI and the occasional review of a claim. Now EPA must 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). EPA also needs to make all determinations regarding CBI claim reviews public. 15 U.S.C. §§ 2613(g)(1), 2625(j)(1). EPA must also develop and apply a system of unique identifiers for chemical identities kept confidential. *Id.* § 2613(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).[68] All of these activities involve processing,

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[66] 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. Analytical Perspectives: Budget of the United States FY 2017, at 218 and 223 https://www.gpo.gov/fdsys/pkg/BUDGET-2017-PER/pdf/BUDGET-2017-PER.pdf (last visited Mar. 25, 2021).

[67] EPA should make the documents providing the basis for this earlier budget estimate available in the docket.

[68] It appears that EPA's estimate for section 14, even if it does include the costs of *all* section 14 activities, is low in part because EPA has stated it expects to receive very few requests from states, health providers or first responders for access to confidential business information. *See* EPA-HQ-OPPT-2017-0652-0002, Draft ICR Supporting Statement at p.8 (Mar. 2018), https://www.regulations.gov/document?D=EPA-HQ-OPPT-2017-0652-0002 (estimating that EPA will receive only six requests per year). This assumption is highly suspect, however. Based on the extensive comments provided on EPA's draft guidance for CBI access by the Environmental Council of States (ECOS), the states of New York and North Carolina, and the International Association of Firefighters (IAFF), there is significant interest from states and other stakeholders in receiving access to CBI, and EPA's estimates should reflect that interest accordingly. *See* Docket at https://www.regulations.gov/docket?D=EPA-HQ-OPPT-2017-0652; *e.g.*, IAFF Comments, https://www.regulations.gov/document?D=EPA-HQ-OPPT-2017-0652-

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).

5. EPA's proposed exemptions from paying fees for risk evaluations have no basis in law and are bad policy.

EPA has proposed no fewer than six exemptions from the payment of fees for companies whose chemicals are undergoing 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 lbs. annually of the chemical; and
(6) manufacturing a chemical as a non-isolated intermediate.[69]

There are many problems with this approach. These activities constitute forms of manufacturing under TSCA. They are activities that TSCA requires be included in the scope of a risk evaluation; hence EPA will incur costs in evaluating those activities. EPA itself advances similar cogent arguments against the exemptions it proposes (p. 1900):

> TSCA requires EPA to evaluate chemicals under their conditions of use, and conditions of use evaluated may involve manufacture of chemicals that are exempt under this proposal including impurities or byproducts, chemicals imported in articles, or chemicals in small amounts solely for the purposes of research and development. In addition, EPA does not consider these exemptions in designating chemical substances as high priority substances for

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0014 ("It would be most beneficial to our members if they could have this information prior to arriving on a scene, as it would provide fire fighters with the knowledge to develop their initial strategy and tactics, determine the proper level of protective equipment, determine if specialized hazardous materials units must be dispatched, properly care for those injured from chemical exposures, and to develop the proper evacuation zone for citizen safety.").

[69] For the reasons described in this section, EDF strongly opposes these exemptions. Should EPA nevertheless decide to finalize any of them, it is essential that EPA only allow an exemption if it applies to 100% of a company's manufacture or other activity subject to the exemption. This appears to be EPA's intent based on its inclusion in proposed § 700.45(a)(3) that manufacturers are excluded from fee payment requirements only "if they *exclusively*" engage in one of the exempted activities (emphasis added).

In addition, should it include any exemptions, which again we strongly oppose, EPA must require thorough recordkeeping by companies, described on p. 1901 of the 2021 proposal, sufficient to establish compliance with the terms of any of the exemptions EPA allows, as well as records documenting an assertion of cessation of manufacture.

risk evaluation, and there may be chemicals designated where that chemical's primary condition of use is covered under one of the five exemptions listed within this Unit, 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.

A. EPA has provided no basis in TSCA or arising from the development of the Final 2018 Fee Rule for now including exemptions from fee-paying.

Neither EPA's Final 2018 Rule nor TSCA itself provides any basis for these exemptions. Indeed, in their comments on the 2018 proposed fee rule, numerous industry stakeholders requested EPA include some of these and many other exemptions from the fees. In the 2018 final fee rule and in subsequent notices issued as recently as 2020, EPA firmly rejected those requests, issuing a final rule without any of these exemptions and noting that TSCA requires EPA to evaluate chemicals under these conditions of use:

- In its 2020 Federal Register notice "Preliminary Lists Identifying Manufacturers Subject to Fee Obligations for EPA-Initiated Risk Evaluations Under Section 6 of the Toxic Substances Control Act (TSCA), EPA stated:[70]

  > All manufacturers (including importers) of these chemical substances, including those who import the chemical as part of an article, or manufacture (including import) chemical substances that are considered an impurity or byproduct, or in small amounts are subject to the Fees Rule requirements. TSCA requires EPA to evaluate chemicals under their conditions of use, and conditions of use evaluated may involve import of articles containing the chemical, the manufacture of the chemical as an impurity or byproduct, or in small amounts. … EPA does not exempt these manufacturers from fee obligations for TSCA section 6 activities.

- In its 2018 final fee rule, EPA stated:[71]

  > [Several commenters] suggested exclusions or discounts for those who manufacture a chemical as an impurity or byproduct, or those who manufacturer chemicals for small, niche markets as their revenue may be insufficient to support a risk evaluation. As indicated earlier, EPA is not adjusting the fee categories in the final rule. 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

[70] See p. 4663 here: https://www.govinfo.gov/content/pkg/FR-2020-01-27/pdf/2020-01320.pdf.
[71] See p. 52699 here: https://downloads.regulations.gov/EPA-HQ-OPPT-2016-0401-0072/content.pdf.

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.

- In its Response to Comments on the proposed 2018 Fee Rule, EPA stated:[72]

  EPA intends for the final list developed through the process described above to be an accurate description of active manufacturers of the subject chemical at the time of the fee event, regardless of variations in the origins of manufacturing processes (such as recycling, importing, or other types of manufacturing) or downstream uses of subject chemicals. … EPA does not believe it would be appropriate to categorically exempt these manufacturers and importers from fee obligations. Therefore, EPA will not add any exemptions or exclusions from the requirement to pay fees.

In advancing its new proposal to exempt six categories of manufacturers from paying fees for risk evaluations of chemicals they manufacture, EPA provides no rebuttal to the reasons EPA repeatedly gave for rejecting such exemptions just recently. Equally notably, EPA has cited no actual evidence other than theoretical arguments and industry complaints as a basis for its assertion that the fees impose any undue burdens on industry.

TSCA section 26(b)(4)(F) authorizes EPA to modify the fees every 3 years – but *only* in order 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" the specified portion of EPA's costs. This provision governing revisions to the fee rule says nothing about EPA exempting categories of manufacturers.

EPA has provided insufficient basis, and no basis is provided in TSCA, for EPA to elevate assertions of industry burdens above Congress' clear intent in enhancing EPA's fee authority to ensure the agency has adequate resources to implement TSCA.

B. EPA does not address numerous serious consequences of its proposed exemptions.

While in theory exempting some manufacturers of a chemical would simply mean that the remaining manufacturers would have to pay more, there is real concern that the exemptions could result in no companies being left to pay the fee or otherwise create inequities. This is not theoretical: After EPA applied these exemptions to its list of manufacturers of the 20 chemicals

[72] See p. 6 here: https://www.epa.gov/sites/production/files/2018-09/documents/final_clean_fees_rtc.pdf.

now undergoing risk evaluations – which it did with absolutely no transparency[73] – the number of subject companies dropped dramatically and in one case left no – zero – companies.[74] That means EPA – and hence the taxpayer – will have to pay the full $5.7 million fee for that risk evaluation.

For one – but only one – of its proposed exemptions, EPA does address the scenario under which an exemption yields no fee payers for a chemical. Proposed § 700.45(a)(3)(vi) states (emphasis added):

> Manufacture (including import) that chemical substance in quantities below a 2,500 lbs. annual production volume as described in § 700.43, unless all manufacturers of that chemical substance manufacture that chemical in quantities below a 2,500 lbs. annual production volume as described in § 700.43, in which case this exemption is not applicable.

EPA never explains why that proviso is applied only to that one of its six proposed exemptions.

EPA also never addresses what will happen if the basis for a company's claimed exemption changes or if its certification is found not or no longer to be true. EPA has addressed such a circumstance in a parallel context: the requirement that a company must certify it has ceased manufacture of a chemical and will not manufacture it for a period of at least five years, in order for the company not to be subject to the risk evaluation fee. In that case, in the preamble EPA makes clear that a resumption in manufacture would constitute a violation of TSCA and the company would be subject to a penalty (see p. 1901), although EPA needs to add this language to the text of the fee rule regulations. EDF strongly supports this approach and opposes the alternative EPA requests comment on of allowing companies to opt back in after fee allocations were assigned; we agree with EPA's arguments that such an alternative would be unworkable and place significant burdens on EPA. EPA also notes the inequities among companies that could arise were it to adopt the opt-back-in approach.

In the case of its proposed exemptions, however, EPA has not raised – let alone addressed – any of these parallel questions. Should it decide to include any exemptions, which we strongly

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[73] Should EPA adopt its exemptions, which we strongly oppose, in finalizing its list of fee payers EPA must be fully transparent by identifying for each entity removed from that list the specific basis for its removal, i.e., what exemption(s) the company asserted it qualified for. This full transparency would be essential if there is to be any accountability to an exemption process of the sort EPA has proposed.

[74] See entry for "Tris(2-chloroethyl) phosphate (115-96-8)" on p. 7 of EPA's Final Lists of Manufacturers Subject to Fees for the 20 High Priority Substances Undergoing TSCA Risk Evaluations, September 4, 2020, available at https://www.regulations.gov/document/EPA-HQ-OPPT-2019-0677-0125.

oppose, EPA should make clear in the text of the fee regulations that a subsequent change by a company resulting in it no longer qualifying for an exemption it claimed constitutes a violation of TSCA and that the company would be subject to a penalty. The same should be made clear for any case where a company's certification is found not to have been or no longer to be true.

C. The policy basis for these exemptions is highly questionable.

EPA's proposed exemptions are often premised on an asserted difficulty companies would have in knowing or determining whether their products contain chemicals subject to a risk evaluation or not. On what reasonable basis would a company make, import, sell or use a product or chemical without knowing whether, for example, it is contaminated with an impurity or byproduct – let alone a chemical that EPA has designated through a lengthy, public process as a high-priority substance warranting risk evaluation under TSCA? Knowledge about the composition of one's products was long ago identified as a pillar of extended producer responsibility policies, policies that industry purports to have embraced.[75]

In its undated "no action assurance" request, which EPA cites in the proposed rule as reference 3, EPA argues that it would be too burdensome on companies to determine whether a subject chemical is present in their products. EPA asserts, for example (p. 2, emphases added), that "there may be barriers to identifying *with certainty* the chemicals that are present in their imported articles and components," and that "many of these companies have not previously been *required to know*, and would need to undertake significant and expensive product testing efforts to find out, what chemical substances may be present."

These same arguments could be advanced, however, in opposition to ever requiring companies to make an informational determination or report *any* information under TSCA. In other contexts, EPA has applied as a reporting standard whether information is "known to or reasonably ascertainable by" a company. This term, defined at 40 CFR § 704.3, means "all information in a person's possession or control, plus all information that a reasonable person similarly situated might be expected to possess, control, or know." EPA could certainly clarify that such a standard would be used in these cases. But providing instead a blanket exemption that would

[75] See, for example, American Chemistry Council, Responsible Care Principles, https://responsiblecare.americanchemistry.com/ResponsibleCare/Responsible-Care-Program-Elements/Guiding-Principles/, which include: To work with customers, carriers, suppliers, distributors and contractors to foster the safe and secure use, transport and disposal of chemicals and *provide hazard and risk information that can be accessed and applied in their operations and products*; to instill a culture throughout all levels of the organizations to *continually identify, reduce and manage process safety risks*; to promote pollution prevention, minimization of waste and conservation of energy and other critical resources *at every stage of the life cycle of products*; and to communicate *product, service and process risks* to stakeholders and listen to and consider their perspectives.

apply even to companies who know or are readily able to determine that a subject chemical is present in their product, is both unnecessary and unwarranted.

D. EPA appropriately rejects a concentration-based exemption.

While EDF does not support EPA's proposed volume-based exemption, a concentration-based exemption would be even more problematic and we support EPA's rejection of that approach. As EPA notes (p. 1900), a concentration-based exemption "could result in manufacturers of large quantities of chemicals being exempt from fee obligations" should the volume's concentration meet a given threshold. This is inappropriate.

6. EPA has provided insufficient basis for its proposal to delay and spread out fee payments.

EPA has proposed further spreading out and delaying the payment of fees for risk evaluations, indirect response to industry's requests. Notably EPA has provided no factual basis for the underlying assumption that the current schedule is too onerous for companies. EPA also fails to acknowledge, let alone assess, this proposal's impact on EPA's ability to conduct risk evaluations:

- EPA's ability to hire staff and engage contractors to do the necessary work requires stability in its budget and advanced planning, both of which will be adversely affected if EPA does not receive fees on time.
- If fees are delayed due to EPA's accommodation of industry concerns,[76] that reduces EPA's capacity to conduct timely, robust risk evaluations. The TSCA clock is already ticking on the next 20 risk evaluations, and EPA is already well behind schedule.

EDF opposes any further delay or spreading out of fee payments under the TSCA fee rule. We continue to support the approach taken in the current fee rule, whereby EPA requires payment of fees before or soon after initiating the activities triggering the fees. EDF agrees with this method of collecting fees for the reasons stated in our 2016 pre-proposal comments, including that EPA's ability to develop and sustain capacity to conduct its activities under TSCA depends on the payment of fees up front.[77]

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[76] Some of the same companies who pressed EPA for this accommodation are adding to EPA's burden by requesting it conduct risk evaluations of their chosen chemicals. If cash were really so tight, they could save some by pulling back those requests and avoid paying fees to cover their 50% share (for chemicals on the 2014 Update to TSCA Work Plan) of those risk evaluations.

[77] EDF Comments on Rule on Fees for the Administration of TSCA at pp. 3-4 (Aug. 2016), https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0401-0010.

The tenses and language Congress used in the statutory text generally support EPA assessing fees when initiating the activities justifying the fees. *See* 15 U.S.C. § 2625(b)(1) (allowing fees to be charged to "any person *required to submit* information under section 4 or a notice or other information *to be reviewed* by the Administrator under section 5, or who manufactures or processes a chemical substance that *is the subject of* a risk evaluation under section 6(b)") (emphases added). This language is consistent with charging fees at or near the outset of a process, and in particular, the language regarding section 5 activities strongly suggests that the fees should be charged before the review commences.

7. EPA has undercounted the number of manufacturer-requested risk evaluations it is conducting.

EPA has underestimated its costs for manufacturer-requested risk evaluations, some of which EPA must recover under section 26(b)(4)(B)(ii). Specifically, TSCA requires that, in addition to the fees flowing from the baseline program costs discussed above, EPA must also set fees "at levels such that the fees will, in aggregate, provide a sustainable source of funds to annually defray *** the costs of risk evaluations specified in subparagraph (D)." 15 U.S.C. § 2625(b)(4)(B)(ii). Subparagraph (D) then provides that for manufacturer-requested risk evaluations, EPA shall "establish the fee at a level sufficient to defray the full costs to the Administrator of conducting the risk evaluation under section 6(b)," with fees set at 50% of the costs to the Administrator for chemicals listed on the 2014 update of the TSCA Work Plan. *Id.* § 2625(b)(4)(D).

It is important to note that EPA's estimate of its program costs presented in Table 1 (p. 1893), excludes its costs for conducting manufacturer-requested risk evaluations. The section 6 amount of $41,998,820 matches the amount shown in Table 4 (p. 1896) for EPA-initiated risk evaluations only. Yet Table 4 shows EPA also incurs costs for conducting manufacturer-requested risk evaluations and, because it can only recoup half of its costs of those evaluations for chemicals on the TSCA Work Plan, the other half of those costs fall to the program. While those costs are not subject to the 25% defrayal provision in TSCA section 26(b)(4)(B)(i)(I) and section 26(b)(4)(F)(i), they are program costs that should be acknowledged as costs to administer TSCA section 6.

Manufacturer requests have now been received for a total of seven chemicals, in four separate requests: DIDP, DINP, D4 and the OTNE category of four chemicals.[78] There are two CAS numbers each for DIDP and DINP; in each case, one was listed on, and the other not on, the 2014 TSCA Work Plan. The chemical D4 and all four of the OTNE chemicals are list on the

[78] See: https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/list-manufacturer-requested-risk-evaluations-under-tsca.

Work Plan, according to EPA.[79] That amounts to five Work Plan chemicals and two non-Work Plan chemicals to date. Hence at least seven substances (and nine CAS numbers) are subject to manufacturer requests. Seven CAS numbers are on the Work Plan, while two are not.

In the 2021 proposed rule, EPA's estimates for how many manufacturer-requested risk evaluations it expects to be conducting are lower than the actual numbers just noted. In its proposed rule (p. 1891) EPA stated it expected to conduct risk evaluations of two Work Plan chemicals every three years (i.e., 0.67 chemicals/year) and one non-Work Plan chemicals/year.

Yet just to meet the current requests that have been received, EPA will be doing at least five Work Plan chemicals in the next three years (i.e., 1.67 Work Plan chemicals/year) and two non-Work Plan chemicals in these same three years (i.e., 0.67 non-Work Plan chemicals/year).[80] It is possible if not likely that more manufacturer requests will be received over the term of this update to the fee rule.

EPA should adjust its section 6 cost estimates to reflect at least the current number of manufacturer-requested risk evaluations it has received, if not more. The amounts shown in Table 4 should be adjusted accordingly, and the costs to EPA should be included in Table 1 even if broken out to indicate they are not part of the baseline costs for purposes of calculating fee levels.

8. EPA should establish a separate fee category for risk management actions.

In its 2018 proposed rule, EPA sought comments on whether there should be a separate fee category under section 6 for risk management actions. 83 Fed. Reg. at 8227. In our comments at that time, we urged EPA to do so, and we reiterate that here.

As a general rule, to ensure that EPA sets fees in a manner that reflect the cost of the relevant activities, EPA should charge a separate fee for risk management actions. Section 26 provides that EPA may charge a fee "from *any person* *** who manufactures or processes a chemical substance that is the subject of a risk evaluation under section 6(b)." 15 U.S.C. § 2625(b)(1) (emphasis added). The Supreme Court has repeatedly interpreted the phrase "any person" to sweep broadly and has rejected interpretations that try to limit this phrase. *See, e.g.*, *Lewis v. United States*, 445 U.S. 55, 60-61 (1980). Thus, EPA can assess a fee on any person

[79] See: https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/list-manufacturer-requested-risk-evaluations-under-tsca#OTNE.

[80] The actual total is 1.67+0.67 = 2.33 chemicals/year – for a total of seven chemicals over the three years – which is higher than EPA estimates in its proposed rule (0.67+1 = 1.67 chemicals/year) – which assumes only five chemicals total over the three years.

manufacturing or processing a chemical substance "that is the subject of a risk evaluation under section 6(b)." That phrase encompasses chemicals subject to completed risk evaluations finding unreasonable risk, and thus EPA should be able to assess a fee for risk management activities under section 6(a) when those risk management activities flow from a completed risk evaluation under section 6(b).

Rather than increase the cost of risk evaluations further to recoup the allowable amount, EPA should have a separate fee category for risk management actions. Not only is a risk management fee permitted by section 26(b), setting a separate fee for risk management actions ensures that EPA recoups its costs in a manner more proportional to the cost of its activities. Also, having a separate fee category for risk management actions would more evenly spread out EPA's fee collection under section 6, as fees could be assessed both upon initiation of a risk evaluation and upon initiation of a risk management rulemaking. Since EPA operates on an annual budget, having a more regular distribution of incoming fees would be beneficial to the successful implementation of TSCA.

EDF also believes EPA can and should collect fees for the risk management rules it must now develop for each of the first 10 chemicals for which it recently completed risk evaluations. In its Final 2018 Fee Rule, EPA declined to collect fees for the first 10 risk evaluations. However, EPA continues to incur costs arising from these evaluations because it identified unreasonable risks and must now develop risk management rules for each. In order to recoup allowable costs, EPA should charge fees to defray the costs of this rule development. See section 4.C.ii.b. of these comments for more on EPA's underestimation of its costs for risk management under TSCA section 6.

9. EPA has failed to account for inflation since 2018, in revising the fee rule, as required.

EPA has failed to account for inflation since the 2018 final rule, as required by TSCA. TSCA section 26(b)(4)(F) requires that EPA adjust fees every three years as necessary to address *both* inflation and defrayment of costs (emphasis added):

> [B]eginning with the fiscal year that is 3 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, and every 3 years thereafter *** increase or decrease the fees established under paragraph (1) as necessary to adjust for inflation *and* to ensure that funds deposited in the Fund are sufficient to defray— (i) approximately but not more than 25 percent of the costs to the Administrator ***; and (ii) the costs of risk evaluations specified in subparagraph.

However, in its proposal, EPA describes consideration of an inflation adjustment as a regulatory alternative considered *instead* of an adjustment based on defraying costs (p. 1904):

> EPA has considered an alternative regulatory action where the fees remain unchanged except for an adjustment for inflation. In the absence of any substantive adjustments or updates, the 2018 TSCA Fees Rule provides for adjusting the fee structure of the current period (fiscal years 2019–2021) according to inflation rate, in setting a fee structure for the next period. This adjustment occurs automatically if no other updates are put forth by EPA. EPA has considered this regulatory alternative, but has found it unsuitable, because it would not recoup the statutorily required 25% of estimated EPA costs for TSCA related actions.

TSCA provides no basis for EPA not to make an inflation adjustment to fees just because it is making other adjustments.

Overall EPA has increased the fees such that the agency expects to collect nearly $2 million more annually (increasing from approximately $19.9 million it estimated in 2018 to approximately $21.9 million now). Yet these changes were made solely to address the requirement to defray 25% of the costs to the Administrator. It is clear from the excerpt directly above that an adjustment for inflation was not incorporated into the proposal. As one case in point, estimated costs and fees for TSCA section 4 have not, with one exception, changed at all from those in the 2018 final rule – indicating that inflation from 2018 to 2021 was not incorporated. (The one exception is the addition of a fee for a single amended test rule, leading to the increase in expected fees of $9,800 a year.) See Table 2 below.

Table 2. Comparison of Section 4 Costs and Fees: 2018 Final Rule and 2021 Proposal

EPA Program Area	**Estimated annual cost to Agency (in dollars)**		**Fee Structure (fee per action in dollars)**	
	2018 final	*2021 proposal*	*2018 final*	*2021 proposal*
Test Order	2,795,000	2,795,000[81]	9,800	9,800
Amended Test Rule	N/A		N/A	9,800
Test Rule	422,000	422,000	29,500	29,500
Enforceable Consent Agreement (ECA)	326,000	326,000	22,800	22,800
TOTAL:	3,543,000	3,543,000	150,300	160,100
Numbers derived from Table 1 and Table 3 of the Final 2018 Fee Rule, Table 1 and Table 2 in the 2021 proposed rule, and Table 3-11 in 2021 Economic Analysis.				

[81] This value appears to exclude the cost of the one amended test rule per year. See section 4.A.vii. for further detail.

In promulgating the final rule, EPA must appropriately adjust both the underlying cost to the agency and the proposed fees to account for inflation from 2018 to 2021, on top of other adjustments. Based on this US Inflation Calculator, $1.00 in 2018 is now worth $1.05 in 2021 (cumulative rate of inflation of 4.7%).[82]

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

Section 700.45(d)(3) of the fee rule states (emphasis added):

> (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, 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.

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.

TSCA section 26(b)(1) makes clear that EPA is to exercise its authority to require fees "by rule." 15 U.S.C. § 2625(b)(1). Nothing in section 26(b) provides for EPA to make decisions regarding the adjustments to the fees pursuant to section 26(b)(4)(F) other than by rule. The provision of EPA's rule cited above is arbitrary in that it provides for public notice and comment through rulemaking where EPA intends to make adjustments beyond accounting for inflation, but precludes that opportunity where EPA intends not to do so. The latter decision may be just as impactful as the former with respect to Congress' intent in providing EPA with authority to collect fees to help defray its costs of implementing TSCA.

EPA needs to amend this provision of its fee rule to require notice-and comment rulemaking whenever it intends to make adjustments to the fees, whether or not its intended adjustments are limited to accounting for inflation.

[82] See: https://www.usinflationcalculator.com/.

APPENDIX: The Lautenberg Act substantially amended TSCA.

This appendix provides a brief discussion of some of the Lautenberg Act's amendments to TSCA that significantly affect EPA's costs of administering sections 4, 5, and 6, as well as the costs of collecting, processing, reviewing, and providing access to and protecting from disclosure as appropriate under section 14 information on chemical substances under TSCA.

A. The Lautenberg Act amended section 26 and expanded EPA's authority to collect fees.

Prior to the Lautenberg Act, EPA had authority to collect user fees, but those fees were limited to persons required to submit data under sections 4 and 5, and the statute included restrictive caps on those fees established by Congress in 1976, more than 40 years ago. 83 Fed. Reg. at 8214. Under section 5, for instance, TSCA only permitted EPA to collect $2,500 for each TSCA section 5 pre-manufacturing notice (PMN), and $100 for each small business submission. *Id.* EPA, and all of the stakeholders involved in the TSCA amendments, understood that those fees "d[id] not reflect the current cost of administering the TSCA sections associated with those submissions." *Id.* Adding to EPA's resource constraints under the old law was that even though EPA had authority to collect fees under section 4, EPA never did so. *Id.* Finally, fees that EPA did collect did not directly fund EPA's activities but rather were diverted to the general treasury.

When the initial Senate bill, S. 697, of the 114th Congress was passed by the Environment and Public Works Committee, the accompanying 2015 Senate Report stated that: "All stakeholders *** indicated an interest in ensuring that EPA has the resources necessary to implement a robust chemical regulatory system, including prioritization screening, safety assessments and determinations, and regulation of new and existing chemical substances where required to manage risks to health and the environment." S. Rep. 114-67, at 6 (June 18, 2015).

Consistent with this initial intent, S. 697 gave EPA broad authority to recoup and expend user fees that would "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]." S. Rep. 114-67, at 29 (June 18, 2015).

As enacted in 2016, section 26 of TSCA now permits EPA to require fees to be paid by any person:

1) required to submit information under section 4;
2) required to submit a notice or other information under section 5; or
3) who manufactures or processes a chemical substance that is undergoing a risk evaluation under section 6(b).

15 U.S.C. § 2625(b)(1). The fees EPA collects are to be used to defray the costs of "carrying out sections 4, 5, and 6, and of collecting, processing, reviewing, and providing access to and protect from disclosure as appropriate under section 14 information on chemical substances under this title." 15 U.S.C. § 2625(b)(4)(B)(i)(I).

In setting these fees initially, TSCA states that "the Administrator shall ***

> (B) set the fees *** at levels such that the fees will, in aggregate, provide a sustainable source of funds to annually defray—
> (i) the lower of—
> > (I) 25 percent of the costs to the Administrator 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 this title, other than the costs to conduct and complete risk evaluations under section 6(b); or
> > (II) $25,000,000 (subject to adjustment pursuant to subparagraph (F))[.]

Id. at § 2625(b)(4)(B). Notwithstanding that provision, for chemical substances for which EPA has granted a manufacturer request to prepare a risk evaluation, EPA shall "establish the fee at a level sufficient to defray the full costs to the Administrator of conducting the risk evaluation" or sufficient to defray 50% of the costs if the granted request pertains to a chemical substance on the 2014 update to the TSCA Work Plan. *Id.* at § 2625(b)(4)(D).

TSCA section 26(b)(4)(F) authorizes EPA to modify the fees every 3 years in order 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" the specified portion of EPA's costs. This provision mandates that, in updates made to the initial rule promulgated in 2018, EPA is to adjust fees so as to continue to defray 25 percent of the specified costs, without regard to the initial annual fee cap of $25,000,000. The proviso in section 26(b)(4)(B)(i)(II) that the initial cap is "subject to adjustment" when updates to the initial fee rule are made makes clear that annual fees can and must exceed the initial cap when necessary to ensure EPA collects fees sufficient to defray 25% of the costs specified in section 26(b)(4)(B)(i)(I). 15 U.S.C. § 2625(b)(4)(B)(i)(I).

B. Amended TSCA gave EPA numerous expanded authorities under sections 4, 5, 6, 8, and 14.

In addition to giving EPA expanded authority to collect user fees under section 26, Congress gave EPA a number of new duties under sections 4, 5, 6, 8, and 14. In estimating the agency's costs under these sections, it appears that EPA has consistently overlooked the fact that Congress significantly increased its workload under each of those sections. EDF has previously commented at length on EPA's increased responsibilities under sections 5, 8, and 14 and how

EPA has failed to fulfill those duties; we incorporate those comments by reference here.[83] Congress also expanded EPA's responsibilities under sections 4 and 6, as we briefly introduce here.

Under section 4, for instance, Congress reduced the evidentiary burden on EPA to require testing by allowing EPA to mandate testing without first showing that a chemical posed potential risk or has resulted or would result in high production and high release or exposure. *Compare* 15 U.S.C. § 2603(a)(1), *with* 15 U.S.C. § 2603(a)(2) (setting forth additional testing authorities). Congress also granted EPA the authority to order testing, whereas previously EPA could only require testing through a multi-year rulemaking process. *See* S. Rep. 114-67, at 3 (June 18, 2015) ("[T]he existing TSCA rulemaking process can place a significant burden on EPA, and test rules can sometimes take many years to complete."). These changes were made, in part, to address the concern that EPA had not been developing sufficient information on chemicals.[84] Congress expanded EPA's section 4 authority with the intention that EPA would require testing more frequently. *See id.* at 10 (stating the Congress specifically intended to provide EPA with "broad authority to obtain new information on chemical substances ***.").

The Lautenberg Act also established new requirements in section 6 for EPA to systematically evaluate the potential risks of existing chemicals. EPA must now undertake a process to (1) select, i.e., "prioritize," chemical substances needing evaluation based on their potential risks to health and the environment; (2) conduct "risk evaluations" of those prioritized chemicals, and some chemicals nominated by manufacturers, to determine whether they present unreasonable risks of injury to health or the environment; and (3) eliminate such risks by issuing rules regulating those chemicals. 15 U.S.C. § 2605(a)-(b). EPA's risk evaluations must also now consider the chemical's "conditions of use," which are defined as "the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed

[83] See, for example, EDF's comments on the New Chemical Review Framework, the proposed system for Unique Identifiers, the CBI guidance documents, and the Inventory Rule update, which detail EPA's authority under sections 5, 8, and 14. *See* EDF comments on Assignment and Application of the Unique Identifier under TSCA, https://www.regulations.gov/document?D=EPA-HQ-OPPT-2017-0144-0022, EDF Comments on CBI Guidance, https://www.regulations.gov/document?D=EPA-HQ-OPPT-2017-0652-0017, EDF Comments on New Chemicals, https://www.regulations.gov/document?D=EPA-HQ-OPPT-2017-0585-0071; EDF comments on the TSCA Notification (Active/Inactive) Requirement, https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0426-0064.

[84] *See, e.g.*, S. Rep. 114-67, at 3 (June 18, 2015) (stating that "EPA has succeeded in requiring the testing under section 4 of only about 200 chemicals in TSCA's almost 40 years.").

of." *Id.* § 2602(4). Previously, EPA could and would complete risk evaluations on only a limited subset of a chemical's uses.[85]

Under the Lautenberg Act, EPA must also now evaluate risks not only to the general population, but to relevant "potentially exposed or susceptible subpopulation[s]." 15 U.S.C. § 2605(b)(1)(A), (b)(4)(A). These include groups such as "infants, children, pregnant women, workers, or the elderly," that, "due to either greater susceptibility or greater exposure," may face greater risks of harm than the general population from chemical exposures. *Id.* § 2602(12). This mandate to specifically consider risks to potentially exposed or susceptible subpopulations significantly expanded EPA's obligations under section 6.

In sum, the amendments to sections 4, 5, 6, 8, and 14 dramatically increased the burden on the agency, and EPA must take into account all of these additional duties in calculating its baseline costs.

* * * * *

EDF appreciates the opportunity to provide comments and EPA's consideration of them.

[85] *See, e.g.*, TSCA Workplan Chemical Risk Assessment for Methylene Chloride at p. 17 tbl. 1-1 (Dec. 2012), https://www.regulations.gov/document?D=EPA-HQ-OPPT-2012-0725-0002 (focusing the assessment on one primary use out of 7 primary uses identified).