



Environmental Defense Fund Comments on

User Fees for the Administration of the Toxic Substances Control Act

Docket # EPA-HQ-OPPT-2016-0401

Submitted May 24, 2018

Background and summary

Environmental Defense Fund (EDF) appreciates the opportunity to provide these comments on the Environmental Protection Agency's (EPA) proposed fee rule, authorized under section 26(b)(1) of the Toxic Substances Control Act (TSCA), as amended by the Lautenberg Act in 2016. 83 Fed. Reg. 8212 (Feb. 26, 2018). 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). EDF met with EPA officials regarding the proposed rule on April 5, 2018, and the questions EDF raised at the meeting are attached as an Appendix.

EPA's proposed fee structure is based on the agency's estimates of its underlying costs for administering only sections 4, 5, 6, and 14, which the agency has calculated at \$80,161,672 annually. EDF has included its own table below (Table 1) that briefly summarizes EDF's understanding of the agency's estimates for the number of actions per year, the costs per action, the total cost, the proposed general fee, and the projected fee revenue for each action:

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 (in dollars)	Cost per year (in dollars)	Proposed Fee Structure (fee per action in dollars)	Total Annual Fees EPA expects to collect (in dollars)
Section 4	Test Order	10	279,463	2,794,630	9,800	98,000
	Test Rule	0.5	844,109	422,054	29,500	14,750
	Enforceable Consent Agreement (ECA)	0.5	651,889	325,949	22,800	11,400
Section 5 ¹	PMN/MCAN/SNUN	462	55,251	25,525,758	16,000	6,415,200
	All Exemptions	560	5,622	3,148,320	4,700	2,293,600
Section 6	Risk Evaluations	8.33	3,884,000	32,352,720	1,350,000	11,245,500
Section 14	CBI Review & CBI LAN ²	NP ³	NP	4,343,281	0	0
Section 6	Office of Research and Development	NP	NP	2,091,000	0	0
	Risk Management	7.5 ⁴	877,867 ⁵	6,584,346	0	0
	Prioritization	NP	NP	2,572,611	0	0
TOTAL COSTS:				80,161,672		
TOTAL FEES:						20,078,450

¹ Under section 5 EPA has assumed that a number of notices will come from small businesses 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.

² 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>.

³ “NP” is “not provided,” and is used in this table because EPA did not provide individualized (i.e., per-activity) estimates under these actions.

⁴ 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, <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0401-0021>.

⁵ The cost estimate was not calculated by EPA, i.e., it is not included in any of the tables in the proposed 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).

EPA has also proposed two alternative fee structures, shown in Table 2 below:

Table 2: EPA’s Proposed Alternative Fee Structures

TSCA Provision	EPA Action	Fees under Alternative A (in dollars)	Fees under Alternative B (in dollars)
Section 4	Test Order	92,000	28,000
	Test Rule	278,000	84,000
	ECA	215,000	65,000
Section 5	PMN/MCAN/SNUN	18,200	10,400
	All Exemptions	1,850	3,500
Section 6	Risk Evaluation	1,280,000	1,670,000

EDF strongly supports EPA’s adoption of a rule to collect fees authorized under TSCA and EPA’s proposal to collect those fees before or as soon as possible after initiating the relevant action.

However, EDF believes that EPA has significantly underestimated 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). In particular, EPA has entirely failed to include any baseline costs associated with activities related to collecting, processing, and reviewing information under sections of TSCA other than section 14, most notably section 8. The statute provides for EPA to defray a portion of its costs from undertaking these activities and EPA needs to include reasonable estimates of them in its baseline. Additionally, such information will play a vital role in informing activities EPA undertakes, in particular under sections 4 and 6.

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). 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).

In addition, EPA must recover its “full costs” for manufacturer-requested risk evaluations (or 50% of the costs for Work Plan chemicals). 15 U.S.C. § 2625(b)(4)(D). In the proposed rule,

EPA discounted its estimates for manufacturer-requested risk evaluations in a manner that does not result in recovering the full costs, violates the Lautenberg Act, and reflects arbitrary and capricious reasoning.

Additionally, EPA should adopt a fee structure similar to Alternative A (after correcting its cost estimates and thus raising the fees) rather than the proposed fee structure, because Alternative A assesses fees in proportion to the costs that the Agency incurs for each particular activity.

Lastly, EPA must charge fees to recoup costs for the work remaining to be completed on the risk evaluations for the first ten chemicals that are currently underway, as well as the costs of any associated risk management under section 6. The cost of those risk evaluations and risk management activities is a significant portion of EPA's near-term total budget, and EPA must ensure that it is collecting fees for the portions of those activities that remain to be undertaken.

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I. The Lautenberg Act substantially amended TSCA.

We begin with a brief discussion of some of the Lautenberg Act's amendments to TSCA because EPA systematically underestimates its 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, by failing to account for its expanded authorities and duties under those amendments.

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, “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).

In proposing the fee rule, EPA has taken a significant step forward in ensuring it can begin to recoup a significant portion of its costs.

B. EPA appears to disregard its 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.⁶

⁶ 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

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.⁷ 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 of.” *Id.* § 2602(4). Previously, EPA could and would complete risk evaluations on only a limited subset of a chemical’s uses.⁸

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>.

⁷ *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.”).

⁸ *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).

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 provides detailed comments below identifying where it appears EPA has failed to take into account its increased responsibilities.

II. EPA has underestimated its annual budget.

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. To seek to understand EPA’s accounting, in addition to the proposed rule itself, EDF examined three other documents in the docket, which we refer to throughout these comments as follows: Technical Background Document (hereinafter, “TBD”), Economic Analysis (hereinafter, “EA”), and TSCA Fees Costing Spreadsheet (hereinafter, “FS”).⁹

As relevant here, 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)(I). For manufacturer-requested risk evaluations, EPA must “establish the fee[s] 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)(D). Thus, EPA must accurately estimate the costs of “carrying out” these various activities to ensure that EPA establishes fees at the legally mandated

⁹ EPA-HQ-OPPT-2016-0401-0020, Technical Background Document, <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0401-0020>; EPA-HQ-OPPT-2016-0401-0018, Economic Analysis of the Proposed Rule for User Fees for the Administration of the Toxic Substances Control Act, <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0401-0018>; EPA-HQ-OPPT-2016-0401-0021, TSCA Fees Costing Spreadsheet, <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0401-0021>.

levels. In addition, accurate estimates are important for determining the specific fees for each activity because EPA should set fees generally proportional to the costs of the underlying activities, as discussed in more detail below, *see infra* section IV.

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:

- Across all the sections, EPA seems to have greatly underestimated its costs associated with the Office of Research and Development (ORD), contradicting public statements indicating broader commitments by ORD to the TSCA program.
- When estimating costs under section 4, EPA has significantly underestimated the amount of testing EPA will need to require to fill information gaps and fulfill its expanded obligations under the Lautenberg Act.
- When estimating costs under section 5, EPA failed to account for several activities necessary to carrying out section 5, such as pre-notification consultations and processing notices of *bona fide* intent.
- With respect to section 6, EPA has failed to include any costs associated with identifying potential candidates for prioritization; and has provided no breakdown of or basis for its cost estimate for prioritization.
- With respect to risk evaluations under section 6, EPA relied on the costs of risk evaluations and risk management actions under the old law, and EPA failed to increase those estimates to reflect EPA's new, broader obligations under the Lautenberg Act. And with respect to risk management actions in particular, EPA provides estimates far lower than the costs of prior, narrower actions, based on unspecified "efficiencies."
- 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. 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 ; developing and implementing the rule establishing the CBI claim review plan called for under section 8(b)(4)(C); and managing and conducting reviews of 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).
- Finally, EPA's estimated costs under section 14 are unreasonably low even as compared to EPA's prior budget estimates for these activities under the old law, and EPA has failed to account for its many new duties under this section as amended by the Lautenberg Act.

A. EPA appears to have seriously underestimated the costs for the Office of Research and Development (ORD) related to activities under sections 4, 5, and 6.

EPA has only included costs for the Office of Research and Development (ORD) under EPA's estimates for activities under Section 6, and in that context only estimates that one full-time equivalent (FTE) from ORD will be utilized to assist with TSCA implementation. TBD at 8, tbl. 11. These estimates are unreasonable and contradict EPA's public statements in other contexts. As discussed below, EPA will likely rely on ORD employees to support activities under numerous sections of TSCA and will almost certainly require assistance from more than one FTE. EPA should increase its estimates for its reliance on ORD to reflect more accurate projections of activity and EPA's other public commitments.

First, ORD resources are likely to be utilized by the Office of Pollution Prevention and Toxics (OPPT) for activities under sections 4 and 5, not just section 6. At EDF's meeting with EPA, an EPA official stated that the estimate for ORD actually is intended to apply across all three sections, in contrast to what the proposed rule states. 83 Fed. Reg. at 8219; *see also* TBD at 8, tbl. 11. If so, EPA must update the final rule to accurately reflect this intent and provide specific activities under each section for which ORD assistance will be used. EPA itself has acknowledged that experts from ORD will be significant in helping to "implement TSCA Section 4(h)." ¹⁰

Second, especially if the ORD estimate in the proposed rule applies across all three sections, the estimate appears to severely underestimate OPPT's utilization of ORD under TSCA. For example, this estimate of only a single FTE cannot be reconciled with EPA's draft Strategic Plan for the Development of Alternative Test Methods, which envisions 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 will include experts in ORD. ¹¹ The responsibilities of the TNT include, but are not limited to, developing appropriate communication materials and collaborating with external parties, working more with academics, and partnering with journals to encourage the publication of negative results. While it is not clear how many experts from ORD will be a part of the TNT, implementing the strategic plan will likely take more than one FTE from ORD. Thus, just this one activity under section 4 will likely require significantly more ORD resources than EPA has estimated for the entire TSCA program.

¹⁰ Response to Comments, at 11 (March 2018), <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2017-0559-0583>.

¹¹ Response to Comments, at 33 (March 2018), <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2017-0559-0583>.

And EPA will likely rely on ORD for numerous other activities as well. For example, ORD appears already to be involved in the development of a method for identifying chemicals for prioritization under section 6. At the 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.”¹² Based on the presentation, it appears that ORD is working to fill data gaps in order to place chemicals into pre-priority bins, and the presentation clearly indicated that there is a lot of work still to be done. 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 implementation of the Lautenberg Act.

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

As discussed above, 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). Even industry commenters have acknowledged that the amendments to TSCA increased EPA’s testing authority.¹³ Yet EPA’s proposed rule indicates that it only anticipates annually working on 10 test orders, one test rule, and one ECA. 83 Fed. Reg. 8217; TBD at 1. 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.* As explained below, these estimates seem 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 not 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 not charge sufficient fees to cover 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.

¹² U.S. ORD, Integration of Traditional and New Approach Methods (Dec. 2017), https://www.epa.gov/sites/production/files/2017-12/documents/session_6_-_tscapre prioritization_tool_public_meeting_dec_2017_final2.pdf.

¹³ *See, e.g.*, Comments by American Chemistry Council on Agency Information Collection Activities; Proposed Renewal of an Existing Collection (Section 4 of TSCA) 2 (May 16, 2016), <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2015-0436-0008> (“EPA is likely to have broader order authority to require the generation of new information”).

EPA's documents have provided scant explanation of how and when it will use each of these testing instruments and what the scope and reach of each will be. Our best understanding of EPA's assumptions for section 4 is as follows:

- 1) Each TSCA section 4 activity will cover one to seven chemicals, 83 Fed. Reg. at 8217;¹⁴
- 2) On average data from seven tests will be required to be submitted per chemical, *id.*;
- 3) An average of four companies will be impacted per chemical, EA at 3-24;¹⁵ and
- 4) Each test order will only apply to a single company.¹⁶

These 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. For instance, EPA has estimated that there will be 25 risk evaluations underway per year, ten of which include the first ten chemicals EPA identified under the Lautenberg Act. According to the most recent data collected under EPA's Chemical Data Reporting (CDR) rule, there are at least 87 manufacturers of the first ten chemicals.¹⁷ As of yet EPA has not issued any section 4 actions regarding the first ten chemicals.

Below we provide some examples of significant information gaps for the first ten chemicals and for other Work Plan chemicals that may be subject to prioritization in the near future.

i. EPA has not accounted for the information gaps for the first 10 chemicals.

As EDF previously noted in comments we submitted to EPA, there are significant gaps in the information available on the first ten chemicals and EPA needs to make robust use of its section 4 authorities to fill those gaps. EDF incorporates those comments by reference here.¹⁸ We provide below a few examples of prominent information gaps for several of the first ten chemicals below. EPA needs to account for these types of data gaps when estimating its activities under section 4 (and 8).

¹⁴ There is a discrepancy in the EA, however, which suggests that EPA estimated that each section 4 activity will cover only one to five chemicals. EA at 3-15.

¹⁵ The EA actually states that this assumption applies to each section 4 activity, *see* EA at 3-24, but during EDF's meeting with EPA agency officials clarified that the assumption applies only to test rules and ECAs.

¹⁶ This assumption is not in the proposed rule or any of the docket materials, but was stated by EPA officials during EDF's meeting on April 5, 2018.

¹⁷ EPA'S FIRST TEN CHEMICALS UNDER REVIEW, <https://www.edf.org/health/epas-first-10-chemicals-under-review> (last visited Apr. 30, 2018).

¹⁸ EDF Comments on Ten Scopes under the Toxic Substances Control Act at pp.14-15, <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0725-0041>.

Hexabromocyclododecane

The 2015 Work Plan Chemical Problem Formulation and Initial Assessment for the cyclic aliphatic bromides cluster,¹⁹ which focuses primarily on hexabromocyclododecane (HBCD), points to a number of information gaps, including lack of carcinogenicity data,²⁰ lack of exposure monitoring data for workers in the US,²¹ and lack of inhalation and dermal route-specific toxicity data.²² EPA considered the latter in particular to be “a critical data gap since the exclusion of dermal and inhalation exposure routes will result in the underestimation of risks.” The data gap is made more critical by the fact that there is no physiologically based pharmacokinetic (PBPK) model readily available for route-to-route extrapolation in lieu of actual toxicity data.²³

In EDF’s 2015 comments²⁴ on the document, we urged EPA to promulgate the following regulations to address these information gaps:

- Section 4 test rule and/or section 8(d) data call-in for inhalation and dermal route-specific toxicity data.
- Section 4 test rule to develop exposure monitoring data for workers in the U.S.
- Section 8(a) reporting rule on the number of individuals exposed in their place of employment and the duration of such exposure.
- Section 4 test rule and/or section 8(d) data call-in for carcinogenicity studies.

The 2017 scope document for the cyclic aliphatic bromides cluster²⁵ ignores or brushes aside some of these information gaps. However, it does acknowledge discrepancies in the available data on reproductive toxicity:

For female reproductive effects, there is some rodent evidence that HBCD may alter fertility and pregnancy outcomes as well as reduce the number of mature and developing follicles in the ovary; however, effects on reproductive organ weight are inconsistent.²⁶

¹⁹ U.S. EPA, TSCA Work Plan Chemical Problem Formulation and Initial Assessment for Cyclic Aliphatic Bromides Cluster Flame Retardants, https://www.epa.gov/sites/production/files/2015-09/documents/hbcd_problem_formulation.pdf.

²⁰ *Id.* at 27.

²¹ *Id.* at 35.

²² *Id.* at 34.

²³ *Id.* at 35.

²⁴ EDF Comments on Work Plan Chemical Problem Formulation and Data Needs Assessment: Cyclic Aliphatic Bromides Cluster Flame Retardants, <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2015-0081-0015>.

²⁵ U.S. EPA. Scope for the Risk Evaluation for Cyclic Aliphatic Bromides Cluster. https://www.epa.gov/sites/production/files/2017-06/documents/hbcd_scope_06-22-17_0.pdf.

EPA could and should use a section 4 test rule or order to obtain more data on reproductive toxicity to resolve these discrepancies.

Methylene chloride

The 2014 Work Plan Assessment for Methylene Chloride identified both developmental neurotoxicity and immunotoxicity from chronic exposure as important information gaps (though the 2017 scope document for methylene chloride completely fails to mention these information gaps).²⁷

According to data collected in 2016 under EPA's CDR rule, about 20 companies reported manufacture of methylene chloride above the reporting threshold. Hence, to collect any needed data on just this one chemical would require twice as many test orders as EPA estimated it would issue annually (given EPA's assumption that each test order will only apply to a single company), or the single test rule or single ECA it estimated it will use once every two years.

1-bromopropane and pigment violet 29

The scope documents of several of the first ten chemicals also point to the lack of environmental monitoring data. For example, the 1-bromopropane scope document notes that environmental monitoring data were not identified in the 2016 draft Work Plan assessment.²⁸ Similarly, EPA did not locate any environmental monitoring data for pigment violet 29 in the process of scoping.²⁹

Such environmental monitoring information will be needed to adequately assess the risk to the general population through air and water. Under TSCA section 4(b)(2)(A), EPA has clear authority to require testing to develop information for "the assessment of exposure or exposure potential to humans or the environment," and, as such, should consider such information gaps when estimating its future activities under section 4. According to data collected in 2016 under EPA's CDR rule, about eight companies reported manufacture of 1-bromopropane. The number of companies reporting manufacture of pigment violet 29 is withheld.

²⁶ *Id.* at 35.

²⁷ Methylene Chloride: Paint Stripping Use, TSCA Work Plan Chemical Risk Assessment at p.115, https://www.epa.gov/sites/production/files/2015-09/documents/dcm_opptworkplanra_final.pdf.

²⁸ U.S. EPA, Scope for the Risk Evaluation for 1-Bromopropane at p.28, https://www.epa.gov/sites/production/files/2017-06/documents/bp_scope_06-22-17.pdf.

²⁹ U.S. EPA, Scope for the Risk Evaluation for Pigment Violet 29 at p.26, https://www.epa.gov/sites/production/files/2017-06/documents/pv29_scope_06-22-17.pdf.

ii. EPA has not accounted for the information gaps for other TSCA Work Plan chemicals.

EPA estimates that it will begin the process to make prioritization decisions on at least 40 chemicals early in 2019.³⁰ Even assuming EPA has all the information it needs to conduct its ongoing risk evaluations of the first 10 chemicals, the amount of testing proposed by EPA suggests EPA believes little or no testing will be required for any of the chemicals undergoing prioritization. While many of these chemicals are likely to be drawn from EPA's Work Plan,³¹ even Work Plan chemicals lack sufficient data to conduct risk evaluations.

For example, in 2015 EPA released a Data Needs Assessment for the brominated phthalates cluster of flame retardants that included substances listed on the Work Plan, concluding that “the toxicological profile and exposure profile for this cluster of chemicals is incomplete and inadequate to develop a TSCA work plan risk assessment.”³² EPA specifically indicated that the intention of the Data Needs Assessment was to “guide the collection of additional data and information to fill the critical data gaps and reduce uncertainties identified during problem formulation.”³³ EDF filed extensive comments on this assessment in January 2015, urging the agency to promptly set forth a plan to obtain the data needed to fill the gaps identified in the assessment, in particular for 2-Ethylhexyl 2,3,4,5- tetrabromobenzoate (TBB).³⁴ There is no evidence that EPA has initiated such information development activities for these chemicals.

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

³⁰ U.S. EPA, 2018 Annual Plan for Chemical Risk Evaluations under TSCA 3 (Jan. 2018), https://www.epa.gov/sites/production/files/2018-01/documents/2018_annual_risk_evaluation_plan_final.pdf.

³¹ U.S. EPA, OPPT, Approaches to Identifying Potential Candidate Chemicals for Prioritization: The TSCA Work Plan as a Tool for Identifying Potential Candidates (Dec. 2017), https://www.epa.gov/sites/production/files/2017-12/documents/session_1_-_pre-prioritization_-_tscawp_v120117.pdf.

³² U.S. EPA, TSCA Work Plan Chemical Problem Formulation and Data Needs Assessment Brominated Phthalates Cluster Flame Retardants (Aug. 2015), <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2014-0491-0002>.

³³ *Id.* at 8.

³⁴ Environmental Defense Fund Comments on Work Plan Chemical Problem Formulation and Data Needs Assessment: Brominated Phthalates Cluster Flame Retardants. <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2015-0068-0028>

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 over 1,000 section 5 notices a year. *See* 83 Fed. Reg. at 8218. 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 rely on voluntary information collection. This is strongly suggested by language in the 2017 Information Collection Request (ICR) for TSCA section 4, which states:

Although the Agency may not have yet made the TSCA section 4(a) finding for a particular chemical substance, EPA may still cooperate with industry or others to identify data gaps and develop testing plans to fill some or all of these gaps. These voluntary efforts help provide additional information about the many chemicals on the TSCA Inventory, and can be used to assess the potential risks associated with the manufacture, processing, distribution, use or disposal of the chemical.³⁵

As EDF has previously commented to EPA, however, EPA's past reliance on voluntary methods of data collection has regularly proven ineffective.³⁶ Given the burden (whether heavy or light) industry 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

³⁵ 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.5 (2017), https://www.reginfo.gov/public/do/PRAViewDocument?ref_nbr=201712-2070-004.

³⁶ 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>.

assumption that stakeholders will meet all or most of the agency’s information needs through voluntary testing and submissions.

v. EPA’s earlier Information Collection Requests (ICRs) provide further evidence that EPA is now underestimating its section 4 needs.

EPA’s earlier Information Collection Requests (ICR) under section 4 provide additional evidence that EPA is currently underestimating its future section 4 actions. 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).”³⁷ In contrast, EPA states in its 2017 ICR renewal for section 4 that it will promulgate only “two rules annually, each involving an average of five chemicals.”³⁸ EPA has not explained why it now proposes to pursue even fewer test rules (EPA now estimates one rule every other year) than it projected in its 2017 ICR, much less than EPA projected in the 2013 ICR. Nor has EPA explained why these estimates under the *amended* law – which eased the evidentiary findings EPA must make in order to require testing – are *lower* than what it projected under the old TSCA.

* * * * *

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, 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.³⁹

³⁷ 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.

³⁸ *Id.*

³⁹ 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.”

C. EPA has underestimated its costs for administering Section 5.

i. EPA failed to include in its estimates the costs it incurs during the initial stages of the section 5 process it intends to utilize.

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.

First, when estimating the costs of new chemical reviews, it appears that EPA has failed to include the costs associated with the pre-notice consultations it intends to provide to companies *before* they submit new chemical notices. EPA has repeatedly indicated its intent to engage in such consultations. For example, in its *Points to Consider When Preparing TSCA New Chemical Notifications* document EPA stated that it will, upon request, engage in back-and-forth discussions with the submitter of a pre-manufacturing notice (PMN) even before a PMN is submitted.⁴⁰ EPA strongly recommended during the December 2017 meeting on New Chemicals that submitters engage in these “pre-notice consultations.” Engaging in potentially hundreds of pre-notice consultations annually will clearly require time and resources that need to be included in cost estimates for EPA’s section 5 activities. Yet EPA did not mention or include any cost for this activity in its estimates. *See* EA at 1-3 (listing out the activities under section 5 encompassed by the proposed rule). Considering the importance EPA has placed on these pre-notice consultations going forward, EPA must include the costs of this activity in its estimates for carrying out section 5, and adjust fees accordingly.

Second, it appears that EPA also 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 violated its own procedural regulations by failing to place sanitized copies of PMNs and the supporting documents in the mandatory, electronic public files it is required to provide upon receipt of the PMN.⁴¹ 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.

⁴⁰ *See* EPA OPPT, *Points to Consider When Preparing TSCA New Chemical Notifications*, 8 (Nov. 6, 2017), https://www.epa.gov/sites/production/files/2017-11/documents/draft_points_to_consider_11-09-17.final.pdf.

⁴¹ EDF Comments on New Chemicals Review Program under the Amended Toxic Substances Control Act at pp. 23-25 (Jan. 2018), <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2017-0585-0071>.

Third, it appears that EPA failed to include the costs associated with reviewing *bona fide* notices of intent when estimating the costs under section 5. To avoid unnecessary PMNs under section 5, EPA allows manufacturers to submit a notice of *bona fide* intent to manufacture the chemical. 40 C.F.R. § 720.25. EPA then reviews the notice, and if EPA determines that the manufacturer has a *bona fide* intent to manufacture, then EPA tells the inquiring manufacturer whether the chemical is on the confidential portion of the Inventory. If it is, then the manufacturer does not need to file a pre-manufacture notice under TSCA § 5. If it is not, then the manufacturer does. EPA must review notices of *bona fide* as part of “carrying out” section 5 of TSCA, so EPA should consider those costs in determining 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 fits neatly within that language. But EPA does not appear to have included those costs, nor proposed to impose any associated fees.

ii. 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, which EPA states in the proposed rule will be allowed for up to six chemicals. 83 Fed. Reg. at 8220. EPA stated in the proposed rule that consolidations require “a *substantially* increased amount of effort over the assessment of a single submission.” *Id.* (emphasis added). Yet EPA did not include this increased workload in its estimate for the cost of reviewing section 5 notices, *see* TBD at 1, and 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 for such consolidated submissions.

In addition, EPA should address those increased costs with a separate fee category that charges more for consolidated submissions. As explained more below, EPA should generally set fees at levels proportionate to EPA’s costs for a given activity, and EPA should do so here.

iii. EPA’s cost estimates for rules and orders under section 5 seem low given EPA’s estimates for similar activities under section 4.

In the proposed rule, EPA estimated the average total cost of processing a PMN, *including* where that review leads to development of an order or a significant new use rule, at \$55,200. 83 Fed. Reg. at 8217-18. EPA’s estimate seems low given that EPA estimates that developing orders and rules under section 4 costs approximately \$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 significant new use rule, these estimates suggest that section 5 orders and rules are massively less expensive than similar activities under section 4. EPA has provided no explanation for these differences. EPA should re-examine its estimated costs and increase its estimates for section 5 activities 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.

D. EPA has failed to include any costs associated with identifying potential candidates for prioritization; and has provided no breakdown of or basis for its cost estimate for prioritization under section 6.

EPA's estimates for its costs under section 6 fail to include costs associated with the identification of potential candidate chemicals EPA will then subject to the prioritization process established under section 6(b)(1) of TSCA. 15 U.S.C. § 2605(b)(1). On December 11, 2017, EPA held a public meeting titled "Approaches to Identifying Potential Candidate Chemicals for Prioritization," provided an extensive Discussion Document and numerous presentations, and solicited public comment on various approaches it was considering adopting.⁴² The meeting and the materials made clear that EPA is considering fairly resource-intensive processes for identifying candidates for potential designation as both high- and low-priority substances. Yet the proposed fee rule makes no mention of this activity and fails to include any apparent associated costs.

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.⁴³ That rule established extensive procedures EPA will use and regulatory requirements it must meet in conducting prioritization. Yet neither the proposed fee rule nor the other materials in the docket provide any breakdown or

⁴² EPA's website for the December 11, 2017, meeting and links to the documents and presentations it provided are available at <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/possible-approaches-identifying-potential-candidates>. EPA's docket that includes the many public comments it received concerning this activity is available at <https://www.regulations.gov/docket?D=EPA-HQ-OPPT-2017-0586>. EDF submitted extensive comments to EPA, available at <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2017-0586-0084>.

⁴³ 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>.

even a description of how EPA derived its cost estimate for prioritization, offering only a vague reference to having used “best professional judgement”. TBD at 3, 8.

While we recognize that prioritization-related activities do not trigger the payment of fees, they 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). Based on our review of the proposed fee rule and the other documents in the docket for the proposed rule, EPA has failed to include any costs for the steps preceding prioritization, and has provided so little information on its cost estimate for prioritization that meaningful public comment is wholly precluded. It must remedy these deficiencies in promulgating the final rule.

E. EPA has underestimated the costs of EPA-initiated Risk Evaluations under section 6 because EPA based its estimates on narrower risk assessments prepared under the old law.

EPA assumed that there will be 25 EPA-initiated risk evaluations underway each year,⁴⁴ and EPA’s proposed estimate for the cost of each EPA-initiated risk evaluations is \$3,900,000 over the life of the activity. 83 Fed. Reg. at 8221. This latter estimate seems plainly incorrect. EPA based this estimate on the cost of the risk assessments EPA conducted on the first 5 Work Plan chemicals, which “totaled about \$3,900,000” each.⁴⁵ TBD at 2. It is unclear to EDF how EPA could argue that the risk evaluations conducted under the new law will cost the same as the risk assessments EPA conducted under the old law. While the Work Plan risk assessments are a helpful starting point, there is every reason to expect that the risk evaluations under the Lautenberg Act will be more costly. EPA even acknowledged that the Work Plan risk assessments were “not as arduous.” TBD at 2. This is primarily the case because the scope of those earlier risk assessments was intentionally narrow and focused only on specific uses of the

⁴⁴ In the TBD, however, EPA estimates that there will be 20 EPA-initiated risk evaluations underway annually. TBD at 2. These sorts of discrepancies, which are numerous throughout the proposed rule and supporting documents, make it difficult for the public to comment meaningfully on the proposed fees, and they also indicate that EPA may not get the fees it is anticipating.

⁴⁵ Some commenters have pointed to a lower estimate provided by EPA in 2015 for the cost of the first five Work Plan risk assessments. See ACC Comment on Fees for the Administration of TSCA at p.3, <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0401-0004> (citing H.R. __, The TSCA Modernization Act of 2015: Hearing Before the H. Subcomm. on Env. & the Economy, 114th Cong. at p.34 (2015) (statement of Jim Jones), https://www.epa.gov/sites/production/files/2015-02/documents/epa_fy_2016_congressional_justification.pdf). This rough estimate was offered shortly after EPA had completed those risk assessments based on little or no analysis, and hence is not indicative of EPA’s actual costs to conduct them.

substances, whereas EPA must now conduct broad risk evaluations on a chemical substance's conditions of use. *See* 15 U.S.C. § 2605(b)(4)(A). As just one example, the scope of the Work Plan risk assessment for trichloroethylene (TCE) only covered four out of nine primary uses identified therein.⁴⁶ EPA has since developed a scope document for its risk evaluation of TCE under the Lautenberg Act, which identified 26 categories and 50 sub-categories of conditions of use.⁴⁷

In addition, the Lautenberg Act expanded EPA's obligations when preparing risk evaluations in other ways. For example, EPA must consider any unreasonable risks to potentially exposed or susceptible subpopulations, 15 U.S.C. § 2605(b)(4)(A), and EPA must comply with the requirements of section 6(b)(4)(F) added to TSCA by the 2016 amendments. It is unreasonable for EPA to estimate that risk evaluations will cost no more under the Lautenberg Act than the much narrower risk assessments it conducted under the old law.

EPA's only other benchmark for its analysis was the cost of a review of a conventional food-use pesticide active ingredient under FIFRA, which costs \$2,900,000. TBD at 2. EPA acknowledged that those reviews have a smaller scope and are less complex than risk evaluations under TSCA, but EPA failed to consider that EPA also typically receives significantly more data under FIFRA reviews.⁴⁸ Risk evaluations under TSCA are likely to cost significantly more because of their broader scope, greater complexity, and the need to develop more information.

F. EPA significantly underestimated the costs of future risk management actions under section 6 when compared to its costs for EPA's three partially completed risk management actions.

EPA has estimated that the cost of section 6 risk management actions will be \$6,584,000 annually, which includes an estimate of 16 FTE. TBD at 8 tbl. 11. According to EPA's Fees Spreadsheet, the agency has assumed that each year there will be 15 ongoing risk management actions, each lasting two years. FS at tab 3. Although EPA did not provide an estimate of each individual risk management action, working from EPA's stated assumptions, EPA is estimating that the cost of a single risk management action averages \$877,867 over the life of the action

⁴⁶ U.S. EPA, OCSPP, TSCA Work Plan Chemical Risk Assessment Trichloroethylene: Degreasing, Spot Cleaning and Arts & Crafts Uses at p. 27, tbl. 1-1 (June 2014), https://www.epa.gov/sites/production/files/2014-11/documents/tce_opptworkplan_chemra_final_062414.pdf.

⁴⁷ U.S. EPA, OCSPP, Scope of the Risk Evaluation for Trichloroethylene at pp. 23-26, tbl. 2-3 (June 2017), https://www.epa.gov/sites/production/files/2017-06/documents/tce_scope_06-22-17.pdf.

⁴⁸ *See* DATA REQUIREMENTS FOR PESTICIDE REGISTRATION, <https://www.epa.gov/pesticide-registration/data-requirements-pesticide-registration> (last visited May 18, 2018).

(and will require only about 1 FTE).⁴⁹ These estimates dramatically understate the cost of risk management actions as compared to the costs EPA provides for its recent risk management actions under section 6. If anything, EPA's future risk management actions under the Lautenberg Act are likely to be more expensive than its recent actions – and far more expensive than EPA assumes in the proposed rule.

EPA's estimates of the costs of the three pending risk management actions EPA proposed in December 2016 and January 2017⁵⁰ provide a helpful starting point in developing a realistic estimate. EPA states that, to date, each of these proposed risk management actions has taken two years, cost EPA \$2,485,000, and required an average of 8 FTE. TBD at 3. Thus, a starting point for estimating the cost of risk management actions under the Lautenberg Act would be \$2,485,000 per action. But there are a number of reasons to assume that the actual costs will be higher.

First, these three risk management actions have not been finalized, and therefore the costs EPA estimated do not reflect a *complete* risk management action.⁵¹ Hence this cost estimate does not reflect the substantial costs associated with finalizing risk management rules. Specifically, in order to finalize the three 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 of those activities were included in the estimate, so EPA should increase the estimate to reflect these additional costs.

Second, these risk management actions addressed only a narrow subset of uses of the chemicals, whereas under amended TSCA a risk management action will likely include more uses because the risk evaluation must have considered *all* the conditions of use.⁵² Thus, risk management

⁴⁹ EPA states that each risk management action will take two years and EPA plans to have 15 underway at a time. By doubling the annual budget of \$6,584,000 and then dividing by fifteen, one arrives at an estimated average of \$877,867 per risk management action.

⁵⁰ Trichloroethylene; Regulation of Certain Uses Under TSCA § 6(a), 81 Fed. Reg. 91592 (December 16, 2016); Trichloroethylene; Regulation of Use in Vapor Degreasing Under TSCA Section 6(a), 82 Fed. Reg. 7432 (Jan. 19, 2017); and Methylene Chloride and N-Methylpyrrolidone; Regulation of Certain Uses Under TSCA Section 6(a), 82 Fed. Reg. 7464 (Jan. 19, 2017).

⁵¹ 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).

⁵² Even under EPA's illegal approach, which limits the conditions of use EPA will consider in a risk evaluation, see 82 Fed. Reg. 33726, 33729-30 (Jul. 20, 2017), the scope of the risk

actions under the Lautenberg Act will generally be more expansive and likely require more EPA resources as a result. Thus, EPA’s estimated costs for future risk management actions should be further increased relative to the costs for the three pending proposed rules.

Despite these facts, astoundingly, EPA estimates that a future risk management action under the Lautenberg Act will cost far less – on the order of 65% less – than the still-incomplete, much narrower risk management actions proposed in December 2016 and January 2017.

EPA vaguely attributes these projected drastic reductions in costs to “efficiencies” it expects to gain in the risk management process, without ever spelling out the nature of such efficiencies and how they will be achieved. TBD at 3. EPA cannot reasonably assume huge increases in efficiencies when EPA has little prior experience in promulgating similar rules and none at all using its new authorities. Given the two factors discussed above that indicate why the reported costs of the prior risk management actions would be substantially lower than the costs of new actions under the Lautenberg Act, EPA has no reasonable basis to assume it will immediately find efficiencies that reduce the cost of future risk management actions by 65% over the costs of those earlier narrower and still-incomplete actions.

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

i. EPA’s baseline costs of collecting, processing, and reviewing information “under this title” are not limited to EPA’s 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.* It appears that EPA has incorrectly interpreted this provision so that only the costs under section 14 of “collecting, processing, and reviewing”

evaluations and risk management actions under the Lautenberg are nevertheless expected to be 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.

information are included in EPA's baseline costs. *See* TBD at 1 (“Cost estimates associated with the administration of TSCA sections 4, 5, 6, and 14 ***.”). 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).

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). 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). 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 preceding 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.

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.

ii. 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:

- 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.

In particular, EPA needs to 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). EPA must promulgate a rule governing that plan soon. 15 U.S.C. § 2607(b)(4)(C). 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 7,300 chemicals;⁵³ EPA will undoubtedly incur significant costs in performing these reviews, a significant portion of which will take place during the FY2019-2021 period. As reflected by the plain text, the vast majority of this work will involve activities and decisions made under section 14, and thus EPA does not even have a pretext for failing to include these costs in its baseline.

⁵³ 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_042018” 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 7,332. That count is expected to increase between now and the October 5, 2018, deadline EPA set for processor reporting under the TSCA Inventory Notification (Active-Inactive) Rule. See <https://www.epa.gov/tsca-inventory/tsca-inventory-notification-active-inactive-rule>.

iii. 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,⁵⁴ risk evaluation,⁵⁵ 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, 25 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
- 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 EPA has stated will need to be “addressed before initiating the prioritization process” under section 6.⁵⁶ Specifically, EPA stated in its *Discussion Document on Possible Approaches and Tools for Identifying Potential Candidate Chemicals for Prioritization* that “utilization of authorities under TSCA sections 4, 8, and 11(c) for the development of necessary information for prioritization and risk evaluation will be important

⁵⁴ 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.”).

⁵⁵ EDF Comments on Risk Evaluation at pp. 18-20 (submitted Mar. 2017), <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0654-0074>.

⁵⁶ EPA, Discussion Document: Possible Approaches and Tools for Identifying Potential Candidate Chemicals for Prioritization at p. 7 (Dec. 2017), https://www.epa.gov/sites/production/files/2017-11/documents/final_pre-prioritization_-_discussion_document_11.13.17.pdf.

information gathering methods which EPA will utilize as appropriate.”⁵⁷ 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.

H. EPA underestimates the costs of its obligations under section 14 by estimating the costs at one-fifth of its prior proposed budget and failing to account for its numerous additional obligations under the Lautenberg Act.

EPA’s proposed rule severely underestimates the costs of information-related activities under section 14. With almost no explanation, EPA assumes that carrying out *all* of its section 14

⁵⁷ *Id.*

activities will cost about \$4 million per year, about 5% of its estimate for total program costs.⁵⁸ It is nearly impossible to parse EPA's estimates for section 14 because EPA made no attempt to itemize its costs under section 14. *See infra* section V.C. (describing in more detail EPA's failure to discuss the requirements under section 14). Despite the absence of an accounting, there is every reason to believe EPA's estimate is far too low.

First, 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 \$20,000,000.⁵⁹ 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 *one-fifth* 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.⁶⁰

Second, 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).⁶¹ All of these activities involve processing,

⁵⁸ Although the TBD only identifies two types of section 14 activities in its estimates, CBI review and CBI Local Area Network (LAN)/IT, *see* TBD at 3, 9 (describing LAN as the "IT infrastructure"), EPA staff stated to EDF at our April 5, 2018, meeting that this estimate includes costs for *all* section 14 activities.

⁵⁹ 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 Apr. 30, 2018).

⁶⁰ EPA should make the documents providing the basis for this earlier budget estimate available in the docket.

⁶¹ 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

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)(B). 15 U.S.C. § 2625(b)(4)(B)(i)(I).

III. EPA has underestimated the costs of conducting manufacturer-requested risk evaluations recoverable under TSCA section 26(b)(4)(B)(ii).

EPA has also underestimated its costs for manufacturer-requested risk evaluations, 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). EPA has discounted its estimates for manufacturer-requested risk evaluations in a manner that violates the Lautenberg Act and reflects arbitrary reasoning.

A. EPA has failed to account for the two “ongoing” manufacturer-requested risk evaluations.

Currently, EPA is required to preparing two such risk evaluations—for Ethanone, 1-(1,2,3,4,5,6,7,8-octahydro-2,3,5,5-tetramethyl-2-naphthalenyl) and Ethanone, 1-(1,2,3,4,5,6,7,8-

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-2017-0652-0014> (“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.”).

octahydro-2,3,8,8-tetramethyl-2-naphthalenyl).⁶² Yet EPA has not even mentioned them in the proposed rule and appears not to have accounted for the costs of conducting these risk evaluations. EPA must clarify and document whether and, if so, how these risk evaluations were included in its estimates. If they were not included, those costs need to be added EPA's baseline costs.

B. EPA has unlawfully assumed that manufacturer-requested risk evaluations will cost less than EPA-initiated risk evaluations.

EPA assumes the cost of conducting a manufacturer-requested risk evaluation will be 67% of the cost of conducting a risk evaluation EPA initiates, and has therefore proposed charging a proportionally lower fee than it would otherwise. 82 Fed. Reg. at 8219. This approach violates several statutory provisions and is illegal, absent compelling evidence that such evaluations will truly cost less than EPA-initiated risk evaluations. But EPA has not provided compelling evidence for the discount; rather, EPA's rationales for this approach lack merit and are arbitrary and capricious. EPA should instead assume that manufacturer-requested risk evaluations will cost the same as EPA-initiated risk evaluations and set the fees accordingly.

EPA cannot legally set the fees for manufacturer-requested risk evaluations at 67% of the cost of a risk evaluation EPA initiates, at least absent clear evidence that this discount reflects reality. The law expressly provides that EPA shall provide no preferential treatment of manufacturer-requested risk evaluations. Specifically, EPA "shall not *** provide special treatment to such [manufacturer-requested] risk evaluations." 15 U.S.C. § 2605(b)(4)(E)(ii). "Special" means "better, greater, or otherwise different from what is usual." *Oxford American Dictionary* 1675 (3d ed. 2010). Using different estimates for manufacturer-requested risk evaluations than the estimates for risk evaluations EPA initiates falls neatly within this prohibition. Estimating that a manufacturer-requested risk evaluation costs less, without adequate evidence, provides illegal "special treatment" for such risk evaluations because the result is that EPA will unfairly set fees for manufacturer-requested risk evaluations at lower levels based on lower estimates than EPA uses when assessing fees for EPA-initiated risk evaluations. EPA cannot treat manufacturer-requested risk evaluations differently in a manner that specially favors such requests, and thus EPA cannot discount its estimates for those risk evaluations. Such special treatment is particularly hard to justify when EPA has no empirical evidence supporting the discount.

In addition, Congress clearly stated that "notwithstanding" other provisions of the law, for manufacturer-requested risk evaluations, EPA must "establish the fee at a level sufficient to defray the *full costs* to the Administrator of conducting the risk evaluation under section 6(b),"

⁶² See IDENTIFIED PBT CHEMICALS AND CONDITIONS OF USE, <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/persistent-bioaccumulative-and-toxic-pbt-chemicals-under#identified> (last visited May 18, 2018).

with a 50 percent fee for those chemicals on the 2014 Work Plan. 15 U.S.C. § 2625(b)(4)(D) (emphasis added). As relevant here, “full” means “not lacking or omitting anything; complete *** (often used for emphasis) reaching the utmost limit; maximum.” *Oxford American Dictionary* 1675 (3d ed. 2010). Congress considered it important that EPA recover the “full costs” for manufacturer-requested risk evaluations, so EPA clearly cannot discount those costs by one-third based on speculation and surmise.

EPA has provided only two rationales for its lower estimate: (1) that manufacturers will provide more information, and (2) that manufacturers will only request risk evaluations on “easy” chemicals. 83 Fed. Reg. at 8219. But these assumptions are entirely speculative and likely inaccurate, and they certainly do not justify such a steep discount. Indeed, one could just as easily speculate that manufacturer-requested risk evaluations are likely to cost significantly more than EPA-initiated risk evaluations.

The assumption that manufacturers will automatically provide the information necessary for EPA to conduct the risk evaluations they request is flawed. EPA’s Risk Evaluation Rule permits manufacturers to provide less information than EPA will need to complete such risk evaluations. Specifically, the rule allows a manufacturer to request risk evaluations on fewer conditions of use of a chemical substance than EPA must consider in a full risk evaluation, and the rule then states that the manufacturer need only submit “a list of all the existing information that is relevant to whether the chemical substance, *under the circumstances identified by manufacturer(s)*, presents an unreasonable risk of injury to health or the environment.” 82 Fed. Reg. 33753, 33749 (Jul. 20, 2017) (40 C.F.R. § 702.37(b)(4)) (emphasis added). Thus, EPA erred when it suggested in the proposed fee rule that the “manufacturers requesting a risk evaluation must provide EPA with a list of existing information that would be *adequate* for EPA to conduct an evaluation.” 83 Fed. Reg. at 8219. EPA’s own rules do not require such a submission. In addition, EPA will still have to check industry’s information and collect other information on other conditions of use beyond the scope of the request. And even for conditions of use within the scope of the request, EPA will also need to expend resources searching for additional information that the manufacturer might not possess, might overlook, or might withhold.

Also, EPA’s own estimates indicate that the costs of information collection are only 10% of the total estimated costs for a risk evaluation. *See* 83 Fed. Reg. at 8219. Even *if* a manufacturer provided all information and covered these costs completely (and, as explained above, that would not occur), EPA could justify at most a 10% discount on the cost of manufacturer-requested risk evaluations compared to EPA-initiated risk evaluations.

EPA’s other rationale for lowering the estimated cost for manufacturer-requested risk evaluations is utterly speculative. EPA asserts, with no factual basis, that manufacturers will

request risk evaluations on “easy” chemicals, i.e. chemicals with low hazard and low exposure. 83 Fed. Reg. at 8219. In fact, there are sound reasons to believe the opposite may well be the case.

First, of the five industry-requested risk evaluations EPA assumes it will be working on each year, EPA assumes two of them will be for Work Plan chemicals. Chemicals were selected for inclusion on the Work Plan precisely because they exhibit high hazard and high exposure. 83 Fed. Reg. at 8221, tbl. 5.⁶³ Thus, EPA’s own assumptions contradict its claim that manufacturer-requested risk evaluations will be relatively “easy” and hence less expensive.

Second, a key rationale for including manufacturer requests in the law was to be able to expedite EPA risk evaluations on chemicals that individual states were taking action on. Indeed, section 6(b)(4)(E)(iii) establishes that EPA is to give preference to manufacturer requests for EPA to conduct risk evaluations of chemicals on which one or more states have imposed restrictions that could have significant impact on interstate commerce or health or the environment. 15 U.S.C. § 2605(b)(4)(E)(iii). Chemicals on which states have imposed restrictions are far more likely than not to be chemicals presenting concerns based on high hazard, exposure or both.

It appears that EPA’s reasons for the discount for manufacturer-requested risk evaluations have no empirical or factual basis, and EPA certainly has not provided a basis for its assumption. Rather, EPA has speculated that such risk evaluations will be easier to conduct and hence less expensive. But it is arbitrary and capricious to base decisions solely on speculation and surmise. *See Water Quality Ins. Syndicate v. United States*, 225 F. Supp. 3d 41, 70 (D.D.C. 2016) (“[A]n agency is not entitled to rely” on “unsupported assumptions”).

Notably, there are several reasons to suspect that manufacturer-requested risk evaluations will likely be more expensive than EPA-initiated risk evaluations. When EPA selects chemicals for risk evaluation, EPA will likely select information-rich chemicals which EPA believes it can complete within the deadlines.⁶⁴ EPA will also already have access to or have collected

⁶³ *See* HOW WERE THE TSCA WORK PLAN CHEMICALS SELECTED?, <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/tsca-work-plan-chemicals#select> (last visited May 18, 2018); *see also* U.S. EPA, TSCA Work Plan Chemicals: Methods Document (Feb. 2012), https://www.epa.gov/sites/production/files/2014-03/documents/work_plan_methods_document_web_final.pdf.

⁶⁴ *See* U.S. EPA, OPPT, Identifying Potential Candidates for Prioritization: Background, Goal, Guiding Principles, and Milestones at slide 7 (Dec. 2017), https://www.epa.gov/sites/production/files/2017-12/documents/00_-_background_and_principles_v3.pdf (“EPA should factor in the need for analyses of candidate’s readiness for both prioritization and risk evaluation in order to ensure responsible implementation of TSCA.”).

considerable information before or during the prioritization process.⁶⁵ And EPA may choose to select chemicals it expects will be designated high-priority that are relatively “easy” to characterize in the sense that they are clearly high-hazard/high-exposure.⁶⁶ For these reasons, if anything, there is a stronger basis for EPA to assume that manufacturer-requested risk evaluations are likely to be more, not less, expensive.

In sum, absent compelling evidence to the contrary, EPA must use the same estimates for manufacturer-requested risk evaluations as EPA-initiated risk evaluations, and EPA should set the fees accordingly.

IV. The fees should more closely reflect EPA’s cost for each activity.

EPA generally should assess fees at a level that consistently mirrors its costs associated with that activity. Notably, Congress consciously decided that the levels of the fees should be a proportion of the costs of the underlying activity, 15 U.S.C. § 2625(b)(4)(B)(i)(I), and stated that fees should be “sufficient and not more than reasonably necessary to defray the cost related to such chemical substance of administering sections 4, 5, and 6, and collecting, processing, reviewing, and providing access to and protecting from disclosure as appropriate under section 14 information on chemical substances under this title,” *id.* § 2625(b)(1). Congress went further to expressly indicate the aggregate level at which fees should be set so as to ensure they defray a stated percentage of EPA’s costs, *id.* § 2625(b)(4). These congressional choices suggest that EPA should set fees that are generally proportionate to its underlying costs for various activities. One way would be to adopt fees that are entirely proportional, which is an attractive feature of Alternative A. Of course, EPA will need to increase the fee levels under Alternative A to reflect accurate estimates of the costs of various activities that have been excluded and underestimated by the proposed rule, *see* sec. II.

⁶⁵ U.S. EPA, Discussion Document: Possible Approaches and Tools for Identifying Potential Candidate Chemicals for Prioritization at p.7 (Dec. 2017), https://www.epa.gov/sites/production/files/2017-11/documents/final_pre-prioritization_-_discussion_document_11.13.17.pdf (“[I]t will be useful for EPA to identify information needs and determine whether any of these needs should be addressed before initiating the prioritization process.”).

⁶⁶ *See, e.g., id.* (EPA’s “guiding principles” for identifying candidates for prioritization states that “EPA should be mindful of its workload and resource constraints – For example, incorrectly identified potential low-priority candidates that are subsequently designated as high-priority could permanently increase the number of ongoing risk evaluations.”).

A. EPA should increase the fees for activities related to section 4 to more proportionally reflect the costs to EPA.

EPA's proposed fee structure provides for disproportionately low fees for testing relative to those for new chemical reviews under section 5 and risk evaluations under section 6. EPA has done so merely based on the request of the industry. *See* 83 Fed. Reg. at 8221-22.

EPA's reasons for charging disproportionately low fees for Section 4 are not consistent with the intent of the statute. The proposed rule sets fees for all section 4 activities at 3.5% of EPA costs – far lower than the average 25% of its costs EPA is to recoup through fees. 83 Fed. Reg. at 8221. The only reason given is that industry asked EPA not to charge much or anything in fees relating to testing requirements, based on the fact that industry pays for the costs of testing itself. 83 Fed. Reg. at 8221-22. But an industry request for lower fees is not sufficient 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. Although EPA asserts that the proposed fee structure would make up for those low fees for testing through higher section 6 fees, *see* 83 Fed. Reg. at 8222, EPA has failed to account for the timing of fee collection under section 6. The timing of collection of section 6 fees is likely to be well into the three-year period addressed by the rule, as they will be triggered by initiation of risk evaluations on the second batch of chemicals identified as high-priority by EPA, which will not occur until at least late 2019. In contrast, as discussed earlier in section II.B, testing needs already exist and EPA should be initiating section 4 actions subject to fees in the very near term. EPA's proposal to charge disproportionately low section 4 fees means that, in the near term, it will not receive fees sufficient to defray a significant portion of its costs to undertake those section 4 actions.

In addition, EPA can and should engage in section 4 activities for chemical substances which do not get designated high-priority, and thus do not undergo risk evaluations under section 6 (or where such a designation and subsequent risk evaluations may not occur for many years). Thus EPA cannot assume that fees "recovered" under section 6 will adequately compensate for the lower fees EPA proposes to assess under section 4.

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.⁶⁷ In fact, Congress made clear in TSCA that

⁶⁷ *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

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 proportional to their costs. Not to do so would have the perverse effect of shifting more of the cost burden for section 4 actions onto the public than Congress intended.

Moreover, the fact that EPA has historically not charged fees under section 4, even though it had the ability to do so, is irrelevant to the current proposed fees. Congress thoroughly rewrote the fee provisions of TSCA with the goal of transforming the system and ensuring that EPA will actually recover a significant portion of its costs, including those incurred under section 4, through fees. *See* 15 U.S.C. § 2625(b). Toward that end, Congress eliminated the earlier caps on fees to ensure that EPA would collect funds proportionate to EPA's actual costs. While the industry undoubtedly prefers the previous policy, charging no or minimal fees under section 4 would merely place significant, unnecessary, burdens on section 5 and section 6 fees.

For these reasons, EPA should impose a fee proportionate to EPA's costs for actions taken under section 4 to ensure EPA recoups sufficient funds in a timely manner.

B. EPA must reasonably allocate fees to section 5 proportionate to the costs EPA incurs for these activities.

EDF agrees with two of EPA's proposals regarding section 5 fees which reflect EPA setting fees proportionate to the costs of the underlying activity. First, EDF approves of EPA's proposal to eliminate the discounted fees for intermediates, given that, as EPA notes, "each intermediate takes about the same amount of effort to review as does the 'final' chemical substance on that

WAIVERS, <https://www.epa.gov/pesticide-registration/pesticide-registration-fees-and-fee-waivers> (last visited May 20, 2018).

pathway.” 83 Fed. Reg. at 8220. This change accurately reflects the amount of work it takes for EPA to review new chemical notices for intermediates. Relatedly, exempting Sustainable Futures graduates from Test Marketing Exemption (TME) fees is reasonable considering the reduced burden that submissions from Sustainable Futures graduates place on EPA. 83 Fed. Reg. at 8222.

Nonetheless, EDF takes strong issue with this statement in the proposed rule:

To make up the difference in funds that would not be collected under TSCA section 4 or 5 based on these proposed fee levels, the Agency proposes to set the risk evaluation fee to be approximately 35% of the costs of those (Ref. 5). Overall, that results in the bulk of the fees expected to be collected under this proposed allocation coming from manufacturers of chemicals subject to EPA-initiated risk evaluations. The Agency considered this approach in part to *try to set section 5 fees at levels that would minimize the potential impact on innovation and competitive standing.*

83 Fed. Reg. at 8222 (emphasis added). There is no basis in the statute for EPA considering factors such as potential impact on innovation and competitive standing in setting fees. *See* 15 U.S.C. § 2625(b). Nor is it the, or even a, mission of the agency to promote innovation or companies’ competitive 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 innovation or companies’ competitive 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 chemicals do not present unreasonable risk.⁶⁸

⁶⁸ Some in industry have complained about the proposed increase in fees for PMNs from the maximum \$2500 allowed under original TSCA – a level that was set over 40 years ago in 1976 – to \$16,000, a fee level that is much more in keeping with assessing fees in proportion to EPA’s

C. EPA should charge fees for the ten risk evaluations currently underway under section 6 because EPA is incurring real costs for those activities and Congress intended that EPA collect fees for them.

Although not directly addressed in the proposed rule, EPA has indicated that it will not charge any fees for its risk evaluations on the first ten chemicals.⁶⁹ EDF disagrees with this decision. While we recognize that these evaluations were underway before proposal and finalization of this fee rule, EPA will continue to incur costs for these evaluations once the fee rule is in place. In order to recoup allowable costs, EPA should charge fees to defray the costs of its remaining risk evaluation activities on these chemicals. Under TSCA, EPA “may *** require the payment [of a fee] from any person *** who manufactures or processes a chemical substances *that is the subject* of a risk evaluation under section 6(b).” 15 U.S.C. § 2624(b)(1) (emphasis added). EPA’s ongoing section 6 risk evaluation activities on the first ten chemicals are clearly covered by this provision. EPA has articulated no reason to exclude manufacturers of the first ten chemicals from paying fees, prorated based on the costs of the remaining activities relating to EPA’s risk evaluations.

Moreover, EPA will likely not recoup the fees it has estimated it will collect, *see* TBD at 12, unless it charges fees for the first ten risk evaluations. Specifically, EPA estimates that it will receive fees arising from the 25 ongoing EPA-initiated risk evaluations it projects during FYs 2019 – FY 2021. FS at tab 3. The risk evaluations on the first ten chemicals began in December 2016, initiating a three-year deadline with a possible extension of up to six months. *See* 15 U.S.C. § 2605(b)(4)(G). Therefore, these risk evaluations will not likely be completed until, at the earliest, December 2019. It may well be that EPA will utilize the six-month extension,⁷⁰ extending the deadline for those risk evaluations to June 2020. Given this timeline for the first ten risk evaluations, if EPA charges no fees on them, EPA would receive no section 6 fees during FY 2019 and much or most of FY 2020.⁷¹ At the earliest, EPA will only begin to recoup section 6 costs in December 2019 on the second batch of chemicals subject to risk

actual costs. In addition, it should be noted that, adjusted solely for inflation, the \$2500 fee today would be about \$10,000. The rise from there to \$16,000 (or to \$18,200, the amount EPA has proposed under Alternative A) is exceedingly moderate given the significantly greater scrutiny the new law requires EPA to give new chemicals.

⁶⁹ EPA indicated that it would not charge fees on the first ten chemicals during the U.S. Small Business Association Environmental Roundtable Meeting on March 30, 2018. EPA then confirmed this during EDF’s meeting with EPA officials on April 5, 2018.

⁷⁰ As of now, late May 2018, we are awaiting release of the problem formulations on the first ten chemicals, which EPA had indicated in June 2017 would be released by December 2017.

⁷¹ The fiscal year is from October 1 to September 20; therefore, FY 2019 is Oct. 1 2018 – Sept. 20, 2019 and FY 2020 is Oct. 1 2019 – Sept. 20, 2020. *See*

https://www.senate.gov/reference/glossary_term/fiscal_year.htm.

evaluations. *See* 15 U.S.C. § 2605(b)(2). Even if EPA were to begin 20 risk evaluations in that second batch, that would fall short of the 25 risk evaluations for which EPA assumed it would receive section 6 fees. In contrast, if EPA collects fees on the risk evaluations for the first ten chemicals, then EPA would not need to initiate as many new risk evaluations to meet its assumed level of fee revenue.

In order to fully recoup EPA's allowable fees, EPA should collect fees on the remaining activities for the risk evaluations of the first ten chemicals. This is feasible because EPA has itemized its section 6 costs. TBD tbl 11. EPA can set the fee at the same percentage as the final section 6 fee, but have it cover only the remaining risk evaluation activities undertaken after the fee rule is finalized, projected for October 2018.

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

EPA has sought comments on whether there should be a separate fee category under section 6 for risk management actions. 83 Fed. Reg. at 8227. As a general rule, to ensure that EPA sets fees in a manner proportional to 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 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 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.

V. EPA’s proposal fails to transparently disclose sufficient detail and information to allow meaningful public comment.

In general, EPA has provided very limited and inconsistent information regarding the breakdown of its costs. For instance, EPA only provided a breakdown of the specific components of EPA-initiated risk evaluations and the cost for each, *see* TBD at 8, and provided no similar breakdown for any of the other “fee-triggering” circumstances under section 4 or section 5 (beyond, in some cases, providing a total estimate of the cost for the overall activity). EPA also failed to break out the cost per activity for the following activities, based on the questionable rationale that they are not activities that trigger payment of a fee:

- CBI claim review
- Alternative test method development
- Risk management for existing chemicals
- Prioritization

Even though EPA has proposed not to charge per-unit fees for these activities, their costs must be accurately reflected in the baseline. EPA should have calculated a cost per unit of each of these activities for the purposes of assessing the level of fees based on “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)(I).

In addition, many of EPA’s estimates are inconsistent and contradictory between the three documents EPA prepared, particularly between the Technical Background Document (TBD) and the Economic Analysis (EA).

The limited transparency EPA has provided in its estimates has made it exceedingly difficult to provide meaningful comments on the proposed rule, and it has also unnecessarily weakened the reliability of EPA’s estimates.

A. EPA’s assumptions informing its section 4 cost and fee estimates are contradictory and in some cases nonsensical.

Several aspects of EPA’s section 4 estimates make little sense and often contradict each other. For example, in the Technical Background Document EPA assumed that it would not collect any fees from small businesses under section 4. TBD at 12, tbl. 16. This contradicts EPA’s assumptions in the Economic Analysis, where EPA estimates that it will be collecting fees, albeit reduced, from small businesses.

More broadly, the Economic Analysis assumes for section 4 actions that:

- each action will involve an average of seven chemicals;
- an average of four firms will be impacted per chemical;
- one of the four firms will be a small business; and
- assuming ten test orders per year, there will be a total of 70 small businesses subject to test orders paying the general fee.

EA at 3-24. These estimates contradict other estimates that EPA has provided. First, in contrast to the Economic Analysis's assumption that each test order will involve multiple companies, EPA staff told EDF at our April 5, 2018, meeting that each test order will apply to only a single company. If the latter statement is correct, then, assuming ten test orders will be issued per year, test orders would affect only ten companies per year, not the 280 EPA calculated in the EA. *See* EA at 3-28, tbl. 3-11. These discrepancies are major ones that dramatically affect EPA's costs estimates and proposed fee levels.

Second, the Economic Analysis assumes that each section 4 activity will affect four businesses, and that one in four of those will be small businesses. EA at 3-24. Based on this estimate, the EA states that 70 small businesses will be affected by test orders. EA at 3-25, tbl. 3-7. Yet, if each test order applies to only one business, EPA will only subject ten businesses to test orders annually, in which case on average only 2.5 small businesses will be subject to test orders, not 70. *See* EA at 3-25, tbl. 3-7.

The inconsistencies here are problematic because they mean EPA will likely receive fewer fees than anticipated. Based on the provisions in the proposed rule, the 2.5 small businesses annually subject to test orders would be entitled to pay a reduced fee. 83 Fed. Reg. at 8231 (40 C.F.R. § 700.45(b)(1)(vi) (“[Small businesses] shall remit a total of twenty percent of the applicable user fee *** for a *** test order.”). In contrast, under the assumptions in the EA, all 70 of the small businesses would be expected to pay the general fee. EA at 3-24; TBD at 12, tbl. 16. That is because under the EA, all of the small businesses subject to section 4 test orders are assumed to be members of groups of companies only some of whose members are made up of small businesses; given that composition, none of the small businesses would be entitled to a reduced fee. *See* 83 Fed. Reg. at 8232 (40 C.F.R. § 700.45(e)(2)) (“For the consortium to qualify for the [reduced] fee *** *each person* in the consortium must qualify as a small business concern.”) (emphasis added). Following the assumption that each test order only applies to a single company, a quarter of the small businesses subject to test orders under section 4 will be entitled to reduced fees, reducing the fees that EPA will recoup.

EPA must clarify in the final rule how many companies will be subject to each test order, and alter its estimated fee recovery if necessary.

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

EPA inconsistently refers to the scope of its determinations under section 5, in places indicating that its cost estimates are based on an illegal, limited scope of review. 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. § 2602(4). In some places EPA correctly states that its costs under section 5 include review of the “intended, known and reasonably foreseen activities associated with the chemical.” 83 Fed. Reg. 8217; EA 3-16. However, the Economic Analysis states that “[t]he benefit of [Pre-manufacture Notice] and [Significant New Use Notice] submissions is that they provide EPA with the opportunity to evaluate the *intended use* of a chemical and, if necessary, to prohibit or limit that activity before it occurs.” EA 4-2 (emphasis added). This language suggests that EPA may have 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 evaluations. 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 failed to explain how it derived its current section 5 cost estimate from its costs of new chemical reviews prior to the Lautenberg Act. The proposed rule states that the cost of a PMN review in 1987 was \$15,000. 83 Fed. Reg. at 8217-18. Adjusted for inflation, this brings the cost to a present-day \$33,586. EPA then indicates that the cost today, with all the additional requirements, is \$55,200. But EPA has not explained or documented at all how this estimate will cover EPA’s additional duties under the Lautenberg Act. As EDF has explained in prior comments, incorporated by reference here,⁷² 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);

⁷² EDF Comments on New Chemicals at pp.4-7,
<https://www.regulations.gov/document?D=EPA-HQ-OPPT-2017-0585-0071>.

2. If EPA lacks sufficient information on a new chemical, 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 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 assumes that EPA will receive 462 PMNs/MCANs/SNUNs 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, EPA’s estimate for the number of FTEs necessary for developing the orders or SNURs is questionable. In the TBD, EPA estimates that the total annual resources required for order issuance will be 7.8 FTE and that SNUR promulgation will require 6.3 FTE. TBD at 7, tbl. 9. It is unclear why/how the number of FTEs for promulgation of *all* SNURs, i.e. both order and non-order SNURs, would be *fewer than* the number of FTEs for order issuance. 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. Considering EPA’s “new approach” to reviewing new chemicals, which would result in significantly more non-order SNURs, it makes little sense that it assumes the FTEs required for SNURs would be fewer than those required for orders.⁷³

⁷³ U.S. EPA, New Chemicals Decision-Making Framework: Working Approach to Making Determinations under Section 5 of TSCA at p. 2 (Dec. 2017), https://www.epa.gov/sites/production/files/2017-11/documents/new_chemicals_decision_framework_7_november_2017.pdf.

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

EPA’s baseline for section 14 costs includes a single point estimate for “CBI review,” but 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.

While EDF did not conduct an exhaustive search, even initial research indicates that EPA receives tens of thousands of CBI claims each year. For example:

- In the data EPA received and has made public from the 2016 CDR, more than 100,000 of the fields in records relating to Consumer and Commercial Use were claimed CBI by reporters, and there was a similar count of CBI claims in the fields in records relating to Industrial Processing and Use.⁷⁴ The great majority of these claims require EPA review.
- Under the Inventory notification process (which is not yet complete), 38,304 active chemicals were reported as of March 30, 2018. Notifiers claimed the specific chemical identity confidential for 19.1% (7,332) of these chemicals. Under a review plan to be established pursuant to section 8(b)(4)(C), EPA must review and make a determination on the chemical identity claims for each of those chemicals. While that plan is to be carried out over five years, a sizeable number of those reviews will fall within the three-year span of the first fee period to be established by this rule.

⁷⁴ **Subset of 2016 CDR CBI Claims**

2016 CDR: Consumer & Commercial Use		2016 CDR: Industrial Processing and Use	
Chem. never at site	10,538	Vol. used	22,061
No. of workers	8,726	Chem. never at site	13,825
Max. conc.	7,865	No. of workers	11,681
Site name	4,488	Max concentration	10,560
Activity	10,002	Physical form	8,059
Vol. used	17,384	Parent Co. name	9,419
Vol. export	18,353	Site name	5,356
Parent Co. name	8,442	Ind. Type	2,143
Submitter first name	8,442	Ind. Sector	3,471
Physical form	6,290	Ind. Cat.	3,123
Product category	1,450	Ind. No. of sites	2,774
Used in child products	149	Ind. No. of workers	1,866
		Activity	12,931
TOTALS:	102,129		107,269

- EPA must also review and make determinations on each claim in a Notice of Commencement (NOC) to maintain the confidentiality of a chemical identity. 40 C.F.R. § 720.102(c)(2). Since passage of the Lautenberg Act, EPA indicates it has received 476 NOCs as of May 22, 2018.⁷⁵ Based on recent data, at least half of the NOCs EPA receives assert such claims.⁷⁶
- EDF recently reviewed the public files containing PMNs for about 70 new chemicals obtained from EPA’s Docket Center.⁷⁷ Those files contained documents asserting many thousands of CBI claims. EPA has estimated it will receive and review 462 PMNs/MCANs/SNUNs each year, and most of the CBI claims in those submissions will require EPA review. Notable among the documents we reviewed were 78 that constituted health and safety studies or data, 55 of which were redacted based on CBI claims, despite the preclusion under TSCA for such information to be claimed CBI (with two narrow exceptions). 15 U.S.C. § 2613(b)(2). EPA should be reviewing and making determinations on these claims, although there is no evidence it has done so.

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 that it must review. Especially considering the often excessive and erroneous manner in which industry has historically claimed information CBI under TSCA,⁷⁸ EPA must provide a much more detailed accounting for its receipt and review of CBI claims in estimating its baseline costs.

Moreover, EPA does not appear to have considered the costs of reviewing all of the CBI claims it is required to review under the law, which extend beyond those for chemical identity. EPA’s statements in the proposed rule and the TBD are inconsistent regarding what claims EPA must review. *Compare* 83 Fed Reg. at 8219 (stating that EPA must review “most” chemical identity claims within 90 days and 25 percent of a subset of other types of CBI), *with* TBD at 3 (stating that EPA “[m]ust now review most chemical identity CBI claims within 90 days,” with no mention of other types of claims requiring review). EPA must correctly identify the claims it

⁷⁵ See Statistics for the New Chemicals Review Program under TSCA at

<https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/statistics-new-chemicals-review>.

⁷⁶ Between passage of the Lautenberg Act and October 31, 2017 (the most recent date for which EPA notices of receipt of NOCs were publicly available before May 21st), EPA received nearly 200 NOCs for chemicals that are still identified by their generic names; it is unclear whether EPA has reviewed those claims or other claims asserted in NOCs received by EPA since then.

⁷⁷ For more detail, see the series of blog posts on what we found in our review of these files, which starts here: <http://blogs.edf.org/health/2018/01/24/epas-appalling-failure-to-provide-public-access-to-public-data-on-tsca-new-chemicals/>.

⁷⁸ 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>.

must review, and then provide a transparent calculation for estimating its costs to conduct those reviews, including how many CBI claims it expects it will review each year.

In addition, as discussed above in section II.H, the section 14 baseline cost estimate fails to take into account a number of EPA's responsibilities under section 14, such as: (1) providing for disclosure to authorized persons under sections 14(d)(4), (5), (6); (2) creating an electronic database to facilitate that disclosure; (3) developing a system for tracking and notification relating to reassertion of claims; (4) maintaining or updating clearance/security activities; and (5) implementing a system of unique identifiers under section 14(g)(4)(B). While many of these activities are identified in the Economic Analysis, EA at 1-5, they do not appear in the breakdown of costs in the TBD, which only includes two extremely broad line items "CBI review" and "CBI LAN." TBD at 3. The five activities just noted do not fall under either of these two categories. EPA must make clear what activities it has included, and the costs for each, in its baseline estimates for section 14.

VI. EPA should be careful in adopting a discount for small businesses that it does not lead to shortfalls in fee revenue.

Regardless of which alternative EPA selects for identifying small businesses, EPA must be careful not to underestimate the extent to which its discount afforded to small businesses will reduce fee revenues EPA receives under TSCA. EDF notes that EPA's proposed discount for small businesses, set generally at 80%, and at 82.5% for PMN and related activities under section 5, is higher than those for pesticides under the Pesticide Registration Improvement Act (PRIA), for instance. *See* 83 Fed. Reg. at 8224. Under PRIA EPA provides 50% and 75% fee waiver reductions for small businesses. If EPA is going to provide steeper discounts for small businesses under TSCA, it needs to ensure that its assumptions are correct and that such reductions in fees from small businesses will be offset through higher fee levels for the remaining payers. Ultimately, EPA must set fees at a level that offset the required costs.

VII. EPA correctly proposes requiring payment of fees before or soon after initiating applicable activities, but EPA should modify the refund window for section 5 fees.

EPA has proposed requiring payment of fees before or soon after initiating the activities triggering the fees. 83 Fed. Reg. at 8225.⁷⁹ EDF agrees with this method of collecting fees for

⁷⁹ Specifically, under section 4, EPA will collect fees within 60 days of the effective date of rule/order or date of signing ECA. Under, section 5, EPA will collect fees prior to reviewing a submission. Section 6 fees will be collected: (1) within 60 days of publication of final scope of a risk evaluation, and (2) within 30 days of granting a manufacturer requested risk evaluation.

the reasons stated in our 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.⁸⁰

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.

As an aside, EDF supports EPA using reports from its CDR as a primary source to identify companies subject to fees for section 6 risk evaluations. However, the agency should also consider additional sources to identify such companies, such as the Toxics Release Inventory (TRI), submissions from the Inventory Notification Rule, and notices of commencement (NOCs) under Section 5.

EPA has proposed providing a 75% refund to submitters of a notice under section 5 if the notice is withdrawn within 10 business days. 83 Fed. Reg. at 8225. Due to the short timeline of section 5 reviews, EPA will often have conducted a significant amount of work within the first 10 business days.⁸¹ For instance, EPA's flowchart for the PMN Review Process indicates that during days 8 through 10 of its review, the agency is conducting a profile of exposure and release, a Structure Activity Team meeting, and a Chemical Review and Search Strategy. Therefore, if EPA does provide such a substantial refund to submitters for withdrawing a notice, the refund should only be available during days 1 through 7, prior to EPA undertaking a significant level of activity in its review of the notice. *See id.*

VIII. EPA should resolve other outstanding inconsistencies.

EDF also noticed a number of other inconsistencies in the proposed rule. These inconsistencies include:

- On page 8230 of the proposed rule, EPA identified the same scenario that would result in fees in sections 700.45(a)(2) and (a)(3). After flagging this issue to EPA staff at our April 5, 2018, we understand that EPA intends to add the following language to section

⁸⁰ 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>.

⁸¹ *See* PMN Review Process, https://www.epa.gov/sites/production/files/2015-09/documents/pmnr_review_process_chart_expanded_09-1-15.pdf (last visited May 1, 2018).

700.45(a)(2): “*** enforceable consent agreement *that is the result of a TSCA Section 5 submission by a manufacturer or processor* shall remit for each such ***.”

- On page 8220, EPA stated that the proposed fees are \$10,000 for test orders, \$32,000 for test rules, and \$25,000 for ECAs, even though the actual proposed fees are \$9,800, \$29,500, and \$22,800 respectively.
- On page 8226, EPA indicated that it expects the number of section 5 submissions to decrease by 10% as a result of higher fees, but on page 8218 EPA indicates the submissions will decrease by 20%.
- In the final rule EPA should make clear that PMN consolidations under section 5 will be limited to at most six chemicals. EPA’s language in the proposal is ambiguous on this point. *See, e.g., id.* (“Consolidations are *typically* not granted for more than six substances in one notice ***.”) (emphasis added).
- On page 8234, it appears that a phrase may be missing; we believe that it should read: “EPA will not initiate a manufacturer-requested risk evaluation ~~that~~ *the request for which* the Agency has otherwise determined to be complete unless the appropriate remittance under ***.”

* * * * *

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

APPENDIX

EDF QUESTIONS FOR 4-5-18 MEETING WITH EPA ON THE PROPOSED FEE RULE

Risk evaluation (RE) costs

You were recently reported as stating that EPA will not charge any fees for the risk evaluations for the first 10 chemicals.

Q1: Was that report accurate? If so, what is the basis for this decision?

Q2: Given that draft risk evaluations have yet to be issued, and that EPA has stated that the fee rule is expected to be finalized by September, are there not extensive costs still to be incurred by EPA for completing these risk evaluations? Shouldn't EPA be planning to assess fees in order to recover at least a portion of these costs?

Q3: What about the costs of any risk management rulemakings ensuing from these risk evaluations? Has EPA included such costs in its baseline for the proposed fee rule?

Q4: If these risk evaluations are not included in the fee proposal, how did EPA arrive at the estimated 25 risk evaluations underway annually shown in the proposed rule?

Q5: EPA estimates that the cost of a RE under amended TSCA is the same as for the risk assessments done on the first 5 Work Plan chemicals under old TSCA (Technical Background Document (TBD), p.2). But the scopes of those assessments were much narrower than those required under the new law, which should have a significant effect on EPA costs. Why has this not been accounted for?

Risk management (RM) costs

p. 3 of the TBD: EPA estimates 8 FTEs and \$620,000 in direct contractor costs for each of the three RM actions it developed for TCE, DCM/NMP. Applying appropriate multipliers, EPA says this is a total cost per action of \$2,485,000 “over the life of the action.”

EPA then says, based on that number, that EPA's annual estimated RM costs going forward will be \$6,584,000.

Q1: How was this cost derived? We cannot find anywhere in the documents in the fee rule docket where this is explained.

Q2: What was assumed to be the length of the “life of the action”?

Q3: The TCE and DCM/NMP rules have not been finalized; are there not additional costs to EPA related to finalizing the rules that are not included in the \$2,485,000?

Q4: How many RM actions annually is EPA assuming will be underway? The “TSCA fees costing spreadsheet” included in the docket (<https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0401-0021>) indicates 15 such RM actions, each lasting two years, will be underway each year. Using that figure and the annual RM cost estimate of \$6,584,000 leads to a dramatically lower cost

per RM action – \$877,867 – than the \$2,485,000 the proposed rule says EPA started with, only about 35% as much.

Q5: Table 11 (on p. 8 of the TBD) indicates a total of 16 FTEs required for RM actions. EPA's starting estimate was that the TCE and DCM/NMP rules each required 8 FTEs. This suggests only two RM actions will be underway each year. How is that to be reconciled with the value of 15 in the spreadsheet cited just above?

Testing costs

Q1: Can EPA use a test order to require testing of more than one chemical, and if so, does EPA anticipate doing so?

Q2: Can a test order be issued that applies to more than one company?

Q3: Has EPA assumed any costs relating to ORD and use of alternative methods for section 4? If so, where is this shown?

Q4: What is the difference between proposed 40 CFR 700.45(a)(2) and (3)? They appear to have the same intent.

Q5: On p. 8220 of the proposed fee rule, EPA states that the proposed fees are 10,000 for test orders, 32,000 for test rules, and 25,000 for ECAs. But these differ from the actual proposed fees, which are 9,800, 29,500, and 22,800 respectively (stated on FR 8222). Are we missing something?

Q6: EPA says it has relied on its experience with HPV chemicals to estimate how many chemicals will be included in a test action, and how many tests per chemical will be done. But HPV test rules were done under the old TSCA which imposed significantly higher evidentiary burdens on EPA to justify requiring testing, and these led to narrower test rules than would likely be the case under the new law. Has EPA considered this?

Q7: It appears EPA only assigned costs associated with use of alternative test methods under section 6. Why did EPA not consider and assign such costs for section 4 and section 5?

New chemicals

Q1: EPA has assumed 462 PMNs/MCANs/SNUNs annually submitted. How many of these is EPA estimating will result in orders? SNURs?

Q2: Has EPA assumed any costs relating to ORD and use of alternative methods for section 5? If so, where is this shown?

Q3: In different places in the proposed fee rule EPA states that it estimates the number of PNMs submitted will be reduced by 10% or by 20% due to the fees. Which is the correct value?