Environmental Defense Fund Comments on

Implementing the New Chemicals Review Program Under Amended TSCA

Docket ID: EPA-HQ-OPPT-2017-0585

Submitted Saturday, January 20, 2018

Environmental Defense Fund (EDF) appreciates the opportunity to provide comments to the Environmental Protection Agency (EPA) on EPA's implementation of changes to the New Chemicals Review Program, as well as comments responding to EPA's draft New Chemicals Decision-Making Framework.

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LEGAL AND FACTUAL BACKGROUND

I. An overview of TSCA § 5 as amended by the Lautenberg Act.

When interpreting a statute, the first question always is "whether Congress has directly spoken to the precise question at issue. If the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress." *Chevron, U.S.A., Inc. v. NRDC, Inc.*, 467 U.S. 837, 842-43 (1984). Before turning to our substantive comments on EPA's implementation, we provide an overview of the statutory language and structure of TSCA § 5 as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act (Lautenberg Act), Pub. L. No. 114-182, 130 Stat. 448 (June 22, 2016).

TSCA § 5 governs EPA's review of "new chemical substance[s]," defined as chemical substances not included on the Inventory. *See* 15 U.S.C. §§ 2604, 2602(11). Generally, no person may manufacture (defined to include import) a "new chemical substance" in the United States without providing EPA notice at least 90 days beforehand. *Id.* § 2604(a)(1). When a person submits a pre-manufacture notice (PMN), EPA must review the PMN and make one of three types of determinations under TSCA § 5(a)(3). *Id.* §§ 2604(a)(1)(B). EPA then must take the actions required by the relevant determination, and the person must comply with any applicable requirement imposed. *Id.*

The PMN must include, "insofar as known to the person submitting the notice or insofar as reasonably ascertainable," numerous pieces of information set forth in TSCA § 8(a)(2). 15 U.S.C. §§ 2604(d)(1)(A), § 2607(a)(2)(A)-(D), (F), (G). This information includes the substance's chemical identity, the uses of the chemical, reasonable estimates of the total amount to be manufactured or processed, a description of byproducts, reasonable estimates of the number of individuals who are or will be exposed, and the manner or method of disposal of the chemical. *See id.* § 2607(a)(2)(A)-(D), (F), (G). In addition, the PMN must include "any information in the possession or control of the person *** which are related to the effect of any manufacture, processing, distribution in commerce, use, or disposal of such substance or any article containing such substance, or of any combination of such activities, on health or the environment." *Id.* § 2604(d)(1)(B). The PMN must also include "a description of any other information concerning the environmental and health effects of such substance." *Id.* § 2604(d)(1)(C). The PMN, and supporting information, "shall be made available, subject to section 14, for examination by interested persons." *Id.* § 2604(d)(1), (b)(3).

Once EPA receives a PMN, EPA must make one of three types of determinations, and each type of determination triggers different obligations for EPA and the submitter.

First, EPA can determine "that the relevant chemical substance *** presents an unreasonable risk of injury to health or the environment." *Id.* § 2604(a)(3)(A). If EPA makes that determination, EPA must either promulgate a rule or issue an order to prohibit, limit, or otherwise regulate the manufacture, processing, or distribution in commerce of the substance "to the extent necessary to protect against such risk." *Id.* § 2604(f)(1).

Second, EPA can determine that "the relevant chemical substance *** is not likely to present an unreasonable risk of injury to health or the environment *** in which case the submitter of the notice

may commence manufacture of the chemical substance." 15 U.S.C. § 2604(a)(3)(C). EPA must then make a public statement of the finding in the Federal Register. *Id.* § 2604(g).

Third, EPA can determine that:

> (i) the information available to [EPA] is *insufficient* to permit a reasoned evaluation of the health and environmental effects of the relevant chemical substance or significant new use; *or*
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> (ii)
>
> > (I) in the absence of sufficient information to permit [EPA] to make such an evaluation, the manufacture, processing, distribution in commerce, use, or disposal of such substance, or any combination of such activities, *may present an unreasonable risk* of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by [EPA]; *or*
> >
> > (II) such substance is or will be produced in substantial quantities, and such substance either enters or may reasonably be anticipated to enter the environment in substantial quantities or there is or may be significant or substantial human exposure to the substance,
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> in which case [EPA] *shall* take the actions required under subsection (e).

15 U.S.C. § 2604(a)(3)(B) (emphases added). In turn, TSCA § 5(e) requires that if EPA makes one of these findings, EPA "*shall* issue an *order* *** to prohibit or limit the manufacture, processing, distribution in commerce, use, or disposal of such substance or to prohibit or limit any combination of such activities to the extent necessary to protect against an unreasonable risk of injury to health or the environment." *Id.* § 2604(e) (emphases added).

After EPA's review process, a person must provide a Notice of Commencement of Manufacture or Import Form (NOC) to EPA within 30 calendar days of the date the substance is first produced or imported for nonexempt commercial purposes. 40 C.F.R. § 720.102(b)(1). Once EPA receives this NOC, EPA adds the chemical to the "inventory" of existing chemicals. 15 U.S.C. § 2607(b)(1) ("[EPA] shall compile, keep current, and publish a list of each chemical substance which is manufactured or processed in the United States.")

In addition, TSCA § 5(a)(2) provides EPA with an additional authority over new *uses* of chemicals. EPA has broad authority to promulgate a significant new use rule (SNUR) defining any new use of a chemical as "a significant new use." 15 U.S.C. § 2604(a)(2). A SNUR requires that, before a person can engage in the significant new use, that person must submit a notification, triggering the above review process for that significant new use. *Id.* EPA may define any new use as a "significant new use" after considering "all relevant factors," including

> (A) the projected volume of manufacturing and processing of a chemical substance, (B) the extent to which a use changes the type or form of exposure of human beings or the environment to a chemical substance, (C) the extent to which a use increases the magnitude and duration of exposure of human beings or the environment to a chemical substance, and (D) the reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of a chemical substance.

Id. Notably, if EPA issues an order under § 5(e), or promulgates a rule or issues an order under § 5(f), regulating a new chemical, then within 90 days EPA must consider whether to promulgate a SNUR defining any new use that does not conform to the order or rule as a significant new use. *Id.* § 2604(f)(4).

TSCA § 5(h) creates five specific statutory exemptions from the § 5 notice requirements. 15 U.S.C. § 2604(h)(1)-(5). For example, EPA may grant exemptions to permit manufacturing and processing for "test marketing purposes." *Id.* § 2604(h)(1). Persons are also automatically exempted from § 5 if manufacturing and processing chemicals "only in small quantities" and "solely for purposes of—(A) scientific experimentation or analysis, or (B) chemical research on, or analysis of such substance or another substance." *Id.* § 2604(h)(3).

Finally, the implementation of TSCA § 5 should be informed by the congressional statement of policies at the beginning of TSCA. 15 U.S.C. § 2601(b). Congress stated that it is the policy of the United States that:

> (1) 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;
>
> (2) adequate authority should exist to regulate chemical substances and mixtures which present an unreasonable risk of injury to health or the environment, and to take action with respect to chemical substances and mixtures which are imminent hazards; and
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> (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). Notably, while industry often invokes and selectively cites this provision's reference to "innovation" as a basis for a more lenient approach to new chemicals, Congress expressly stated that "the *primary purpose* of [TSCA is] 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." *Id.* (emphases added). Given that the development and application of new chemicals are a clear source

of innovation, EPA must engage in robust scrutiny of new chemicals to fulfill this purpose of assuring that innovation does not present unreasonable risk.

II. The Lautenberg Act made numerous major improvements to the new chemicals provisions of TSCA, addressing critical flaws in the original law.

Some people have expressed the view that the Lautenberg Act did not significantly amend TSCA § 5. Nothing could be further from the case. Congress revamped TSCA § 5 in numerous, significant ways, and any lawful implementation of TSCA § 5 must give effect to those amendments. *See, e.g.*, *Pierce County v. Guillen*, 537 U.S. 129, 145 (2003) ("[W]hen Congress acts to amend a statute, we presume it intends its amendment to have real and substantial effect.") (quoting *Stone v. INS*, 514 U.S. 386, 397 (1995)). We outline some of the crucial amendments here.

A. EPA must review each new chemical and make an affirmative finding as to its safety. The old law had neither mandate.

Under the Lautenberg Act, EPA *must* review each new chemical and make a determination related to whether it presents or may present an unreasonable risk of injury to health or the environment. Lautenberg Act, Pub. L. No. 114-182, § 5(a)(3), 130 Stat. 448, 455 (June 22, 2016) (codified at 15 U.S.C. § 2604(a)(3)) (requiring that EPA make a determination). In addition, a manufacturer cannot begin manufacturing the chemical until EPA "conducts [that] review" and "makes a determination under subparagraph (A), (B), or (C) of paragraph (3) and takes the actions required in association with that determination." Lautenberg Act, Pub. L. No. 114-182, § 5(a)(1)(B)(ii), 130 Stat. 448, 455 (June 22, 2016) (codified at 15 U.S.C. § 2604(a)(1)(B)(ii)). Prior to the Lautenberg Act, EPA could simply "drop" a chemical without making a final determination, and the manufacturer could begin manufacture without a final determination.[1]

Notably, in introducing the mandate that EPA *must* review each chemical and make a determination, the Lautenberg Act also articulated (in TSCA § 5(a)(3)) the substantive standard that EPA must apply and the three types of determinations, one of which EPA must now make.

B. 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.

One of the new types of determinations introduced in § 5(a)(3)(B) is that, if EPA finds that a chemical substance lacks sufficient information, EPA must issue an order to regulate that chemical. *See* 15 U.S.C. § 2604(a)(3), (e). Specifically, TSCA § 5(a)(3)(B)(i) provides that: "[EPA] *shall* review [the] notice and determine *** that the information available to [EPA] is *insufficient* to permit a reasoned evaluation of the health and environmental effects of the relevant chemical substance or significant new use *** in

[1] *See* STATISTICS FOR THE NEW CHEMICALS REVIEW PROGRAM UNDER TSCA, https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/statistics-new-chemicals-review (last visited Jan. 18, 2018).

which case [EPA] *shall* take the actions required under subsection (e)." *Id.* § 2604(a)(3)(B)(i) (emphases added). In turn, TSCA § 5(e) requires that if EPA makes this determination, EPA "*shall* issue an *order* *** to prohibit or limit the manufacture, processing, distribution in commerce, use, or disposal of such substance or to prohibit or limit any combination of such activities to the extent necessary to protect against an unreasonable risk of injury to health or the environment." *Id.* § 2604(e) (emphases added).

Significantly, the Lautenberg Act expressly turned the earlier, permissive "may" of § 5(e) into a mandatory "shall." Lautenberg Act, Pub. L. No. 114-182, § 5(e), 130 Stat. 448, 458 (June 22, 2016) (codified at 15 U.S.C. § 2603(e)). This change removes any possibility that EPA has discretion to decide not to issue an order. *If* there is "insufficient" information (*or* EPA makes one of the other § 5(a)(3)(B) determinations), then EPA must issue an order. Notably, an order can also require testing to acquire more information and to ensure that the order's restrictions are sufficient to mitigate unreasonable risks.

Under the old law, EPA often allowed manufacture to commence, without restrictions, for new chemicals lacking sufficient information. Because the great majority of new chemical notices include no health and environmental data,[2] EPA has had to rely on estimation approaches, with little ability to know, account for, or address the level of uncertainty this entailed. And for many health endpoints of greatest concern, reliable estimation methods simply do not exist. Absent information sufficient to establish a new chemical "may present an unreasonable risk" under the prior version of TSCA § 5(e), EPA simply "dropped" the chemical from further review and made no final determination. As a result, EPA only rarely attached any conditions on new chemicals, and even more rarely required any testing.

The Lautenberg Amendments were designed to *fix* that old system. Congress eliminated EPA's discretion to simply "drop" a chemical and allow unregulated manufacture to commence. EPA must now make an *affirmative* "not likely to present a risk" determination to allow unregulated manufacture. Congress also shifted the legal consequences of uncertainty or insufficient information toward regulation because now, if information is insufficient, EPA must issue an order.

C. EPA *must* consider issuing a SNUR after it issues an order under TSCA § 5(e).

As explained above, EPA must issue a TSCA § 5(e) order whenever it makes certain determinations. The Lautenberg Act also introduced a new provision, TSCA § 5(f)(4), imposing an additional duty that must follow any § 5(e) order. 15 U.S.C. § 2604(f)(4). Specifically,

> Treatment of nonconforming uses. Not later than 90 days after taking an action under [5(f)(2) or 5(f)(3)] or issuing an order under [5](e) relating to a chemical substance with

[2] "The information included in PMNs is limited: 67% of PMNs include no test data and 85% include no health data." Overview: Office of Pollution Prevention and Toxics Laws and Programs (March 2008), https://archive.epa.gov/oppt/pubs/oppt101_tscalaw_programs_2008.pdf; OPPT, Draft Q&A for the New Chemicals Program, Q 118-5 at 1-55 (2004), https://www.epa.gov/sites/production/files/2015-09/documents/qanda-newchems_new.pdf ("Fewer than 5% of all PMN submissions contain ecotoxicity data.").

> respect to which [EPA] has made a determination under [5](a)(3)(A) or (B), [EPA] shall consider whether to promulgate a rule pursuant to [5](a)(2) that identifies as a significant new use any manufacturing, processing, use, distribution in commerce, or disposal of the chemical substance that does not conform to the restrictions imposed by the action or order, and, as applicable, initiate such a rulemaking or publish a statement describing the reasons of [EPA] for not initiating such a rulemaking.

15 U.S.C. § 2604(f)(4). Thus, after issuing a § 5(e) order (or taking action under § 5(f)), EPA must consider whether to promulgate a SNUR to ensure that the PMN submitter or other companies making or processing the same chemical first notify EPA before deviating from the terms of that order so that EPA can conduct a review of any significant new use. *Id.* § 2604(f)(4). EPA must either initiate the SNUR rulemaking or publish a statement explaining why it is not doing so. *Id.* Under the old law issuing such a SNUR was entirely discretionary.

D. 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.

The Lautenberg Act introduced a new term of art to TSCA, "conditions of use," and TSCA § 5(a)(3) requires that EPA review a new chemical under its "conditions of use" when reviewing a PMN. *See* Lautenberg Act, Pub. L. No. 114-182, §§ 3(4), 5(a)(3), 130 Stat. at 449, 455-56 (June 22, 2016) (codified at 15 U.S.C. §§ 2602(4) and 2604(a)(3) respectively). EPA can only determine that a new chemical substance or significant new use "is not likely to present an unreasonable risk of injury to health or the environment *** under the conditions of use." 15 U.S.C. § 2604(a)(3). Thus, EPA may only support a "not likely" determination for a new chemical substance if unreasonable risk is not likely "under the conditions of use."

TSCA defines the term "conditions of use" to "mean[] the circumstances, as determined by [EPA], 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). Thus, EPA has to consider the "reasonably foreseen" circumstances of production, processing, distribution, use or disposal at the same time as it considers those intended by the company providing the new chemical notice to EPA. By including this language, Congress foreclosed any practice EPA may have previously had of confining its review of potential risks of new chemicals to those associated with only the specific conditions of use identified by the company submitting the PMN.

E. EPA must protect against potential risks to "potentially exposed or susceptible subpopulations," including workers.

As with "conditions of use," the Lautenberg Act introduced an additional new term of art, "potentially exposed or susceptible subpopulation," and applied it to EPA's new chemical reviews. *See* Lautenberg Act, Pub. L. No. 114 182, §§ 3(12), 5(a)(1)(B)(ii), 130 Stat. at 449, 455-56 (June 22, 2016) (codified at 15 U.S.C. §§ 2602(12) and 2604(a)(3) respectively). Specifically, every risk determination in TSCA § 5(a)(3)

requires that EPA consider any "unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by [EPA]." *See* 15 U.S.C. § 2604(a)(3)(A), (a)(3)(B)(ii)(I), (a)(3)(C).

TSCA defines the term "potentially exposed or susceptible subpopulation" to mean

> a group of individuals within the general population identified by [EPA] who, due to either greater susceptibility or greater exposure, may be at greater risk than the general population of adverse health effects from exposure to a chemical substance or mixture, such as infants, children, pregnant women, workers, or the elderly.

15 U.S.C. § 2602(12). Notably, Congress expressly identified "workers" as such a group, and, appropriately, "workers" are often identified by EPA as relevant in new chemical reviews. *See, e.g.*, TSCA Section 5(a)(3)(C) Determination for Premanufacture Notice (PMN) P-18-0026, https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/tsca-section-5a3c-determination-80.

III. EPA's implementation and new proposed changes.

A. EPA's initial implementation was largely sound, it correctly led to many more chemicals being subject to conditions or testing requirements, and it was workable and timely.

For a period of time after passage of the Lautenberg Act, if EPA's review identified risk concerns relating to conditions of use beyond those strictly identified by a company submitting a new chemical notice to EPA, EPA properly made a "may present an unreasonable risk" determination and pursued development of a consent order with the company sufficient to ameliorate those concerns. (While EPA has authority to issue orders unilaterally, it typically negotiates with the company to arrive at a consent order that both parties sign.) Similarly, if the information was "insufficient to permit a reasoned evaluation," EPA would develop a consent order to address its concerns.

Notably, because the law's requirements were immediately effective, a temporary backlog developed as EPA re-started its review for chemicals already in the pipeline, determined how to meet new requirements, and added more staff. But EPA managed to clear that backlog *without* (to our knowledge) taking the legally dubious actions we will shortly address,[3] as of August 7, 2017, when Administrator Pruitt reported that the backlog was eliminated. Press Release, EPA, EPA Eliminates New-Chemical Backlog, Announces Improvements to New Chemical Safety Reviews (Aug. 7, 2017), https://www.epa.gov/newsreleases/epa-eliminates-new-chemical-backlog-announces-improvements-new-chemical-safety-reviews.

Starting at that time, EPA proposed new, illegal changes to the program that both weaken public health protections and may well introduce delay.

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[3] Nonetheless, as discussed below at pp. 23-30, EPA's implementation violated certain statutory and regulatory provisions regarding transparency and public involvement. EPA should cure those violations.

Unfortunately, that backlog (despite having been eliminated) became an excuse to weaken the new chemicals review program. EPA announced new, forward-looking policies that violate the law on the very same day (August 7, 2017) that EPA announced the end of the backlog. Press Release, EPA, EPA Eliminates New-Chemical Backlog, Announces Improvements to New Chemical Safety Reviews (Aug. 7, 2017), https://www.epa.gov/newsreleases/epa-eliminates-new-chemical-backlog-announces-improvements-new-chemical-safety-reviews. We address those policies next, but it bears emphasis that the new policies were not necessary to eliminate the backlog and make the program more workable. As illustrated in the chart below, the new policies were announced after the reduction in the backlog was achieved.

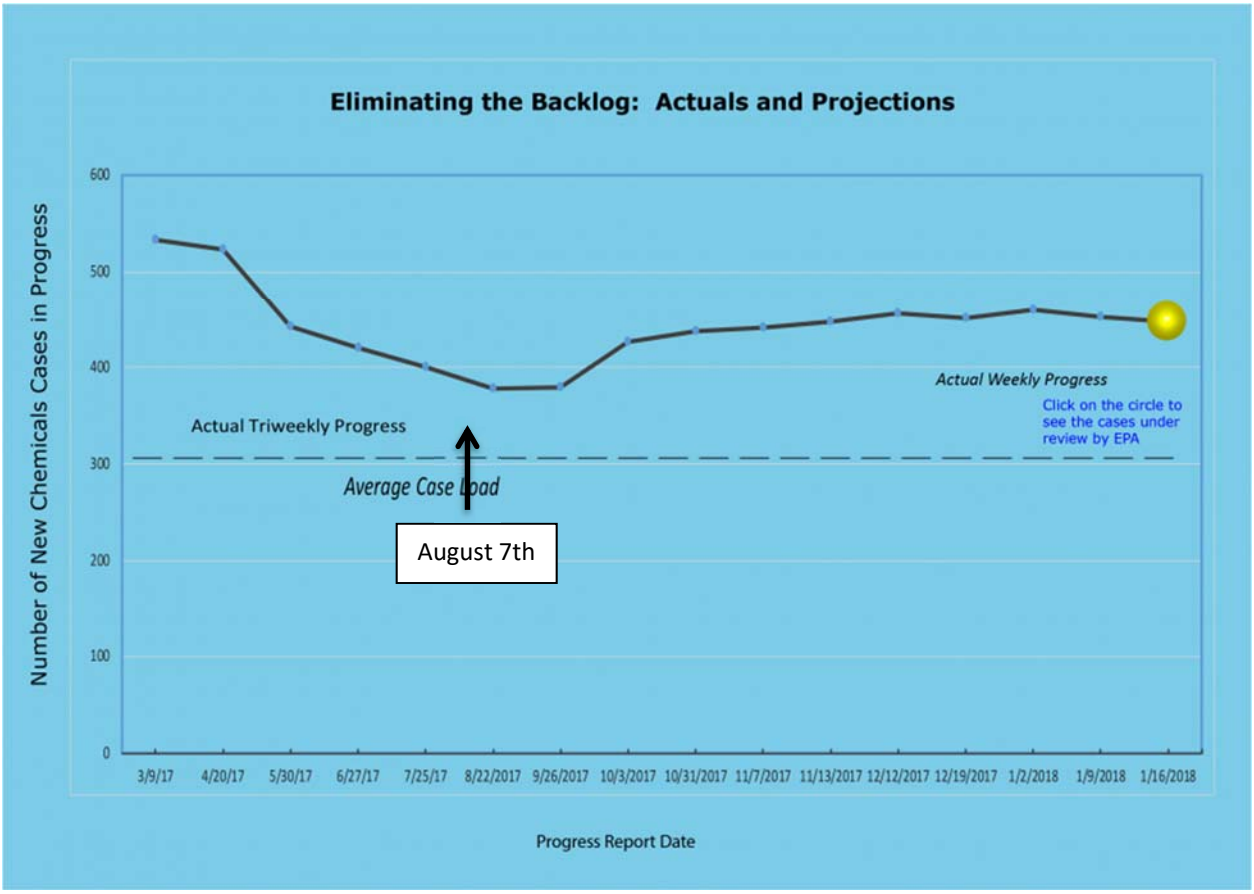

Figure 1: Statistics for the New Chemicals Review Program under TSCA, https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/statistics-new-chemicals-review (last visited Jan. 20, 2018).

As one can see, EPA made forward progress clearing the backlog until August, when the new policies were announced. Indeed, the new policies could introduce additional delay.

EPA's "New Chemicals Decision-Making Framework" and other public statements[4] indicate that, going forward, EPA will take steps to avoid following the TSCA § 5(a)(3) requirement to analyze all reasonably foreseen conditions of use along with intended conditions of use when doing so would result in issuance of orders under TSCA § 5(e) or orders or rules under § 5(f). Indeed, EPA seems intent on avoiding issuing TSCA § 5(e) orders and § 5(f) orders or rules whenever possible.

Specifically, when EPA has concerns that a chemical may present an unreasonable risk, rather than make the required determination under § 5(e) and issuing an order, EPA plans to use a SNUR as "an effective and efficient way to address *reasonably foreseen conditions of use* about which EPA has *concerns*, as part of the basis for EPA to conclude that the chemical is *not likely to present an unreasonable risk* of injury to health and the environment under the conditions of use under section 5(a)(3)(C)." ACTIONS UNDER TSCA SECTION 5: SNURS FOR NEW CHEMICALS, https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/actions-under-tsca-section-5#SNURs (last visited Jan. 18, 2018). (emphases added). In other words, even when EPA has "concerns" about the "reasonably foreseen conditions of use," EPA still plans to determine "the chemical is not likely to present an unreasonable risk." *Id.* EPA's theory for this illogical approach appears to be that, if EPA promulgates or intends to promulgate a SNUR, EPA may then limit its analysis of the chemical to those conditions of use that are expressly intended by the company, as identified in the PMN. Specifically, EPA plans to rely on SNURs "to focus its technical analysis on the intended conditions of use of a chemical and *defer further analysis of reasonably foreseen conditions of use* until such time as the submitter (or any other entity) actually intends to undertake them." *Id.* (emphasis added).

Furthermore, EPA will allow the submitter to redefine the intended uses by amending the PMN, and EPA will then only consider the conditions of use as identified in the final PMN, ignoring conditions of use that the company *previously* identified as intended. *See* EPA, New Chemicals Decision-Making Framework (Nov. 7, 2017), https://www.regulations.gov/document?D=EPA-HQ-OPPT-2017-0585-0004 ("If EPA had concerns regarding the conditions of use, such concerns were adequately addressed through amendment of the PMN made during the review period in conjunction with the issuance of a SNUR."). But it bears noting that PMNs, standing alone, are not legally binding on the submitter; absent a final SNUR that is fully in effect, a submitter can at any time engage in conditions of use beyond those identified in the PMN without even notifying EPA.

Thus, going forward, when EPA has concerns about a chemical's reasonably foreseen conditions of use, EPA will generally plan to address those concerns solely with a SNUR, not with a TSCA § 5(e) order followed by a SNUR under § 5(f)(4). The SNUR will then form "part of the basis for EPA to conclude that the chemical is not likely to present an unreasonable risk of injury to health and the environment under

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[4] Press Release, EPA, EPA Eliminates New-Chemical Backlog, Announces Improvements to New Chemical Safety Reviews (Aug. 7, 2017), https://www.epa.gov/newsreleases/epa-eliminates-new-chemical-backlog-announces-improvements-new-chemical-safety-reviews; ACTIONS UNDER TSCA SECTION 5, https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/actions-under-tsca-section-5#SNURs (last visited Jan. 18, 2018).

the conditions of use under section 5(a)(3)(C)." ACTIONS UNDER TSCA SECTION 5: SNURS FOR NEW CHEMICALS, https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/actions-under-tsca-section-5#SNURs (last visited Jan. 18, 2018). One result will be that EPA will no longer issue *binding* orders to address even intended conditions of use under TSCA § 5(e) since these orders can only be issued as part of the new chemical review or Significant New Use Notification (SNUN) review process. Another result is that EPA is explicitly *deferring* its analysis of reasonably foreseen conditions of use, rather than conducting a holistic and comprehensive review of new chemicals, as Congress intended.

This "SNUR-only approach" is illegal, and it also raises a host of policy concerns. We address each below. But to be clear: EDF's concern is not with the SNURs themselves. It is with EPA's attempt to rely on SNURs to avoid following the statutory mandates of TSCA § 5(a)(3), 5(e), and 5(f) governing new chemical reviews, which require *binding* orders when a chemical may present (or presents) an unreasonable risk under the conditions of use *or* when there is insufficient information to analyze the risks *or* when EPA makes an exposure-based finding.

EPA's documents reveal a number of other illegal changes as well. For example, in its Press Release, EPA stated that: "It is reasonable to foresee a condition of use, for example, where facts suggest the activity is not only possible, but, over time under proper conditions, probable." Press Release, EPA, EPA Eliminates New-Chemical Backlog, Announces Improvements to New Chemical Safety Reviews (Aug. 7, 2017), https://www.epa.gov/newsreleases/epa-eliminates-new-chemical-backlog-announces-improvements-new-chemical-safety-reviews. As explained below, "reasonably foreseen" does not mean "probable."

ARGUMENTS AGAINST EPA'S PROPOSED SNUR-ONLY APPROACH

IV. TSCA does not allow EPA to avoid issuing a § 5(e) order for a new chemical substance based on a SNUR; if a chemical substance may present an unreasonable risk under its reasonably foreseen conditions of use, or if EPA has insufficient information on the substance, or if EPA makes an exposure-based finding, the plain text of TSCA requires that EPA issue a § 5(e) order.

A. EPA's SNUR-only approach violates the plain text of TSCA § 5 which requires EPA to analyze "new chemical substance[s]," as distinct from significant new uses, and requires EPA to analyze the substances' reasonably foreseen conditions of use.

TSCA § 5(a)(1)(A)(i) prohibits any person from "manufactur[ing] a new chemical substance" without notice, and TSCA § 3(11) defines "new chemical substance" to "mean[] any chemical substance which is not included in the chemical substance list compiled and published under section 8(b)." 15 U.S.C. § 2604(a)(1)(A)(i), 2602(11). A person may not manufacture the new substance without submitting a notice on the *substance*; this provision does not contemplate a person submitting a notice where EPA will then limit its review of the unlisted substance to only those conditions of use identified by the submitter. Nor does it allow EPA to limit its review and determination for a new substance based on whether or not a SNUR for the substance has been or is intended to be issued. Crucially, TSCA § 5 expressly and repeatedly distinguishes between (a)(1)(A)(i), which addresses new chemical substances,

and (a)(1)(A)(ii), which addresses significant new uses. *See, e.g.*, 15 U.S.C. §§ 2604(a)(3), (f)(1), (g). EPA cannot conflate the two.

For example, TSCA § 5(a)(3) requires EPA to review PMNs and make a determination about "the relevant [new] chemical substance" without qualification and as distinct from a "significant new use." 15 U.S.C. § 2604(a)(3). Nothing in the language of § 5(a)(3) allows EPA to limit its review and determination for a new substance based on whether or not a SNUR has been or is intended to be issued. In addition, nothing in this provision allows EPA to limit its review or determination to intended conditions of use.

The statute expressly states that if EPA makes one of the § 5(a)(3)(B) determinations, then EPA "shall" issue a § 5(e) order "to prohibit or limit" the conditions of use of such substance to the extent necessary to protect against an unreasonable risk. 15 U.S.C. § 2604(a)(3)(B), (e). Nothing in the text of § 5(a)(3)(B) or 5(e) authorizes EPA to rely on a SNUR to avoid analyzing the substance under all of its conditions of use *or* to avoid issuing the mandatory "order." Nor does anything in the text of § 5(a)(3)(A) or 5(f) authorize EPA to rely on a SNUR to avoid analyzing the substance under all of its conditions of use *or* to avoid issuing the mandatory "order" or "rule." Rather, the use of the phrase "shall issue" leaves no room for EPA to decide it can adopt anything less than a rule or order. *See Sierra Club v. Johnson*, 541 F.3d 1257, 1265 (11th Cir. 2008) ("Congress's use of the word 'shall' creates a nondiscretionary duty for the Administrator.").

Under TSCA § 5(a)(3)(C), EPA is to make a "not likely to present an unreasonable risk" finding on the "chemical substance" "under the conditions of use." "Conditions of use" is defined to include the circumstances "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) (emphasis added). SNURs do not change the statutory requirement that EPA consider *all* conditions of use in its review of the PMN, especially because a SNUR does not permanently foreclose any conditions of use (*i.e.*, they remain reasonably foreseen, and only a subsequent order or rule issued by EPA following its review of a SNUN could foreclose such a condition of use).

In sum, nothing in any of this language allows EPA to limit its review and determination for a new substance based on whether or not a SNUR has been or is intended to be issued. Tellingly, EPA has not advanced any interpretative legal theory behind its SNUR-only approach.

B. EPA's SNUR-only approach violates the overall structure of TSCA § 5 because § 5(f)(4) expressly creates the opposite relationship between orders and SNURs and because § 5 is built around EPA's analysis of new chemical substances as a whole.

While the plain text is determinative for the reasons given above, EPA's approach also violates the overall structure of TSCA § 5. *First and foremost*, TSCA § 5(f)(4) establishes that a § 5(e) order should generally lead to a SNUR. Using a SNUR to avoid a § 5(e) order completely inverts the relationship Congress expressly created between the two. Specifically, Congress directed that no "later than 90 days after *** issuing an order under [5](e) relating to a chemical substance," EPA "shall consider whether to promulgate a rule pursuant to [5](a)(2) that identifies as a significant new use any [use] of the chemical substance that does not conform to the restrictions imposed by the *** order." 15 U.S.C. § 2604(f)(4). If

EPA declines to issue a SNUR, EPA must publish a statement explaining its reasons for not doing so. *Id.* Given that Congress intended for § 5(e) orders: (1) to come first and (2) to generally trigger SNURs that include the same conditions as appear in the order, it would contravene Congress's intent to have the SNUR come first and then eliminate the § 5(e) order.

Second, the timing provisions work if EPA follows the law, but under EPA's SNUR-only approach, EPA will struggle to meet its deadlines. As designed, the law anticipates EPA will make its determination on a new chemical substance within 90 days of receiving a complete and valid PMN for that substance (subject to up to a 90-day extension). *See* 15 U.S.C. § 2604(b)(1)(B), (c). EPA then has an additional 90 days to initiate a rulemaking to promulgate a SNUR through notice-and-comment rulemaking or publish a statement explaining why it chose not to do so. *See id.* § 2604(f)(4). But even assuming for the sake of argument that EPA's SNUR-only approach were otherwise legal (which it is not), for reasons explained below at pp. 15-16, EPA would have to promulgate a legally-effective SNUR through notice-and-comment rulemaking *before* it could rely on that SNUR in reaching a "not likely" determination on the new chemical substance. Even if EPA were to take expedited action to promulgate the SNUR through a direct final rule, EPA's regulations require that EPA afford at least 30 days for interested persons to provide notice of intent to submit adverse or critical comments on SNURs. *See* 40 C.F.R. §§ 721.160, 721.170. In practice, EPA has afforded at least 30 days. *See, e.g.*, 82 Fed. Reg. 48,637 (Oct. 19, 2017) (providing 32 days to submit notice of intent to submit adverse comments on direct final rule); 82 Fed. Reg. 44,079 (Sept. 21, 2017) (providing 32 days to submit notice of intent to submit adverse comments on direct final rule); 82 Fed. Reg. 26,644 (June 8, 2017) (providing 32 days to comment on proposed rule). In addition, SNURs promulgated through direct-final rulemaking do not become legally effective until 60 days after publication at the earliest, and SNURs promulgated through normal notice-and-comment rulemaking take even longer to become effective. *See, e.g.*, 40 C.F.R. § 721.170(d)(4)(i)(B) ("The Federal Register document will state that, unless written notice is received by EPA within 30 days after the date of publication that someone wishes to submit adverse or critical comments, the SNUR will be effective 60 days from date of publication."); 82 Fed. Reg. 26,644 (June 8, 2017) (proposing SNUR for chemical substance identified in PMN P-11-482 through notice-and-comment rulemaking); 82 Fed. Reg. 45,990 (Oct. 3, 2017) (finalizing that SNUR with effective date of November 2, 2017, more than 140 days after proposal). And of course, rulemaking requires more time than just the comment period and time for the rules to become effective, since EPA must also draft the rule, issue it, and then review comments received before issuing the final rule. These timing provisions also counsel against EPA's SNUR-only approach.

In fact, EPA's delays in completing the mandatory TSCA § 5(f)(4) actions to date indicate that EPA is unlikely to be able to complete SNURs within 90 days of receiving a PMN. As noted, TSCA § 5(f)(4) directs that, after EPA issues an order under § 5(e), EPA must within 90 days consider whether to promulgate a SNUR and either "initiate such a rulemaking or publish a statement describing the reasons of [EPA] for not initiating such a rulemaking." A significant number of consent orders EPA has finalized after the date of enactment of the Lautenberg Act were issued well over 90 days ago. For many of them, however, it does not appear that EPA has yet taken either of the actions specified under TSCA § 5(f)(4) because neither a SNUR nor public statement has appeared in the Federal Register. *See, e.g.*,

Federal Register Documents for "P-16-0534," https://www.federalregister.gov (search "P-16-0534") (last visited Jan. 18, 2018) (indicating that no SNUR has yet been proposed for this PMN even though the consent order was signed March 7, 2017). EPA has issued SNURs for 29 chemicals subject to orders under § 5(e), though outside the 90-day window for many of them. *See* 82 Fed. Reg. 48,637 (Oct. 19, 2017). In addition, for those SNURs EPA has issued, it often took EPA months to finalize the SNURs. For example, EPA posted prepublication versions of Federal Register notices that indicated EPA was to publish SNURs, as direct final rules, for 37 substances on April 5, 2017, and for another 29 substances on July 7, 2017. However, even though EPA sought to expedite these SNURs by issuing them as direct final rules, they were not finalized for months, finally being published in the Federal Register on September 21, 2017, and October 19, 2017, respectively. It took this long, through direct-final rulemaking, even though no one submitted an intent to submit adverse comment; it would have taken even longer if someone had submitted an intent to do so. Given these substantial delays in finalizing SNURs and taking mandatory actions under TSCA § 5(f)(4), EPA is unlikely to complete SNURs within 90 (or even 180) days of receiving a PMN for a new chemical substance.

Third, and more broadly, the text and structure of TSCA are generally built around the analysis of chemical substances as a whole, not just specific conditions of use of chemical substances,[5] and in particular, new chemical reviews under TSCA § 5 are built around analyses of chemical substances *as distinct* from determinations about a "significant new use."

Indeed, when Congress intended to allow a § 5 risk determination to be limited to certain conditions of use or certain intended uses, Congress expressly authorized such a limited analysis. For example, § 5(h)(1) allows a test marketing exemption "for the specific conditions of use identified in the application." 15 U.S.C. § 2604(h)(1); *see also, e.g.*, 15 U.S.C. §§ 2605(c)(2)(C), 2605(g), 2613(b)(4)(B)(iii). If Congress had intended for EPA to limit its analysis to the conditions of use identified in the PMN, similar language would appear in § 5(a)(3) governing review of PMNs for new chemical substances. It does not.

[5] Industry has made numerous requests for EPA to shift the analysis of chemicals under TSCA as amended by the Lautenberg Act from chemical substances as a whole to only specific conditions of use. The SNUR-only approach is just one example; similar requests have been made regarding the analyses for § 6 prioritization and risk evaluation. But the language of §§ 4, 5, and 6 requires EPA to make findings about each "chemical substance." It does not support analyzing only some of the conditions of use of the chemical substance. *See, e.g.*, 15 U.S.C. § 2605(b)(1)(A) ("[T]he Administrator shall establish, by rule, a risk-based screening process, including criteria for designating chemical substances as high-priority substances for risk evaluations or low-priority substances for which risk evaluations are not warranted at the time."); *id.* § 2605(b)(3)(A) ("Upon designating a chemical substance as a high-priority substance, [EPA] shall initiate a risk evaluation on the substance."); *id.* § 2604(d)(2)(A) (EPA must publish notice which "identifies the chemical substance for which notice or information has been received.").

C. EPA's SNUR-only approach is inconsistent with the purpose and legislative history of the amendments to TSCA § 5.

As revealed by the text and structure discussed above, one of the purposes of the new chemical review program is for EPA to conduct comprehensive risk reviews of chemicals before they enter the market, including by examining any reasonably foreseen conditions of use. Congress intended for EPA to issue § 5(e) orders (or take action under § 5(f)) to address any unreasonable risks presented by chemicals under their reasonably foreseen conditions of use.

EPA's concerted effort to avoid issuing TSCA § 5(e) orders for new chemicals contradicts that purpose. It also is contrary to the views expressed by Congress in the legislative history:

> For the first time, EPA will be required to review all new chemicals and significant new uses and make an affirmative finding regarding the chemical's or significant new use's *potential* risks as a condition for commencement of manufacture for commercial purposes and, in the absence of a finding that the chemical or significant new use is not likely to present an unreasonable risk, manufacture will not be allowed to occur. If EPA finds that it lacks sufficient information to evaluate the chemical's or significant new use's risks or that the chemical or significant new use does or may present an unreasonable risk, it is *obligated to issue an order or rule that precludes market entry or imposes conditions sufficient to prevent an unreasonable risk*. EPA can also require additional testing. *Only* chemicals and significant new uses that EPA finds *are not likely* to present an unreasonable risk can enter production *without restriction*. This affirmative approach to better ensuring the safety of new chemicals entering the market is essential to restoring the public's confidence in our chemical safety system.

162 Cong. Rec. S3516 (daily ed. June 7, 2016) (emphases added) (statement of intent submitted by lead negotiators). Congress specifically intended for only those chemicals that are not likely to present unreasonable risk to enter the market without restriction. Nothing in this language suggests that EPA can limit its analysis to the conditions of use identified in the PMN, and nothing allows EPA to ignore certain conditions of use because they are encompassed by a SNUR. Indeed, Congress specifically wanted EPA to consider a chemical's "potential risks." *Id.* Congress also explained that the term "conditions of use" "explicitly provides" "a mandate for EPA to consider conditions of use that are not currently known or intended but can be anticipated to occur." *Id.*

Similarly, Senator Vitter (another lead negotiator) explained that "when EPA does not have the information sufficient for the evaluation of a new chemical, or when EPA determines that a new chemical may present an unreasonable risk, the compromise requires EPA regulate the new chemical *to the extent necessary to protect against unreasonable risk*." 162 Cong. Rec. at S3520 (emphasis added), *compare with* Lautenberg Act, Pub. L. No. 114 182, § 5(e) (June 22, 2016) (codified at 15 U.S.C. § 2604(e)) (requiring that EPA "shall issue an order" regulating a chemical substance "*to the extent necessary to protect against an unreasonable risk* of injury to health or the environment") (emphasis added). Notably, Senator Vitter used the language of TSCA § 5(e), making it clear that when a chemical

may present an unreasonable risk or there is insufficient information, EPA must issue an *order* under TSCA § 5(e). Senator Vitter did not refer to EPA relying on its SNUR authority under § 5(a)(2) instead.

D. Giving weight to a SNUR that is not finalized and legally in-force would be arbitrary and capricious *and* would undermine the legality of the SNUR.

As explained above, EPA cannot legally rely on a SNUR to narrow its review of a PMN for a new chemical substance under *any* circumstances. Quite simply, the statutory language does not permit it. Nonetheless, relying on non-finalized SNURs would introduce several *additional* legal problems that would make it even more illegal than relying on finalized, legally in-force SNURs.[6]

First, if a SNUR is not legally in-place and in-force at the time EPA makes a determination on the substance, EPA cannot rationally give it any weight. Among other things, it would be arbitrary and capricious to consider speculative future SNURs that have not been promulgated through rulemaking and do not yet have legal effect. As discussed in detail above, SNURs do not become legally effective until 60 days after publication at the earliest. *See, e.g.*, 40 C.F.R. § 721.170(d)(4)(i)(B).

Second, EPA cannot reasonably assume that it will know whether a SNUR will be finalized or, if so, the final SNUR's terms and conditions, until it has completed the notice-and-comment process for the SNUR and promulgated it as a final rule. *See Nat'l Rest. Ass'n v. Solis*, 870 F. Supp. 2d 42, 50 (D.D.C. 2012) ("[C]omments received by the agency are expected to shape the outcome of a final rule."). "The whole rationale of notice and comment rests on the expectation that the final rules will be somewhat different and improved from the rules originally proposed by the agency." *Trans-Pac. Freight Conf. of Japan/Korea v. Fed. Mar. Comm'n*, 650 F.2d 1235, 1249 (D.C. Cir. 1980). And if EPA issues a "not likely" finding for a chemical while relying on a SNUR that has not yet gone through notice-and-comment, then adverse commenters can fairly argue that EPA illegally predetermined the outcome of the SNUR rulemaking process before it was completed. *See, e.g.*, *Metcalf v. Daley*, 214 F.3d 1135, 1143 (9th Cir. 2000) (finding agency impermissibly predetermined outcome of administrative process by committing in writing to a particular outcome before completing administrative process).

In sum, as a basic matter of administrative law, EPA cannot rely on SNURs until they are fully promulgated through notice-and-comment and are legally in effect. If EPA gives weight to a SNUR that it merely intends to promulgate or has merely proposed, then both the "not likely" finding and the SNUR will violate the Administrative Procedure Act (APA). The "not likely" finding and the SNUR will be arbitrary and capricious, and the SNUR will violate the notice-and-comment requirements of the APA. To be clear, relying on a SNUR at any time is contrary to law for the reasons articulated previously, but relying on a non-finalized SNUR presents additional APA problems.

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[6] Some industry representatives have suggested that EPA might be able to rely on a SNUR even if it is not yet legally in-force and instead is simply proposed or contemplated by EPA. *See, e.g.*, Wiley Rein LLP, *TSCA PMNs: The New Regime, Part Three: Preparing CBI Claims and Negotiating Consent Orders*, Slides 49-50 ("Alternative view: EPA can issue finding letter that PMN submitter use meets the safety standard before issuing the SNUR.").

V. EPA's SNUR-only approach is also unsound policy and does not protect public health and the environment as robustly as using TSCA § 5(e) orders and 5(f) orders or rules, combined with a SNUR.

The SNUR-only approach EPA is now deploying differs dramatically from (and provides less health protection than) what the law requires: using orders, with SNURs as a backstop. There are ample reasons why Congress called on EPA to use orders to address concerns and then use SNURs as backstop: *Orders (including consent orders) and SNURs are not created equal*. Here, we discuss numerous key differences with respect to: (A) the legal requirements available with an order versus a SNUR; (B) the scope of risk review under an order versus a SNUR; (C) the legal requirements for issuing an order versus a SNUR; and (D) the incentives and disincentives companies face under an order versus only a SNUR. These key differences reveal that Congress had good reasons for adopting the approach it did. In addition, EPA must consider these relevant factors and policy concerns when implementing the new chemicals program; EPA cannot reasonably adopt its SNUR-only approach in light of these policy concerns.

A. EPA can impose legal requirements with an order beyond those it can implement through a SNUR.

i) *A consent order imposes legally binding conditions on the company that signs it.*

Where EPA identifies potential risk, significant expected release or other exposure, or a lack of sufficient information, TSCA requires that it impose binding conditions that must regulate the chemical "to the extent necessary to protect against an unreasonable risk of injury to health or the environment." 15 U.S.C. § 2604(e). Even where a SNUR defines a significant new use as any activity outside of those same conditions, the conditions are not binding and the only requirement on a company is to notify EPA prior to engaging in that significant new use (by filing what is called a Significant New Use Notification, or SNUN). The SNUN then undergoes a review similar to that for a PMN. Only if that review leads to a risk finding, an exposure-based finding, or an insufficient information finding can EPA impose binding conditions—which would likely be done through a consent order applicable to the SNUN submitter. (Note also that the provisions in a PMN are not legally binding on the submitter; only if codified in an order would they be binding.)

ii) *Consent orders are readily enforceable because the party subject to a consent order is known and has consented to abide by the conditions of it.*

A consent order must also be posted visibly within any workplace where activities subject to the consent order are taking place. In contrast, EPA has very limited means to know if companies are complying with the conditions of a SNUR or should have, but did not, file a SNUN.

iii) *Testing requirements cannot be imposed through SNURs, but can be through consent orders.*

TSCA § 5 requires EPA to issue an order whenever "the information available to [EPA] is insufficient to permit a reasoned evaluation of the health and environmental effects of a chemical substance," 15

U.S.C. §2604(e)(1)(A)(i), without limitation to a company's intended conditions of use, and § 5 orders provide a critical direct mechanism for EPA to address the data gaps that characterize the great majority of PMNs.

Given that only about 15% of PMN submissions include health data as part of the submission, EPA is typically making determinations based on limited data about the PMN substance, often relying exclusively on analogs. *See* Overview: Office of Pollution Prevention and Toxics Laws and Programs (March 2008), https://archive.epa.gov/oppt/pubs/oppt101_tscalaw_programs_2008.pdf ("The information included in PMNs is limited: 67% of PMNs include no test data and 85% include no health data."); *see also* OPPT, Draft Q&A for the New Chemicals Program, Q 118-5 at 1-55 (2004), https://www.epa.gov/sites/production/files/2015-09/documents/qanda-newchems_new.pdf ("Fewer than 5% of all PMN submissions contain ecotoxicity data."). There is no current ability to quantitatively evaluate how predictive an analog is of the PMN substance's properties; at best EPA can make a qualitative determination. Relying on a SNUR instead of a consent order provides no opportunity to generate new information nor to subsequently use that information to reassess EPA's initial evaluation based on limited information.

iv) *Consent orders can be reopened and revised based on new information (including results of required testing).*

If testing shows a chemical is more toxic than initially thought, EPA can tighten conditions in the order. *No such option exists with a SNUR*: If companies are engaging in activities that do not trigger notification under a SNUR but later those activities are found to present potential or actual risk, those activities generally cannot be brought under the original SNUR or addressed by a new SNUR, because industry would argue that they are now ongoing uses. EPA's only option at that point would likely be to pursue action under TSCA § 6: designate the substance as high-priority and undertake a risk evaluation, which could take over three years to complete; and then, if EPA determines the substance presents an unreasonable risk, promulgate a rule under § 6(a), which would take additional years to complete.

In contrast, a consent order includes both actual *restrictions* to protect against the unreasonable risk and a "reopener" provision: If testing indicates that EPA underestimated the magnitude of the risk, then the terms of the consent order allow EPA to modify it to require further restrictions to protect against the unreasonable risk. In the SNUR-only scenario, because there is no testing requirement, EPA will not even be able to learn whether its initial estimate of the risks was accurate.

B. Following the correct approach will result in comprehensive risk evaluations of new chemical substances including their reasonably foreseen conditions of use; EPA's illegal SNUR-only approach explicitly *defers* analysis of risks from reasonably foreseen conditions of use.

As explained above, through the reforms made by the Lautenberg Act, Congress required that EPA subject new chemicals to risk reviews and risk determinations that extend to reasonably foreseen as well as intended conditions of use. The goal is to achieve an integrated and holistic analysis of the risks of the chemical substance. If EPA makes a risk finding, an exposure-based finding, or an insufficient-

information finding for *either* category of conditions of use, then the law requires that EPA issue an order.

In contrast, EPA's proposed SNUR-only approach explicitly defers *the risk or related finding requirement with respect to reasonably foreseen conditions of use, potentially evading that review entirely.* This is because a risk or related finding is not required to be made in order for EPA to issue a SNUR, only consideration of certain factors delineated in TSCA § 5(a)(2). 15 U.S.C. § 2604(a)(2). While a SNUN submitted in response to a SNUR undergoes a review similar to that for a PMN, EPA may similarly truncate that review under its proposed approach. Specifically, if EPA chooses to similarly limit the SNUN review only to the *new* intended conditions of use identified by the submitter of the SNUN, then EPA may yet again not make a risk finding, an exposure-based finding, or an insufficient information finding, and hence again not issue a consent order imposing binding conditions on that company.

To bring together the points made above: Under the Lautenberg Act, EPA's review of a new chemical requires a comprehensive risk review and risk determination, whereas under EPA's approach, EPA would issue a SNUR in order to avoid such a comprehensive review or determination. Similarly, the terms of an order issued under § 5 of TSCA must meet a specific, protective risk standard: EPA must issue an order that regulates the chemical "to the extent necessary to protect against an unreasonable risk of injury to health or the environment *** including an unreasonable risk to a potentially exposed or susceptible subpopulation." 15 U.S.C. § 2604(e). In contrast, the terms of a SNUR, standing alone, do not need to meet *any* specific risk standard. *See id.* § 2604(a)(2).

Congress gave EPA a mandate under the law to consider *together both* intended and reasonably foreseen conditions of use of a new chemical in deciding whether conditions, to be imposed through an order, are warranted. *It did not intend for EPA to pursue a more piecemeal approach under which EPA evaluates only intended conditions of use initially and promulgates a SNUR to allow it later to address any concerns over reasonably foreseen conditions of use*.

In addition, under its SNUR-only approach, it appears EPA is warping the concepts of intended versus reasonably foreseen conditions of use. When a PMN is submitted and EPA finds potential risks based on the scenarios in the PMN, EPA apparently now typically works with the company to identify additional restrictions to include in the PMN to protect against the risks. In its SNUR-only approach, EPA is *de facto* redefining the intended conditions of use to include those new restrictions. EPA then defines the reasonably foreseen uses for that chemical to be those originally proposed by the PMN submitter (*i.e.*, without those new restrictions). *See* EPA, New Chemicals Decision-Making Framework (Nov. 7, 2017), https://www.regulations.gov/document?D=EPA-HQ-OPPT-2017-0585-0004 ("If EPA had concerns regarding the conditions of use, such concerns were adequately addressed through amendment of the PMN made during the review period in conjunction with the issuance of a SNUR."). As previously noted, however, the provisions in a PMN are not legally binding on the submitter; only if codified in a consent order would they be binding.

The result is that EPA will make a "may present" finding for intended conditions of use *only* if there is no feasible way for the company to add conditions to its PMN sufficient to protect against the risk. In other

words, EPA and the submitter iterate the process—with EPA effectively serving as a free consultant or coach to the PMN submitter. The process keeps moving the goal posts until a "not likely" finding can be made that avoids EPA ever having to make the initial "may present" finding and issue an order, clearly not what Congress intended. And crucially, even these additional conditions added to the PMN are not binding on the PMN submitter in the absence of an order.

Relying on a SNUR instead of a consent order may result in EPA only analyzing the specific intended conditions of use of the new chemical in isolation and never analyzing the chemical substance comprehensively, whereas § 5 of TSCA contemplates that a new chemical substance will receive a comprehensive analysis based on sufficient information. That is, deferring the review of potential risks arising from *reasonably foreseen conditions of use* to a setting that is removed in time and divorced from the risk review of *intended conditions of use* provides no assurance that EPA will ever conduct a robust review of potential risk under all of the new chemical's conditions of use.

In addition, the specific proposed conditions of use in the PMN only reflect the knowledge that the PMN submitter has of its market and downstream users at the time of PMN submission, which may be quite limited and not reflect the full range of potential conditions of use and users. If EPA only looks narrowly at the conditions of use in the PMN to make its determination, EPA's review and determination may well not reflect or be representative of the actual conditions of use once the chemical enters commerce. Congress clearly intended for EPA to take a more expansive and prospective approach when reviewing new chemicals under reformed TSCA.

EPA proposes to relegate its consideration of any potential risk beyond that specifically presented by the conditions of use in a PMN to a SNUR instead of protecting against those risks in an order. To even begin to achieve a sufficient level of protection, EPA would need to write a SNUR in a way that does not allow *any* activity that could present additional potential risk beyond the activities specified in the company's PMN to occur without prior notification. Otherwise, *EPA will be allowing risks to occur (with no consequence) that extend beyond those it deemed acceptable when it determined that the PMN was not likely to present unreasonable risk*. Consider, for example:

> A PMN specifies a company will require its workers to use a respirator with an air protection factor (APF) of 1000. Unless the SNUR triggers notification if a company does not require its workers to use a respirator with the same level of protection, a "risk gap" will result.
>
> A PMN specifies a company will produce 50,000 pounds of a chemical annually. If the SNUR does not set a volume trigger or sets a volume trigger that would allow more than 50,000 pounds of the chemical to be produced annually when aggregated across what could be multiple producers that are each in compliance with the SNUR, a "risk gap" will result.

In such cases, the SNUR-only approach would allow conditions of use that result in risk in excess of the conditions of use EPA deemed "not likely" to result in risk in the PMN review. That excess risk—even though it by definition exceeded the "not likely" standard—will never be reviewed, let alone subjected to restrictions, because the SNUR notification requirement will not be triggered.

The only way the SNUR-only approach could seek to prevent any "risk gap" would be to have the SNUR notification triggers so tightly aligned with the PMN specifications as to exactly mirror the conditions specified in the PMN, with any deviation whatsoever triggering notification. Otherwise, EPA will have conducted a new chemical review with an outcome insufficient to ever address the risks of the chemical's reasonably foreseen conditions of use, in clear violation of the law.

C. The SNUR-only approach raises a number of procedural concerns because, unlike consent orders, SNURs must be promulgated through rulemaking.

    i) *While EPA can simply issue an order in response to a PMN, EPA may only promulgate a SNUR through notice-and-comment rulemaking. As a result, relying solely upon SNURs raises numerous uncertainties.*

EPA's designation of what constitutes a significant new use generally applies upon proposal of a SNUR. However, even upon proposal, that significant new use can be engaged in until the SNUR is finalized (assuming it is in fact finalized), at which point such activity must cease, either altogether or pending the outcome of EPA's review of a subsequently-filed SNUN.

If there is a time gap between a PMN submitter's commencement of manufacture (which puts the new chemical on the Inventory) and EPA's proposal of a SNUR for that chemical, it runs the risk that a company (including the PMN submitter) could engage in the significant new use activity about which EPA is concerned. The company would then be able to argue that its activity negated EPA's ability to propose or finalize the SNUR because that use would then be ongoing.

While EPA can try to promulgate a SNUR as a direct final rule, if anyone files, or notifies EPA of their intent to file, an adverse comment, EPA must withdraw the rule and propose it for public comment.

    ii) *Once a SNUR is final, it can be judicially challenged, with any final resolution significantly delayed and subject to significant uncertainty.*

While orders can be judicially challenged, a company cannot challenge a consent order that it willingly signed.

While some EPA staff have informally suggested in the past that they would seek to ensure that a SNUR is finalized before making a "not likely" finding that allows the PMN submitter to commence manufacture, EPA has not made any public commitment to this approach nor identified any means to ensure this will happen. Nor has it addressed the scenario of what happens in the event of an adverse comment being filed on a direct final SNUR or a judicial challenge to the final SNUR. In contrast to the SNUR-only approach, a consent order includes provisions that bind the PMN submitter, and indirectly its downstream users, to the conditions of the order throughout the interval until a SNUR is promulgated.

iii) *Seeking to address a new chemical's risks through rulemakings rather than orders has several additional downsides.*

While, under an informal agreement with EPA, the Office of Information and Regulatory Affairs (OIRA) does not currently call in SNURs for regulatory review, that agreement could be changed at any point. OIRA has considerable discretion to determine what constitutes a significant regulatory action and is subject to an OIRA-managed interagency review. Such a review would add months to the rulemaking process.

The extent to which President Trump's regulatory executive orders apply to SNURs is highly uncertain. Certain aspects apply to all rules, and the executive orders give OIRA considerable discretion in deciding which provisions apply to which rules. As one example, OIRA could decide that President Trump's 2-for-1 Executive Order would require that two rules be rescinded for each SNUR adopted. Exec. Order No. 13,771, 82 Fed. Reg. 9339 (Jan. 30, 2017).

Administrator Pruitt has included SNURs among the potential regulatory actions that must be logged into his new EPA regulatory database upon initiation, signaling that SNURs may be subject to greater scrutiny under this Administration. Memorandum from Administrator E. Scott Pruitt on Improved Management of Regulatory Actions to EPA Officials (March 24, 2017), https://www.eenews.net/assets/2017/04/04/document_gw_05.pdf (last viewed January 20, 2018).

Finally, the anti-regulatory climate that prevails at present will likely mean that all new proposals to promulgate rules will be closely scrutinized.

D. Incentives and disincentives under a consent order versus a SNUR support EPA's relying on orders instead of relying solely upon SNURs.

If EPA fails to ensure that a final SNUR is in place before it provides a PMN submitter with a "not likely to present an unreasonable risk" determination, and EPA instead makes that determination in advance of a finalized SNUR and allows the submitter to proceed to commence manufacture, that company might have a strong incentive to oppose, seek to delay or weaken, or even judicially challenge a SNUR applicable to its chemical. This is because that SNUR would apply to the submitter and could constrain its future ability to expand use of its new chemical. And because the company would not be subject to a consent order, it would not already be constrained.

Companies have long complained that SNURs "stigmatize" their chemicals, which would also add incentives for the PMN submitter to resist promulgation of a SNUR. The company would have a number of means by which it (or others it could influence, such as a trade association to which it belongs) could seek to prevent, delay or weaken the SNUR, including:

- preventing its issuance as a direct final rule by notifying EPA of its intent to file adverse comments;
- filing adverse comments;

- seeking to have OIRA subject the SNUR to interagency review;
- using its political influence with EPA management, the White House and Congress; and
- challenging the SNUR in court.

In contrast, a PMN submitter subject to a consent order would have significant incentive to support EPA's promulgation of an accompanying SNUR, in order to "level the playing field" with its competitors who are not subject to the order. Only through such a SNUR would its competitors likely be held to most of the same conditions that the submitter is already subject to through the consent order.

The Lautenberg Act contemplates that such SNURs following orders would likely be promulgated, by requiring EPA to either initiate development of the SNUR or publish a statement indicating why one is not necessary within 90 days of issuance of an order. *See* 15 U.S.C. § 2604(f)(4).

In sum, the SNUR-only approach EPA is now adopting differs dramatically from and provides far less risk protection than would result from EPA simply doing what the law requires: issuing § 5(e) orders (or orders or rules under § 5(f)), with SNURs as a supplement.

ARGUMENTS ABOUT OTHER ASPECTS OF THE NEW CHEMICAL PROGRAM

VI. EPA errs in describing the standards it must apply during the § 5 process.

Uncertainty does not default to a "not likely" determination. In its Framework, EPA articulates an approach to "uncertainty" that is overly selective and confuses its actual options under TSCA. Specifically, the Framework contrasts a § 5(a)(3)(A) "presents an unreasonable risk" determination with a § 5(a)(3)(C) "not likely to present an unreasonable risk" determination and concludes that "the level of uncertainty in a reasoned evaluation to inform a 'not likely' determination could be greater than that in an evaluation to inform a 'presents' determination." EPA, New Chemicals Decision-Making Framework (Nov. 7, 2017), https://www.regulations.gov/document?D=EPA-HQ-OPPT-2017-0585-0004. By doing so, EPA ignores that it can also address "uncertainty" by finding that the "information available to the Administrator is insufficient" under § 5(a)(3)(B). 15 U.S.C. § 2604(a)(3)(B). In addition, EPA fails to give adequate consideration to its ability to make a "may present" an unreasonable risk determination under § 5(a)(3)(B), which also can accommodate a degree of uncertainty at least comparable to that accompanying a "not likely" determination. In other words, Congress clearly indicated that if EPA lacks the certainty necessary to make a "not likely" determination, EPA should make a § 5(a)(3)(B) determination and issue a § 5(e) order.

The Framework also errs in suggesting that EPA may find that even where the risk associated with exposure to a new chemical exceeds benchmarks of unreasonable risk traditionally used by the agency, such risks "are not likely to be unreasonable." Specifically, the Framework indicates the following situation may result in a "not likely to present unreasonable risk" determination: "Health and environmental risks are above the appropriate benchmarks, but other risk-related factors—such as severity of endpoint, reversibility of effect, or exposure-related considerations (duration, magnitude, population, etc.)—lead EPA to determine that the risks are not likely to be unreasonable." EPA, New

Chemicals Decision-Making Framework (Nov. 7, 2017), https://www.regulations.gov/document?D=EPA-HQ-OPPT-2017-0585-0004. This proposed strategy and the examples provided are deeply troubling. What type of endpoint is not severe for the people suffering the effect? Why does the reversibility of an effect make the risk of the effect "not likely to present an unreasonable risk"? Is a chemical that causes dizziness, nausea, and eye irritation "not likely to present unreasonable risk" if these effects only occur while or for a short time after an individual is in contact with the chemical? Furthermore, duration and magnitude of exposure are typically integrated into assessments of chemical risks, which are then evaluated against benchmarks. EPA's suggestion that these are "risk-related" factors as opposed to actual risk factors is unclear and seemingly at odds with the basic practices of risk assessment. In short, EPA's proposal to make a "not likely to present an unreasonable risk" determination by ignoring clearly identified potential risks (*i.e.*, exceedances of benchmarks) is wholly inappropriate and not health-protective.

In addition, EPA appears intent on further warping Congressional intent by asserting as a new operating principle that it is redefining "reasonably foreseen" to mean "probable," thereby setting a higher evidentiary bar than Congress intended for EPA to consider conditions of use that are reasonably foreseen. Press Release, EPA, EPA Eliminates New-Chemical Backlog, Announces Improvements to New Chemical Safety Reviews (Aug. 7, 2017), https://www.epa.gov/newsreleases/epa-eliminates-new-chemical-backlog-announces-improvements-new-chemical-safety-reviews ("It is reasonable to foresee a condition of use, for example, where facts suggest the activity is not only possible, but, over time under proper conditions, probable.").[7] But "reasonably foreseen" does not mean "probable." It is well established under the law that "[a] natural and probable consequence is a foreseeable consequence. But to be reasonably foreseeable [t]he consequence need not have been a strong probability; a possible consequence which might reasonably have been contemplated is enough." *People v. Medina*, 46 Cal. 4th 913, 920 (Cal. 2009) (internal citations and quotation marks omitted). Reasonably foreseen is a term of art with a long history in the law, and EPA should turn to the ample precedent interpreting this language to inform implementation of this legal requirement.

VII. EPA must disclose more information for each new chemical substance noticed and reviewed, EPA must implement the requirements of § 14, and EPA must better explain its reasoning for its new chemical determinations.

A. EPA is already committing procedural violations by failing to make complete public files for PMNs electronically available to the general public; EPA must cure those violations.

Under TSCA § 5(d), each PMN "shall be made available, subject to section 14, for examination by interested persons." 15 U.S.C. § 2604(d)(1). EPA's implementing regulations provide that "*[a]ll*

[7] Notably, at the public meeting on December 6, 2017, EPA refused to articulate whether the Framework document overruled the "operating principles" articulated in this press released. See Transcript p. 4, https://www.regulations.gov/document?D=EPA-HQ-OPPT-2017-0585-0042 (finding no discrepancy between operating principles and Framework). Thus, as far as the public knows, this illegal operating principle is still in-force.

information submitted with a notice, including any health and safety study and other supporting documentation, will become part of the *public file* for that notice. . . ." 40 C.F.R. § 720.95 (emphasis added). Those "[p]ublicly available docket materials are available at the address[] in § 700.17(b)(1). . . ." *Id.* Section 700.17(b)(1) states that "[p]ublicly available docket materials are available in the electronic docket at http://www.regulations.gov." *Id.* § 700.17(b)(1). Thus, complete public files must be publicly available in electronic dockets at regulations.gov.

EPA's regulations also require that PMN submitters, if they claim any information in either the PMN or attachments is confidential, "must also provide EPA with a sanitized copy." 40 C.F.R. § 720.40(d)(2); *see also* 720.80(b)(2). Indeed, "the notice review period will not begin until EPA receives the sanitized copy." 40 C.F.R. §§ 720.80(b)(2)(iii); *see also* 720.65(b)(vii) ("[T]he notification period does not begin if *** the submitter does not submit a second copy of the submission with all confidential information deleted for the public file."). Once received, "EPA will place [the] sanitized copy in the public file." *Id.* § 720.80(b)(2)(ii) (emphasis added). Therefore, EPA should not even begin to review a PMN until EPA has received sanitized copies of all materials for public release, and EPA then is required to place those sanitized copies in the public files.

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 upon receipt. EDF previously drew EPA's attention to these regulatory violations, in a letter we sent to EPA on August 16, 2017, and again in our questions submitted on November 20, 2017, more than 150 and 60 days ago, respectively. Richard A. Denison and Robert P. Stockman, letter dated August 16, 2017, to OPPT Director Jeffery Morris, with attached list of questions, http://blogs.edf.org/health/files/2017/11/EDF-LetterQs-for-EPA-on-new-chemicals-8-16-17.pdf; and EDF Questions for Public Meeting on Implementing Changes to the New Chemicals Review Program under Amended TSCA, pp.4-5, https://www.regulations.gov/document?D=EPA-HQ-OPPT-2017-0585-0014. EPA has not yet remedied these violations.

At the December 6, 2017, public meeting on EPA's New Chemical Review Program, EPA stated to EDF and other attendees that "[s]anitized PMNs and their attachments can be requested directly from the EPA Docket Center." So EDF tried this approach, even though it does not fulfill EPA's obligations described above. On December 13, 2017, EDF requested from the docket center "electronic versions of the sanitized Pre-Manufacturing Notices (PMNs), any health and safety studies, and any other supporting documentation associated with each chemical substance for which, since June 22, 2016, EPA has made a finding under § 5(g), in accordance with § 5(a)(3)(C), that the new chemical substance is 'not likely to present an unreasonable risk of injury to health or the environment.'" EDF received a CD from the docket center on December 26, 2017. The CD contained files for 67 PMNs, which EDF has been reviewing.

Both the type of files included for each PMN and the extent of the redaction vary significantly and in ways that seem inconsistent with the disclosure requirements of TSCA §§ 5 and 14, described more below. In many of the PMN files sent to EDF, there were entirely blank documents (or, in one case, each page was entirely blacked out). *See, e.g.*, the file for P-14-0314 (blank); P-17-0016 (blacked out). Even where a list of attachments indicated they contained multiple pages, the corresponding documents

were often limited to a single blank page. *See, e.g.*, the file for P-16-0518. In another PMN file, the attachment documents were blank except for a title left on the pages that were redacted. *See* the file for P-17-0219. Only a handful of the PMN files contained documents that were redacted so that only potentially protectable information was concealed. *See, e.g.*, the file for P-17-0256. There is no consistency in the way these documents were redacted, and although EPA is required to review confidentiality claims, based on the entirely blank pages we received, it seems unlikely that EPA is in fact doing so. *See* 15 U.S.C. § 2613.

One of the most frustrating flaws in the files we received is illustrated by a PMN with a cover letter that stated that six health and safety studies were included with the PMN submission, yet the file we received did not include any such studies. *See* P-14-0314. In another case, a document identified as a 37-page health and safety study listed in the PMN consisted of a single wholly blank page. These results raise a host of concerns. First, were these studies submitted to EPA and then, whether intentionally or unintentionally, not included in the public file, which would be a violation of TSCA? Alternatively, did the company never submit these documents to EPA for review, which in turn also violates TSCA? Whatever the explanation, this experience indicates the utter unreliability and unacceptability of EPA pointing the public to this method for obtaining PMN files.

The redactions within the health and safety studies also varied drastically. While one PMN file included marginally redacted health and studies that contained the descriptions of the study and the results, *see* P-17-0219, another PMN file included health and safety studies that were extensively redacted. *See* P-17-0256. For instance, a section on the "treatment of numerical values" was redacted and six tables referenced in the document are missing from the file, also likely redacted. *Id.*

In addition, the law and EPA's regulations require that the PMNs be available to the public generally (not just EDF) shortly after their receipt, which demands online electronic disclosure. Will EPA commit to promptly making publicly available electronic dockets containing all PMNs, supporting documentation, the results of EPA's PMN reviews, and all consent orders issued for new chemicals reviewed under the new law (with the only information redacted properly subject to confidentiality claims asserted and substantiated under TSCA § 14)?

Among the reasons this public access is so important is that EPA is adopting an approach to reviewing new chemicals under which it argues that the information in a PMN is a sufficient basis for making a regulatory determination that the substance is "not likely to present an unreasonable risk." EPA will then develop a SNUR that is supposed to closely mirror those aspects of the PMN that allowed EPA to make that determination. Without ready and timely public access, there is simply no way for the public to be able to assess whether these assertions by EPA are sufficient and accurate, and to have any faith and trust whatsoever in the approach the agency is taking.

B. EPA needs to implement the requirements of TSCA §§ 14 and 26.

EPA has an affirmative obligation to review at least 25% of non-chemical identity confidentiality claims under TSCA, 15 U.S.C. § 2613(g), and EPA has stated that it is implementing that obligation by "review[ing] every fourth submission received that contains non-chemical identity [confidential business

information (CBI)] claims." EPA REVIEW AND DETERMINATION OF CBI CLAIMS UNDER TSCA, https://www.epa.gov/tsca-cbi/epa-review-and-determination-cbi-claims-under-tsca (last visited Jan. 18, 2018). Thus, on balance, EPA should be reviewing all confidentiality claims asserted in at least approximately one fourth of the PMNs it receives. Most such claims are required to be accompanied by substantiating information at the time they are asserted, *i.e.*, when the PMN is submitted. EPA must complete reviews of confidentiality claims within 90 days of receipt of the claims, and if EPA denies a claim, EPA must disclose the information that had been claimed confidential 30 days after notifying the claimant of the denial, absent a challenge to the denial in district court. 15 U.S.C. § 2613(g)(1)(A), (g)(2)(B). When EPA reviews the confidentiality claims for a PMN, EPA should place both the original sanitized copy and a final, reviewed, and re-sanitized copy in the dockets, along with any documentation of EPA's "determinations" about those confidentiality claims.

TSCA § 14(g) states that EPA's decisions on confidentiality claims are "determination[s]." 15 U.S.C. § 2613(g). In turn, TSCA § 26(j) requires that "[s]ubject to section 14, [EPA] shall make available to the public—all notices, *determinations*, findings, rules, consent agreements, and orders of [EPA] under this title." *Id.* § 2625(j)(1) (emphasis added). Thus, EPA must disclose all its determinations on confidentiality claims. EPA currently is violating that statutory mandate by failing to disclose those determinations. What plan does EPA have to cure these violations by making these determinations, including associated substantiations, available to the public?

In addition, TSCA requires disclosure of "any health and safety study which is submitted under [TSCA] with respect to *** any chemical substance or mixture *** for which notification is required under section 5." 15 U.S.C. § 2613(b)(2)(A). TSCA also requires disclosure of "any information reported to, *or otherwise obtained by*, [EPA] *from* a health and safety study which relates to [such] a chemical substance. . . ." *Id.* § 2613(b)(2)(B) (emphases added). Thus, any health and safety studies and related information on these chemicals must be disclosed. TSCA defines "health and safety study" to mean "any study of any effect of a chemical substance or mixture on health or the environment or on both, including underlying information and epidemiological studies, studies of occupational exposure to a chemical substance or mixture, toxicological, clinical, and ecological studies of a chemical substance or mixture, and any test performed pursuant to this Act." *Id.* § 2602(8). EPA has provided further details on this expansive definition of "health and safety study," explaining that it encompasses, among other things, "[a]ny data that bear on the effects of a chemical substance on health or the environment" and "[a]ny assessments of risk to health and the environment resulting from the manufacture, processing, distribution in commerce, use, or disposal of the chemical substance." 40 C.F.R. § 720.3(k). Thus, any health and safety study or other information on health or environmental effects or any assessment of risk EPA prepared must be disclosed. The only exception from that disclosure requirement is for "information *** that discloses processes used in the manufacturing or processing of a chemical substance or mixture or, in the case of a mixture, the portion of the mixture comprised by any of the chemical substances in the mixture." 15 U.S.C. § 2613(b)(2).

C. EPA needs to implement the Unique Identifier requirement of TSCA § 14(g)(4).

For any chemical identity a company had asserted to be confidential business information in its PMN and for which the company seeks to maintain protection from disclosure upon filing a notice of commencement (NOC), the company again must assert and now substantiate the claim. EPA must review all such claims to determine if they meet the requirements of § 14. 15 U.S.C. § 2613(g)(1)(C)(i). For each such claim EPA approves, EPA must assign a unique identifier, as required under TSCA § 14(g)(4). 15 U.S.C. § 2613(g)(4). EPA has violated that obligation since there is no evidence that EPA is reviewing such claims or assigning unique identifiers. For example, EPA published notice of receipt of 12 NOCs received in November of 2016 that provide only a generic name (suggesting EPA should have reviewed the confidentiality claim for the specific identity, since the 90 days within which EPA must review such claims has by now long passed), 81 Fed. Reg. 91,162, 91,168 (Dec. 16, 2016). EPA's statistics as of January 16th show it has received 420 NOCs since passage of the Lautenberg Act. STATISTICS FOR THE NEW CHEMICAL REVIEW PROGRAM UNDER TSCA, https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/statistics-new-chemicals-review#noc (last visited Jan. 18, 2018). It is impossible to believe that, if indeed EPA has reviewed the claims for all of these chemicals, none had chemical identity confidentiality claims EPA found valid—yet EPA has not publicly assigned a single unique identifier. EPA should cure these violations by assigning unique identifiers as the law requires.

As EDF has previously explained in comments to EPA, the Lautenberg Act expressly requires that EPA create a single, unique identifier for each specific chemical identity and then apply that identifier "consistently to all information relevant" to the chemical substance. *Id.* § 2613(g)(4)(A)(ii). EDF incorporates those comments in full here. *See* EDF, Comments on Assignment and Application of the "Unique Identifier" Under TSCA Section 14, https://www.regulations.gov/document?D=EPA-HQ-OPPT-2017-0144-0007.

To reiterate some of the core statutory points, TSCA § 14(g)(4)(A)(i) provides that EPA must "assign *a* unique identifier to *each specific* chemical identity for which [EPA] approves a request for protection from disclosure." 15 U.S.C. 2613(g)(4)(A)(i). The dictionary definitions of these terms leave no doubt that "each specific chemical identity" must receive a singular "unique identifier," allowing the public to link all non-confidential information related to the chemical substance. "Unique" means "being the only one of its kind; unlike anything else; *** (unique to) belonging or connected to (one particular person, group, or place); *** from French, from Latin *unicus*, from *unus* 'one.'" OXFORD AMERICAN DICTIONARY 1891 (3d ed. 2010). If EPA were to apply multiple identifiers to a single chemical identity, those identifiers would no longer be "unique." "Each" is "used to refer to *every one* of two or more *** things, regarded and identified separately," OXFORD AMERICAN DICTIONARY 544 (3d ed. 2010) (emphasis added), and "specific" means "clearly defined or identified; *** belonging or relating uniquely to a particular subject," OXFORD AMERICAN DICTIONARY 1676 (3d ed. 2010). Thus, for EPA to assign the unique identifier correctly, it must be applied to a unique and clearly defined "chemical identity," and it must be applied only to that chemical identity.

Structurally, "specific chemical identity" has a consistent meaning throughout TSCA, so EPA cannot attempt to define it differently for the purposes of § 14(g)(4) given its established meaning elsewhere, including in the context of the TSCA Inventory process. *See, e.g.*, 15 U.S.C. § 2607(b)(7)(A) (requiring EPA to "make available to the public—each specific chemical identity on the nonconfidential portion of the list published under paragraph (1) along with [EPA]'s designation of the chemical substance as an active or inactive substance").

TSCA also expressly mandates that EPA "apply that identifier *consistently* to *all* information relevant to the applicable chemical substance." 15 U.S.C. § 2613(g)(4)(A)(ii) (emphases added). "All" is "used to refer to the whole quantity or extent of a particular group or thing; *** any whatever." OXFORD AMERICAN DICTIONARY 41 (3d ed. 2010). EPA must also "ensure that *any* nonconfidential information received by [EPA] *** identifies the chemical substance using the unique identifier." 15 U.S.C. § 2613(g)(4)(C) (emphasis added). Both "all" and "any" have expansive meanings, and EPA has no statutory basis for refusing to apply the unique identifier to all information relevant to the chemical substance. *See, e.g.*, *Ali v. Fed. Bureau of Prisons*, 552 U.S. 214, 219 (2008) ("We have previously noted that read naturally, the word 'any' has an expansive meaning, that is, one or some indiscriminately of whatever kind.") (quoting *United States v. Gonzales*, 520 U.S. 1, 5 (1997)) (internal quotation marks and modifications omitted). Applying the plain meaning of § 14(g)(4)'s provisions will accomplish Congress's purpose in including this provision in TSCA: it will become possible for the public to aggregate all non-confidential information about each chemical substance, increasing the public's knowledge about chemical substances and increasing the likelihood that any risks presented by the chemicals might be identified. "A textually permissible interpretation that furthers rather than obstructs the document's purpose should be favored." A. SCALIA & B. GARNER, READING LAW: THE INTERPRETATION OF LEGAL TEXTS 63 (2012).

In addition, § 14(g)(4)(B) requires that EPA "annually publish and update a list of chemical substances, referred to by their unique identifiers, for which claims to protect the specific chemical identity from disclosure have been approved, including the expiration date for each such claim." 15 U.S.C. § 2613(g)(4)(B). Thus, EPA must "list" "chemical substances, referred to by their unique identifiers," indicating that each chemical substance has one unique identifier. This language reinforces that the unique identifier is for the chemical substance, without qualification or restriction. Since over a year and a half have passed since passage of the Lautenberg Act, EPA has already violated this provision by failing to publish the annual list. EPA should cure that violation.

D. EPA's "statement of Administrator findings" required for each "not likely" determination must document EPA's compliance with its statutory obligation to use the "best available science."

When EPA finds that a chemical substance "is not likely to present an unreasonable risk," EPA "shall make public a statement of [EPA's] finding." 15 U.S.C. § 2604(g). Currently, these findings consist largely of boilerplate language, and they are insufficient to establish that EPA is complying with the § 26(h) scientific standards, particularly in light of EPA's regulatory definition for those standards. *See* 40 C.F.R. § 702.33.

Section 26(h) states that in "carrying out sections 4, 5, and 6, to the extent that [EPA] makes a decision based on science, [EPA] shall use scientific information, technical procedures, measures, methods, protocols, methodologies, or models, employed in a manner consistent with the best available science." 15 U.S.C. § 2625(h). EPA has now defined "best available science" to mean:

> Science that is reliable and unbiased. Use of best available science involves the use of supporting studies conducted in accordance with sound and objective science practices, including, when available, peer reviewed science and supporting studies and data collected by accepted methods or best available methods (if the reliability of the method and the nature of the decision justifies use of the data). Additionally, EPA will consider as applicable: (1) The extent to which the scientific information, technical procedures, measures, methods, protocols, methodologies, or models employed to generate the information are reasonable for and consistent with the intended use of the information; (2) The extent to which the information is relevant for [EPA]'s use in making a decision about a chemical substance or mixture; (3) The degree of clarity and completeness with which the data, assumptions, methods, quality assurance, and analyses employed to generate the information are documented; (4) The extent to which the variability and uncertainty in the information, or in the procedures, measures, methods, protocols, methodologies, or models, are evaluated and characterized; and (5) The extent of independent verification or peer review of the information or of the procedures, measures, methods, protocols, methodologies or models.

40 C.F.R. § 702.33. Currently, EPA's statements of findings do not establish that EPA is meeting this best available science standard. For example, the statements do not identify all of the supporting studies or discuss the extent to which those studies have been peer reviewed or independently verified. The statements do not document the clarity and completeness of the underlying data, assumptions, methods, and analyses. The statements do not evaluate and characterize the variability and uncertainty in the information.

EPA needs to publicly release the documents that provide the actual basis (*e.g.*, hazard and exposure/release information) for these findings, and EPA must document that these findings are consistent with the definition of "best available science" that EPA itself has adopted.

For example, EPA may conclude that a new chemical is not likely to present an unreasonable risk of injury to the environment because the amount of the chemical expected to be released into water is below a level of concern. Those levels of release and of concern are not identified in EPA's statements of Administrator findings and in their absence there is no ability for anyone to independently evaluate EPA's finding. It should be further noted that such information constitutes, in many cases, health and safety studies and underlying information as defined under TSCA, which is not eligible for protection as CBI. Will EPA make available (appropriately redacted versions of) the documents generated in its reviews of PMNs?

E. EPA needs to promptly release an updated version of its "category" description document that includes the new categories it has developed, as well as other information about policy decisions regarding new chemicals.

EPA also needs to update or disclose the scientific and policy documents that inform the new chemicals program generally. Multiple legal authorities require the disclosure of these documents. The Freedom of Information Act (FOIA) requires that EPA disclose these documents to the extent they provide statements of procedure, policy, or interpretation, or to the extent that EPA staff rely on these documents when making decisions in the new chemicals program. *See* 5 U.S.C. § 552(a)(2) (requiring, among other things, disclosure of "administrative staff manuals and instructions to staff that affect a member of the public"). TSCA §§ 14 and 26 also require disclosure of many of these materials. In particular, many of these materials are health and safety studies or underlying information which must be disclosed under § 14, as described above.

For example, EPA should share any changes that it has made to the New Chemicals Program under TSCA Chemical Categories Document. EPA should also disclose the new categories that it has been developing, including the information on perfluorinated compounds (PFCs) that it noted in one of the presentations at the public meeting. Tala R. Henry, Chemical Categories slide 8 (Dec. 6, 2017), https://www.epa.gov/sites/production/files/2017-12/documents/presentation_4_and_5_-_categories_sustainable_futures_december_6th_pub.pdf. Much of this information clearly falls within the definition of health and safety studies which must be disclosed.

Based on the August 7 news release and other sources, EPA appears to have made a number of other policy decisions regarding new chemicals, for example, basing "not likely" findings on application of a polymer flag to the Inventory listing, and changes or clarifications to LVE/LoREx exemption request decisions. *See, e.g.*, Press Release, EPA, EPA Eliminates New-Chemical Backlog, Announces Improvements to New Chemical Safety Reviews (Aug. 7, 2017), https://www.epa.gov/newsreleases/epa-eliminates-new-chemical-backlog-announces-improvements-new-chemical-safety-reviews. EPA needs to publicly announce the details of these new policies, along with the legal and scientific justifications for them. To the extent EPA has shared this information with PMN submitters or other industry interests, EPA cannot have any basis for concealing this information from the public.

VIII. EPA needs to make use of its testing authorities to fill data gaps, not just to address already identified risk concerns.

EPA also appears to be re-creating the infamous *Catch-22* of TSCA prior to passage of the Lautenberg Act, under which EPA could only require testing where it already had evidence of at least potential risk. In its August, 2017 operating principles, EPA incorrectly states that the "purpose of testing in a Section 5 order is to reduce uncertainty in regard to risk. Specifically, it is to address risk concerns that gave rise to a finding of 'may present unreasonable risk' or another Section 5 finding other than 'not likely to present unreasonable risk.'" Press Release, EPA, EPA Eliminates New-Chemical Backlog, Announces Improvements to New Chemical Safety Reviews (Aug. 7, 2017), https://www.epa.gov/newsreleases/epa-

eliminates-new-chemical-backlog-announces-improvements-new-chemical-safety-reviews. In fact, testing is also required to fill data gaps and to *identify* risk concerns as well.

While the analogous language in the New Chemicals Framework appears to have been somewhat improved and made more consistent with the law by acknowledging the use of testing to address cases of insufficient information, EPA has yet to clarify which statement—the operating principles issued by Administrator Pruitt or its New Chemicals Framework—applies going forward.[8] Moreover, the Framework still fails to address several core issues related to testing; it mentions testing in only a single bullet. *See* EPA, New Chemicals Decision-Making Framework (Nov. 7, 2017), https://www.regulations.gov/document?D=EPA-HQ-OPPT-2017-0585-0004 ("The purpose of testing in a section 5 order is to reduce uncertainty in making risk determinations. Specifically, it is generally to reduce uncertainty associated with assessments that gave rise to a finding of 'may present unreasonable risk' or to an 'insufficient information' determination."). This discussion leaves many important issues unaddressed. For example, the framework provides no specificity as to how and when EPA intends to use its enhanced information generation authority under the Lautenberg Act.

Section 4 now expressly gives EPA additional testing authority, providing that EPA "may, by rule, order, or consent agreement—require the development of new information relating to a chemical substance or mixture if [EPA] determines that the information is necessary—to review a notice under section 5" or "to implement a requirement imposed in a rule, order, or consent agreement under [5](e) or [5](f)." 15 U.S.C. § 2603(a)(2)(A)(i), (ii).

The framework only refers to testing in the context of issuing a § 5 order. *First*, this limited discussion ignores the Lautenberg Act's express provision of authority during the § 5(a)(3) review process, *before* the implementation of a requirement under § 5(e) or 5(f). Why does the framework ignore EPA's authorities under § 4 to require the development of new information as necessary for the review of § 5 notices?

Second, as discussed above, much of the framework seems designed to evade issuing § 5(e) orders and instead to rely only on SNURs. One significant concern with that approach is that EPA can mandate testing to address insufficient information with a § 5(e) order, but SNURs do not provide this direct authority to require testing. Why is this substantial difference not mentioned in the framework, and how does EPA intend to address it? How will EPA address insufficient information with a SNUR?

[8] Does the framework language now supplant the press release, and if so, when will EPA update and clarify its operating principles it included in the news release? Notably, at the public meeting on December 6, 2017, EPA refused to articulate whether the Framework document overruled the "operating principles" articulated in this press released. See Transcript p. 4, https://www.regulations.gov/document?D=EPA-HQ-OPPT-2017-0585-0042 (finding no discrepancy between operating principles and Framework). Thus, as far as the public knows, this operating principle is still in-force.

IX. EPA needs to consider all "reasonably available information," which under EPA's regulations includes information that EPA can reasonably generate, obtain, and synthesize for use.

In addition, TSCA § 26(k) requires that in carrying out § 5, EPA must consider "[r]easonably available information," and specifically that EPA "shall take into consideration information relating to a chemical substance or mixture, including hazard and exposure information, under the conditions of use, that is reasonably available to [EPA]." 15 U.S.C. § 2625(k). In a recent regulation, EPA interpreted "[r]easonably available information" in § 26(k) to mean "information that EPA possesses or can reasonably generate, obtain, and synthesize for use *** considering the deadlines specified." 40 C.F.R. § 702.33 (promulgated at 82 Fed. Reg. 33,748 (July 20, 2017)). Thus, under its own interpretation, EPA has to consider information that it "can reasonably generate, obtain, and synthesize." *Id.* While that regulation applies to risk evaluations, 40 C.F.R. § 702.31, EPA adopted this interpretation of § 26(k) with the knowledge that it would apply more broadly. *See* 82 Fed. Reg. at 33,731. The Framework does not mention this TSCA § 26(k) obligation, but it undoubtedly applies to the § 5 new chemicals review process.

X. EPA needs to explain how it addresses combined exposures resulting from production by multiple companies.

EPA issues some SNURs that place limitations on the amount of a chemical that can be manufactured and/or released. But it is not clear whether or how EPA accounts for the potential combined risk arising from the activities of multiple companies, each of which is complying with the terms of the SNUR. For example, even where each company complies with a volume limit, the aggregate volume could be of concern if multiple companies start to make or use a chemical. If EPA is accounting for these possible combined effects, EPA needs to articulate how it does so. If EPA is not accounting for these combined effects, EPA needs to explain why it believes they do not present a concern.

XI. EPA's implementation of the new chemical program is skewed too far in industry's direction.

Based on what we have gleaned from press reports, conversations with companies and EPA staff, and agency and industry webinars, EPA's proposed changes and other recent changes to the new chemicals program threaten to cut the public out entirely and turn the program into essentially a service operation for the chemical industry.

First and foremost, EPA appears to be working to avoid at all costs issuing orders or rules regulating new chemicals. This approach is problematic for the reasons discussed above, but two deserve special note here. First, EPA cannot require testing by relying solely on SNURs, so EPA is going to fail to obtain necessary information about new chemicals. Second, once a new chemical is added to the Inventory, if EPA later suspects or identifies an unreasonable risk, absent an order it generally must rely on the much more onerous and time-consuming regulatory processes for existing chemicals in TSCA § 6. In contrast, if EPA regulates a new chemical through an order under § 5 but later determines that it either underestimated or overestimated the risks, EPA can easily tighten or loosen the regulatory requirements. Given the potential for risks to human health and the environment, combined with the

larger procedural and evidentiary hurdles to address under-regulation after market entry, on balance, EPA should take a protective approach to new chemicals. Despite those facts, EPA is doing the opposite.

Second, EPA is taking many steps to act as though the chemical industry is EPA's client. EPA used to argue it was not EPA's role to serve as a coach or consultant to companies to help them "fix" problematic PMNs. Now EPA is routinely doing so, working with companies to iterate their PMNs in order to be able to make "not likely" findings limited to the companies' now-revised intended uses.

For companies that were initially to be subject to an order, we understand EPA is now offering the alternative of a SNUR-only approach. That is, companies get to decide whether, and if so, how, their new chemicals will be regulated.

Where orders in progress required testing, companies have successfully argued for removal of that requirement by noting that the SNUR-only route would not require it. Similarly, companies are successfully arguing for any triggered testing in their orders to be modified to be pended testing, citing other companies' orders that do so.[9]

In addition, according to numerous reports, it is common for PMN submitters to repeatedly provide new and additional information to EPA in response to concerns raised by EPA. EPA has previously identified this iterative process as one source of delay in the PMN review process. *See, e.g.*, OPPT, Presentation on New Chemicals Review Process slide 23 (Dec. 14, 2016), https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0658-0010 (flow diagram depicting the numerous times EPA must go back to the company during the PMN review process); OPPT, Presentation on New Chemicals Review Making the Process More Efficient slide 2 (Dec. 14, 2016), https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0658-0010 ("Having more information in the PMN submission will decrease the back-and-forth between EPA and the submitter, which takes time and resources."). While some additional submissions are to be expected, it bears repeating that companies are legally required to submit much of this material at the outset of the process. *See* 15 U.S.C. §§ 2604(d)(1)(A), § 2607(a)(2)(A)-(D), (F), (G), (d)(1)(B), (d)(1)(C). EPA needs to enforce these requirements and remind companies that failure to submit these materials violates the law; instead, EPA appears to treat the failure to submit these materials as completely excusable with no consequence beyond potential delay in processing the PMN. Among other things, failure to enforce these requirements can ultimately lead to EPA making decisions without all of the relevant and necessary information.

Third, despite claiming a commitment to greater transparency, EPA is taking many steps to share more information with industry than with the general public. For example, EPA has shared numerous written documents with industry to the exclusion of other stakeholders. These include: four or five so-called

[9] Triggered testing is required when a provision in the order (the trigger) is met or exceeded. An order could require a company to conduct a certain test before exceeding a specific production volume, for example. Pended testing is testing that is not required under any provisions of the order and would only be required in order to modify the order.

"category documents" relating to lung toxicity concerns, and drafts of the "points to consider" document.

Simultaneously, EPA also has taken steps to make the PMN process less transparent. Beginning in August of 2017 (around when EPA announced its new operating principles), EPA slowed or ceased updating its online PMN status database (which has existed for many years), depriving the public of its only reasonable means to discern what interim and final decisions the agency is making on new chemicals. EPA then not only reversed earlier changes to the website made to better implement the Lautenberg Act, but actually made the site less transparent than it has been for decades. EDF documented these changes in the following piece: Richard Denison, *Hiding its tracks: The black box of EPA's new chemical reviews just got a whole lot blacker*, EDF HEALTH BLOG (Jan. 4, 2018), http://blogs.edf.org/health/2018/01/04/hiding-its-tracks-the-black-box-of-epas-new-chemical-reviews-just-got-a-whole-lot-blacker/. We incorporate that post and its arguments by reference here. The key change: *EPA will now hide from the public any information about whether the initial review of a new chemical by its professional staff raises any concerns or warrants a more extensive review*.

Through these actions, EPA is returning the new chemicals program to its dark ages under the old TSCA, making it again into a black box within which EPA acts as if its only stakeholder is the chemical industry. EPA should reverse course and implement the new chemicals program in a balanced manner.

XII. EPA cannot legally transfer its duties to the Occupational Safety and Health Administration (OSHA).

In December, an industry group called the TSCA New Chemicals Coalition (NCC), the members of which have not been disclosed, submitted a letter to EPA's new chemicals docket asserting that, when EPA identifies an unreasonable risk to workers presented by a new chemical:

> NCC believes that EPA should disfavor issuing TSCA Section 5(e) orders that mandate use of particular PPE or other workplace-specific measures to mitigate occupational exposure. Instead, the TSCA NCC recommends the following approach if EPA identifies a workplace-specific risk concern:
>
> 1. EPA should consult with OSHA on the workplace risk concern.
>
> 2. EPA should inform the notifier of its assessment and concerns.
>
> 3. After the OSHA consultation and notifier communications are completed, EPA should *no longer engage* but instead rely on the employer's responsibilities mandated by OSHA, as well as OSHA's established expertise and robust existing regulatory program, to ensure worker protection.

TSCA New Chemicals Coalition Letter—OSHA Consultation, (Dec. 1, 2017), https://www.regulations.gov/document?D=EPA-HQ-OPPT-2017-0585-0027 (emphasis added).

Such an approach would be completely illegal, contrary to congressional intent, and unsound as a matter of policy. EPA should reject this recommendation.

A. NCC's assertion that EPA's obligation to consult with OSHA would allow EPA to evade its duties under TSCA § 5 is contrary to the text, structure, and purpose of the Lautenberg Act; it also is contrary to precedent governing consultation.

The text of TSCA does not support NCC's interpretation. TSCA § 5(f)(5) provides, in full:

> (5) WORKPLACE EXPOSURES.—*To the extent practicable*, [EPA] shall *consult* with the Assistant Secretary of Labor for Occupational Safety and Health *prior* to adopting any prohibition or other restriction relating to a chemical substance with respect to which [EPA] has made a determination under subsection (a)(3)(A) or (B) to address workplace exposures.

15 U.S.C. § 2604(f)(5) (emphases added). Nothing in that text supports NCC's suggestion that EPA can or should rely on OSHA to regulate new chemicals in the workplace. Indeed, the text makes it clear that EPA still has its duties under TSCA § 5(e) and 5(f). Specifically, this text instructs EPA, "[t]o the extent practicable," to "consult" with OSHA "prior to [EPA's] adopting any prohibition or other restriction." *Id.* The provision clearly contemplates that *EPA* will still adopt the relevant prohibitions or restrictions; it does not refer to *OSHA* regulating. "Consult" means to "have discussions or confer with (someone), typically before undertaking a course of action." OXFORD AMERICAN DICTIONARY 373 (3d ed. 2010). In other words, EPA should seek advice from OSHA, but EPA still has an obligation to "undertak[e] a course of action." *Id.*

Moreover, consistent with this plain language reading, the legal precedent interpreting obligations "to consult" makes clear that, when one agency must consult with another, the underlying obligation to comply with the law remains with the original "action agency" (here, EPA). The action agency must consider the input of the consultant agency, but the requirement to consult does not allow the action agency to transfer its obligations to the consultant agency. Thus, even when an agency has an obligation to consult with another agency, "the ultimate responsibility for compliance with the [statutory mandate] falls on the action agency," and "the action agency must not blindly adopt the conclusions of the consultant agency, citing that agency's expertise." *City of Tacoma v. FERC*, 460 F.3d 53, 76 (D.C. Cir. 2006).

Thus, even after consulting with OSHA, EPA retains its obligation under TSCA § 5(e)

> to prohibit or limit the manufacture, processing, distribution in commerce, use, or disposal of such substance or to prohibit or limit any combination of such activities to the extent necessary to protect against an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by [EPA] under the conditions of use.

15 U.S.C. § 2604(e). Nothing in that language allows EPA to transfer that duty to OSHA or to consider *potential* OSHA regulations and enforcement as an alternative to EPA's duty to regulate. Notably, the qualifier "to the extent practicable" appears in the clause requiring consultation, but no similar qualifier appears in EPA's mandates under TSCA § 5(a)(3), (e), or (f). In such circumstances, to the extent there is any tension between the consultation duty and the affirmative mandates in the other provisions, the consultation duty must give way. *Cf. Oceana, Inc. v. Locke*, 670 F.3d 1238, 1243 (D.C. Cir. 2011).

Structural elements of TSCA and the reforms made by the Lautenberg Act also strongly counsel against NCC's interpretation of this duty. As discussed above at pp. 6-7, the Lautenberg Act introduced an additional new term of art to TSCA, "potentially exposed or susceptible subpopulation," and incorporated that term into the § 5 process by requiring that EPA protect against unreasonable risks to such subpopulations. *See* Lautenberg Act, Pub. L. No. 114 182, § 3(12), § 5(a)(3)(A) (June 22, 2016) (codified at 15 U.S.C. §§ 2602(12), 2604(a)(3)(A) respectively). The Lautenberg Act expressly identifies "workers" as a "potentially exposed or susceptible subpopulation." 15 U.S.C. § 2602(12). Congress' decision to retain and extend additional protection to workers is wholly inconsistent with NCC's assertion that EPA can or should transfer that obligation to OSHA.

B. The text of the Occupational Safety and Health (OSH) Act plainly does not preempt TSCA.

NCC strangely relies on the preemption language of the OSH Act, but that language clearly does not preempt other federal laws; it does the opposite. The Supreme Court has interpreted the language in § 4(b)(1) of the OSH Act to mean that the "coverage of the [Occupational Safety and Health] Act does not extend to working conditions that are regulated by other federal agencies." *Chao v. Mallard Bay Drilling, Inc.*, 534 U.S. 235, 241 (2002). NCC is incorrect to suggest that EPA cannot regulate where Congress has granted EPA authority to act merely because it has been in OSHA's "domain" for a long time. Rather, the Supreme Court has stated that OSHA is preempted where other federal agencies have "exercise[d]" their authority, and the Court did not indicate that, when deciding whether to exercise authority, the other federal agency would have to consider the length of time OSHA has acted in that domain. Of course, "OSHA is only pre-empted if the working conditions at issue are the particular ones 'with respect to which' another federal agency has regulated, and if such regulations 'affect occupational safety or health.'" *Id.*

In any event, TSCA has provided EPA with the authority to regulate chemical exposures in workplaces since its first passage in 1976, and EPA has regularly exercised that authority. Given that long history of regulation, if Congress meant to withdraw that authority, it would have done so clearly. But to the contrary, as explained above, the Lautenberg Act not only retained that authority that overlaps with OSHA's, it *strengthened* that authority, by explicitly identifying workers as a "potentially exposed or susceptible subpopulation."

C. TSCA § 5(e) orders have numerous advantages as compared to protection through OSHA's general provisions.

TSCA § 5 orders have important advantages from a worker protection standpoint compared with efforts to enforce general OSHA provisions. Two OSHA provisions are primarily relevant here: the OSH Act's

General Duty clause and the respirator standard. The General Duty clause requires each employer to provide a workplace that is free of recognized hazards that are likely to cause death or serious physical harm. 29 U.S.C. § 654(a)(1) ("Each employer shall furnish to each of his employees employment and a place of employment which are free from recognized hazards that are causing or are likely to cause death or serious physical harm to his employees."). OSHA can enforce this requirement, but employers may argue that OSHA must prove, among other things, that the new chemical presents a serious hazard to employees in the conditions present in the workplace, that this hazard is "recognized" by the employer or generally by experts familiar with the issue, and that there is a feasible means by which the employer could eliminate or reduce the hazard. The "recognized" element could be particularly difficult to prove in the context of new chemicals. In sum, OSHA faces a heavy, resource-intensive burden potentially requiring lots of expert testimony. Moreover, under the OSH Act, an employer may not be required to correct a violation alleged by OSHA until the completion of administrative proceedings before an independent agency, the OSH Review Commission. *See* 29 U.S.C. § 659(b). These proceedings can take years.

NCC also asserts that the respirator standard is relevant here. TSCA New Chemicals Coalition Position Statement - OSHA Consultation, at p. 4 (Dec. 2017), https://www.regulations.gov/document?D=EPA-HQ-OPPT-2017-0585-0028 (emphasis added). There are several problems with NCC's suggestion that this respirator standard provides protections equivalent to TSCA § 5(e) orders. The respirator standard first requires an employer "to prevent atmospheric contamination" "as far as feasible by accepted engineering control measures," but "[w]hen effective engineering controls are not feasible, or while they are being instituted, appropriate respirators shall be used pursuant to this section." 29 C.F.R. § 1910.134(a)(1). The respirator standard then requires that "[a] respirator shall be provided to each employee when such equipment is necessary to protect the health of such employee." *Id.* § 1910.134(a)(2). If OSHA seeks to prove a violation of this standard, many employers would respond that OSHA must prove that the new chemical was hazardous at the level found in the employer's workplace. And proving that would not necessarily establish the specific exposure maximum going forward. The respirator standard does not include any specific requirements for monitoring exposures such as are found in OSHA's standards for individual chemicals. The respirator standard requires that the employer "identify and evaluate the respiratory hazard(s) in the workplace; this evaluation shall include a reasonable estimate of employee exposures to respiratory hazard(s)." *Id.* § 1910.134(d)(1)(iii). If an employer were proven not to be making a reasonable estimate, OSHA could order the employer to do, but this would not necessarily require any specific procedure. The absence of specific exposure limits and monitoring requirements are major disadvantages compared with a TSCA § 5(e) order from an enforcement perspective.

EPA can issue a TSCA § 5(e) order that eliminates any question about whether the chemical presents a recognized hazard and can set the exposure level to eliminate any unreasonable risk. The TSCA § 5(e) order can also mandate the specifics of monitoring, respiratory protection, and ancillary measures needed to protect the workers who could be exposed to the chemical. The analogous OSHA provisions are more general. Even if OSHA proved that an employer's practices violated these general provisions,

the resulting abatement order would not necessarily establish the specific practices the employer must follow in the future.

The NCC letter suggests that EPA's hazard and risk assessments of the new chemical would have the effect of "triggering" the OSHA requirements. OSHA could make use of the EPA findings, but it would still have the burden of proof if an employer contested the above issues. OSHA can only enforce its own requirements, and EPA assessments would not be determinative.

D. Congress refused to adopt the OSH Act risk standard and instead embraced TSCA's more stringent unreasonable risk standard; as a result, OSHA cannot protect workers to the extent that TSCA requires.

NCC knows full well that OSHA's risk standard—"no significant risk of material harm"—is, as a practical matter, more lenient than TSCA's unreasonable risk standard. *See, e.g.*, *N. America's Bldg. Trades Unions v. OSHA*, 2017 U.S. App. LEXIS 26315, *8 (D.C. Cir. 2017) ("Before OSHA promulgates any permanent health or safety standard, it must make a 'threshold finding' that 'it is at least more likely than not that long-term exposure' to the regulated substance at current exposure levels 'presents a significant risk of material impairment' that 'can be eliminated or lessened by a change in practices.'") (quoting *Industrial Union Department, AFL-CIO v. American Petroleum Institute (Benzene)*, 448 U.S. 607, 642, 653(1980)). Many in the industry for years argued (unsuccessfully) in the debate over TSCA reform to use the OSHA standard instead of the unreasonable risk standard that Congress retained. As interpreted by the courts and subsequently implemented by OSHA, the OSHA standard allows risk to workers that are multiple orders of magnitude higher than those EPA would consider constitute unreasonable risks.

If NCC believes that OSHA's standard should apply to any new chemical risks EPA drops into OSHA's lap, then workers would receive far less protection under NCC's proposed approach. If on the other hand NCC believes TSCA's risk standard would still apply in such cases, how does it expect OSHA to use its limited authority to achieve this far more stringent standard?

OSHA itself acknowledges the severe limitations to its authority. For example, OSHA notes that its standard-setting system is broken, and in fact it has been able to issue standards for only 39 agents since 1971 (and only three in the last 15 years):

> OSHA recognizes that many of its permissible exposure limits (PELs) are outdated and inadequate for ensuring protection of worker health. Most of OSHA's PELs were issued shortly after adoption of the Occupational Safety and Health (OSH) Act in 1970, and have not been updated since that time.

The Government Accountability Office (GAO) affirmed this state of affairs in a 2012 reported titled "Multiple Challenges Lengthen OSHA's Standard Setting." OSHA attributed its lack of action in this area, in part, to the legal requirements it must meet under the OSH Act, as interpreted by the courts. 79 Fed. Reg. 61,384, 61,386 (Oct. 10, 2014). Any reasoned decision to refer any identified risks of new chemicals to OSHA would have to account for this 40-year history and explain why it would be reasonable to

expect OSHA to take effective action on these chemicals in a reasonable timeframe, as informed by the 90- or 180-day deadlines governing new chemical review.

OSHA also lacks authority (not to mention capacity) to protect workers to the extent that EPA must do so under TSCA's new chemicals program. As just one example, OSHA has no authority to mandate that companies test their chemicals. If OSHA needs data on chemical hazards, it must request, through the Interagency Testing Committee, that EPA require the testing under TSCA. That process has rarely gone well or quickly. In 1991, OSHA requested through the ITC that EPA require a simple dermal absorption test to be conducted on 658 chemicals for which it had concerns about worker exposure. Thirteen years later, EPA finally issued the rule—covering only 34 of those chemicals. *See* 69 Fed. Reg. 22402 (May 26, 2004).

E. Giving weight to an OSHA action that is not finalized and legally in-force would be arbitrary and capricious.

In addition, as a matter of law, for EPA to reasonably rely on actions that might be able to be taken by OSHA to make a TSCA section 5(c)(3) determination, those OSHA actions could not be speculative and theoretical. Before it could make a determination, EPA would need to wait for OSHA to actually act. (This need applies for the same reasons that EPA cannot rely on non-finalized SNURs, discussed above at pp. 15-16.) That process would be time-consuming, but if NCC truly believed the theory it is espousing, then it would also accept that EPA could not issue a final determination on a new chemical until OSHA took final action, even if that delayed an EPA finding for weeks, months, or years. NCC's theory that EPA could simply "no longer engage" has no basis in TSCA or the plain meaning of "consult."

Congress expressly gave EPA greater authority to regulate chemicals in the workplace with the Lautenberg Act. Nothing in the Lautenberg Act would justify EPA ceding its authority and transferring its obligations over to a far weaker agency. EPA should reject this proposal.

* * * * *

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