Environmental Defense Fund
Comments on
Updated Working Approach To Making New Chemical Determinations
Under the Toxic Substances Control Act (TSCA)
Docket ID: EPA–HQ–OPPT–2019–0684

Submitted February 18, 2020

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 "TSCA New Chemical Determinations: A Working Approach for Making Determinations under TSCA Section 5" (the "Working Approach").[1]

These comments are organized as follows:

- Legal and factual background on changes made to TSCA Section 5 by the Lautenberg Act and on EPA's initial implementation and new changes.
- Arguments against EPA's SNUR-only approach.
- Arguments about EPA's failure to protect workers.
- Arguments about other aspects of the New Chemicals Program.

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[1] Available at https://www.regulations.gov/document?D=EPA-HQ-OPPT-2019-0684-0002.

LEGAL AND FACTUAL BACKGROUND

1. 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*
> (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 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
> (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.

2. 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.[2]

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 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).

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[2] *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 Feb. 12, 2020) (view tab "Statistics Prior to June 22, 2016").

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,[3] 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 respect to which [EPA] has made a determination under

[3] U.S. EPA, *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."); U.S. EPA, *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.").

> [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.[4]

3. EPA's initial implementation and new 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.

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[4] *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.

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,[5] as of August 7, 2017, when Administrator Pruitt reported that the backlog was eliminated.[6]

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

B. Citing the backlog, EPA adopted a new, illegal approach that resulted in fewer orders and less protection against unreasonable risks.

Unfortunately, that backlog (despite having been eliminated) became an excuse to weaken the new chemicals review program. On the very same day (August 7, 2017) that EPA announced the end of the backlog, EPA announced its intention to implement new policies going forward that violate the law.[7] 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.

EPA's November 2017 "New Chemicals Decision-Making Framework"[8] and other public statements[9] indicated that, going forward, EPA would 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 especially 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 indicates it will instead use a SNUR as "an effective and efficient way to address *reasonably foreseen conditions*

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[5] Nonetheless, as discussed below, EPA's early implementation violated certain other statutory and regulatory provisions regarding transparency and public involvement, problems that remain today. EPA should cure those violations.

[6] 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.

[7] *Id.*

[8] U.S. EPA, New Chemicals Decision Making Framework (Nov. 2017), https://www.regulations.gov/document?D=EPA-HQ-OPPT-2017-0585-0004.

[9] *Id.*; 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 Feb. 12, 2020).

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)."[10] In other words, even when EPA has "concerns" about the "reasonably foreseen conditions of use," as long as it does not have concerns about the intended 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 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 relies on SNURs so that it can "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).

C. EPA's new document does not resolve these concerns; it continues EPA's illegal SNUR-only approach and introduces new concerns as well.

Crucially, EPA's new document—TSCA New Chemical Determinations: A Working Approach for Making Determinations under TSCA Section 5 (the "Working Approach")[11]—updating the 2017 Framework continues this approach and does not eliminate any of the concerns just discussed. In this Working Approach, EPA states that:

> Where EPA identifies reasonably foreseen conditions of use associated with a new chemical notice, but *lacks sufficient information* to perform a reasoned evaluation and/or *has identified potential risks* associated with those conditions of use, EPA may consider whether a SNUR would address those concerns. Specifically, prior to making a determination under TSCA section 5(a)(3), EPA may consider proposing a SNUR designating those reasonably foreseen conditions of use as significant new uses. Where EPA does not identify risks associated with the known or intended conditions of use during its review of a PMN, proposal of a SNUR enables the Agency to make a "not likely to present an unreasonable risk" determination on the notice while ensuring that any manufacturing or processing activity outside of the known and intended conditions of use would first be subject to closer scrutiny by EPA through

[10] 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 Feb. 3, 2020) (emphases added).
[11] U.S. EPA, TSCA New Chemical Determinations: A Working Approach for Making Determinations under TSCA Section 5 (Dec. 2019), https://www.regulations.gov/document?D=EPA-HQ-OPPT-2019-0684-0002.

> submission of a SNUN. In the absence of the SNUR, such a determination by EPA would not be possible.[12]

Thus, even where EPA makes a finding of insufficient information or potential risk about reasonably foreseen uses, which requires it to issue an order under TSCA § 5(a)(3)(B), EPA plans to issue a SNUR, and on that basis, avoid issuing the order. If there were any doubt that EPA intends to use SNURs in this manner, that doubt is eliminated by other parts of the Working Approach where EPA notes that "SNUR Considerations" can allow it to "address information insufficiencies and/or risk concerns associated with a reasonably foreseen condition of use." Working Approach at p.11. EPA openly acknowledges that it may make a "not likely" finding based on having proposed or finalized a "SNUR that would require review and regulation (if appropriate) of reasonably foreseen conditions of use that might otherwise present unreasonable risks or for which the Agency lacks sufficient information to conduct a reasoned evaluation." *Id.* at p.13. And EPA suggests that "present," "may present," or "insufficient information" findings depend, in part, on whether EPA has not proposed or finalized a SNUR. *See id.* at pp.13-14.

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* Working Approach at p.9 ("Where the submitters provide written amendments to their submission, EPA generally identifies the conditions of use in those amended submissions to be the new intended conditions of use, where appropriate."). But it bears noting that PMNs, standing alone, are not legally binding on the submitter; absent a final SNUR that is fully in effect and identifies as significant new uses any conditions of use beyond those identified in the PMN, a submitter can at any time engage in those conditions of use 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 the conditions of use under section 5(a)(3)(C)."[13] One result will be that EPA will no longer issue *binding* orders to address even intended conditions of use

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[12] U.S. EPA, *TSCA New Chemical Determinations: A Working Approach for Making Determinations under TSCA Section 5* p.6 (Dec. 2019), https://www.regulations.gov/document?D=EPA-HQ-OPPT-2019-0684-0002 (hereinafter the "Working Approach").

[13] 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 Feb. 2, 2020).

under TSCA § 5(e) since these orders can only be issued as part of the PMN 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 at the outset, 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 (or rules) 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."[14] As explained below, "reasonably foreseen" does not mean "probable."

D. The consequences of EPA's approach are a dramatic and unwarranted increase in unconditioned approvals of new chemicals.

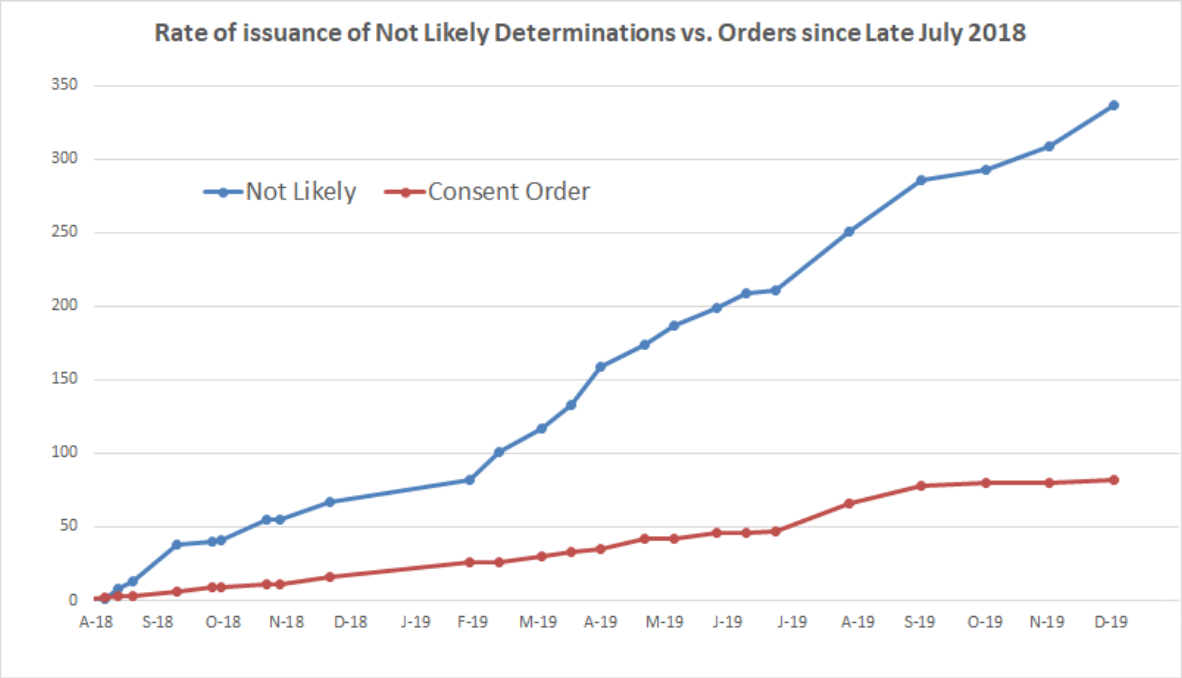
The result of the changes EPA has made has been dramatic. The new policies began to be applied in earnest in late July 2018. Since that time, the vast majority of new chemicals reviewed by EPA have been approved by EPA, receiving "not likely" determinations. In what are becoming relatively rare instances, EPA still sometimes negotiates a consent order with a company, and follows it up with a SNUR – the process that the 2016 reforms to TSCA set out as the primary path but that EPA has rendered an increasingly uncommon exception.

In the period since late July 2018:

- EPA issued "not likely" determinations for 297 PMNs.
- EPA finalized 88 consent orders for PMNs. Of these, however, many were already in motion before EPA's policies changed. Excluding these, EPA has finalized 68 consent orders.
- Hence, "not likely" determinations represent 81% of the final determinations EPA has made for PMNs in that time period, while consent orders represent 19%.

[14] 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.

The chart below shows the rate at which EPA has been issuing "not likely" determinations compared to consent orders between late July 2018 and January 2020, based on EPA's own tracking statistics[15] that we have compiled over time:



ARGUMENTS AGAINST EPA'S SNUR-ONLY APPROACH

4. 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

[15] USEPA, Statistics for the New Chemicals Review Program under TSCA, available at https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/statistics-new-chemicals-review#stats.

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 each PMN 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 can only make a "not likely to present an unreasonable risk" finding based on its review of 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).

Throughout the Working Approach, EPA misstates what TSCA requires, suggesting that EPA may make a "not likely" finding based solely on "known or intended" conditions of use. Working Approach at p.6. This ignores the requirement that EPA consider "reasonably foreseen" conditions of use when making a determination under TSCA § 5(a)(3)(C). And in those circumstances where a "reasonably foreseen" condition of use may present a risk or has insufficient information for evaluation, EPA must make the determination required by TSCA § 5(a)(3)(B) and issue an order under TSCA § 5(e). This statutory directive is directly contrary to EPA's suggestion that it can make such a finding and issue a SNUR instead of an order. *See* Working Approach at pp.6, 13-14. Similarly, when EPA states that "[i]n the absence of the SNUR, [a Not Likely] determination by EPA would not be possible," *id.*, EPA essentially concedes that it should be issuing a different finding because the statute does not in any way suggest that EPA's findings under TSCA § 5(a)(3) should depend on SNURs.

On page 7 of the Working Approach, EPA poses a question that highlights that it is ignoring the statutory requirements. EPA indicates that part of its inquiry is: "Can EPA address information deficiencies or risk concerns for reasonably foreseen conditions of use through the issuance of a SNUR?" Working Approach at p.7. Similarly, EPA repeatedly states that it will not make certain findings under TSCA § 5(a)(3)—such as "presents an unreasonable risk," "insufficient information," or "may present a risk"—for reasonably foreseen conditions of use if EPA has proposed or finalized a SNUR. *See* Working Approach at pp.12-14. But this approach has no basis in the statutory text; nothing suggests that issuing a SNUR should modify the findings that EPA makes under TSCA § 5(a)(3). Rather, the text links these circumstances with EPA making a determination under TSCA § 5(a)(3) and issuing an order under TSCA § 5(e) or an order or rule under § 5(f).

In sum, nothing in the text of TSCA 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 in subsection D., 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 and address comments received before issuing the final rule. These timing provisions also counsel against EPA's SNUR-only approach.

In fact, as outlined below in subsection D.i., EPA has never once promulgated a SNUR *before* making its "not likely" finding, despite EPA's mischaracterizing certain SNURs as "preced[ing] 'not likely' determinations." Working Approach at p.6.

Third, and more broadly, the text and structure of TSCA are built around the analysis of chemical substances as a whole, not just a subset of conditions of use of chemical substances,[16] 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.

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.

[16] 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.").

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 introduces several *additional* legal problems that make it even more illegal than relying on finalized, legally in-force SNURs. Throughout the Working Approach, EPA indicates that it relies on non-final SNURs. Working Approach at p.6 (describing "SNURs that precede 'Not Likely' determinations" as "EPA *may consider* whether a SNUR would address those concerns"); *id.* at p.13 (stating that a "not likely" determination can turn on whether "EPA has *proposed* or finalized a SNUR.") (emphases added). EPA's reliance on non-finalized SNURs is illegal and arbitrary and capricious.

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, even if they were otherwise legal (which they are not), EPA could not rely on SNURs until they were fully promulgated through notice-and-comment and were 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 the additional APA problems discussed above.

i. As a factual matter, EPA never finalizes a SNUR before making the related "not likely" finding.

In its Working Approach (p. 6) EPA states that one category of SNURs it relies on are "SNURs that Precede "Not Likely" Determinations." Based on our review, not a single final SNUR has been issued for any of the hundreds of new chemicals receiving "not likely" determinations prior to the dates of those determinations.

Being charitable, we thought perhaps EPA meant that it proposes the SNURs prior to making the "not likely" determinations. So we compared the dates of the determinations with the dates on which the corresponding SNURs were proposed. Here's what we found:

As of February 18, 2020, since the 2016 reforms to TSCA, EPA has proposed SNURs for 70 new chemicals receiving "not likely" determinations where EPA's determination indicates it was *based on* issuance of the SNUR. Of those 70 chemicals:

- For 59 of them (84%), the date of the SNUR proposal followed the date of the determination, lagging behind by anywhere from 4 to 61 days.
- Only for 11 of them (16%), did the date of SNUR proposal precede the date of the determination.
- For only 13 of these 70 chemicals has EPA finalized a SNUR – and those came a whopping 178 days after their "not likely" determinations were made. For the remaining 57 chemicals, EPA has not finalized a SNUR even now, much less before making the "not likely" determination.

Given that EPA never promulgates SNURs that precede its "not likely" determinations, it is not clear why EPA describes these SNURs as preceding "not likely" determinations.

ii. Failing to finalize the SNUR before issuing the "not likely" also has negative policy consequences.

If there is a significant lag between EPA's "not likely" determination and the issuance of a SNUR, all kinds of problems arise, which EDF has discussed previously: See EDF blog post

(Nov. 30, 2017), *Too little, too late: Why SNURs alone are not a sufficient alternative to consent orders for new chemicals*," http://blogs.edf.org/health/2017/11/30/too-little-too-late-why-snurs-alone-are-not-a-sufficient-alternative-to-consent-orders-for-new-chemicals/. To name two:

- If a company engages in what EPA plans to deem a "significant new use" during the gap between the determination and at least proposal of a SNUR, then EPA likely cannot subject that use to the notification requirements of the SNUR because the use is "ongoing" and no longer "new." That includes a new use engaged in by the company that got a green light for its chemical based on EPA's review of only its intended conditions of use.
- Such a company that wants to have the ability to engage in uses beyond those it said it initially intended would have serious incentives to seek to avoid having EPA issue the SNUR. Because SNURs are done through rulemaking, the company can urge EPA to block or modify the SNUR through the rulemaking process. It can also apply pressure on EPA not to pursue a SNUR at all.

5. EPA's "SNURs that follow 'Not Likely' determinations" also present concerns.

A. EPA's "SNURs that follow 'Not Likely' determinations" also should have been preceded by TSCA § 5(e) orders because they are generally addressing risks or information gaps posed by reasonably foreseen uses.

EPA describes a second category of "SNURs that follow 'Not Likely' Determinations" and asserts that the SNURs are addressing circumstances that are allegedly "not reasonably foreseen." *See* Working Approach at p.7. However, in such cases EPA essentially always is addressing circumstances that *are* reasonably foreseen, properly interpreted. As explained below in section 12.C., EPA has adopted an illegal interpretation of "reasonably foreseen," rendering it too narrow and overlooking many reasonably foreseen circumstances. 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). Many of the circumstances addressed by EPA's SNURs that follow "not likely" determinations are in fact "possible consequence[s] which might reasonably have been contemplated." *Id.* Because these circumstances are reasonably foreseen, EPA should be analyzing them when making an initial determination about the chemical, and where insufficient information exists or one or more of these circumstances may present a risk, EPA should be issuing the order required by TSCA § 5(a)(3)(B).

B. EPA has failed to issue such SNURs even where they are clearly warranted by the underlying information.

EPA's approach to "SNURs that follow 'not likely' determinations" is arbitrary and capricious because EPA fails to issue such SNURs in numerous circumstances where they appear warranted, without explaining why EPA believes a SNUR is unnecessary. Below we provide examples of PMNs where EPA should have issued an order that identified certain conditions of use as reasonably foreseen. Moreover, even under EPA's "follow on" approach, EPA should have issued a follow-on SNUR because the evidence establishes that there are circumstances which "should they occur in the future" may present risk concerns, or about which EPA appeared to have insufficient information. This arbitrary approach to "follow on" SNURs leaves both PMN submitters and the public with no way to understand EPA's rationale for adopting SNURs in some but not other cases.

- P-17-0322:
  - EPA made its Not Likely Determination on September 18, 2018.
  - EPA found that the chemical presents moderate environmental hazard and is very likely to migrate to groundwater. EPA did not identify any environmental risk because EPA "expects" that surface water concentrations will not exceed the acute and chronic concentrations of concern (COCs). In these circumstances, EPA should have analyzed the "reasonably foreseen" circumstance that the surface water concentrations exceed the COCs, and EPA likely should have issued a TSCA § 5(e) order to address these environmental concerns. But even if for the sake of argument one were to agree with EPA that these circumstances are not "reasonably foreseen," such a case would still meet EPA's criteria under its "follow on" approach and would warrant issuance of a SNUR for the potential circumstance where concentrations do exceed the COCs.
  - EPA found no risk to workers based on the solution concentrations identified in the PMN, which were part of the intended COU: "Manufacture in solution at a concentration of approximately [claimed CBI] and process to a concentration of approximately [claimed CBI] for industrial use as an optical brightener in paper applications." EPA has provided no rationale for why it is not reasonably foreseeable that the chemical would be manufactured at higher concentrations, let alone explained why EPA did not issue a SNUR under its "follow on" approach to address such the circumstances.
- P-18-0132:
  - EPA made its Not Likely Determination on February 26, 2019.
  - The PMN states that the company intends only to import the chemical, but the company has nine manufacturing sites in the United States.[17] On what basis is

[17] CABOT WORLDWIDE LOCATIONS, http://www.cabotcorp.com/company/worldwide-locations (last visited Feb. 12, 2020) (filter by "manufacturing").

domestic manufacturing not a reasonably foreseen use? If such manufacturing were to occur, on what basis does EPA know that this activity would be not likely to present unreasonable risk?

- EPA found that the chemical presents moderate environmental hazard and is very likely to migrate to groundwater. EPA did not identify any environmental risk because EPA assumed that surface water concentrations would not exceed the acute and chronic COCs. In these circumstances, EPA should have analyzed the "reasonably foreseen" circumstance that the surface water concentrations exceed the COCs, and EPA likely should have issued a TSCA § 5(e) order to address these environmental concerns. But even if for the sake of argument one were to agree with EPA that these circumstances are not "reasonably foreseen," such a case would still meet EPA's criteria under its "follow on" approach and would warrant issuance of a SNUR for the potential circumstance where concentrations do exceed the COCs.

- P-18-0277:
  - EPA made its Not Likely Determination on February 28, 2019.
  - EPA found that the chemical presents moderate environmental hazard and is very likely to migrate to groundwater. EPA did not identify any environmental risk because EPA assumed that surface water concentrations would not exceed the acute and chronic COCs. In these circumstances, EPA should have analyzed the "reasonably foreseen" circumstance that the surface water concentrations exceed the COCs, and EPA likely should have issued a TSCA § 5(e) order to address these environmental concerns. But even if for the sake of argument one were to agree with EPA that these circumstances are not "reasonably foreseen," such a case would still meet EPA's criteria under its "follow on" approach and would warrant issuance of a SNUR for the potential circumstance where concentrations do exceed the COCs.
  - EPA also stated that the "risk for lung surfactancy for workers was not assessed because inhalation exposures are negligible," but EPA never explains why exposures are expected to be negligible. Is it not reasonably foreseeable that there inhalation exposures may be higher especially if someone other than 3M manufactures or processes the chemical? Is EPA assuming use of Personal Protective Equipment (PPE) or engineering controls in deciding that inhalation exposures will be negligible? If so, should not EPA consider the reasonably foreseen circumstance that, in the absence of any binding requirement, 3M or other manufacturers and users might not use the same engineering controls and PPE? EPA likely should have issued a TSCA § 5(e) order to require such engineering controls and PPE. But even if for the sake of argument one were to agree with EPA that these circumstances are not "reasonably foreseen," such a case would still meet EPA's criteria under its "follow on" approach and would warrant issuance of a SNUR for the potential circumstance where persons fail to use engineering controls or PPE.

- Also, this chemical is an acrylate, and EPA has generally been proposing SNURs for other acrylates, and in them establishing as a significant new use the failure to use a respirator with an APF of 1000 for spray applications; e.g., see proposed SNURs for P-18-0169 and P-18-0279. It is not at all clear why EPA did not propose a follow-on SNUR for this chemical at all, when it should have done so and specified as a SNU the failure to use a respirator with an APF of 1000 for spray applications.

- P-18-0241, 244, 245:
  - EPA made its Not Likely Determination on June 30, 2019.
  - EPA found that the chemical presents moderate environmental hazard, but EPA did not identify any environmental risk because EPA assumed that the acute and chronic COCs would not be exceeded by surface water concentrations. In these circumstances, EPA should have analyzed the "reasonably foreseen" circumstance that the surface water concentrations could exceed the COCs, and EPA likely should have issued a TSCA § 5(e) order to address these environmental concerns. But even if for the sake of argument one were to agree with EPA that these circumstances are not "reasonably foreseen," such a case would still meet EPA's criteria under its "follow on" approach and would warrant issuance of a SNUR for the potential circumstance where surface water concentrations do exceed concentrations of concern.
  - EPA states: "Risks were not evaluated for workers via inhalation exposure since inhalation exposures were expected to be negligible," but EPA never explains why these risks are considered negligible. Is EPA assuming use of Personal Protective Equipment (PPE) or engineering controls in deciding that inhalation exposures will be negligible? If so, should not EPA consider the reasonably foreseen circumstance that, in the absence of any binding requirement, the PMN submitter or some other manufacturers and users might not use the same engineering controls and PPE? EPA likely should have issued a TSCA § 5(e) order to require such engineering controls and PPE. But even if for the sake of argument one were to agree with EPA that these circumstances are not "reasonably foreseen," such a case would still meet EPA's criteria under its "follow on" approach and would warrant issuance of a SNUR for the potential circumstance where persons fail to use engineering controls or PPE.
  - Also, this chemical is an acrylate, and EPA has generally been proposing SNURs for other acrylates, and in them establishing as a significant new use the failure to use a respirator with an APF of 1000 for spray applications; e.g., see proposed SNURs for P-18-0169 and P-18-0279. It is not at all clear why EPA did not propose a follow-on SNUR for this chemical at all, when it should have done so and specified as a SNU the failure to use a respirator with an APF of 1000 for spray applications.

C. When EPA does develop SNURs, it is often unclear why certain notifications are included in some but not other relevant SNURs.

One other problem with EPA's SNUR-only approach is that it is unclear why EPA appears to be inconsistent in including certain notification requirements when developing some SNURs but not others that are addressing similar circumstances. Notably, when EPA develops a TSCA § 5(e) order, the order must meet the statutory requirement of EPA "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." 15 U.S.C. § 2604(e). Then any SNUR that follows the TSCA § 5(e) order must mirror the order's requirements unless EPA provides reasons for deviating from the terms of the order. Therefore, if EPA were issuing the required TSCA § 5(e) orders, then the notification requirements of the SNURs would all match a statutory standard.

Instead, EPA proposes SNURs with notification provisions where inclusion or exclusion of certain requirements remains largely unexplained.

For the 114 SNURs proposed following a "not likely" determination issued as of Dec. 13, 2019, we found that the following types of provisions were included as notification triggers (i.e., SNUs) in only a subset of the proposed SNURs:

- 42 of 114 have release to water notification triggers
- 55 of 114 have a notification trigger for any use that results in "inhalation exposures"
- 25 of 114 have manufacture other than import notification triggers
- 18 of 114 have concentration notification triggers
- 13 of 114 have production volume notification triggers
- 12 of 114 have use as a consumer product notification triggers
- Many of the SNURs have notification triggers for a use other than the use specified in the PMN.

What is wholly unclear from this examination – and is not addressed at all in the Working Approach – is what criteria EPA uses to decide whether to include or not include particular notification triggers in various SNURs. We would note that certain PMNs identified such limits (albeit non-binding) in describing their intended conditions of use (which were then incorporated into EPA's analyses), but EPA then failed to include those limits as notification triggers in the proposed SNURs, meaning that the SNUR would fail to require notification under conditions of use exceeding those limits despite the fact that EPA limited its analysis of potential risk to those circumstances.

Consider the following examples of these problems in SNURs EPA has proposed:

- P-16-0400:
    - Intended conditions of use include a limit on the volume of production and concentration limits, but these are not reflected in the SNUR.
- P-18-0118
    - Intended conditions of use include a limit on volume of production and concentration limits, but these are not reflected in the SNUR.
- P-18-0137
    - Intended conditions of use include concentration limits, but these are not reflected in the SNUR.
    - Intended condition of use is for import, but that is not reflected in the SNUR.
- P-18-0276
    - Intended condition of use is for import, but that is not reflected in the SNUR.
- P-18-0085
    - Intended use is for "industrial use in oilfields" but there is no use provision at all included in the proposed SNUR.
    - Compare this PMN to P-17-0347, where the intended use is use as an "oilfield surfactant" and the proposed SNUR applied to "[u]se of the PMN substances other than for the confidential use described in the PMN."
- P-18-0101
    - Intended use is for "industrial use" but there is no commercial or consumer use provision at all included in the proposed SNUR.
- P-18-0282
    - Intended condition of use in the PMN is as an "adhesive" but there is no provision in the proposed SNUR requiring notice for any other use.
    - Because use other than industrial use is not identified as a SNU, the chemical could be offered for use by consumers even though the not likely determination says "[e]xposures to consumers were not assessed because consumer uses were not identified as conditions of use."[18]

EPA's approach evidenced by these proposed SNURs that follow "not likely" determinations appears to be completely arbitrary; it is not at all clear what standards EPA is applying to choose which notification obligations it includes or excludes, and EPA's Working Approach fails to discuss this issue at all.

[18] TSCA Section 5(a)(3) Determination for Premanufacture Notice (PMN) P-18-0282, https://www.epa.gov/sites/production/files/2019-06/documents/p-18-0282_determination_non-cbi_final.pdf.

6. 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 a 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). Unlike an order, even where a SNUR defines a significant new use as any activity outside of those same conditions, 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. As evidence of this, according to EPA's Enforcement and Compliance History Online Tool, there have only been 69 cases in the entire history of TSCA where the civil section cited under TSCA

was for the "failure to comply with significant new use rules" or to file required premanufacture notices.[19] Because these two categories are lumped together, even fewer than 69 cases may involve failure to comply with significant new use rules.

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,[20] EPA is typically making determinations based on limited data about the PMN substance, often relying exclusively on analogs. EPA has failed to describe whether or how it evaluates and determines how predictive an analog is of the PMN substance's properties; it provides no quantitative measure of the level of confidence warranted, or even a qualitative determination. Relying on a SNUR instead of a consent order provides no opportunity to require the generation of new information that could evaluate this question, nor an opportunity 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,

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[19] ENFORCEMENT CASE SEARCH, https://echo.epa.gov/facilities/enforcement-case-search (last visited Dec. 10, 2019).

[20] *See* U.S. EPA, *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* U.S. EPA, *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.").

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 legal, and more health protective, approach will result in comprehensive risk reviews of new chemical substances including their reasonably foreseen conditions of use; EPA's illegal SNUR-only approach explicitly *defers* and isolates any 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 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 on the chemical substance as whole, 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 issues 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 (as well as any known) 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* Working Approach at p.9 ("[C]onditions of use that were identified in an initial notice and later omitted in an amended submission may be determined to be reasonably foreseen conditions of use."). 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, as discussed below in section 12.D.

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 own 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.

Beyond the problem of bifurcating the mandated risk review, EPA's approach relegates 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 always 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 allows to take place – without any risk review – 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.[21]

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.[22]

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.

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[21] *See, e.g.*, Long-Chain Perfluoroalkyl Carboxylate and Perfluoroalkyl Sulfonate Chemical Substances; Significant New Use Rule, https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=201910&RIN=2070-AJ99 (pending at OIRA since Fall 2019).

[22] 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 Feb. 12, 2020).

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 be held to most of the same conditions that the submitter is already subject to through the consent order, absent prior notification to and review by EPA.

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 using 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.

7. While SNURs are no substitute for the required orders, EDF supports issuing SNURs as a supplemental backstop.

As explained above, EDF strongly believes that EPA must analyze the chemical substance as a whole, including reasonably foreseen uses, and issue an order whenever EPA makes a risk finding, an exposure-based finding, or an insufficient information finding. Nonetheless, while orders are important, SNURs also play a crucial supplemental role in the agency processes.

While a SNUR is no replacement for an order, a SNUR does at least require that persons notify EPA before engaging in any significant new use. This notification requirement is preferable to a completely green light to engage in circumstances that may present an unreasonable risk or about which EPA may have insufficient information. This is why, when EPA issues the required orders, Congress considered it important that EPA generally follow-up those orders with a

SNUR (or explain why it declined to do so) codifying the order's limitations to ensure that other entities would have to notify EPA before engaging in the circumstances covered by the order. *See* 15 U.S.C. § 2604(f)(4).

EDF would also note that EPA does not need to make specific risk findings to issue SNURs. 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.

15 U.S.C. § 2604(a)(2). Crucially, *unlike* with EPA's duties under TSCA § 5(a)(3), SNURs are not limited to a chemical's "conditions of use." EPA has full authority to issue a SNUR to cover circumstances, *even if they are not reasonably foreseen*. Nothing in the statute limits EPA's authority to issue a SNUR to cover such circumstances, so EPA may do so. While EDF believes that EPA has misinterpreted "reasonably foreseen," EPA is correct that it may promulgate a SNUR to cover circumstances even if they are not reasonably foreseen. Working Approach at p.7.

ARGUMENTS ABOUT EPA'S FAILURE TO PROTECT WORKERS

8. EPA improperly assumes that risk-mitigating measures will be used despite a lack of binding requirements that they be used.

In the Working Approach, EPA at numerous points simply *assumes* that risk-mitigating practices (such as use of engineering controls and personal protective equipment (PPE)) will be used with new chemicals. This approach allows EPA to assume that unreasonable risks will be mitigated without actual scientific evidence supporting that finding, and without any legally binding requirement that the risk be mitigated.

For example, for intended conditions of use, EPA assumes that the PMN submitter will use all risk-mitigating measures identified in the PMN, despite the fact that the PMN is not binding on the submitter. *See* Working Approach at p.3 ("Risk mitigating practices and controls identified in the submission (e.g., production volume estimates, controls on releases to air or water,

disposal practices, use of engineering controls, and personal protective equipment (PPE), etc.) are generally considered to be part of the intended conditions of use."). Then, for reasonably foreseen conditions of use, EPA assumes that use of risk-mitigating measures will be ensured by the Occupational Safety and Health Administration (OSHA) and Safety Data Sheets (SDSs):

> The requirements set forth by the Occupational Safety and Health Administration (OSHA), including OSHA's worker protection standard require employers to provide and have affected employees use PPE wherever it is necessary by reason of hazards present in the workplace. EPA generally expects the submitter and any future manufacturers and processors to comply with federal and state laws to protect workers, including OSHA's worker protection standards. Additionally, because EPA requires that the original submitter's Safety Data Sheet (SDS) reflects Agency recommendations to protect workers from risks identified in EPA's assessment, including PPE and hazard communication, future users of the chemical will have this information available to them when determining how to comply with OSHA's worker protection standards. Therefore, unless case-specific facts indicate otherwise, EPA believes that a chemical is generally not likely to present unreasonable risks to workers if the use of PPE and/or other exposure controls would mitigate potential risk.

Working Approach at pp.8-9.

These assumptions are wrong for a number of reasons. First, these assumptions mischaracterize the actual legal requirements imposed (or not imposed) by OSHA and SDSs. Second, these assumptions have no factual basis, and in fact, studies have repeatedly shown that persons do not always understand or comply with the recommendations included in SDSs. Third, this approach favors the use of PPE over other risk mitigating measures, such as engineering controls, in direct conflict with the industrial hygiene hierarchy of controls, which represents the best available science on risk-mitigating measures. Fourth, often the requirements that serve as EPA's basis for its "not likely" determination do not appear in the underlying SDS, so even accepting *arguendo* that these assumptions were true, EPA is not actually requiring the original submitter to update the SDS. Fifth, EPA's approach problematically conflates risk evaluation and risk management—EPA should be considering these risk-mitigation measures when deciding how to mitigate risks under TSCA §5(e), not when evaluating the risks under TSCA § 5(a)(3).

A. SDSs are not binding on employers or employees.

With respect to SDSs, they impose no binding requirements either on employers or their employees to follow the terms in an SDS. The mere presence of language in an SDS is completely insufficient to conclude that PPE is actually utilized or is sufficiently effective and

protective. While SDSs are required to be provided as a hazard communication tool, the only legal requirement under OSHA is that the employer provide the SDS to employees and train them on how to access and understand them. For example, the 2012 OSHA Hazard Communications Standard[23] explains (emphases added):

> While the current HCS [Hazard Communication Standard] and this final standard require the provision of information on recommended control measures, including respiratory protection, personal protective equipment, and engineering controls, *there is no requirement for employers to implement the recommended controls*. An employer should use all available information when designing an appropriate protective program, but *a recommendation on a safety data sheet by itself would not trigger the need to implement new controls*.

Any legal requirement under OSHA that SDS recommendations be followed would come through a separate requirement such as where there is an OSHA exposure limit for the substance that also mandates risk-mitigation measures. For new chemicals, OSHA obviously has no such standards.[24] The problems with relying on OSHA regulations and duties to ensure implementation of required controls are discussed in the next subsection.

Even companies' own SDSs acknowledge this reality, including when it comes to an SDS that accompanies a chemical as it moves downstream to other processors and users. For example, the SDS for P-18-0070[25] states that the manufacturer:

> assume[s] no responsibility regarding the suitability of this information for the user's intended purposes or for the consequences of this use. Individuals should make a determination as to the suitability of the information for the particular purpose(s).

Despite these limitations of SDSs, EPA simply assumes, with no actual evidence, that there will be 100% use and efficacy of the PPE specified in an SDS by all workers throughout a chemical's supply chain and lifecycle.

Moreover, it bears emphasis that, while EPA states that it "requires the original submitter's Safety Data Sheet (SDS) reflects Agency recommendations," Working Approach at p.9, EPA has

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[23] OSHA, Hazard Communication, 77 Fed. Reg 17693 (March 26, 2012), available at https://www.federalregister.gov/documents/2012/03/26/2012-4826/hazard-communication.
[24] PELs UPDATE, https://www.osha.gov/archive/oshinfo/priorities/pel.html (last visited Feb. 12, 2020).
[25] *See* ArrowStar, LLC, Safety Data Sheet dated 9/12/2018, p. 6, available at http://blogs.edf.org/health/files/2020/02/ARROPOL-36-SDS.pdf.

no authority to make these changes permanent, other than through issuance of a section 5 order or rule. EPA has no ability to ensure that PMN submitters do not modify their SDS after receiving their "not likely" determinations. Companies have broad discretion to change their SDSs, so it is certainly reasonably foreseeable that some companies will modify the SDS as they choose after receiving the "not likely" determination.

B. EPA relies on OSHA regulations that do not specify that employees or employers must comply with risk-mitigating measures for new chemicals.

EPA also assumes that OSHA's general PPE standard will require employers to provide PPE. Working Approach at p.8 (citing 29 C.F.R. § 1910.132(a) and (d)). But these regulations have several very important limitations as to when they are applicable and hence when use of PPE is mandatory: They apply only where the *employer* has determined that workers are subject to sufficient *hazards* from chemical exposures, and they apply only "*wherever it is necessary*." 29 C.F.R. § 1910.132(a) (emphases added) ("[PPE] shall be provided, used, and maintained in a sanitary and reliable condition *wherever it is necessary by reason of hazards*."). Similar caveats appear in the specific PPE standards applicable to a small number of existing chemicals, none of which applies to any new chemicals. These caveats mean that it is the employer who gets to decide both whether and what hazards exist and whether worker use of PPE is necessary. Given this legal reality, EPA cannot accurately assume that these regulations will effectively require that persons use PPE because the PMN submitter will have broad discretion in interpreting what duties they have under this regulation going forward.

Under OSHA's regulations, employers have considerable latitude in deciding whether a hazard exists in the workplace. Even a hazard classification of a chemical issued by an authoritative government body need not be relied on. That is, the employer can apply his/her own weight-of-evidence (WoE) approach to decide a chemical does not present a hazard even if a government authority has determined that it does. The employer can do so even if that government authority applied a WoE approach to make its hazard determination.

For example, for many chemicals, government authorities such as EPA's Integrated Risk Information System (IRIS) or the National Toxicology Program (NTP) have reached determinations as to which human health hazards are posed by a particular chemical, such as whether a chemical is known or suspected to cause cancer in people. They do so by applying WoE approaches that have been subject to independent peer-review. Yet even where such a government body has classified a chemical as a carcinogen, under OSHA's Hazard Communication Standard and associated guidance a company can decide the chemical is not carcinogenic, by weighing the evidence differently using its own methodology.

This issue figured prominently in 2016, when OSHA took public comment on its draft "Guidance on Data Evaluation for Weight of Evidence Determination" as it related to changes OSHA made in 2012 to the HCS.[26] In that draft (p.9), OSHA proposed to give deference to decisions made by authoritative bodies:

> If a classifier reaches a final WoE conclusion that differs from that of the NTP or IARC [International Agency for Research on Cancer], OSHA would look, in the event of a compliance inspection, for a clear justification for the different classification. If OSHA disagrees with the classifier's classification after evaluating the classifier's justification, OSHA may issue a citation.

However, this and other language in the draft still retained the HCS's approach of providing the company with the option of making its own determination that differs from that made by an authoritative body. And that determination would only be questioned in the rather unlikely event of a compliance inspection that focused on this aspect of a company's SDS.

An example of a company's SDS substituting the company's own conclusions about a chemical's hazards for those of authoritative government bodies is this 2015 Dow Chemical SDS for methylene chloride, which asserts: "Methylene chloride is not believed to pose a measurable carcinogenic risk to humans when handled as recommended."[27]

This despite the following:

- EPA's IRIS program 2011 weight-of-evidence characterization determined that the chemical is "Likely to be carcinogenic to humans."[28]
- The National Toxicology Program's latest (2016) Report on Carcinogens classifies the chemical as "Reasonably anticipated to be a human carcinogen."[29]

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[26] OSHA, Draft Guidance on Data Evaluation for Weight of Evidence (WoE) Determination: Application to the 2012 Hazard Communication Standard, available at https://www.regulations.gov/document?D=OSHA-2016-0004-0002 (last visited Feb. 18, 2020).
[27] Dow SDS for Methylene Chloride, http://208.112.58.204/pridesol/documents/sds/Methylene%20Chloride%20Tech%20-%20Dow%20-%202015-03-04.pdf (last visited Feb. 12, 2020).
[28] DICHLOROMETHANE CASRN 75-09-2, https://cfpub.epa.gov/ncea/iris2/chemicalLanding.cfm?substance_nmbr=70 (last visited Feb. 12, 2020).
[29] NIH, *Report on Carcinogens, Dichloromethane CAS No. 75-09-2* (14th ed.), https://ntp.niehs.nih.gov/ntp/roc/content/profiles/dichloromethane.pdf.

- The International Agency for Research on Cancer (IARC) classified the chemical in 2017 as "Probably carcinogenic to humans."[30]

EDF[31] and numerous other commenters[32] urged OSHA to require companies to rely on hazard classifications by authoritative bodies identified by OSHA for chemicals, where they exist. Unfortunately, it appears this guidance did not move forward.

Moreover, if EPA issues a "not likely to present an unreasonable risk" finding for the chemical, the company will likely rely on that finding to argue that there is an absence of clear evidence of hazard. Certainly, the company will not be bound by any findings of risk that EPA made during its review; if companies can dismiss IRIS findings, NTP's findings, and IARC's findings, they will surely dismiss any findings of potential risk that EPA makes during its risk assessments of these chemicals under TSCA § 5. Such findings would only be dispositive if EPA articulates such findings and codifies the required risk management in an order under TSCA § 5(e).

Second, an employer can decide that worker protections are not "necessary" under OSHA standards, and will likely do so unless it believes there is clear evidence of a hazard. Usually, with a new chemical such clear evidence of hazards is limited or lacking altogether. In contrast, properly implemented, under TSCA the lack of sufficient information to evaluate a new chemical's hazards and risks – in and of itself – mandates that EPA issue an order to address any potential risks pending receipt of information sufficient to support an alternative determination (see TSCA section 5(e)(1)).

Third, in deciding whether a hazard necessitating protections exists, the company's point of reference will be OSHA's, not TSCA's, safety standard. Here is how the two standards differ:

TSCA's safety standard: The 2016 amendments to TSCA explicitly preclude EPA from considering feasibility or other non-risk factors when determining whether a chemical presents an "unreasonable risk," including to workers. Moreover, in implementing TSCA (even before the amendments) and its other environmental statutes, EPA has generally sought to reduce population risks from chemicals in commerce that are carcinogens to below about one case per one million people, or in some cases one case per 100,000 people.[33] And the head of EPA's

[30] LIST OF CLASSIFICATIONS, https://monographs.iarc.fr/list-of-classifications/ (Feb. 12, 2020).
[31] Comments from the Environmental Defense Fund on the Draft Guidance on Data Evaluation for Weight of Evidence Determination: Application to the 2012 Hazard Communication Standard, May 2, 2016, https://www.regulations.gov/document?D=OSHA-2016-0004-0035.
[32] See public comments at https://www.regulations.gov/docket?D=OSHA-2016-0004.
[33] *See* Nat'l Academy of Sciences, *Review of the Army's Technical Guides on Assessing and*

TSCA office at the time the new law was passed indicated she expected the same approach should and would be taken under amended TSCA in identifying chemicals in commerce that "present an unreasonable risk."[34] Notably, even the Working Approach acknowledges that an appropriate benchmark for TSCA is 1 x 10^{-6}. *See* Working Approach at p.12 n.22.

In the present case, we are talking about new chemicals not yet in commerce. For them, TSCA requires EPA to regulate the chemical even if it "*may* present an unreasonable risk" – which means an even lower level of risk should trigger regulatory action.

OSHA's safety standard: In contrast, the Occupational Safety and Health Act allows OSHA to regulate only "significant" risks in the workplace. And as a result of the landmark 1980 *Benzene* case, *Industrial Union Department, AFL-CIO v. American Petroleum Institute et al*., 448 U.S. 607 (1980), for carcinogenic chemicals OSHA has interpreted as "significant" only a risk as high as one or more cases per 1,000 workers.[35] This means that OSHA tolerates risks to workers from chemicals that are *several orders of magnitude higher* than are allowed under TSCA.

In addition, OSHA can only regulate workplace exposures where it is "feasible" to do so. In practice, OSHA has frequently concluded that it is infeasible to reduce workplace risks below or even down to the 1 in 1,000 level, leaving workers at even greater risk than contemplated by the *Benzene* decision.

Thus, EPA is relying on OSHA standards that do not meet TSCA's standard and do not ensure that risk-mitigation measures will be implemented to the extent required by TSCA. For this additional reason, EPA's assumption that OSHA regulations will require the use of PPE and other mitigation measures is faulty and contrary to the law.

C. The empirical evidence actually establishes that SDSs are often not understood or followed.

It is unreasonable in the face of the existing evidence to assume compliance with risk-mitigating measures that are actually not binding on the user. There is significant evidence that SDSs are frequently not understood or followed. For example, one recent systematic search and review of the literature identified serious problems with the use of SDSs even as hazard communication

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Managing Chemical Hazards to Deployed Personnel, Appendix B: Review of Acceptable Cancer Risk Levels p. 140 (2004), https://www.nap.edu/download/10974.

[34] Charles M. Schmidt, *TSCA 2.0: A New Era in Chemical Risk Management*, 124:10 ENVT'L HEALTH PERSPECTIVES 182, 183 (Oct. 2016), https://ehp.niehs.nih.gov/doi/pdf/10.1289/ehp.124-A182.

[35] *Id.* at 138.

tools: they are often inaccurate, incomplete, and too technical for workers to understand.[36] The 2012 OSHA Hazard Communications Standard corroborates these findings.[37] For example, the Standard reports that "several studies show that employees do not understand approximately one-third of the safety and health information listed on SDSs prepared in accordance with the current standard" and that "[s]tudies also report that roughly 40% of persons reviewing SDSs found them difficult to understand."[38] Also, see OSHA's *Inspection Procedures for the Hazard Communication Standard* for more on the limitations of SDSs.[39]

D. EPA's approach relies on PPE instead of other risk-mitigation measures that are favored under the industrial hygiene hierarchy of controls.

EPA's approach also favors the use of PPE over other measures to reduce risk—this is reflected by EPA's assumption that PPE will eliminate the unreasonable risks and EPA's reliance on the OSHA regulations governing PPE. But reliance on PPE as a primary measure to protect workers is counter to OSHA's Industrial Hygiene Hierarchy of Controls (HOC), a long-standing principle that prioritizes measures to eliminate or reduce the presence of a hazard in occupational settings (e.g., substitution/use of less toxic chemicals and institution of engineering controls) over measures that shift burdens onto the workers themselves, such as through reliance on PPE and warning labels. The HOC exemplifies the best available science for creating safe, healthful workplace environments.

Reliance on PPE has major practical limitations and, at best, exhibits mixed effectiveness in the real world. For example, OSHA concluded that respirators are the "least satisfactory approach to exposure control." The agency provides the following explanation:

> [T]o be effective, respirators must be individually selected, fitted and periodically refitted, conscientiously and properly worn, regularly maintained, and replaced as necessary. The absence of any one of these conditions can reduce or eliminate the protection the respirator provides.
>
> Respirator effectiveness ultimately relies on the practices of individual workers who must wear them. *** Furthermore, respirators can impose substantial physiological burdens on workers, including the burden imposed by the weight of

[36] Anne-Marie Nicol, et al., *Accuracy, comprehensibility, and use of material safety data sheets: A review*, 51:11 AM. J. OF INDUSTRIAL MEDICINE 861-76 (Jul. 2008), https://onlinelibrary.wiley.com/doi/abs/10.1002/ajim.20613.
[37] 77 Fed. Reg. 17574, 17593-95, 17603 (Mar. 26, 2019).
[38] *Id.* at 17603.
[39] OSHA, *Inspection Procedures for the Hazard Communication Standard* (HCS 2012) (Jul. 2015), https://www.osha.gov/OshDoc/Directive_pdf/CPL_02-02-079.pdf.

> the respirator; increased breathing resistance during operation; limitations on auditory, visual, and olfactory sensations; and isolation from the workplace environment.
>
> OSHA therefore continues to consider the use of respirators to be the least satisfactory approach to exposure control ***.[40]

Similarly, EPA refers to the limitations of successful implementation of respirators in its preambles to both of its proposed TCE section 6 rules and its proposed DCM and NMP section 6 rule.[41]

Yet reliance on PPE identified in the SDSs and as allegedly required by OSHA's PPE regulations are the only ways EPA indicates risks to workers can be "expected" to be eliminated. EPA's "not likely" determination documents make little or no mention of the use of measures preferred under the HOC, and instead prominently feature their assumptions regarding use of PPE based on its description in a company's SDS. To the extent that EPA is relying on companies' use of such preferred measures, EPA must fully and transparently describe them and demonstrate why use of PPE rather than further reliance on preferred measures is necessary.

Notably, if EPA were correctly applying TSCA, it would find that these conditions of use may present an unreasonable risk under the reasonably foreseen conditions of use, and EPA would issue orders imposing mitigation measures consistent with the HOC. While these orders might require PPE, they also should require engineering controls and other, more effective mitigation measures as the options of first resort. Such orders would also be binding on the company, in contrast to the SDSs and PMNs that EPA now relies upon.

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[40] Comment submitted by David Michaels, Assistant Secretary for Occupational Safety and Health, on Significant New Uses of Chemical Substances; Updates to the Hazard Communication Program and Regulatory Framework; Minor Amendments to Reporting Requirements for Premanufacture Notices (Nov. 21, 2016), https://www.regulations.gov/document?D=EPA-HQ-OPPT-2014-0650-0041.

[41] Methylene Chloride and N-Methylpyrrolidone; Regulation of Certain Uses Under TSCA Section 6(a), 82 Fed. Reg. 7464, 7481 (proposed Jan. 19, 2017), https://www.regulations.gov/docket?D=EPA-HQ-OPPT-2016-0231; Trichloroethylene; Regulation of Certain Uses Under TSCA § 6(a), 81 Fed. Reg. 91592, 91595, 91599 (proposed Dec. 16, 2016), https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0163-0001; Trichloroethylene (TCE); Regulation of Use in Vapor Degreasing Under TSCA Section 6(a), 82 Fed. Reg. 7432, 7435, 7439 (proposed Jan. 19, 2017), https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0387-0001.

The extent to which EPA now relies on an "expectation" that employers will provide and workers will always wear PPE as a basis for determining that a new chemical "is not likely to present an unreasonable risk" has becoming overwhelming. Since late July 2018, when EPA's policy changes began to take effect, EPA has issued "not likely" determinations for 302 PMNs and SNUNs.[42] ***In 230—76%—of these cases, EPA identified potential risks to workers but dismissed those risks based on an assumption of PPE use.*** Each of EPA's accompanying determination documents state the following:

> Risks will be mitigated if exposures are controlled by the use of appropriate PPE, including impervious gloves, eye protection, and respiratory protection. EPA expects that employers will require and workers will use appropriate PPE (i.e., impervious gloves, eye protection, and respiratory protection), consistent with the Safety Data Sheet prepared by the PMN submitter, in a manner adequate to protect them.[43]

E. EPA often finds that specific PPE is necessary for the "not likely" determination and claims that the SDS requires that PPE, but an examination of the SDS reveals that it does not specify the necessary PPE.

Factually, EDF has found that in many cases, the specific PPE that EPA claims to be specified in the SDSs—and that EPA asserts is sufficient to protect all workers handling the chemical—is not in the SDSs. Specifically, EDF has identified at least two PMNs where the PMN's "not likely" determination identified certain PPE as necessary for protection of workers but the accompanying SDS did not include the necessary PPE:

P-19-0021/22: Here is what the "not likely" determination document for P-19-0021 and P-19-0022 states:[44]

Risks to workers: Lung overload via inhalation.

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[42] USEPA, Chemicals Determined Not Likely to Present an Unreasonable Risk Following Pre-Manufacture Notification Review, https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/chemicals-determined-not-likely.

[43] See, e.g., TSCA Section 5(a)(3) Determination for Premanufacture Notice (PMN) P-18-0367, p. 6, available at https://www.epa.gov/sites/production/files/2020-02/documents/p-18-0367_determination_non-cbi_final.pdf (last visited February 17, 2020).

[44] TSCA Section 5(a)(3)(C) Determination for Premanufacture Number (PMN) P-19-0021-0022, https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/tsca-section-5a3c-determination-160.

PPE EPA relies on:

> Risks will be mitigated if exposures are controlled by the use of appropriate PPE, *including a respirator with APF of 50*. EPA expects that workers will use appropriate PPE *consistent with the SDS prepared by the PMN submitter*, in a manner adequate to protect them. (p. 5, emphases added)

The associated SDS that EDF received upon requesting the public file makes only this reference to respiratory protection: "**Respiratory protection** Mist respirator, include single use respirator."[45]

Nowhere does the SDS specify use of a respirator with an APF of 50. The SDS is clearly not consistent with EPA's own description of it.

P-18-0212: Here is what the "not likely" determination document for P-18-0212 states:[46]

Risks to workers: Systemic effects via inhalation exposure; portal of entry/contact effects to the eyes, lungs and skin following ocular, inhalation, and dermal exposures

PPE EPA relies on:

> The risks and hazards identified will be mitigated if exposures are controlled by the use of appropriate PPE, including impervious gloves, *respirators with an APF of at least 10*, and eye protection. EPA expects that workers will use appropriate personal protective equipment (i.e., impervious gloves, *respirator with an APF of at least 10*, and eye protection), *consistent with the Safety Data Sheet submitted with the PMN*, in a manner adequate to protect them. (p. 5, emphases added)

The associated SDS that EDF received upon requesting the public file makes this reference to respiratory protection:

> **Respiratory Protection:** For operations where inhalation exposure can occur use an approved respirator. Recommendations are listed below. Other protective respiratory

[45] NIPPON KAYAKU AMERICA, INC., SDS-CNTOP-Pigment-ink-Yellow, p. 3, available at http://blogs.edf.org/health/files/2019/05/SDS-CNTOP-Pigment-ink-Yellow.pdf.
[46] TSCA Section 5(a)(3)(C) Determination for Premanufacture Number (PMN) P-18-0212, https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/tsca-section-5a3c-determination-134.

equipment may be used based on user's own risk assessment. Recommended respirators include those certified by NIOSH.

Recommended: Full Face Mask with a combination particulate/organic vapor cartridge.[47]

Nowhere does the SDS specify use of a respirator with an APF of 10. The SDS is clearly not consistent with EPA's own description of it.

In each of these cases, EPA identified a particular type of respirator as necessary for its finding that the chemical is not likely to present an unreasonable risk, and in each case, EPA asserted that the corresponding SDS specified that type of equipment. But in fact, in each case, the SDS does *not* specify that type of respirator. EPA's decisions run counter to the actual evidence before the agency, and EPA has actually mischaracterized that evidence. That amounts to arbitrary decision-making. Practically speaking, this mismatch means that workers could follow the SDS perfectly and be using a respirator that is not sufficient to protect them against the chemical's identified risks.

F. The structure of TSCA § 5 bifurcates risk evaluation and risk management, and EPA's approach improperly conflates the two.

TSCA § 5 creates a precise structure for EPA's review of new chemicals. At the first step, EPA is supposed to evaluate the risk and make one of the findings under TSCA § 5(a)(3). This risk review is supposed to be "without consideration of costs or other nonrisk factors." 15 U.S.C. § 2604(a)(3)(A), (B), (C). It is only after EPA makes a finding under TSCA § 5(a)(3) that EPA's focus is supposed to shift to risk management under TSCA § 5 (e) or 5(f). EPA's approach improperly conflates the risk management stage by inserting risk management considerations in the form of assumed use of PPE into the risk review and determination. EPA's approach violates TSCA's structure, and EPA should not be considering these issues of risk management until after it has completed its risk review and determination.

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

EPA has been lobbied heavily by numerous industry sources that it should entirely defer to OSHA in addressing potential risks new chemicals pose in the workplace. Unfortunately, EPA has largely fallen in line with these requests.

[47] Allnex USA Inc., SDS for RESYDROL® AY 6838w/35WA liquid coating resins, available at http://blogs.edf.org/health/files/2019/05/RESYDROL-AY-6838-US-SDSRevised.pdf.

As discussed below, such an approach is completely illegal, contrary to congressional intent, and unsound as a matter of policy.

A. EPA's obligation to consult with OSHA does not allow EPA to evade its duties to protect workers under TSCA § 5, and doing so 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 provide any basis for EPA to rely on OSHA to regulate new chemicals in the workplace. 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 the 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 EPA's deferral of its duties to OSHA. The Lautenberg Act introduced a 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 EPA's actions to transfer that obligation to OSHA.

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

The preemption language of the OSH Act 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). It would be 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" and making their protection a mandatory duty of EPA.

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.

There are also several problems with any assumption that OSHA's 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.

Moreover, EPA's hazard and risk assessments of the new chemical would not necessarily 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.

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.[48] As interpreted by the courts and

[48] *See, e.g.*, Pat Rizzuto, *Latest Version of Safe Chemicals Act Called 'Remarkably Different' From 2011 Bill* (Sept. 15, 2012),

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

OSHA itself acknowledges the severe limitations to its authority.[49] 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."[50] 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,[51] that EPA require the testing under

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https://www.khlaw.com/Files/15696_Chemical%20Regulation%20Reporter%20on%20Webinar%202012-09-.pdf.

[49] *See* PERMISSIBLE EXPOSURE LIMITS – ANNOTATED TABLES, https://www.osha.gov/dsg/annotated-pels/ (last visited Feb. 13, 2020).

[50] GAO, *Workplace Safety and Health:Multiple Challenges Lengthen OSHA's Standard Setting* (Apr. 2012), https://www.gao.gov/products/gao-12-602t.

[51] INTERAGENCY TESTING COMMITTEE, https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/interagency-testing-committee (last visited Feb. 13, 2020).

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 in section 4.D.) That process would be time-consuming, and 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.

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.

ARGUMENTS ABOUT OTHER ASPECTS OF THE NEW CHEMICALS PROGRAM

10. EPA's new Working Approach does not fulfill EPA's commitments to Congress to provide a statutory and scientific justification for the approaches described, as well as to respond to public comments.

In January, 2019, Administrator Wheeler sent a letter to Senator Carper committing EPA to undertake certain actions. As relevant here, EPA described its prior framework on new chemicals and EPA stated that it "will publish its next version of this framework. *** EPA's framework will specify: (i) the statutory and scientific justifications for the approaches described, (ii) the policies and procedures EPA is using/plans to use in its PMN reviews, and (iii) its responses to public comments received."[52]

Despite these commitments, with its new Working Approach, EPA still has failed to provide any statutory or scientific justification for its approaches to new chemicals. EPA also failed to meaningfully respond to comments; instead, EPA simply published a two-page document that

[52] Letter from Administrator Andrew R. Wheeler to Senator Carper, p. 2 (Jan.. 2019), http://files.chemicalwatch.com/01-19AWtoTCTSCA.pdf.

summarily dismissed the comments without engaging with them. Such a "wan" response to comments is arbitrary and capricious. *Del. Dep't of Natural Res. & Envtl. Control v. EPA*, 785 F.3d 1, 15 (D.C. 2015).

Indeed, EPA's repeated disclaimers that the Working Approach does not control EPA's decisionmaking process reflect that EPA has failed to engage with its statutory obligations. Throughout the Working Approach, EPA includes language emphasizing that it may deviate from the Working Approach at any time. For example, on page one, EPA states: "EPA may choose to depart from this approach with respect to any specific submission as the Agency deems appropriate. This working approach does not create new authority, does not limit EPA's discretion in any way, nor does it bind the public." Working Approach at p.1. On page 12: "*These discussions are not intended to be interpretations of what is required by TSCA or the range of discretion afforded by TSCA*; nor are they a recitation of the elements of a specific determination." *Id.* at p.12 (emphasis added). How can EPA be presenting its "Working Approach" to TSCA § 5 without interpreting TSCA § 5?

EPA's failure to engage with its statutory obligations demonstrates that the Working Approach is not rooted in EPA's obligations under the law. And EPA's repeated emphasis that it can deviate from the Working Approach highlights that EPA has not tried to articulate its legal duties. The result is a lawless document, divorced from TSCA's text, structure, and purpose. It also fails to ensure any consistency in EPA's implementation, or any clear direction for EPA to follow in its implementation.

11. EPA fails to deliver on its stated policy, and its stated policy erroneously commits EPA to promoting innovation when TSCA's text is directly to the contrary.

EPA describes its Overall Policy as follows:

> EPA's new chemicals program is intended to ensure that new chemicals do not present an unreasonable risk of injury to health or the environment under the conditions of use. EPA implements its authority under TSCA in a manner that facilitates timely reviews and does not impede unduly or create unnecessary economic barriers to technological innovation in chemical manufacturing.

Working Approach at p.3. But EPA completely fails to execute the first part of this policy in its Working Approach. EPA does not identify a single choice that it made in the implementation of the new chemicals program "to ensure that new chemicals do not present an unreasonable risk of injury to health or the environment under the conditions of use." And many of EPA's choices reduce the extent to which EPA will be preventing unreasonable risks. In particular, as explained above, EPA does not explain how its decision to avoid TSCA § 5(e) orders is designed

to – or will – increase protection from unreasonable risk. Similarly, EPA's narrow interpretation of "reasonably foreseen" does not further this goal. EPA cannot simply assert that it has a laudatory and positive goal and then fail to implement it at every step.

Moreover, EPA's goal of avoiding barriers to innovation distorts the intent of TSCA through selective citing, and thereby ignores that TSCA emphasizes that the primary purpose of the statute is to assure that such innovation does not present an unreasonable risk. Specifically, TSCA provides that:

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

15 U.S.C. § 2602(b)(3) (emphasis added). Given that the development and application of new chemicals are a clear source of innovation, the best way to ensure that innovation and commerce in chemicals does not present unreasonable risk is through robust scrutiny of new chemicals prior to their commercialization. EPA's truncated reference to this policy ignores the "primary purpose" identified by the statute itself.

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

A. EPA too often elides that it is supposed to regulate chemicals even upon a finding that they "may present" an unreasonable risk or in the face of "insufficient information."

The Working Approach errs in describing the standard that EPA must apply in implementing TSCA § 5. For example, on page 2, EPA states: "EPA utilizes a risk-based approach to assess whether a new chemical substance, under the conditions of use (as determined by the Administrator), *presents* an unreasonable risk of injury to health or the environment." Working Approach at p.2 (emphasis added). In fact, the relevant questions are generally whether a chemical substance "may present" or is "not likely to present" an unreasonable risk or if there is "insufficient information"; TSCA requires EPA to regulate new chemicals when it has evidence of potential risk even when EPA lacks the certainty necessary to make a "presents an unreasonable risk" finding. In addition, TSCA § 5 was specifically drafted to require regulation whenever there is "insufficient information," requiring regulation in the face of uncertainty.

B. EPA states that it need not find risks unreasonable even when its own risk benchmarks are exceeded.

The Working Approach 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 Working Approach 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.), or others—lead EPA to determine that the chemical is not likely to present a risk that is *unreasonable*. Working Approach at pp.12-13. This proposed strategy and the examples provided are deeply troubling:

- What type of endpoint does EPA have the prerogative to determine 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"?
- Why 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, without a more robust explanation and detailed criteria for applying this approach, EPA's decisionmaking will result in inconsistent and unjustified results, resulting in an arbitrary and capricious application of the approach.

C. EPA adopts an approach to "reasonably foreseen" that completely ignores the legal precedent indicating that it sweeps broadly to include "possible consequences."

It is unclear how precisely EPA interprets "reasonably foreseen,"[53] but the Working Approach does not adopt a broad enough definition of "reasonably foreseen." Notably, the Working

[53] In the past, EPA misinterpreted "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

Approach states at one point that "[r]easonably foreseen conditions of use are future circumstances under which the Administrator might expect the new chemical substance to be manufactured, processed, distributed, used, or disposed of." Working Approach at p.4. This definition is incomplete, and EPA should further develop its interpretation of "reasonably foreseeable" based on the legal precedent. 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.

Looking at the Working Approach as a whole, EPA further distorts "reasonably foreseen" by defining the circumstances of reasonably foreseen so narrowly as to exclude many reasonably foreseen uses. EPA only identifies three circumstances where a use would be "reasonably foreseen." *First*, EPA suggests that a use "*may be*" reasonably foreseen if it "already [is] currently used outside the U.S." for that particular use. Working Approach at p.8 (emphasis added). But such conditions of use are already "known" to be occurring; they are certainly reasonably foreseen.

Second, EPA suggests that a known condition of use of an analogue is only a reasonably foreseen use "[w]hen there is at least one use in common with an intended condition of use for the new chemical." Working Approach at p.8. But if an analogue is good enough for EPA to using it to estimate the hazards and environmental and biological behavior of a chemical, why isn't the analogue, standing alone, sufficient to establish that a chemical might be used in the same way? And notably, EPA does not even commit to finding a known condition of use "reasonably foreseen" in the circumstances where the analogue does share one or more uses in common with the intended conditions of use of a chemical. *See id.* (noting that EPA "may determine" that further uses are reasonable foreseen). As a general matter, EPA should be finding that analogues' uses are "reasonably foreseen," and if EPA decides otherwise, then EPA

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."). But "reasonably foreseen" does not mean "probable." It is unclear whether EPA is still applying this operating principle or whether it has been supplanted by the Working Approach.

must also reconsider any reliance on that analogue to predict or estimate other characteristics of the PMN substance.

EPA's rationale briefly mentioned at the public meeting for its narrow approach to finding conditions of use reasonably foreseen based on analogues was that this is "necessary to ensure the chemistry is indicative of the ability of the PMN substance to be used for the other use." But EPA goes farther and demands that the analog actually is being used for the exact same use as the PMN substance, not just that it could be—an approach inconsistent with the meaning of "reasonably foreseen." Moreover, if the analogue is deemed sufficiently similar to the PMN substance for estimating the latter's properties, that in and of itself is indicative of the ability of and potential for the PMN substance to be used for the analogue's use(s).

Third, EPA states that conditions of use that were originally intended by the submitter "*may* be determined to be reasonably foreseen." Working Approach at p.9 (emphasis added). Such conditions of use are *clearly* reasonably foreseen – the original submitter originally stated that it intended to use the chemical substance consistent with those conditions of use, so such use is clearly "a possible consequence which might reasonably have been contemplated." *People v. Medina*, 46 Cal. 4th 913, 920 (Cal. 2009) (internal citations and quotation marks omitted). EPA should *always* consider these circumstances as conditions of use when analyzing a chemical substance.

On this point, EPA's approach seems to inviting companies to game the system. EPA provides companies with all of the models that it uses in new chemical reviews, so a company can, on its own and in advance of submitting its PMN, vary inputs to those models, e.g., for use or concentration, until it achieves outputs that it expects or knows from past experience will not or are unlikely to raise a red flag during EPA's review. The company can then submit as its intended conditions of use only those that it expects will pass muster. Under EPA's overly narrow interpretation of "reasonably foreseen," EPA will likely not identify any reasonably foreseen conditions of use, the company will get its "not likely" determination, and EPA will not pursue a SNUR. Once it gets its "not likely" determination, there is nothing stopping the company from then engaging in conditions of use beyond those it included in its PMN. The likelihood of this scenario may even be heightened by EPA's encouragement of companies to engage in "pre-notice" consultations, through which companies may be made aware of any potential concerns EPA may have with their chemicals and be able to remove from its formal submission any such red flags. Given these very real possibilities and the reality that PMNs are not binding on the submitter (discussed in subsection D. below), EPA should be analyzing circumstances *beyond* those that a PMN submitter identifies in its original PMN instead of blissfully ignoring them.

Fourth, EPA ignores many reasonably foreseen conditions of use involving workers. Specifically, EPA includes in its Working Approach a description of "conditions of use involving workers," in which it strongly suggests that it is not "reasonably foreseen" that workers would not always use Personal Protective Equipment (PPE) or that the PPE may not be effective. Working Approach at p.9. Above, we discuss in more detail the problems with EPA's assumptions about workers, but as a significant body of evidence establishes, it is certainly reasonably foreseeable that workers may not always use PPE or that it may not always be effective.

While EPA need not engage in endless speculation, "reasonably foreseen" sweeps broadly and requires EPA to find many more conditions of use reasonably foreseen than it is doing. It is generally reasonably foreseeable that a chemical might be used without all the engineering controls, PPE, and disposal protections that are described in a PMN—it is generally easier or less expensive to use a chemical without these risk-mitigating measures, so use without them is "a possible consequence which might reasonably have been contemplated." *People v. Medina*, 46 Cal. 4th 913, 920 (Cal. 2009) (internal citations and quotation marks omitted). EPA's adoption of an incredibly narrow definition of "reasonably foreseen" violates the statutory text and the precedent governing this term.

D. PMNs are not binding, so deviation from the stated intended uses is reasonably foreseen.

In its Working Approach, EPA relies heavily upon the specific circumstances described in the PMN submission to identify "intended" conditions of use, but neither PMN submitters nor other users of the chemical substance are bound to follow the risk mitigating practices and controls identified in the PMN submission. The potential to deviate from those practices and controls is certainly reasonably foreseen, as it would often be easiest to use the chemical without these extra precautions and measures.

Somewhat confusingly, PMNs contain a "binding option" that is not actually binding on the submitter. As EPA's own Points to Consider document explains:

> [i]ndicating a willingness to be bound to certain information (see sub-bullets below) in the notification does not by itself prohibit the submitter from deviating after the end of the review from the information (except chemical identity) which

had been reported in [PMN] (unless the submitter and the Agency enter into a binding TSCA § 5(e) Consent Order).[54]

Similar language appears in the PMN form itself and in EPA's *Questions and Answers on New Chemicals.* [55]

Even when a PMN submitter has selected the "binding option," the submitter is not bound to adhere to any conditions in the PMN *unless* such conditions have been codified in TSCA § 5(e) order.

It is therefore unreasonable for EPA to treat the conditions in the PMN as a definitive description of what the PMN submitter will actually do with the chemical substance. For the mitigation measures to become binding, EPA must codify them in an order issued under TSCA § 5(e). Where such measures are necessary to eliminate an unreasonable risk, EPA must codify them.

For example, EPA often assumes inhalation exposures are "negligible."[56] This assumption is often unexplained, but to the extent EPA is simply assuming that the chemical will only be used as identified in the PMN, EPA is likely overlooking reasonably foreseen circumstances where the same chemical may be used without all the engineering controls or other risk mitigation measures described in the PMN.

E. EPA repeatedly mischaracterizes what TSCA § 5(f)(4) requires.

In the Working Approach, EPA mischaracterizes the obligation under TSCA § 5(f)(4) to follow the issuance of an order under TSCA § 5(e) either with a SNUR or an explanation for why EPA is declining to adopt a SNUR. EPA states that: "Pursuant to section 5(f)(4), EPA must also consider issuing a SNUR that would conform to the restrictions in the order, or publish a statement describing the reasons for not taking such action." Working Approach at pp.13-14. This is inaccurate. TSCA § 5(f)(4) provides that:

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[54] U.S. EPA, *Points to Consider When Preparing TSCA New Chemical Notifications* p.35 (2018), https://www.epa.gov/sites/production/files/2018-06/documents/points_to_consider_document_2018-06-19_resp_to_omb.pdf.

[55] U.S. EPA, *Questions and Answers on New Chemicals* p.1-16 (2015), https://www.epa.gov/sites/production/files/2015-09/documents/qanda-newchems_new.pdf; EPA, PMN Sample Form p.1, https://www.epa.gov/sites/production/files/2018-07/documents/pmnviewonly11-30-18.pdf.

[56] *See* EPA, TSCA Section 5(a)(3) Determination for Premanufacture Notice (PMN) P-18-0329 p.4, https://www.epa.gov/sites/production/files/2020-01/documents/p-18-0329_determination_non-cbi_final.pdf.

> Treatment of nonconforming uses. Not later than 90 days after taking an action under paragraph (2) or (3) or issuing an order under subsection (e) relating to a chemical substance with respect to which the Administrator has made a determination under subsection (a)(3)(A) or (B), the Administrator shall consider whether to promulgate a rule pursuant to subsection (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 the Administrator for not initiating such a rulemaking*.

15 USCS § 2604(f)(4)(emphasis added). Thus, EPA *must* issue a SNUR or publish a statement explaining why it has failed to do so. EPA has no discretion not to do one of these things. EPA's shorthand description of this duty suggests that EPA need only *consider* developing the SNUR *or* publish the statement about why the SNUR is not necessary. This is not correct.

F. EPA incorrectly implies that it cannot find a chemical "may present an unreasonable risk" without also finding that there is a "high level of uncertainty" about risk.

In its descriptions of the findings that EPA must make under TSCA § 5(a)(3), EPA states that it will not make a "may present an unreasonable risk" finding unless "there is a high level of uncertainty associated with the data used and the identified risk(s)." Working Approach at p.13. EPA's approach ignores the structure of TSCA, where Congress clearly intended for EPA to make a "may present" an unreasonable risk finding where EPA could not make a "not likely" finding or a "presents" an unreasonable risk finding. The statutory language thus covers a broad category of risks, with varying degrees of certainty, between "not likely" to present an unreasonable risk and "presents" an unreasonable risk—and EPA must make a "may present" finding whenever a case falls between these two extremes. Moreover, EPA's approach conflates the "may present" finding with the "insufficient information" finding, which EPA should make in the circumstances where "there is a high level of uncertainty." By suggesting that EPA may only make a "may present" finding where there is insufficient information, EPA conflates two findings that are distinct. To be sure, EPA may make a "may present" finding even when there is a high level of uncertainty.

13. EPA identifies the correct benchmark for unreasonable risk under TSCA, but it is not clear that EPA consistently applies that benchmark in its "not likely" determinations.

In the Working Approach, EPA acknowledges that "1 x 10^{-6} cancer risk estimate has often been considered a 'benchmark' above which EPA has concerns for exposure to the general

population." Working Approach at p.12 n.22. In implementing TSCA (even before the amendments) and its other environmental statutes, EPA has generally sought to reduce population risks from chemicals in commerce that are carcinogens to below about one case per one million people. For example, when setting standards under the Clean Air Act in 1989, EPA stated that: "EPA believes *** that it should reduce risks to less than 1 x 10^{-6} for as many exposed people as reasonably possible." National Emission Standards for Hazardous Air Pollutants; Radionuclides, 54 Fed. Reg. 51,654, 51,686 (Dec. 15, 1989). Nor does EPA only apply this standard under the Clean Air Act. When setting Clean Water Act criteria:

> EPA intends to use the 10^{-6} risk level, which the Agency believes reflects an appropriate risk for the general population. EPA's program office guidance and regulatory actions have evolved in recent years to target a 10^{-6} risk level as an appropriate risk for the general population. EPA has recently reviewed the policies and regulatory language of other Agency mandates (e.g., the Clean Air Act Amendments of 1990, the Food Quality Protection Act) and believes the target of a 10^{-6} risk level is consistent with Agency-wide practice.[57]

When Congress amended TSCA to include the unreasonable risk standard, it did so knowing that agency practice was to regulate cancer risks at the 10^{-6} risk level. It should be presumed that Congress meant to adopt this risk standard when codifying the unreasonable risk standard.

Problematically, in its draft risk evaluations, EPA has often applied a benchmark of 1 x 10^{-4} as the cancer risk benchmark for workers.[58] Yet EPA is required to protect workers, both generally and as a "potentially exposed or susceptible subpopulation," under TSCA. The 2016 amendments to TSCA strengthened EPA's already-existing mandate to protect workers. TSCA's new definition of "potentially exposed or susceptible subpopulation" has no asterisk next to workers, and in fact if anything elevates the level of protection that should be afforded workers (relative to TSCA prior to 2016) by explicitly identifying them as a "potentially exposed or susceptible subpopulation" alongside infants, children, pregnant women and the elderly. There is no basis in TSCA for EPA to provide less protection to workers than any other such subpopulation, let alone than the general population. Yet that is exactly what EPA has done in those draft risk evaluations.

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[57] U.S. EPA, *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health* p. 2-6 (2000), https://www.epa.gov/sites/production/files/2018-10/documents/methodology-wqc-protection-hh-2000.pdf.

[58] Draft Risk Evaluation for Methylene Chloride (Dichloromethane, DCM) pp. 425, 436, https://www.epa.gov/sites/production/files/2019-10/documents/1_methylene_chloride_risk_evaluation_peer_review_draft_heronet_public.pdf.

The 2016 amendments to TSCA also explicitly preclude EPA from considering feasibility or other non-risk factors when determining whether a chemical presents an "unreasonable risk," including to workers; see TSCA section 6(b)(4)(A). Yet in the draft risk evaluations EPA has invoked standards under other statutes that lack this prohibition in an effort to claim precedent for its 1 x 10^{-4} benchmark.[59]

EPA should apply its 1 x 10^{-6} cancer risk benchmark when reviewing new chemicals' risks to workers under TSCA § 5.

14. There is no statutory basis for limiting TSCA § 5 orders to the circumstances described in the Working Approach.

Based on EPA's faulty assumptions about OSHA and SDSs, EPA suggests that, with respect to workers, it will limit findings that a chemical may present an unreasonable risk and the resulting TSCA § 5(e) orders to two circumstances:

> [1] there may be circumstances where even a short lapse in PPE protection may present unreasonable risks (e.g., acute lethality). In such cases, EPA may issue an order under section 5(e) to reinforce the measures necessary to protect workers. [2] As another example, if a submitter declines to amend their notice or associated SDS to align with EPA's assessment on the appropriate type and level of controls to protect workers, there is a greater chance that both the submitter and any future user will not take the appropriate actions on worker protection.

Working Approach at p.9. While a finding that the chemical may present an unreasonable risk would generally be appropriate in these circumstances, EPA appears to be imposing limits on when it can or will make such a finding that appear nowhere in TSCA. TSCA requires that EPA make a finding that a chemical "may present an unreasonable risk of injury to health or the environment" based on EPA's review of the chemical's intended, known, and reasonably foreseen conditions of use. 15 U.S.C. § 2604(a)(3)(B)(ii)(I). Thus, if there is a potential unreasonable risk, EPA must make the required finding and issue a TSCA § 5(e) order. Nothing in the statutory text limits such risks to circumstances of acute lethality or where a PMN manufacturer has failed to update its SDS. By imposing these additional restrictions on when EPA can make such findings, EPA is deviating from the statutory text in violation of congressional intent.

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[59] *See* Draft Risk Evaluation for Methylene Chloride (Dichloromethane, DCM) p. 426, footnote 22, https://www.epa.gov/sites/production/files/2019-10/documents/1_methylene_chloride_risk_evaluation_peer_review_draft_heronet_public.pdf.

15. 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 must improve the transparency of the new chemicals program, as EDF has previously commented.

On January 24, 2020, EDF submitted comments to EPA describing needed improvements to EPA's CBI claim reviews and public access to information.[60] Among other things, those comments described problems with EPA's approach to confidentiality claims and publication of PMNs and public files for new chemicals. EDF incorporates those comments by reference and urges EPA to implement the requirements of TSCA §§ 5 and 14 to provide greater transparency to the new chemicals program.

As EDF has previously explained to EPA, the exemption process for new chemicals is overly opaque and lacking in transparency. On May 30, 2019, EDF sent a letter to EPA requesting that EPA maintain a public list of the chemical identities of chemical substances for which it receives low volume exemption (LVE) and low environmental releases and human exposures exemption (LoREX) applications.[61] EDF has never received any response from EPA to this letter. We incorporate the points made in that letter by reference and urge EPA to increase the transparency around exemption applications immediately.

B. 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

[60] EDF Comment on New Chemicals Program Implementation Under the Amended Toxic Substances Control Act (TSCA), https://www.regulations.gov/document?D=EPA-HQ-OPPT-2019-0637-0007.
[61] *See* Letter from EDF to Pamela Myrick (May 30, 2019) (attached as Appendix A).

the best available science." 15 U.S.C. § 2625(h). In its regulations 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.*, SAT reports, exposure reports, engineering reports, chemistry report, fate report, and human health assessments) for these findings for each new chemical substance *at the time* the determination for that substance is published, and EPA must document that these findings are consistent with the definition of "best available science" that EPA itself has adopted.

For example, EPA often concludes 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, and the bases for them, 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. EPA must make available (subject only to appropriate redaction) the documents generated in its reviews of PMNs.

C. 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 and 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 TSCA Chemical Categories Document it is employing.[62] EPA should also disclose the new categories that it has been developing, including the information on perfluorinated compounds (PFCs) that it described in one of the presentations at the December 6, 2017, public meeting on new chemicals but has never released to the public.[63] Much of this information clearly falls within the definition of health and safety studies which must be disclosed.

Based on the August 7, 2017, 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.[64] EPA needs to publicly announce the details of these

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[62] U.S. EPA, *TSCA New Chemicals Program (NCP) Chemical Categories* (2010), https://www.epa.gov/sites/production/files/2014-10/documents/ncp_chemical_categories_august_2010_version_0.pdf.

[63] 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.

[64] *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.

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.

16. EPA needs to make use of its testing authorities to fill data gaps, as well as to address already identified risk concerns.

In practice, EPA 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 stated 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.'"[65] In fact, testing is also required to fill data gaps as well as to *identify* risk concerns.

While the analogous language in the Working Approach 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 Working Approach—applies going forward.[66] The Working Approach correctly recognizes that EPA has authority to "to require development of new information to characterize the risk pertaining to a chemical substance submitted under TSCA section 5(a). Generally, EPA requires additional information when there is insufficient information to perform a reasoned evaluation of health or environmental effects." Working Approach at p.5.

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).

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[65] 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.

[66] Does the Working Approach 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 10, 2020, EPA refused to articulate whether the Working Approach overruled the "operating principles" articulated in this press released. Thus, as far as the public knows, this operating principle is still in-force.

While the Working Approach suggests otherwise, EPA uses its testing authorities exceedingly rarely under TSCA § 5 to address insufficient information as part of reviewing the notices under TSCA § 5. EPA has issued virtually no orders requiring upfront testing in its implementation of TSCA § 5. For example, EPA has not issued a single order barring commercialization pending the development of information for at least the past 18 months. And as discussed above, much of the Working Approach 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. Notably, the Working Approach inaccurately implies that SNURs *can* mandate testing, *see* Working Approach at p.10, but in reality SNURs cannot mandate testing, and EPA has acknowledged as much in the past. *See* 84 Fed. Reg. 43,266, 43,267 (Aug. 20, 2019) ("[S]ection 5(a)(2) never has provided authority to require testing in SNUNs."). Why is this substantial difference not mentioned in the Working Approach, and how does EPA intend to address it? How will EPA address insufficient information with a SNUR?

Indeed, EPA's SNURs have shifted the language around testing to emphasize that the SNURs impose no information obligations or even expectations. Specifically, EPA has ceased to identify "recommended testing" and instead only identifies "potentially useful information" that EPA indicates is only being "provided for informational purposes." 83 Fed. Reg. at 37717. EPA's framing of such information highlights that it is not mandated by the SNUR and appears consistent with EPA's general efforts to avoid requiring testing of new chemicals at all costs.

17. EPA fails to give adequate weight to Congress's decision to specifically authorize EPA to make a finding that information is insufficient.

The 2016 reforms to TSCA authorized EPA to find that "the information available to the Administrator is insufficient to permit a reasoned evaluation of the health and environmental effects of the relevant chemical substance or significant new use." 15 U.S.C. § 2604(a)(3)(B)(i). Under the Lautenberg Act, in those circumstances, EPA *must* regulate the chemical through a TSCA § 5(e) order. Thus, in reforming TSCA, Congress specifically considered the scenario where EPA has insufficient information to assess a chemical and Congress required regulation in these circumstances.

In the Working Approach, EPA gives inadequate weight to this option. Working Approach at p.4. And EPA declines to define what "sufficient information" is; instead, EPA simply asserts broad discretion to decide whether it has sufficient information. The result is that it is impossible to discern how and when EPA would determine that it has insufficient information about a new chemical. EPA states that it may have sufficient information when it has "compelling data indicating a chemical poses no hazard," but EPA provides no detail on what compelling data

would be sufficient to establish that a chemical presents no hazard or that in the absence of such data it will determine data to be insufficient.

EPA also refers to its "longstanding practice" of relying on analogues, but that practice predates the requirement that EPA make risk decisions based solely on sufficient information. Given that Congress transformed the standard for EPA action under TSCA § 5, EPA cannot rely on its old practices without change. Even if analogues were appropriate when EPA lacked a mandate to regulate a new chemical based on insufficient information, it does not follow that EPA can now rely on analogues when it has authority to require testing and must make its findings based on sufficient information. Notably, EPA's new chemicals program has failed to adopt any quantitative metric for measuring the accuracy of an analogue and EPA determinations fail to provide any description, let alone analysis, of the degree of confidence to be placed in its selection of analogue chemicals. EPA's Office of Research and Development (ORD) does have a method of assessing analogues, and EPA should consider adopting ORD's approach. At a minimum, EPA must clearly articulate the uncertainty that arises as a result of using a particular analogue.

When an analogue is assessed as less accurate or more uncertain than necessary to support a reasoned evaluation of a new chemical's potential risks, EPA should be finding that it has "insufficient information" and issue a TSCA § 5(e) order with testing requirements to establish the level of concern presented by the PMN substance. The testing should be aimed to address the fact that the reliance on the analogue has introduced uncertainty into EPA's decision. Crucially, EPA can always revise the order to make it more stringent if the testing finds that the analogue underestimated the level of risk presented by the chemical—this option is not available with a SNUR.

Elsewhere in the Working Approach, EPA states that:

> In analyzing the issue of information sufficiency, EPA generally considers:
> • Whether there is information sufficient to characterize both hazard and exposure to render those characterizations into a quantitative or robust qualitative characterization of risk, and
> • The level of certainty or confidence in the data used in the risk estimate.

Working Approach at p.10. Yet earlier in this same document, EPA suggested that it could make a risk determination without any information on exposure. *Id.* at p.4. And in practice EPA does not appear to actually require that it have information sufficient to characterize both hazard and exposure, and EPA often makes "not likely" findings where EPA is unable to perform a

quantitative characterization of risk.[67] EPA has failed to describe what it considers a "robust qualitative characterization of risk," leaving this description completely undefined and unclear. EPA also provides no real information or criteria on what "level of certainty or confidence in the data" is necessary for EPA to conclude that it has sufficient information. Notably, EPA's "not likely" determinations provide no characterization of certainty or confidence in the data.

18. EPA's Working Approach entirely fails to explain how the agency identifies and addresses potentially exposed or susceptible subpopulations.

One of the major transformations to TSCA made by the Lautenberg Act was the additional requirement that EPA identify and avoid unreasonable risks new chemicals pose to "potentially exposed or susceptible subpopulations." 15 U.S.C. §2604(a)(3). Despite this key new duty, EPA completely fails to grapple with this new statutory obligation in the Working Approach.

In nearly all "Not Likely" determinations, EPA has identified using boilerplate language the same three categories of potentially exposed or susceptible subpopulations: workers, general population with drinking water exposures, and consumers of specific products. EPA has not explained why it is ignoring other such subpopulations such as those who live near manufacturing facilities, workers with asthma, pregnant women or infants. EPA should be evaluating the risk to *all* potentially exposed or susceptible subpopulations.

Moreover, the identification of workers as a "potentially exposed or susceptible subpopulation" does not appear to have *any* impact on how EPA evaluates potential worker exposures and risks. Despite their express identification as a potentially exposed or susceptible subpopulation in the statute, *see* 15 U.S.C. §2602(12), EPA does not use a protective benchmark for workers and EPA does not generally protect workers even when EPA's findings establish that the workers face an unreasonable risk.

19. 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.

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

[67] *See, e.g.*, TSCA Section 5(a)(3) Determination for Premanufacture Notice (PMN) P-18-0236 p.8, https://www.epa.gov/sites/production/files/2020-02/documents/p-18-0236_determination_non-cbi_final.pdf ("Sensitization hazards to workers via dermal contact were identified based on [claimed CBI]. Risks for these endpoints were not quantified due to a lack of dose-response for these hazards.").

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 Working Approach does not mention this TSCA § 26(k) obligation, but it undoubtedly applies to the § 5 new chemicals review process.

20. EPA fails to explain whether or how it addresses combined exposures resulting from production by multiple companies.

EPA issues some SNURs that require notification and review prior to exceeding 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, a clearly reasonably foreseen circumstance. 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 start doing so or explain on what basis it has concluded they do not present a concern.

21. EPA needs to combine dermal and inhalation exposures to accurately assess overall exposures.

In its "not likely" determinations, EPA generally assesses risk from dermal exposure and inhalation exposure separately.[68] But in reality, people often experience both dermal and inhalation exposure at the same time. EPA should be combining these exposures to get an accurate assessment of overall, combined exposure. In its draft risk evaluations, EPA has claimed that it does not assess this combined exposure because of "uncertainty," but to the extent there are uncertainties in an additivity analysis, such uncertainties do not support assuming exposure is less than the sum of the exposures; by not combining the exposures EPA is clearly underestimating the exposure. Uncertainty does not justify ignoring the fact that these exposures can actually be experienced in combination.

[68] TSCA Section 5(a)(3) Determination for Premanufacture Notice (PMN) P-18-0114, p.5, https://www.epa.gov/sites/production/files/2020-01/documents/p-18-0114_determination_non-cbi_final.pdf ("Risks to human health for the new chemical substance were evaluated using the route-specific effect level (i.e., LOAEL) described above.") (separately reporting inhalation and dermal results).

22. EPA's environmental analyses are generally limited to water exposure, and too often EPA ignores exposures through land and air releases and risks to terrestrial and avian species as well as sediment-dwelling organisms.

EPA's "Not Likely" determinations, to the extent they analyze environmental risk, almost always limit that risk to solely an assessment of aquatic exposures.[69] As a result, EPA ignores all exposures through releases of the chemical to land and air, and all risks to terrestrial and avian species as well as sediment-dwelling organisms. But a "not likely" finding must find that the chemical is "not likely to present an unreasonable risk of injury to health or the *environment*." 15 U.S.C. § 2604(a)(3)(C) (emphasis added). "Environment" has a broad meaning encompassing "the natural world," OXFORD AMERICAN DICTIONARY 580 (3d ed. 2010), and it is not limited to the aquatic environment. EPA must expand its environmental analyses to encompass the whole environment, including land and air exposures and risks to terrestrial and avian species as well as sediment-dwelling organisms.

23. EPA fails to address bioaccumulation and persistence, and in practice, EPA has not been accurately assessing bioaccumulation or following its PBT policy.

The Working Approach document does not address persistence or bioaccumulation, despite these factors being key aspects of new chemical reviews. In practice, EPA has adopted an approach towards bioaccumulation that overlooks certain types of bioaccumulation and fails to implement EPA's persistent, bioaccumulative, and toxic ("PBT") policy.[70] EPA should address all types of bioaccumulation and should implement its PBT policy going forward.

A. When assessing bioaccumulation, EPA overlooks the bioaccumulation of chemicals like perfluorinated chemicals.

Typically, when assessing bioaccumulation, EPA relies on estimated bioconcentration factors (BCF) or bioaccumulation factors (BAF) and focuses on lipophilic partitioning.[71] EPA does

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[69] *See, e.g.*, TSCA Section 5(a)(3) Determination for Premanufacture Notice (PMN) P-18-0232, p. 6, https://www.epa.gov/sites/production/files/2019-12/documents/p-18-0232_determination_non-cbi_final.pdf ("Risks to the environment were evaluated by comparing estimated surface water concentrations with the acute and chronic concentrations of concern. Risks from acute and chronic exposures to the environment were not identified due to releases to water that did not exceed the acute or chronic COC.").

[70] *See* 64 Fed. Reg. 60194 (Nov. 4, 1999), https://www.gpo.gov/fdsys/pkg/FR-1999-11-04/pdf/99-28888.pdf (hereinafter "PBT Policy") (adopting criteria for identification of new chemicals as PBTs).

[71] *See, e.g.*, TSCA Section 5(a)(3) Determination for Premanufacture Notice (PMN) P-18-0236, pp.4-5, https://www.epa.gov/sites/production/files/2020-02/documents/p-18-0236_determination_non-cbi_final.pdf.

mention whether the chemical might accumulate "in organisms by other mechanisms," but EPA provides no detail on how it assesses this factor or considers whether the chemical may bioaccumulate by another mechanism. How does EPA account for chemicals that accumulate in blood rather than fatty tissues, which a BCF does not account for?[72]

EPA's discussion of the bioaccumulation potential of PFOA, a perfluorinated chemical, makes clear that traditional BCF values are derived using methods that do not capture bioaccumulation and bioconcentration of chemicals like PFOA, despite other clear evidence that they are in fact bioaccumulative:

> It is recognized[,however] that BCFs determined by existing standard methods derived from lipid-partitioning are not an appropriate metric for assessing bioconcentration of PFOA (EFSA 2008; UNEP 2015). Although evidence of PFOA accumulation in many organisms has been documented, reported BAFs and BCFs for the chemical also fall below traditional criteria used to assess bioaccumulation potential (Loi et al. 2011; Martin et al. 2003a, 2003b; Morikawa et al. 2005; Quinete et al. 2009). Field evidence of PFOA biomagnification, considered to be the preferable metric for assessing bioaccumulation potential (Gobas et al. 2009), has been documented in many organisms from many locations worldwide (UNEP 2015). Trophic magnification has also been evaluated (Environment Canada and Health Canada, 2012; Houde et al. 2006; Kelly et al. 2009; Loi et al. 2011; Martin et al. 2004). Some field trophic studies revealed TMFs greater than 1, which indicates that PFOA accumulated and increased in concentration with increasing trophic level; other studies reported TMFs less than 1 for some food webs. The weight of evidence for trophic magnification was deemed sufficient to consider PFOA to be bioaccumulative by the Stockholm Convention Persistent Organic Pollutants Review Committee (UNEP 2015).

Id. EPA must assess all bioaccumulation, not just bioaccumulation captured by BAF and BCF.

B. EPA has not consistently applied its PBT policy.

Under EPA's PBT Policy:

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[72] *See, e.g.*, U.S. EPA, Drinking Water Health Advisory for Perfluorooctanoic Acid (PFOA) 25 (May 2016), https://www.epa.gov/sites/production/files/2016-05/documents/pfoa_health_advisory_final-plain.pdf.

> Chemical substances suspected as persistent bioaccumulators under the criteria listed in the table in Unit IV.A. of this document may need to undergo testing on "P" and "B" endpoints which, if confirmed, would be followed by appropriate toxicity testing to identify "PBT chemical substances." Control action under TSCA section 5(e) may be needed in varying degrees, based upon the level of risk concern. Agency control actions taken under TSCA section 5(e) for chemical substances meeting these criteria would be based upon the level of certainty for the PBT properties of a PMN substance (e.g., measured vs. estimated values), the magnitude of Agency concerns, and conditions of expected use and release of the chemical.[73]

Under the PBT Policy, EPA considers a chemical to be persistent if its transformation half-life is greater than 2 months, and to be bioaccumulative if its bioaccumulation factor (BAF) is greater than or equal to 1,000. EPA considers a chemical to be very persistent if its transformation halflife is greater than 6 months and to be very bioaccumulative if its BAF is greater than or equal to 5,000.[74]

But EPA has not consistently applied this policy to new chemicals in the new chemicals program. EDF has repeatedly commented on this issue in our comments on proposed SNURs. These comments are incorporated by reference.[75]

EPA has provided no basis for deviating from its longstanding PBT Policy and it should not do so. If EPA nevertheless chooses to deviate from its established policy, EPA must acknowledge these departures, and EPA must provide an explanation for those departures. The PBT policy itself states that when EPA departs from the policy, "EPA will explain why a different course was taken." 64 Fed. Reg. at 60204. More broadly, where an agency changes its policy and practice, the agency must acknowledge that change and provide a well-reasoned and complete explanation for its action. *See FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009) ("An agency may not, for example, depart from a prior policy sub silentio."); *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43-44 (1983).

When EDF raised these issues in public comments on the SNURs, EPA summarily dismissed these concerns as "constitute[ing] challenges to certain TSCA §5(a)(3) determinations rather than to the basis for or the content of the SNUR. EPA is not responding to these comments in

[73] PBT Policy at p. 60,202.
[74] *Id*. at 60202.
[75] *See, e.g.*, EDF Comments on Significant New Use Rules on Certain Chemical Substances pp. 14-18 (Dec. 21, 2018)**,** https://www.regulations.gov/document?D=EPA-HQ-OPPT-2018-0650-0208.

this notice and declines to withdraw the SNURs on the basis of these comments."[76] EPA then indicated that the PBT policy does not require a ban pending testing for all very persistent and very bioaccumulative chemicals, but EPA failed to explain its failure to require sufficient testing, let alone any testing in some cases, in line with the PBT policy.

24. 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, as well as our analysis of EPA's new chemical decisions, EPA's 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 using this approach. 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.

[76] Public Comments on Proposed Significant New Use Rule (18-3) and EPA Responses, https://www.regulations.gov/docket?D=EPA-HQ-OPPT-2018-0650.

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.[77]

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.[78] 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 shared numerous written documents with industry to the exclusion of, or in advance of sharing with, other stakeholders. These include: four or five so-called "category documents" relating to lung toxicity concerns,[79] and drafts of the "points to consider" document.

EPA also has taken some steps that have reduced the transparency of the PMN process. EPA made the website less transparent in a key respect than it had been for decades. EDF documented this change in the following piece: Richard Denison, *Hiding its tracks: The black*

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[77] 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.

[78] *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.").

[79] Presentation by Dr. Tala 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.

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 now hides 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*.

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