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**Comments from the Environmental Working Group**

**On EPA's Framework for Decision-Making on New Chemicals**

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

January 20, 2018

The Environmental Working Group is a public interest group dedicated to using the power of information to protect public health and the environment. EWG advocated for reforms to the Toxic Substances Control Act for over a decade and was actively involved in the debate over the Lautenberg amendments to TSCA. With these comments, EWG urges the Environmental Protection Agency (EPA) to focus on establishing a new chemicals assessment system that would put public health first and especially prioritize addressing chemical risks to children's health.

There is a great deal at stake. The Lautenberg amendments significantly overhauled the evaluation of new chemicals under section 5 of TSCA, requiring the EPA for the first time to make an affirmative safety finding on chemical substances *before* they are commercialized. This improved one of the principle flaws of the old law, which allowed new chemicals to be approved for manufacture without any safety finding or health data.[1] A robust new chemicals program rooted in adequate data, that identifies and manages risks, including risks to children and other vulnerable subpopulations, under *all* conditions of use, is critical to meeting the goals of the law and to restoring the public trust that was lost under the old law.

EWG was encouraged by EPA's early implementation of the Lautenberg amendments to the new chemicals program. EPA appeared to be taking seriously its new responsibilities by reviewing premanufacture notices, or PMNs, for potential risks posed by the substance as a whole—including for both intended and reasonably foreseeable uses. EPA issued a significant number of "may present an unreasonable risk" findings accompanied by consent orders, often based on concerns about those reasonably foreseeable uses. This practice adhered to both the letter and the spirit of the law, and EWG filed comments in support of EPA's approach in January 2017.[2]

Things have changed a lot since then. EWG and other public health advocacy organizations throughout the country have vocally opposed the abrupt shift in the EPA's

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[1] *See, e.g.*, EPA Office of Inspector General, *EPA Needs a Coordinated Plan to Oversee Its Toxic Substances Control Act Responsibilities* 6 (2010), https://www.epa.gov/sites/production/files/2015-11/documents/20100217-10-p-0066.pdf (finding that the new chemicals program was limited at the time by an absence of test data, and raising concern about the lack of data included in PMN submissions).

[2] Environmental Working Group, Comments Submitted on New Chemicals Review Program Under Amended Toxic Substances Control Act (January 17, 2017), https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0658-0037.

approach to regulation of new chemicals that took place in the last half of 2017. EWG was especially alarmed to discover to what a great extent the changes in the EPA's framework align with chemical industry demands. EWG is further concerned that EPA developed this decision-making framework, and launched a pilot study, with input only from the regulated industry. EPA did not give other stakeholders the opportunity to provide input until now. Moreover, at the December 2017 public meeting, the agency indicated that it is already using this industry-friendly framework to guide its new chemicals decisions, prior to any public comment or serious examination of the legality of this approach.

Given that the EPA did not follow a full and inclusive stakeholder process, EWG urges the agency to suspend the use of this incomplete, biased framework immediately and instead focus on establishing a new chemicals assessment system that would put public health first. In particular, EWG comments that:

- EPA's use of significant new use rules, or SNURs, as a replacement for consent orders for new chemicals is unlawful and puts public health at risk;
- PMN amendments are not a substitution for consent orders and details on PMN meetings should be transparent and public;
- EPA is unduly narrowing the scope of its PMN reviews and excluding potential uses and exposures;
- EPA must consider children and other vulnerable populations, including workers, when assessing risk and crafting restrictions;
- EPA does not have the authority to delegate its responsibility to address workplace risks to OSHA; and
- EPA must enhance transparency by making public information more readily accessible, and by ensuring that submitters make health and safety studies publicly available and substantiate all confidential business information.

**Use of SNURs**

Perhaps the most drastic, and controversial, change to EPA's implementation of the new chemicals program has been the shift away from enforcement orders in favor of significant new use rules. In fact, EPA has eschewed orders so much that the word "order" is only mentioned once in the entire framework document. And even then, EPA discusses orders only in the context of how it plans to limit the use of orders for additional testing data.

This near-total absence of discussion of orders is alarming because orders are the primary enforcement tool under section 5. If EPA finds that a new chemical presents an unreasonable risk, including an unreasonable risk to a potentially exposed or susceptible population, EPA is required to control those risks under section 5(f), either via a section 6(a) rule or an order.[3] If EPA does not have sufficient information to permit a reasoned evaluation, or if the substance is produced in substantial quantities or could cause

[3] 15 U.S.C. § 2604(a)(3)(A); 15 U.S.C. § 2604(f).

significant or substantial human exposure, EPA is *required* to issue a section 5(e) order.[4] Section 5(e) very clearly states that 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."[5]

The law is clear that these orders are not discretionary. As such, EWG is deeply concerned by the framework document's approach, which would abandon orders in favor of SNURs. The framework document says that:

> Where EPA has concerns with reasonably foreseen conditions of use, but not with the intended conditions of use as described in the submission (original or amended), EPA will assess whether those concerns can be addressed through significant new use rules (SNURs). The expectation is that SNURs will generally be effective vehicles to address such concerns and that, as a general matter, EPA will address such concerns through SNURs.

At the December 6, 2017, public meeting, Jeff Morris suggested that this new approach is designed to increase efficiency. He justified the change, in part, by stating that SNURs often have to be issued after an order to bind parties other than the submitter. Therefore, EPA believes it is more efficient to drop the order and rely on SNURs instead, so that the process is only one step instead of two.[6] However, the two-step process (an order with a follow-up SNUR) that EPA would like to discontinue is exactly what the statute envisions. Section 5(f)(4) states that EPA *shall* consider whether to issue a SNUR "*after* taking an action under paragraph (2) or (3) [to mitigate unreasonable risks] or issuing an order under subsection (e)." EPA is supposed to *first* address the risks from an unreasonable risk or insufficient information finding through a rule or order, and *then* issue a follow-up SNUR. In other words, SNURs are designed to supplement, not supplant other 5(f) and 5(e) restrictions.

EWG also strongly disagrees with Jeff Morris' assertion at the December 6 meeting that a SNUR-only approach would provide "equivalent health protections" to a two-step process with an order and follow-up SNUR. As detailed in an Environmental Defense Fund analysis, SNURs and orders are not interchangeable tools, and SNURs are less health protective than orders in a number of significant ways.[7] As EDF points out, orders, among other things, impose legally binding conditions, are readily enforceable, can be used to impose testing requirements, can be reopened when there is new information, and

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[4] 15 U.S.C. § 2604(a)(3)(B)("in which case the Administrator *shall* take the actions required under subsection (e)") (emphasis added).
[5] 15 U.S.C. § 2604(e) (emphasis added).
[6] Maria Hegstad, *Citing Efficiency, EPA Defends Strategy for Some 'New TSCA Chemicals'*, Inside EPA (Dec. 6, 2017), https://insideepa.com/daily-news/citing-efficiency-epa-defends-strategy-some-new-tsca-chemicals.
[7] Richard Denison, *Too Little, Too Late: Why SNURs Alone are Not a Sufficient Alternative to Consent Orders for New Chemicals*, Environmental Defense Fund (Nov. 30, 2017), 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/

can be issued more quickly and efficiently than SNURs. The extended rule making process and the associated long length of time required to finalize SNURs is a significant concern. For example, in January 2015 EPA proposed, and has to date not finalized, a SNUR for PFOA and PFOA-related chemicals to ensure that at the culmination of a decade-long phaseout agreement, no other companies would be able to bring these chemicals to market without notifying the EPA.[8] However, three years later the SNUR has yet to be finalized, meaning manufacturers can continue to use these chemicals without notifying EPA.

As such, EPA's actions to issue SNURs instead of orders are not only unlawful, but undermine the public health goals of the law. EPA should suspend this practice immediately, and resume issuing orders, followed-up by SNURs as needed.

**Use of Amended PMNs**

EWG is also concerned by EPA's expanded reliance on PMN amendments to reach "not likely to present an unreasonable risk" findings. The framework document states that EPA plans to review the intended uses presented in the PMN and if EPA has concerns, it will give the submitting party an opportunity to amend the PMN to include additional engineering controls and workplace protections. The framework document implies that these additional controls will make it easier for the agency to make a "not likely to present an unreasonable risk" finding. This is problematic because merely including proposed engineering controls and workplace protections in a PMN is insufficient to ensure workers are adequately protected. As discussed later in these comments, common workplace protections like personal protective equipment is often insufficient to protect workers from risks. Moreover, conditions included in a PMN are not binding. If such controls or protections are needed to ensure the substance is not likely to present an unreasonable risk, EPA should bind the submitter to those controls through the use of an order.

This approach is also problematic because the agency's role is not to be an industry consultant. EPA should not spend its already-limited resources advising PMN submitters on how to best amend PMN submissions to get a favorable risk evaluation. It is the responsibility of industry to submit complete PMNs that provide ample hazard and exposure data, information about potentially exposed and susceptible populations, and that identify all conditions of use, including reasonably foreseeable uses. In fact, as EPA has confirmed, a major contributor to the backlog of PMNs that was the source of so much industry ire was industry's own failure to provide complete and accurate information in PMN submissions.[9] EPA should emphasize in its section 5 implementing documents that the agency's primary responsibility under section 5 is to make risk

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[8] Long-Chain Perfluoroalkyl Carboxylate and Perfluoroalkyl Sulfonate Chemical Substances; Significant New Use Rule, 80 Fed. Reg. 2855 (proposed Jan. 21, 2015) (to be codified at 40 C.F.R. pt. 721).

[9] Letter from Liz Hitchcock, Gov't Affairs Director, Safer Chemicals Healthy Families, et al., to Dr. Jeff Morris, Acting Director, Office of Pollution Prevention and Toxics (Oct. 16, 2017), http://saferchemicals.org/sc/wp-content/uploads/2017/11/SCHF-PMN-letterfinal.pdf?x33530 ("as you confirmed at the meeting, a major contributor to inefficiencies in the PMN program is industry itself . . .").

determinations supported by adequate information. Manufacturers should understand that if they fail to include complete information in a PMN submission, the law requires EPA to issue a section 5(e) order mitigating potential risks.[10]

**Analyzing Chemical Substances as a Whole Under the Conditions of Use**

The framework document describes a two-step process for analyzing potential risks under the conditions of use: 1) determining if the intended conditions of use meet the "not likely to pose an unreasonable risk" standard and then 2) determining whether there are reasonably foreseeable uses that may pose an unreasonable risk that can be addressed through a significant new use rule.

This two-step process is a clear departure from the law, which requires EPA to look at a chemical substance *as a whole*. Throughout section 5, the law instructs both manufacturers and the EPA to take actions either on a "chemical substance" or a "significant new use." Aside from significant new uses, nowhere in the statute is EPA given discretion to analyze only some uses. Section 5(a)(1) prohibits manufacture of a "new chemical substance" unless it has gone through the PMN review process.[11] Section 5(d) requires manufacturers to provide information about the "substance" it intends to manufacture, including "uses of such substance."[12] Section 5(a)(3) requires EPA to make a risk determination on the "relevant chemical substance."[13]

The law further requires EPA to determine if the "relevant chemical substance" presents an unreasonable risk "under the conditions of use."[14] "Conditions of use" is defined in the statute as "the circumstances, as determined by the Administrator, under which a chemical substance is *intended, known, or reasonably foreseen* to be manufactured, processed, distributed in commerce, used or disposed of."[15] Analyzing a "substance" "under the conditions of use" therefore means looking at all those uses together.

In the preamble to the Proposed Rule for Procedures on Risk Evaluation issued on January 19, 2017, EPA interpreted very similar language under section 6, and concluded that it had a legal obligation to analyze a chemical as a whole. In particular, EPA stated that:

> TSCA section 6(b)(4)(A) specifies that a risk evaluation must determine whether ''a chemical substance'' presents an unreasonable risk of injury to health or the environment ''under the conditions of use.'' *The evaluation is on the chemical substance—not individual conditions of use*—and it must be based on ''the conditions of use.'' *In this context, EPA believes the word ''the'' is best interpreted as calling for evaluation that considers all conditions of use*. First, if

[10] 15 U.S.C. § 2604(a)(3)(B).
[11] 15 U.S.C. § 2604(a)(1).
[12] 15 U.S.C. § 2604(d).
[13] 15 U.S.C. § 2604(a)(3).
[14] 15 U.S.C. § 2604(a)(3)
[15] 15 U.S.C. § 2602(4) (emphasis added).

> EPA were free to base its determination of whether a chemical substance, as a whole, presents an unreasonable risk or injury (as the statute requires) on merely a subset of individual uses, it could, for example, determine that a chemical substance with 10 known uses does not present an unreasonable risk of injury based on an evaluation of a single one of those uses, with no further obligation to evaluate the remaining uses within the three-year statutory deadline. This is a strained reading of the commands to determine whether the chemical substance presents an unreasonable risk, under the conditions of use . . .[16]

Although EPA dropped this text in the preamble to final risk evaluation rule, EWG continues to assert that this is the correct interpretation, and that the same logic applies to new chemicals evaluated under section 5. By allowing a "not likely to present an unreasonable risk" finding based solely on intended uses first and then analyzing reasonably foreseeable uses at a later step, EPA is impermissibly narrowing the scope of its PMN review and failing to look at the chemical as a whole. This has real public health consequences, because EPA will make decisions about chemical safety without considering the full scope of likely exposure, leading to determinations based on incomplete information.

**Reasonably Foreseeable Uses**

EPA's interpretation of "reasonably foreseeable" is also impermissibly narrow. In an August 7, 2017, press release, EPA committed to an operating principle where "identification of reasonably foreseen conditions of use will be fact-specific." EPA went on to say that "It is reasonable to foresee a condition of use, for example, where facts suggest the activity is not only possible, but over time and proper conditions, *probable*."[17]

This interpretation has no legal basis. Foreseeable and probable are not equivalent terms. Courts have recognized that neither criminal nor tort law requires there to be a strong probability for a consequence to be considered reasonably foreseeable.[18] Likewise, it is easy to imagine scenarios under TSCA where a use may be reasonably foreseeable, but it is hard to know whether it would be probable. EPA may be able to foresee that a chemical could be part of an accidental release, but would have no way of knowing the probability of that happening. Likewise, it may be foreseeable that downstream users will misuse a chemical or ignore warning labels, but it is hard to know the likelihood that they will.

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[16] Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act, 82 Fed. Reg. 7565-66 (proposed Jan. 19, 2017) (emphasis added).

[17] Press Release, Environmental Protection Agency, 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.

[18] *See People v. Nguyen*, 21 Cal. App. 4th 518, 535 (Cal. Ct. App. 1993)("In criminal law, as in tort law, 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....'")(citing to (1 Witkin & Epstein, Cal. Criminal Law (2d ed. 1988) § 132, p. 150.)

EPA did not include the word "probable" in the framework document, but it is unclear whether EPA continues to adhere to this interpretation under the operating principles announced in the August 7 release. At the December 6, 2017, public meeting EPA representatives indicated that a use would not need to be probable in order to be considered foreseeable, but EPA has not taken formal steps to correct the operating principles released in August.

EPA should explicitly state in any implementing document that it does not interpret reasonably foreseeable to mean probable. EPA should further commit to a broader, more-health protective interpretation of reasonably foreseeable. As EWG has previously commented with regards to section 6 risk evaluations, reasonably foreseeable uses should include potential accidents, off-label uses, and misuses, even when misuses violate the law.[19]

By definition, EPA must also include foreseeable uses throughout the entire life cycle of the chemical from cradle to grave. The definition of "conditions of use" includes the circumstances under which the chemical substance may be "manufactured, processed, distributed in commerce, used, or disposed of."[20] Although section 5 evaluates chemicals at the beginning of that life cycle, EPA's analysis must also consider risks from potential downstream uses, recycling, and disposal. EPA should revise its framework materials to include discussion of how EPA plans to take these later life uses into consideration.

Additionally, while the framework document mentions that EPA plans to address risks from chemicals and their degradation products, EPA should also consider byproducts, like the formation of the substance as an impurity or contaminant, as reasonably foreseeable uses.

**Testing Orders**

The Lautenberg amendments to section 5 make clear that EPA can no longer approve PMNs without adequate data about the chemical's potential health and environmental impacts. EPA's risk determinations under section 5(a)(3) must be based on sufficient information "to make a reasoned evaluation."[21] If information is inadequate, EPA must issue a section 5(e) order restricting use of the chemical.[22] Thus, EPA may only make a "not likely to present an unreasonable risk" finding on a PMN when it has adequate data to do so.

This is a significant improvement over the old law. Prior to the Lautenberg amendments to TSCA, there was no requirement for EPA to affirmatively review the safety of a chemical before it could be manufactured. As a result, many chemicals came onto the

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[19] Environmental Working Group, Comment on the Proposed Rule on Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act (March 20, 2017), https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0654-0089.
[20] 15 U.S.C. § 2602(4).
[21] 15 U.S.C. 2604(a)(3).
[22] *Id.*; § 2604(e).

market simply because the 90-day review period ended; not because EPA had reviewed health and environmental data, and concluded the chemical was safe. In fact, an EPA inspector general report found that 85% of pre-manufacture notices contained no toxicity data and 50% included no test data at all.[23] The need for new chemicals decisions to be rooted in adequate health data was also memorialized in EPA's own Essential Principles for Reform of Chemicals Management which said that "manufacturers should provide EPA with the *necessary information* to conclude that new and existing chemicals are safe and do not endanger public health or the environment."[24]

To meet these new data requirements, the Lautenberg amendments strengthened EPA's ability to require new data generation through orders. Specifically, EPA may now by rule, order, or consent agreement require the development of new information to review a PMN, or as part of an 5(e) or 5(f) action to restrict a chemical.[25] This expanded testing authority offers a significant opportunity for EPA to fill critical data gaps before making safety decisions. By including testing requirements in its 5(e) and 5(f) orders, EPA can also provide itself with the necessary flexibility to revisit and refine restrictions after the testing is completed and after EPA has more information about how the substance has actually been used in the market.

EWG is therefore concerned by implications that EPA plans to use this authority sparingly. The framework document only mentions EPA's testing authority once and states that the purpose of test orders is "to reduce uncertainty when making a risk determination." EPA must clarify what it means by "reduce uncertainty." Importantly, EPA must emphasize that the primary purpose of test orders under section 5 is to fill data gaps about a chemical's potential health and environmental effects. For example, when EPA completed a work plan problem formulation and initial assessment of three flame retardant clusters in 2015, environmentalists criticized EPA for failing to assess risks from dermal and inhalation exposures, despite EPA's acknowledgment that both pathways were likely to be significant sources of human exposure.[26] If EPA reviews a PMN for a new flame retardant cluster, it should be able to use its testing authority to acquire this kind of dermal and inhalation data. EPA should be able to use this authority if a PMN submitter provided no information on those endpoints and also if the information provided is not sufficient for EPA to make a determination. Under no circumstances should EPA be required to show evidence of risk before it can use a test order to "reduce uncertainty." Such a requirement would recreate the infamous catch-22 that severely hindered EPA's ability to fill data gaps under the old law.

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[23] EPA Office of Inspector General, *EPA Needs a Coordinated Plan to Oversee Its Toxic Substances Control Act Responsibilities* 4 (2010), https://www.epa.gov/sites/production/files/2015-11/documents/20100217-10-p-0066.pdf.

[24] EPA, *Assessing and Managing Chemicals Under TSCA*, https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/essential-principles-reform-chemicals-management-0 (accessed Jan. 20, 2018) (emphasis added).

[25] 15 U.S.C. § 2603(a)(2).

[26] Earthjustice, Natural Resources Defense Council, and Washington Toxics Coalition, Comment Letter on the Problem Formulation and Initial Assessment Documents for Three Flame Retardant Clusters (Nov. 18, 2015), https://www.regulations.gov/document?D=EPA-HQ-OPPT-2015-0068-0027.

## Adverse Impacts and Exposures

In the framework document, EPA indicates that it will consider the "potential adverse impact (e.g., severity or reversibility of effect)" when analyzing a substance to determine if it presents an unreasonable risk. In March 20, 2017, comments on the proposed risk evaluation rule, a group of leading science academics recommended that EPA remove references to reversibility as a risk factor because to do so "includes a base assumption that adverse health effects are reversible."[27] The comments point out that EPA regulates some adverse effects, such as ozone, that are reversible but still constitute a public health risk.[28] EPA should remove these references to reversibility, and clarify what it means by "severity."

The framework document also states in several places that EPA's exposure analysis will include consideration of factors like duration, magnitude, and population. While these are important considerations, EPA should not equate low exposure with low risk as a default assumption. To do so would disregard the significant body of evidence that hormone disruptors and developmental toxicants may cause adverse effects at very low doses, and ignores the possibility of nonmonotonic dose-response curves.[29] The pharmaceutical literature is rife with examples of nonmonotonicity, timing, and age-group specific toxicity concerns.[30]

Aggregate and cumulative exposure should also be taken into consideration whenever possible. When analyzing the conditions of use for a chemical, EPA should also consider potential aggregate exposure effects from the different intended, known, and reasonably foreseen uses. EPA should consider potential cumulative exposure to groups of similar chemicals, and use the Adverse Outcome Pathway framework and database[31] to identify where cumulative effects may be an issue. EPA should follow the cumulative risk assessment process recommended by NAS in its Phthalates and Cumulative Risk Report.[32] When specific information is not available, EPA may use default values to account for cumulative exposures.

## Risks to Children and Other Vulnerable Populations

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[27] Juleen Lam et al., Comment on the Proposed Rule on Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act (March 20, 2017), https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0654-0088.

[28] Id.

[29] *See, e.g.*, Nat'l Acad. Sci., *Science and Decisions: Advancing Risk Assessment* (2009), http://www.nap.edu/catalog/12209/science-and-decisions-advancing-risk-assessment; Philippe Grandjean et al., The Faroes Statement: Human Health Effects of Developmental Exposure to Chemicals in Our Environment, 102 Basic Clinical Pharmacological Toxicology 73-75 (2008), https://www.ncbi.nlm.nih.gov/pubmed/18226057.

[30] *See, e.g.*, *Non-monotonic Dose Response Curves*, Our Stolen Future, http://www.ourstolenfuture.org/NewScience/lowdose/nonmonotonic.htm (last visited Mar. 20, 2017).

[31] *Adverse Outcome Pathway Knowledge Database*, Org. for Econ. Co-Operation & Dev., http://aopkb.org/ (last visited January 20, 2018).

[32] Nat'l Acad. Sci., *Phthalates and Cumulative Risk Assessment: The Tasks Ahead* (2008), https://cfpub.epa.gov/ncea/risk/recordisplay.cfm?deid=202508.

The Lautenberg amendments to TSCA imposed significant new requirements on EPA to specifically consider particularly vulnerable populations when assessing risks. In section 5 alone there are six different references to consideration of risks to "a potentially exposed or susceptible subpopulation." Thus, it is surprising and alarming that the framework document only mentions susceptible populations once, and in a footnote at that. Any section 5 implementing document should include a robust discussion of potentially exposed or susceptible populations, how EPA plans to identify those populations, and what EPA will do to account for unique risks to those populations.

As EWG has previously commented, the appropriate processes and procedures to identify susceptible and highly exposed populations may vary.[33] For example, communities contaminated by legacy uses of chemicals may have unique vulnerabilities to new, but similar chemicals introduced as replacements. For example, communities grappling with contamination from perfluorinated compounds like PFOA that have largely been phased out of commerce may face unique risks from next generation per- and polyfluorinated chemicals (PFAS or PFC), such as Gen X, PFBS, or some of the other hundreds of chemicals that EPA has already reviewed as replacements.[34] Review of any PMNs for new perfluorinated compounds, or review of significant new uses for perfluorinated compounds, must take into consideration legacy PFC exposure across the entire population and the unique risks faced by highly contaminated communities. To the extent practicable, EPA should seek communities and public health experts' input as to the appropriate means of identifying vulnerable and chemically overburdened populations who may face unique risks to new chemicals.

EPA should make use of appropriate population-based defaults to ensure that risks to relevant subpopulations are accounted for. As leading science academics pointed out in March, the science has evolved away from the use of standard defaults that are applied uniformly across different chemicals and health outcomes.[35] Instead, EPA should make use of science-based defaults that account for various life stages, including fetal, infancy, childhood, and other vulnerable developmental periods.[36] EPA should also consider differences in both biological response and exposure scenarios for given life stages. EPA should draw on research from other federal, state, and academic institutions to set appropriate values. For example, the California EPA has developed child-specific risk values for certain chemicals, like lead, nickel, heptachlor, and chlorpyrifos. Those values

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[33] Environmental Working Group, Comment on the Proposed Rule on Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act (March 20, 2017), https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0654-0089.

[34] Environmental Protection Agency, New Chemicals Program Review of Alternatives for PFOA and Related Chemicals, https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/new-chemicals-program-review-alternatives-pfoa-and (last visited January 20, 2018).

[35] Juleen Lam et al., Comment on the Proposed Rule on Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act (March 20, 2017), https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0654-0088 (citing to Nat'l Acad. Sci., *Science and Decisions: Advancing Risk Assessment* (2009), http://www.nap.edu/catalog/12209/science-and-decisions-advancing-risk-assessment).

[36] Id.

compare children's susceptibility to adults' by specifically examining child-specific routes of exposure.[37] EPA should review California EPA's approach and adopt its risk values for similar new chemicals as appropriate. Because recent advances in science suggest that EPA's default safety factor of ten to account for variability and susceptibility in people is often not sufficiently health-protective, EPA should apply a more protective safety factor when possible.[38] EPA should also apply its own established principles for promoting environmental justice when determining the potential risk to vulnerable populations from a new chemical.[39]

**Worker Exposures**

Workers are also a uniquely vulnerable population that EPA must consider when evaluating a new chemical substance. Unlike other vulnerable populations, the framework document does loosely address considerations about worker exposures. In particular, EPA states that information provided about "workplace practices and exposure controls" and reported "engineering controls and other worker protections" in PMNs and PMN amendments will be considered as part of the chemicals' intended conditions of use.

EPA should not make a default assumption that reported engineering controls and worker protections will be adequate to protect workers from unreasonable risks. Instead, as recommended in comments by Earthjustice on the flame retardant hexabromocyclododecane, EPA must instead rely on world exposure scenarios, particularly with regards to personal protective equipment.[40] As the commenters point out, PPE is not universally worn, particularly when the work is carried out by small businesses and subcontractors, or by unskilled workers with low pay. In many cases the prescribed PPE is not even provided to workers.[41] EPA has also recognized the limits of PPE in its proposed rule on methylene chloride and n-methylpyrrolidone, stating:

> Not all workers can wear respirators. Individuals with impaired lung function, due to asthma, emphysema, or chronic obstructive pulmonary disease, for example, may be physically unable to wear a respirator. … Also, difficulties associated with selection, fit, and use often render them ineffective in actual application, preventing the assurance of consistent and reliable protection, regardless of the assigned capabilities of the respirator. Individuals who cannot get a good

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[37] Cal. EPA, Office of Envtl. Health Hazard Assessment, *Child-Specific Reference Doses Finalized to Date*, http://oehha.ca.gov/risk-assessment/chrd/table-all-chrds (Jun. 22, 2010).
[38] Juleen Lam et al., Comment on the Proposed Rule on Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act (March 20, 2017), https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0654-0088
[39] Alaska Community Action on Toxics, et al., Comments on Scope of the Risk Evaluations for the First Ten Chemicals under the Toxic Substances Control Act (Mar. 15, 2017), https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0723-0023.
[40] Alaska Community Action on Toxics, et al,, Comments on the Scope of the Risk Evaluation for Cyclic Aliphatic Bromides Cluster (Sept. 19, 2018), https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0735-0060.
[41] Id.

> facepiece fit, including those individuals whose beards or sideburns interfere with the facepiece seal, would be unable to wear tight fitting respirators. In addition, respirators may also present communication problems and vision problems, increase worker fatigue, and reduce work efficiency.[42]

When EPA is reviewing a PMN that may pose risks to workers, EPA should not evaluate exposure potential for an "ideal" worker correctly using the appropriate PPE. Instead, EPA should generally evaluate for incorrectly using PPE and workers using no PPE, particularly in industries like the construction trades where there are often not rigid safety policies or enforcement.

**OSHA Consultations**

EWG is deeply concerned by recent efforts from industry to undermine EPA's responsibility to protect workers from potential risks posed by new chemicals under section 5. In particular, a December 2017 position statement from the so-called "Toxic Substances Control Act New Chemicals Coalition" (hereinafter NCC) argues the Occupational Safety and Health Administration consultation requirement under section 5(f)(5) gives OSHA, not the EPA, primary authority to address worker risks from chemicals under TSCA.[43]

NCC's position is absurd. Section 5(f)(5) merely states that "to the extent practicable," EPA should consult with OSHA about potential risks.[44] Consulting with OSHA "to the extent practicable" is hardly a transfer of power. It is an opportunity for EPA to confer with the experts at OSHA and compare science in order to craft better restrictions. A mere consultation certainly does not absolve EPA of its duty to take steps to mitigate unreasonable risks to potentially exposed or susceptible populations like workers through rules, orders, or consent agreements.

EWG strongly disagrees with the NCC's position that merely passing along information about potential risks to manufacturers and OSHA satisfies EPA's obligation to address risk to workers. The statute very clearly says that if EPA finds there may an unreasonable risk, including to subpopulations like workers, EPA *shall* take action to mitigate those risks under section 5(f).[45] Likewise, if EPA does not have sufficient information for a reasoned evaluation and there may be a risk to a vulnerable population, like workers, the law says that EPA *shall* issue an order under section 5(e) to address those risks.[46] There is no provision in the law that allows EPA to delegate this responsibility to other agencies.

What's more, OSHA has neither the existing authority nor the capacity to ensure new chemicals will not present an unreasonable risk to workers. OSHA regulations ascribe to

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[42] *Id.* (*citing to* 82 Fed. Reg. at 7473-74, 7477; 82 Fed. Reg. at 7441, 7444-45).
[43] TSCA New Chemicals Coalition, Position Statement Concerning the Consultation with OHSA Required by New TSCA and EPA Adoption of Restrictions to Address Workplace Exposures (Dec. 7, 2017), https://www.regulations.gov/document?D=EPA-HQ-OPPT-2017-0585-0028.
[44] 15 U.S.C. § 2604(f)(5).
[45] 15 U.S.C. § 2604(a)(3)(A) (emphasis added).
[46] 15 U.S.C. § 2604(a)(3)(B) (emphasis added).

a different, more lenient safety standard of "no significant risk of material harm."[47] OSHA regulations designed to the meet this safety standard most likely would not be sufficiently health-protective to meet the more protective "unreasonable risk" standard required under TSCA.

It's also extremely unlikely that OSHA would ever issue regulations to control risks from new chemicals coming onto the market. OSHA has limited resources, most of its existing chemical regulations are out of date, and thousands of workplace chemicals have no enforceable restrictions under OSHA. Onerous feasibility and economic analysis requirements have further hampered OSHA's ability to protect workers from chemical exposures. Even OSHA's own website states that most of OSHA's chemical restrictions, known as permissible exposure levels, "have not been updated since 1971, and current scientific data suggests that, in many instances, the outdated PELs are not sufficiently protective of worker health."[48] OSHA's site goes on to lament that "of the thousands of chemicals used in workplaces, OSHA had PELs for less than 500" and that "since 1971 OSHA has been successful in establishing or updating PELs for only about 30 chemicals."[49]

As of January 16, 2018, EPA had completed 1,238 new chemical reviews since the enactment of the Lautenberg Act.[50] It is not only illegal, but ludicrous to suggest that OSHA should be burdened with primary responsibility for ensuring that workers are safe from all of those new chemicals that have occupational exposures, given its diminished authority and capacity, and own backlog of chemical risks to address. EPA should not adopt any of the recommendations in the NCC letter. Instead, EPA should clearly and explicitly recognize EPA's responsibility to address worker exposures in any section 5 implementation documents.

**Transparency**

Finally, EWG is concerned that EPA is failing to implement the Lautenberg amendments to section 5 in a way that is open, transparent, and seeks input from *all* stakeholders. EWG is deeply alarmed by reports at the December 6 public meeting that EPA had shared and sought feedback from industry on the framework document, draft points to consider, and category documents, and launched an industry pilot program using the framework without any feedback from public health groups. EPA also did not make previous drafts of these documents, which were presumably revised following industry feedback, available before the December 6 meeting. Even more troubling is that EPA had

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[47] *See, e.g.*, *Industrial Union Dep't, AFL-CIO v. API*, 448 U.S. 607, 639 (1980)(finding that the OSHA act requires OSHA to determine that a chemical poses a "significant risk of material impairment" before it can set a safety standard).

[48] Occupational Safety and Health Administration, Preventing Occupational Illnesses Through Safer Chemical Management, https://www.osha.gov/chemicalmanagement/index.html (last visited January 20, 2018).

[49] Id.

[50] Environmental Protection Agency, Status of Pre-Manufacture Notices Reviewed Under Section 5 of the Toxic Substances Control Act, https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/status-pre-manufacture-notices (last visited January 20, 2018).

been using the approaches laid out in the decision-making framework prior to the December 6 public meeting, and prior to receiving and reviewing public comments. EPA offered no indication that it would suspend use of the framework document pending review of the public comments.

Several basic transparency requirements are included in or apply to section 5. Section 5(b)(3) requires information in PMN submissions to be made available for examination by interested persons.[51] Section 5(b)(4)(A)(i) gives EPA discretion to keep a list of all new chemical substances its finds present or may present an unreasonable risk.[52] Section 5(d) requires EPA to regularly publish information in the Federal Register about PMNs and related information received.[53] Additionally and importantly, whenever EPA makes a "not likely to present an unreasonable risk" finding, EPA is required to issue a "statement on administrator finding" under section 5(g).[54] Section 14 on Confidential Business Information also applies to section 5 chemicals. Section 14 identifies a range of information, including health and safety studies, that is not entitled to confidential business protections.[55] Likewise, the Lautenberg amendments to section 14 require substantiation of most new chemical CBI claims.[56] EPA should be making efforts to ensure that information not subject to protection is not claimed as CBI and that all CBI claims are actually substantiated, and update the public on these efforts.

Unfortunately, the framework document does not address how EPA will work to expand transparency by making information available and easily accessible to the public. The framework document also does not address the limits on CBI or the agency's commitment to ensuring that CBI claims are properly substantiated under section 14. EPA has also not reiterated that health and safety studies included in PMN submissions are not subject to CBI or how it plans to make the information in these studies more widely available. EPA should include more transparency information in its implementing documents to section 5.

Additionally, EPA should make efforts to expand transparency, even where not explicitly required to do so under the law. For example, while section 5(g) requires EPA to issue a statement on administrator finding when EPA makes a "not likely to present an unreasonable risk finding," robust summaries of other EPA determinations like "may present an unreasonable risk" or "insufficient information to make a reasoned evaluation" would also be helpful.

Finally, EWG is frustrated that EPA's PMN database is not particularly user-friendly and obtaining meaningful information about EPA's actions on new chemicals, and about those chemicals themselves, can be difficult. Beginning in August, EPA slowed or ceased updating the database for several months, leaving the public without a critical source of

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[51] 15 U.S.C. § 2604(b)(3).
[52] 15 U.S.C. § 2604(b)(4)(A)(i).
[53] 15 U.S.C. § 2604(d).
[54] 15 U.S.C. § 2604(g).
[55] 15 U.S.C. § 2613(b).
[56] 15 U.S.C. § 2613(c)(3).

information about EPA's ongoing section 5 actions. EPA finally updated its database recently, but with some concerning changes. According to a recent analysis by the Environmental Defense Fund, EPA is no longer disclosing key information about whether its initial review of section 5 chemicals warrant a more extensive review or potential restriction.[57] Instead EPA is now reporting only that a "focus meeting occurred," which provides the public with no information about whether EPA had any initial risk concerns.[58] These changes are particularly egregious in light of EPA's August 7, 2017, claim in a press release that "EPA needs to be more transparent in how it makes decisions on new chemicals under TCSA."[59]

**Conclusion**

Section 5 constitutes one of the cornerstones of EPA's chemical management program under TSCA. Making affirmative safety findings that adequately consider all uses and vulnerable populations is a critically important part of protecting the public and environment from potential risks posed by new chemicals. The data gaps and lackluster review process that plagued the new chemicals program under the old law significantly contributed to an erosion of public trust in chemical safety and the EPA. Ensuring the Lautenberg amendments to section 5 are implemented in a health-protective and transparent manner is key to restoring that public trust. This is underscored by the fact that if the EPA finds a PMN is not likely to present an unreasonable risk without accompanying restrictions under sections 5(f) or 5(e); EPA would have to evaluate the chemical under section 6 if it identifies new risks in the future. That process is much more time and resource-intensive, and it can take several years before any restrictions are promulgated. Based on the incredibly slow process of evaluating chemicals under section 6, nearly all new chemicals that come on the market are unlikely to be reviewed again in the foreseeable future. As such, it is critically important that EPA have procedures in place to make sure it is making health-protective determinations *before* a chemical is commercialized, and to the extent practicable, making use of section 5(f) and 5(e) tools that would allow EPA to revisit its section 5 determinations as new science and information about actual uses and applications emerge.

EWG looks forward to continuing to participate in the TSCA implementation process. Any questions on these comments or other aspects of TSCA implementation should be directed to Melanie Benesh, Legislative Attorney, mbenesh@ewg.org, 202-939-0120.

Sincerely,

Melanie Benesh

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[57] Richard Denison, Hiding its Tracks: The Black Box of EPA's New Chemical Reviews Just Got a Whole Lot Blacker, Environmental Defense Fund (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/.

[58] Id.

[59] Press Release, Environmental Protection Agency, 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.