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Environmental Working Group Comments on EPA TSCA Prioritization White Paper: A Working Approach for Identifying Potential Candidate Chemicals for Prioritization

Docket ID: EPA-HQ-OPPT-2018-0659

November 15, 2018

EWG appreciates the opportunity to comment on EPA's "A Working Approach for Identifying Potential Candidate Chemicals for Prioritization" (hereinafter "White Paper"). The Lautenberg amendments significantly overhauled section 6 of TSCA and require for the first time that EPA systematically assess existing chemicals and take steps to mitigate potential risks. Prioritization is the first official step in that new process, which will serve as the basis and guidance for ongoing and future chemical assessments. EWG urges the agency to make children's health the foundation of the prioritization process to ensure that the most vulnerable and susceptible populations are protected from the effects of chemicals in consumer products and the environment. EWG also urges the agency to apply new science and new scientific approaches in a way that ensures the safety of human health and the environment, rather than create shortcuts for manufacturers to avoid the regulatory scrutiny of potentially problematic chemicals.

Working through the backlog of unregulated existing chemicals is a monumental undertaking. The first update to EPA's TSCA inventory under the Lautenberg amendments indicates that there are over 40,000 chemicals on the active TSCA inventory and scores of other chemicals with legacy uses or that continue to persist in the environment.[1] EPA itself has acknowledged that there are more than 1,000 chemicals that need to be thoroughly evaluated for safety.[2] Given the large number of chemicals that need to be reviewed and likely regulated, it is imperative that EPA be transparent in prioritizing chemicals and focus its limited resources on identifying "high-priority" chemicals. Transparency should include making public the full results of simulated chemical prioritizations under the separate methods proposed at the December 2017 public meeting.

EWG was encouraged by EPA's initial approach to prioritization, as delineated in EPA's January 19, 2017, proposed framework rule. EWG filed comments in March 2017 that were generally supportive of that approach. EWG was deeply concerned, however, by the significant changes that were made to that rule when it was finalized in July 2017 and filed comments outlining our concerns. EWG also attended the public meeting EPA held in December 2017 and filed written comments expressing our concerns with some of the approaches to prioritizations proposed at that meeting.

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[1] Environmental Protection Agency, List of Substances Reported Under the TSCA Inventory Notification Rule, https://www.epa.gov/tsca-inventory/list-substances-reported-under-tsca-inventory-notification-active-inactive-rule (last visited Nov. 15, 2018).

[2] *Frank R. Lautenberg Chemical Safety for the 21st Century Act: Hearing on S.697 Before the S. Comm. on Env't & Pub. Works*, 114th Cong. 68 (2015) (testimony of Jim Jones, Assistant Adm'r, EPA Office of Chem. Safety & Pollution Prevention), http://www.epw.senate.gov/public/_cache/files/6072fb1c-06a0-48b5-9dd4-2d894a81e9c0/spw031815.pdf.

Unfortunately, EWG is disappointed that the White Paper largely ignores the concerns and feedback stakeholders in the environmental and public health communities provided during the previous comment periods. In particular, EWG is concerned that:

- EPA is introducing a new method of pre-prioritization, the so-called "binning" method, that was not discussed in previous meetings or documents and that it appears the EPA has already committed to moving forward with this approach prior to taking public comment.
- The proposed binning method is complex, resource-intensive, unnecessary, and scientifically flawed.
- The proposed binning method would exclude scores of chemicals from prioritization without formally designating those chemicals as low-priority.
- EPA's proposed binning approach fails to adequately consider vulnerable populations, including children.
- Despite acknowledging the popular support for building upon the existing Work Plan methodology, EPA does not discuss this approach in the White Paper.
- EPA's approach to identifying and filling data gaps relies too heavily on public notification and voluntary data submissions.
- EPA implies that it will only prioritize chemicals on the active portion of the TSCA inventory.
- EPA plans to integrate New Approach Methodologies which may not be adequate for prioritization.
- EPA is considering giving industry stakeholders an opportunity to "sponsor" chemicals for low-priority designation.
- EPA is considering using ChAMP assessments as a source for identifying low-priority chemicals, despite significant data gaps.
- EPA gives preference to chemicals based on other EPA office needs but will not consider those uses in risk assessments.

Binning the TSCA inventory is unnecessary, unscientific, resource-intensive and counterproductive

Nearly half of the White Paper is dedicated to explaining EPA's proposed binning approach, which is being presented to the public for the first time in this document. This approach would use a complex algorithm to score and sort thousands of chemicals into categories as a means of pre-prioritization. While the document describes how EPA hopes to bin chemicals on the active inventory, and next steps EPA anticipates taking, EPA never requested comment on *whether* it should bin chemicals. EWG believes that it should not.

The binning approach is at odds with EPA's previous comments about prioritization methods. In EPA's response to public comments on the prioritization rule, EPA stated that:

> TSCA's mandate for the prioritization procedural rule does not require "sequencing" the universe of chemicals for input into the prioritization pipeline, undertaking some type of

quantitative exercise to score or rank individual chemicals, or otherwise lining up large batches of chemicals in a queue to be prioritized.[3]

EPA does not explain in the White Paper what prompted its shift in thinking. Moreover, EPA's proposed binning method is complex and resource-intensive. Given the relatively small number of chemicals that will undergo risk evaluation as high-priority chemicals at any given time, it seems unnecessary to invest valuable agency resources in sorting and binning the tens of thousands of chemicals on the TSCA inventory, most of which have significant data gaps. EWG also has concerns with some of the scientific assumptions underlying EPA's proposed scoring mechanism, which are detailed below.

EPA's proposed binning approach is also wholly unnecessary when EPA already has the Work Plan to rely on as a model for chemical prioritization. Indeed, EPA even notes in the White Paper that in comments on EPA's last prioritization discussion document, "Use of the 2014 Update to the TSCA Work Plan (2014 Work Plan) as the starting point for identifying high-priority candidates was the approach with the **most consistent support.**"[4] The Work Plan methodology has already been subject to significant stakeholder feedback through public meeting and public comment. EPA also has six years of experience applying the Work Plan prioritization criteria to build off and learn from.

a. EPA's proposed binning approach creates an implied low-priority designation

EPA's proposed binning approach clearly sidesteps the statutory process envisioned for designating low-priority chemicals. In the White Paper, EPA states that through the binning approach, EPA will "attempt to identify a portion of the Active Inventory that can be set aside as not containing candidates for high-priority designation."[5] By taking this approach, EPA unlawfully implies that these chemicals are low-priority chemicals, without actually ensuring that those chemicals meet the rigorous statutory requirements for low-priority designation.

Unlike high-priority chemicals, the law sets a very high bar for low-priority designations. Section 6 requires all low-priority designations be "based on information *sufficient* to establish" that the chemical "*does not* meet the standard" for a high-priority chemical designation.[6] A high-priority chemical is a chemical that "*may* present an unreasonable risk of injury to health or the environment because of a *potential* hazard and a *potential* route of exposure under the conditions of use . . ."[7] Therefore, information must be "sufficient" to alleviate EPA concerns about risks from potential hazard or potential exposure, including to vulnerable subpopulations—especially children, pregnant women, and workers.

To the extent data is missing about particular endpoints, exposures, or susceptible populations, EPA would not have "sufficient" information to make a low-priority designation. EWG anticipates that this is the case for most chemicals. Even industry acknowledges a lack of

[3] Environmental Protection Agency, *"Procedures for Prioritization of Chemicals for Risk Evaluation under TSCA": Response to Public Comments*, at 2 (Oct. 2, 2017), https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0636-0076.
[4] Environmental Protection Agency, *A Working Approach for Identifying Potential Candidates for Prioritization*, at 3 (Sept. 28, 2018) (emphasis added).
[5] *Id.* at 17.
[6] 15 U.S.C. § 2605(b)(1)(B)(ii) (emphasis added).
[7] 15 U.S.C. § 2605(b)(1)(B)(i) (emphasis added).

adequate information. In comments submitted to the agency in December 2017 regarding PBT chemicals, the American Chemistry Council noted how the EPA, unlike the data collection in Europe that informs regulation, did not have sufficient use, exposure, release, or supply chain information on chemicals to fully assess risk or potential health impacts.[8] Given these significant data gaps, it follows that most chemicals will not meet the information requirements to be designated "low-priority."

Binning large numbers of chemicals as "not candidates for high-priority designation" creates a low-priority presumption that is at odds with the clear statutory intent to set a high bar for low-priority designation. EPA's proposed binning approach could allow some manufacturers to market their chemicals as "not candidates for high-priority designation" and imply that those chemicals are safe when EPA has not actually made a safety determination.

EPA's proposed approach would also allow chemicals binned as "not candidates for high-priority designation" to evade the statutory requirement for judicial review of low-priority designations.[9] This removes an important tool for stakeholders to challenge EPA decisions about safety.

b. Human hazard-to-exposure ratio component

EPA overemphasizes a "human hazard-to-exposure" ratio score in the White Paper. This approach locks in a threshold approach for all endpoints. This approach, as described in the White Paper, depends on the use of points-of-departure from traditional oral in vivo repeat dose toxicity studies. However, when animal toxicology studies are lined up with human epidemiology studies, researchers have observed that animal toxicology methods have missed crucial toxicity endpoints or unique sensitivities of children that are revealed by human data. This has been documented for pesticides such as chlorpyrifos;[10] industrial and consumer product chemicals such as the PFAS family of chemicals;[11] and naturally occurring chemicals such as arsenic.[12] Thus, an exclusive reliance on traditional toxicology studies, as the White Paper advocates, has a likelihood of missing specific health outcomes of concern for children's health, such as the effects of developmental toxicants on brain development in fetus and young child, the effects of endocrine-disrupting chemicals, and the potentially greater sensitivity of people compared to laboratory animals to certain chemical exposures.

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[8] American Chemistry Council, Comments on Use Documents on PBT Expedited Action Chemicals, Dockets EPA-HQ-OPPT-2016- 0724; EPA-HQ-OPPT-2016-0730; EPA-HQ-OPPT-2016-0734; EPA-HQ-OPPT-2016-0738; EPA-HQ-OPPT-2016-0739 (Dec. 21, 2017), https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0724-0006.

[9] 15 U.S.C. § 2618(a)(1)(C).

[10] Environmental Protection Agency, Chlorpyrifos: Revised Human Health Risk Assessment for Registration Review, Docket ID EPA-HQ-2015-0653 (Nov. 3, 2016), https://www.regulations.gov/document?D=EPA-HQ-OPP-2015-0653-0454.

[11] Phillippe Grandjean, *Delayed Discovery, Dissemination, and Decisions on Intervention in Environmental Health: a Case Study on Immunotoxicity of Perfluorinated Alkylate Substances*, 17 Environmental Health 62 (2018), https://ehjournal.biomedcentral.com/articles/10.1186/s12940-018-0405-y; *see also* New Jersey Drinking Water Quality Institute, Health Effects Subcommittee, Health-Based Maximum Contaminant Level Support Document, Perfluorooctane Sulfonate (PFOS) (June 5, 2018), https://www.state.nj.us/dep/watersupply/pdf/pfos-recommendation-appendix-a.pdf.

[12] Environmental Protection Agency, Integrated Risk Information System (IRIS), Chemical Assessment Summary, Arsenic, Inorganic, CASRN 7440-38-2, https://cfpub.epa.gov/ncea/iris/iris_documents/documents/subst/0278_summary.pdf#nameddest=woe.

EPA further indicates that it will rely on a threshold of toxicological concern approach to identify potential risk. As comments from the Environment Defense Fund submitted in January 2018 explain, the TTC approach is inappropriate in the context of prioritization. This approach assumes that there is a safe threshold for chemical exposures and ignores the possibility of nonmonotonic dose-response curves, even when there is an absence of data identifying a safe exposure level.[13] Science increasingly rejects the idea that there is always a safe level of exposure. There is a growing body of scientific evidence showing that hormone disruptors and developmental toxicants can cause adverse effects at very low doses and in some cases may have higher impacts at low doses than high doses.[14] The pharmaceutical literature is rife with examples of nonmonotonicity, timing, and age-group specific toxicity concerns.[15] The TTC approach also fails to account for cumulative exposures from different chemicals or multiple routes of exposure to the same chemical.[16]

Additionally, the TTC approach has not been validated as having any predictive power for protecting children's health from chemical exposure and is therefore inappropriate for use in the prioritization process for chemicals that children can be exposed to.

Finally, EWG is concerned with EPA's approach to combining toxicity and exposure information into ratios like HER, BER, and TER. These ratios fail to consider the extent to which production volumes and uses of chemicals change over time. Furthermore, EPA's own analysis from the November 2017 discussion document shows that incorporating the hazard to bioactivity exposure ratio (H/BER) results in fewer chemicals being identified as potentially of high concern and more chemicals as low concern.[17] Similarly, this proposed method behaved as an outlier when compared to the other 4 methods proposed, indicating a potential for misclassification of a chemical as high, moderate or low concern. EWG also urges EPA to release the full list of chemicals classified as high, moderate or low concern from each of the methods presented so that stakeholders can further evaluate the reliability of such proposed methods and EPA can uphold its commitment to data transparency.

c. The genotoxicity factor is too narrow

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[13] Environmental Defense Fund, Comments on Identifying Approaches to Potential Candidates for Prioritization for Risk Evaluation Under Amended TSCA, Docket EPA-HQ-OPPT-2017-0586, at 13 (Jan. 25, 2018), http://blogs.edf.org/health/files/2018/01/EDF-Comments_TSCA-Identifying-Priority-Candidates-Final.pdf.
[14] *See, e.g.*, Thaddeus T. Schug, *Endocrine Disrupting Chemicals and Disease Susceptibility*, 127 J. Steroid Biochemistry and Molecular Biology 204 (2011), https://www.sciencedirect.com/science/article/abs/pii/S096007601100166X?via%3Dihub; Heather B. Patisaul & Heather B. Adewale, *Long-Term Effects of Environmental Endocrine Disruptors on Reproductive Physiology & Beahvior*, 3 Frontiers in Behavioral Neuroscience 1 (2009), https://www.frontiersin.org/articles/10.3389/neuro.08.010.2009/full.
[15] *See, e.g.*, *Non-monotonic Dose Response Curves*, Our Stolen Future, http://ourstolenfuture.com/NewScience/lowdose/nonmonotonic.htm (last visited Nov. 15, 2018).
[16] Environmental Defense Fund, Comments on Identifying Approaches to Potential Candidates for Prioritization for Risk Evaluation Under Amended TSCA, Docket EPA-HQ-OPPT-2017-0586, at 13 (Jan. 25, 2018), http://blogs.edf.org/health/files/2018/01/EDF-Comments_TSCA-Identifying-Priority-Candidates-Final.pdf.
[17] Environmental Protection Agency, *Discussion Document: Possible Approaches and Tools for Identifying Potential Candidate Chemicals for Prioritization*, at 61, 63 (Nov. 14, 2017), https://www.regulations.gov/document?D=EPA-HQ-OPPT-2017-0586-0003.

It is essential to protect human health from chemicals that can damage DNA, and EWG agrees with the agency's focus on genotoxic chemicals. However, EPA should not focus exclusively on genotoxic chemicals, but rather should consider all chemicals that can increase the risk of cancer, whether by genotoxic or non-genotoxic mechanisms. Focus on genotoxic carcinogens only, as this section of the White Paper implies, fails to protect public health and is not consistent with the latest science on mechanisms of carcinogenicity and pathways towards tumor development.[18]

d. EPA must consider other environmental effects in addition to aquatic toxicity

EPA's discussion of environmental effects in the White Paper focuses entirely on aquatic toxicity. This approach overemphasizes water solubility as a risk factor and assumes that if a chemical cannot dissolve in water it will not have environmental effects. That narrow approach ignores exposure to soil- and sediment-dwelling organisms which may be exposed directly rather than through water ingestion.

e. EPA must take a more expansive approach to assessing potential risks to vulnerable subpopulations

The White Paper limits consideration of vulnerable populations to "presence in children's products" as reported in the EPA Consumer Product Database and EPA Chemical Data Reporting results.[19] This approach singularly focuses on an arbitrary subset of children's products and ignores the myriad ways that children are actually exposed to chemicals.

The statute clearly requires EPA to consider all *known, intended, and reasonably foreseeable* uses, and therefore potential exposures to, a chemical.[20] EPA must therefore account not only for exposures through children's products, but also all the other reasonably foreseeable ways that a child might be exposed to a chemical. This includes adult products that children may use and other exposure pathways like food, air, water, and breastmilk. Dust is also a key source of exposure to environmental toxins that is of particular concern to children's health.[21] EPA's Children's Health Protection Advisory Committee recommended in requested guidance that EPA prioritize "chemical substances potentially of concern for children's health; substances that children are likely to encounter; and substances detected in biomonitoring studies of children, women of reproductive age, cord blood, or pregnant women."[22]

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[18] Mark F. Miller et al., *Low-Dose Mixture Hypothesis of Carcinogenesis Workshop: Scientific Underpinnings and Research Recommendations*, 125 Environmental Health Perspectives 163 (2017), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5289915/

[19] Environmental Protection Agency, *A Working Approach for Identifying Potential Candidates for Prioritization*, at 23 (Sept. 28, 2018).

[20] 15 U.S.C. § 2602(4).

[21] *See, e.g.*, Allison L. Phillps et al., *Children's Residential Exposure to Organophosphate Ester Flame Retardants and Plasticizers: Investigating Exposure Pathways in the TESIE Study*, 116 Environmental International 176 (2018), https://www.sciencedirect.com/science/article/pii/S0160412018302927?via%3Dihub; Kristin Larsson et al., *Phthalates, Non-Phthalate Plasticizers and Bisphenols in Swedish Preschool Dust in Relation to Children's Exposure*, 102 Environmental International 114 (2017), https://www.sciencedirect.com/science/article/pii/S0160412016307929?via%3Dihub; Todd P. Whitehead et al., *Concentrations of Persistent Organic Pollutants in California Children's Whole Blood and Residential Dust*, 49 Environmental Science & Technology 9331 (2015), https://pubs.acs.org/doi/10.1021/acs.est.5b02078.

[22] Letter from Barbara Morrissey, M.S., Chair, Children's Health Protection Advisory Committee, to Scott Pruitt, Administrator, Environmental Protection Agency (March 30, 2017), https://www.epa.gov/sites/production/files/2017-04/documents/2017.03.30_chpac_tsca_letter.pdf.

EPA must also consider vulnerable subpopulations other than children. The statute defines "potentially exposed or susceptible subpopulation" as "a group of individuals within the general population identified by the Administrator 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*."[23]

EPA also has authority to consider subpopulations not included in the statutory definition. CHPAC recommended that "in addition to infants, children and pregnant women; other lifestages and subpopulations are important to consider under amended TSCA, including pre-conception, adolescence, lactating women, and populations whose traditional diets or other indigenous practices may increase the risk for toxicant exposure."[24] EPA's proposed rule on risk evaluation supported taking into consideration both intrinsic (*e.g.,* life stage, reproductive status, age, gender, genetic traits) and acquired (*e.g.,* pre-existing disease, geography, socioeconomic, cultural, workplace) factors when identifying vulnerable populations.[25] There is significant scientific evidence that both intrinsic and acquired factors can make individuals and populations more vulnerable to harm from toxic chemicals.[26] The White Paper fails to account for any of these other important populations.

EPA acknowledges these shortcomings in its "caveats and potential limitations" under section 7.12, stating that "the initial strategy does not fully account for all routes of exposure (e.g., dermal) or all populations (e.g., elderly)."[27] EPA should remedy these limitations and ensure it takes into consideration all routes of exposure and all potentially vulnerable subpopulations when screening chemicals for prioritization.

f. EPA's proposed approach relies too heavily BCF/BAF

The White Paper states that it will measure bioaccumulation "based on bioaccumulation factors (BAF) or bioconcentration factors (BCF)."[28] Bioaccumulation is an important risk factor, but this approach is outdated, overly narrow, and could cause EPA to miss important health concerns. Reliance solely on BCF/BAF could exclude groups of chemicals like PFAS, which according to EPA, have BAFs and BCFs that fall below criteria used to evaluate bioaccumulation potential

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[23] 15 U.S.C. § 2602(12) (emphasis added).
[24] Letter from Barbara Morrissey, M.S., Chair, Children's Health Protection Advisory Committee, to Scott Pruitt, Administrator, Environmental Protection Agency (March 30, 2017), https://www.epa.gov/sites/production/files/2017-04/documents/2017.03.30_chpac_tsca_letter.pdf.
[25] Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act, 82 Fed. Reg. 7562, 7568 (proposed Jan. 19, 2017)(to be codified at 40 C.F.R. pt. 702) ("As suggested by the statute, EPA is also proposing to include specific authorization for EPA to consider both intrinsic (e.g., life stage, reproductive status, age, gender, genetic traits) and acquired (e.g., pre-existing disease, geography, socioeconomic, cultural, workplace) factors when identifying this population.").
[26] *See* National Academy of Sciences, Science and Decisions: Advancing Risk Assessment (2009), https://www.nap.edu/catalog/12209/science-and-decisions-advancing-risk-assessment.
[27] Environmental Protection Agency, *A Working Approach for Identifying Potential Candidates for Prioritization*, at 28 (Sept. 28, 2018).
[28] *Id.* at 24.

because PFAS accumulate in blood, not fat tissue.[29] Although PFAS chemicals accumulate in blood rather than fat tissue, the risks from PFAS chemicals are well understood.

EPA instead should prioritize chemicals using augmented Work Plan methodology

The White Paper acknowledges there was consistent support for using the Work Plan methodology as a starting place for prioritization among the comments submitted on the November 2017 discussion document. However, the White Paper fails to discuss how EPA will incorporate the Work Plan methodology into its prioritization decisions. Instead of the flawed binning approach proposed in the White Paper, EPA should refocus its efforts on augmenting the Work Plan in accordance with the statutory requirements of the Lautenberg Act.

a. The Work Plan is heavily emphasized in the statute

EPA's 2012 Work Plan and its 2014 update were EPA's first attempts at systematically prioritizing the tens of thousands of chemicals on the TSCA inventory. Given the significant amount of public input that went into developing the Work Plan criteria, and the parallels to the prioritization process under TSCA, the Work Plan criteria offer a logical starting point.

Starting with the Work Plan criteria is also consistent with the statute and congressional intent. The Work Plan is heavily emphasized in the Lautenberg amendments to TSCA. In section 6 alone, there are nine different references to the Work Plan. Half of all EPA's high-priority chemical designations are required to come from the Work Plan.[30] The amendments also provide that EPA "shall give preference" to Work Plan chemicals with a Persistence and Bioaccumulation Score of 3, and Work Plan chemicals that are known human carcinogens and have high acute and chronic toxicity.[31] The statute emphasizes the need for timely evaluation of Work Plan chemicals by forbidding deadline extensions on most risk management actions for these chemicals.[32] It also requires expedited assessment of certain persistent, bioaccumulative, and toxic, or PBT, chemicals identified on the Work Plan.[33]

Congress' preference for the Work Plan chemicals and accompanying criteria is also reflected in the legislative record. The Senate committee report specifically points to the Work Plan as a model, stating that:

> The existing provisions of TSCA do not require EPA to systematically assess and determine the safety of priority chemicals. Consequently, there are relatively few EPA policies and procedures in place to address the safety assessment, safety determination and rulemaking requirements of Section 6. It is the Committee's intention that EPA rely on existing processes, *such as those established under the Agency's TSCA Work Plan Chemical program*, to manage the process as new policies and procedures are developed.[34]

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[29] Environmental Protection Agency, Drinking Water Health Advisory for Perfluorooctanoic Acid (PFOA) (May 2016), https://www.epa.gov/sites/production/files/2016-05/documents/pfoa_health_advisory_final-plain.pdf.
[30] 15 U.S.C. § 2605(b)(3)(B).
[31] 15 U.S.C. § 2605(b)(3)(D).
[32] 15 U.S.C. § 2605(c)(1)(C).
[33] 15 U.S.C. §2605(h).
[34] S. Rep. 114-67, at 9 (2015), https://www.congress.gov/114/crpt/srpt67/CRPT-114srpt67.pdf (emphasis added).

The House committee report states that:

> The Committee understands that the TSCA Work Plan represents the Agency's current priorities for risk review and potential risk management under TSCA. Nothing in this bill is intended to require the Agency to change or revise those priorities.[35]

It is not surprising, therefore, that when EPA issued its proposed rule on prioritization in January 2017, there was significant overlap with EPA's Step 1 Work Plan criteria. Specifically, EPA proposed the following criteria for narrowing candidates for prioritization: (1) persistent, bioaccumulative, and toxic; (2) used in children's products; (3) used in consumer products; (4) Detected in human and/or ecological biomonitoring programs; (5) potentially of concern for children's health; (6) high acute and chronic toxicity; (7) probable or known carcinogen; (8) Neurotoxicity; or (9) other emerging exposure and hazard concerns to human health or the environment, as determined by the Agency.[36] These nine criteria are nearly identical with the Work Plan Step 1 factors,[37] with the addition of a "catch-all" provision, and EPA acknowledged as much in the proposed rule.[38]

EWG was disappointed that the final rule on prioritization no longer explicitly included these factors.[39] EWG was particularly disappointed that the final rule did not include biomonitoring, which is a clear indication of exposure,[40] and that it no longer explicitly included children's health or children's products as risk factors. Although ultimately left out of the final rule, inclusion of these factors in the proposed rule does signal that the agency's early thinking about prioritization was centered on the existing Work Plan criteria.

b. *The Work Plan criteria alone are not sufficient to meet all new statutory requirements*

In order to meet all the new statutory requirements under the Lautenberg amendments to TSCA, it is necessary that EPA supplement the Work Plan methodology before applying it to chemical prioritizations under TSCA.

The statute instructs EPA to consider several criteria when determining the potential hazard or potential exposure from a chemical. Those factors are: (1) the chemical substance's hazard and

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[35] H.R. Rep. 114-176, at 24 (2015), https://www.congress.gov/114/crpt/hrpt176/CRPT-114hrpt176.pdf.
[36] *Compare* Procedures for Prioritization of Chemicals for Risk Evaluation Under the Toxic Substances Control Act, 82 Fed. Reg. 4825, 4830 (proposed Jan. 17, 2017) (to be codified at 40 C.F.R. pt. 702) *with* Environmental Protection Agency, *TSCA Work Plan Chemicals: Methods Document* p. 2-3 (2012), https://www.epa.gov/sites/production/files/2014-03/documents/work_plan_methods_document_web_final.pdf.
[37] Environmental Protection Agency, *TSCA Work Plan Chemicals: Methods Document* p. 2-3 (2012), https://www.epa.gov/sites/production/files/2014-03/documents/work_plan_methods_document_web_final.pdf.
[38] Procedures for Prioritization of Chemicals for Risk Evaluation Under the Toxic Substances Control Act, 82 Fed. Reg. at 4830. ("These criteria are drawn from EPA's 2012 Work Plan methodology, which … was the process EPA had been using to prioritize chemical substances for assessment under TSCA.").
[39] Procedures for Prioritization of Chemicals for Risk Evaluation Under the Toxic Substances Control Act, 82 Fed. Reg. 33753 (July 20, 2017).
[40] EWG has frequently advocated for the use of biomonitoring to prioritize chemicals for EPA review. Specifically, EWG has urged that EPA request biomonitoring data from companies, which should conduct biomonitoring. *See, e.g.*, Letter from Kenneth A. Cook, President, Envtl. Working Grp., to Lisa P. Jackson, Adm'r, EPA (June 2, 2011), http://static.ewg.org/pdf/EWG-Letter-to-EPA-Biomonitoring-6-2-2011.pdf.

exposure potential; (2) the chemical substance's persistence and bioaccumulation; (3) potentially exposed or susceptible subpopulations; (4) storage of the chemical substance near significant sources of drinking water; (5) the chemical substance's conditions of use or significant changes in conditions of use; and (6) the chemical substance's production volume or significant changes in production volume.[41] EPA also included a catch-all provision in both the proposed and final prioritization rule that allows EPA to consider: "(7) other risk-based criteria that EPA determines to be relevant to the chemical substance's priority."[42] As comments from leading academics and scientists on the 2017 discussion document point out, most of these factors are also taken into consideration in the Work Plan methodology.[43]

Unlike the Work Plan, the statute also requires EPA to consider production volumes and proximity to drinking water sources. It also encompasses a broader group of potentially vulnerable subpopulations. Whereas the Work Plan focuses on children's products and children's health, the statute instructs EPA to look at "potentially exposed or susceptible populations" which is defined to include infants, children, pregnant women, workers, the elderly, and any other group that "may be at greater risk than the general population of adverse health effects from exposure to a chemical substance."[44]

Most notably, the Lautenberg amendments require EPA to look at the chemical substance's "conditions of use." This requires EPA prioritize the chemical as a whole by considering all known, intended, or reasonably foreseen uses of the chemical throughout the life cycle of the chemical.[45] This departure from previous agency practice, presumably under the Work Plan, was acknowledged clearly in the final rule on prioritization:

> EPA believes the addition of the phrase "the *conditions* of use" (emphasis added) was intended to move the Agency away from its past practice of assessing only narrow uses of a chemical substance, towards a more inclusive approach to chemical substance management. Note that the phrase is plural, rather than singular (conditions, not condition). While under the definition of "conditions of use," the Administrator retains some discretion to "determine" the conditions of use for each chemical substance, that discretion is not unfettered. As EPA interprets the statute, the Agency is to exercise that discretion consistent with the objective of determining in a risk evaluation whether a chemical substance – not just individual uses or other individual activities – presents an unreasonable risk.[46]

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[41] 15 U.S.C. § 2605(b)(1)(A).
[42] Procedures for Prioritization of Chemicals for Risk Evaluation Under the Toxic Substances Control Act, 40 C.F.R. § 702.9 (2017); *see also* Procedures for Prioritization of Chemicals for Risk Evaluation Under the Toxic Substances Control Act, 82 Fed. Reg. at 33759 ("The final rule also includes an additional criterion, consistent with the proposal . . . As explained in the proposal, this final criterion allows the screening review to adapt with future changes in our understanding of science and chemical risks.").
[43] Academics, Scientists and Clinicians; Comment on Approaches for Identifying Potential Candidates for Prioritization for Risk Evaluation Under Amended TSCA, Docket EPA-HQ-OPPT-2017-0586, at 10 (Jan. 25, 2018), https://prhe.ucsf.edu/sites/prhe.ucsf.edu/files/wysiwyg/2018%201%2025%20UCSF%20comments%20on%20pre-prioritization%20FINAL.pdf.
[44] 15 U.S.C. § 2602(12).
[45] 15 U.S.C. § 2602(4).
[46] Procedures for Prioritization of Chemicals for Risk Evaluation Under the Toxic Substances Control Act, 82 Fed. Reg. at 33755.

Because these additional factors, in particular the requirement to prioritize a chemical as a whole, are not considered under the Work Plan, it is necessary that EPA consider them in addition to the Work Plan criteria.

c. Additional factors to consider

EPA is neither limited to the Work Plan criteria nor to the new factors identified in the statute in what it considers for prioritization. Indeed, the inclusion of seventh, "catch-all" factor in the final rule explicitly gives EPA the discretion to consider additional risk factors as needed.

To that end, EWG recommends that EPA also consider risks from aggregate exposure whenever practicable. This would include potential exposures from not only TSCA-regulated uses, but also uses regulated under other environmental laws like FIFRA or the Safe Drinking Water Act, or by other agencies like the Food and Drug Administration or the Consumer Product Safety Commission. Potential hazard and exposure analysis should also consider all potential routes of exposure, including dermal, oral, and inhalation; and pathways of exposure, including in consumer products, via occupational exposure, or through air, soil, or water. When possible, EPA should also consider potential *cumulative* exposures to a chemical in conjunction with other chemicals or stressors that might add to that chemical's environmental or health risks.

The criteria to consider proximity to drinking water sources could be further expanded to also include vulnerable populations in communities near places where chemicals will be manufactured, processed, stored, or disposed—even if those facilities do not border drinking water sources. When chemical persistence or presence poses unique threats to a particular community—such as fence-line communities adjacent to chemical processing facilities or oil refineries—those chemicals should be considered high-priority.

When considering vulnerable populations, prioritization decisions should take into account who is exposed to the chemical and how. This includes occupational exposures for workers who manufacture and process chemicals, workers exposed to the chemicals through their trades, and workers responsible for disposing of chemicals and chemical byproducts. It also includes exposures at different human life stages, such as fetal exposures, childhood exposures at various developmental stages, potential effects on men and women of childbearing age, and exposures that may uniquely affect the elderly. For instance, chemicals found in products intended to be used by children is a Step 1 factor, however EPA should acknowledge that children regularly interact with and come into contact with many household items not intended for their use. EPA should also consider not only intrinsic traits, but also acquired factors like genetics or pre-existing diseases, as initially proposed in the January 2017 risk evaluation rule.[47] Although this language was ultimately stricken from the final risk evaluation rule, EPA acknowledges its authority to take these factors into consideration.[48] EPA should engage in dialogue with high-risk communities like workers, tribes, and fence-line communities to determine their highest priority chemicals.

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[47] Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act, 82 Fed. Reg. at 7568.

[48] Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act, 82 Fed. Reg. 33726, 33732 (July 20, 2017) ("EPA interprets the statutory definition broadly and believes it does not prevent EPA from including any subpopulation that may be at greater risk due to greater susceptibility or exposure, or from identifying additional subpopulations other than those listed in the statute, where warranted.").

Importantly, when considering potential risks from different exposures, EPA should be cautious not to equate low exposures with low risks. Low exposure alone should not be the basis for designating a chemical as low-priority. In some cases, particularly with regards to endocrine-disrupting chemicals, low-dose exposures to a chemical can be just as dangerous as—or more dangerous than—high-dose exposures.

In addition to the above factors, as EWG has previously commented, there are some kinds of chemicals that should always be considered high-priority. This includes carcinogens classified by IARC, NTP, EPA, and California EPA; and chemicals identified as high priorities under REACH (Substances of Very High Concern). If EPA has received an 8(e) substantial risk submission for a chemical, that chemical should also always be considered high-priority. EPA should also reference the European Commission's priority list of endocrine-disrupting chemicals, the European Union's (EU) Globally Harmonized System of Classification and Labelling of Chemicals hazard and toxicity classifications, the Association of Occupational and Environmental Clinic's Exposure Code List for asthma-causing substances, and the American Conference of Governmental Industrial Hygienists' (ACGIH) Threshold Limit Value (TLV) Basis for potential candidates.[49]

d. Work Plan chemicals should carry a presumption of high-priority status.

EWG is concerned by EPA's assertion in the White Paper that it is "not bound by the findings of EPA's 2014 Work Plan."[50] Chemicals on the Work Plan should carry a presumption of high-priority designation. The criteria developed for the 2012 Work Plan screened chemicals for key risk factors including potential concern for children's health; persistence, bioaccumulation, and toxicity; probable or known carcinogenicity; use in consumer products; and detection in biomonitoring programs.[51] By definition, a high-priority chemical is any chemical that *may* present an unreasonable risk of injury to health or the environment, based on *potential* hazard and a *potential* route exposure.[52] Even with new science and new information, it is hard to imagine that EPA would be able to show that any Work Plan chemical no longer shows any potential risk. Therefore, Work Plan chemicals should be presumed to be high-priority chemicals.

[49] Environmental Working Group, Comment on the Proposed Rule on Procedures for Prioritization of Chemicals for Risk Evaluation Under the Amended Toxic Substances Control Act, p. 10 (March 20, 2017), https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0636-0070.

[50] Environmental Protection Agency, *A Working Approach for Identifying Potential Candidate Chemicals for Prioritization*, at 6-7 (Sept. 28, 2018) ("EPA is not bound by the findings of the 2014 Work Plan. EPA recognizes that science approaches have evolved and additional information has been developed for chemicals on the 2014 Work Plan.").

[51] Environmental Protection Agency, *TSCA Work Plan Chemicals: Methods Document* p. 2-3 (2012), https://www.epa.gov/sites/production/files/2014-03/documents/work_plan_methods_document_web_final.pdf.

[52] 15 U.S.C. § 2605(b)(1)(B)(i)("The Administrator shall designate as a high-priority substance a chemical substance that the Administrator concludes, without consideration of cost or other non-risk factors, *may* present an unreasonable risk of injury to health or the environment because of a *potential* hazard and a *potential* route of exposure under the conditions of use, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator").

Congress also anticipated that the Work Plan chemicals would be high-priority chemicals. The Senate committee report asserted that "the Work Plan chemicals are, in effect, substances EPA has already prioritized for review."[53]

EPA must consider both active and inactive chemicals for prioritization

In the White Paper, EPA states "if chemicals are identified as potential candidates that are not on the 2014 Work Plan, EPA's [sic] intends to select chemicals on the TSCA Active Inventory."[54] EPA also suggests that it will only bin chemicals on the active inventory. EPA should prioritize both active and inactive chemicals.

TSCA is a cradle-to-grave statute. TSCA defines "conditions of use" to mean the circumstances "under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, *or disposed of*."[55] This takes into consideration the whole life cycle of the chemical, including disposal of chemicals that may no longer be manufactured or sold, but that may still present an unreasonable risk. As such, EPA has clear authority to prioritize and conduct risk evaluations on chemicals that are no longer in commerce. This is backed by the Senate committee report on the Lautenberg Act, which expressly recognizes that "there may be exposures of concern from substances that are not currently or no longer in commerce, and the section provides EPA authority to prioritize inactive substances that meet certain criteria."[56]

The final prioritization rule also clearly states that inactive substances are eligible for prioritization:

> Chemicals that are designated as "inactive" pursuant to the Active/Inactive Inventory rule (RIN 2070-AK24) are still chemicals [sic] substances on the TSCA inventory, and therefore subject to prioritization. Nothing in TSCA prohibits EPA from initiating the prioritization process on an "inactive" chemical substance and ultimately from designated the priority of that chemical substance.[57]

Chemicals that are no longer actively manufactured and used in commerce can pose substantial public health and environmental risk nonetheless. For example, a recent New York Times article documented the continued global human health and environmental impacts from polychlorinated biphenyls,[58] which were banned as part of the 1976 TSCA.[59] Even though PCBs have been out of production for decades, they pose a significant health risk to top-of-food-chain animals like orcas. Studies estimate orcas are at risk of losing half their population in the coming decades based on the threat from PCBs alone. Likewise, EWG estimates that as many as 110 million Americans are exposed to drinking water contaminated by unsafe levels of PFAS chemicals,

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[53] S. Rep. 114-67 at 12 (2015), https://www.congress.gov/114/crpt/srpt67/CRPT-114srpt67.pdf.
[54] Environmental Protection Agency, *A Working Approach for Identifying Potential Candidate Chemicals for Prioritization*, at 7 (Sept. 28, 2018).
[55] 15 U.S.C. § 2602(4) (emphasis added).
[56] S. Rep. 114-67 at 11 (2015), https://www.congress.gov/114/crpt/srpt67/CRPT-114srpt67.pdf.
[57] Procedures for Prioritization of Chemicals for Risk Evaluation Under the Toxic Substances Control Act, 82 Fed. Reg. at 33,753.
[58] Karen Weintraub, *Killer Whales Face Dire PCBs Threat*, N.Y. Times (Sept. 27, 2018), https://www.nytimes.com/2018/09/27/science/killer-whales-pcbs.html.
[59] 15 U.S.C. § 2605(e).

some of which, like PFOA and PFOS, which have largely been phased out of commerce.[60] There are scores of other inactive chemicals that persist in the environment, expose people through so-called legacy uses, and continue to present potential risks to human health and the environment.

EPA should use its authority to fill data gaps and prioritization should be data inclusive

a. EPA should not rely on public notification to fill data gaps

EWG agrees with EPA's position that it is important to identify and fill data gaps early and before a chemical enters the formal prioritization process.[61] EWG also agrees with EPA's acknowledgement that it has various authorities to request or demand information, including authority under sections 4, 8, and 11 of TSCA.[62]

However, EWG is concerned that EPA repeatedly indicates that it primarily plans to use "public notification," rather than its statutory authorities to obtain information. For example, EPA provides in the White Paper that when developing information:

> EPA may provide public notification of any Work Plan chemicals found to have insufficient information to undergo prioritization. EPA's information gathering authorities include public notification processes, and may be used to develop necessary information for a chemical substance or chemical category. Once generated, the new information will feed into analyses and decisions supporting the selection of candidate chemicals beyond the initial 20 high- and low-priority candidates and the prioritization within statutory timeframes.[63]

This language suggests that EPA will only select chemicals for prioritization that are already data-rich or can be made so via public notification and voluntary information submission. The White Paper does not discuss how EPA intends to use its other information-gathering authorities under the Lautenberg Act or what kind of information EPA expects to collect.

Taking stock of "reasonably available" information is a logical starting point to determine whether EPA has enough information to formally start the prioritization process. The Lautenberg Act requires EPA to take into consideration all information that is "reasonably available" for section 4, 5, and 6 actions, including prioritization.[64] This would clearly encompass information already in EPA's possession, including but not limited to information routinely collected under section 8(a), section 8(c) adverse events, section 8(d) health and safety studies, section 8(e) substantial risk reports, pertinent information collected on new chemicals under section 5, information from EPA's toxic release inventory, and information collected under other EPA

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[60] Environmental Working Group, *Report: Up to 110 Million Americans Could Have PFAS-Contaminated Drinking Water* (May 22, 2018), https://www.ewg.org/research/report-110-million-americans-could-have-pfas-contaminated-drinking-water.

[61] *See, e.g.*, Environmental Protection Agency, *A Working Approach for Identifying Potential Candidate Chemicals for Prioritization*, at 4 (Sept. 28, 2018) ("When information gaps are identified, ideally those gaps would be filled early in the process to allow EPA to complete its screening review by the statutory deadline.").

[62] *Id.* at 5.

[63] *Id.* at 8.

[64] 15 U.S.C. § 2625(k) ("In carrying out sections 2603, 2604, and 2605 of this title, the Administrator 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 the Administrator.").

statutes like FIFRA, the Clean Water Act, the Clean Air Act, the Safe Drinking Water Act, CERCLA, and RCRA.

As EWG has argued in previous comments, EPA should interpret "reasonably available" broadly to include all information that EPA is reasonably aware of—including information published in scientific journals; possessed by other state, federal and international government bodies; and information that it can directly request from companies.[65] This interpretation is consistent with the proposed definition of "reasonably available" in the final prioritization rule, which includes not only information the EPA possesses, but also information that it can "reasonably generate, obtain and synthesize."[66] This would include information already collected by state governments like the California Environmental Contaminant and Biomonitoring Program or under foreign regulations like the Registration, Evaluation, Authorisation, and Restriction of Chemicals (REACH) in Europe. If EPA knows this information exists and was submitted to other governments, it should take measures to request the same information from the manufacturers or processors responsible for its submission. Information that can be obtained or generated through testing should also be considered reasonably available.[67]

After reviewing the reasonably available information, EPA should identify any data gaps and take steps to fill them. EWG echoes the recommendation made by leading academics and scientists that EPA define the data needed to show that a chemical does not pose particular hazards. Their comments on the November 2017 discussion document recommended that EPA's requirements be consistent with established approaches from other agencies like the NTP, IARC, and EPA's own guidelines, including cancer guidelines.[68] Those comments point out that "these guidelines clearly define what constitutes the determination of no hazard, such as the requirement for multiple concurring lines of evidence from different species in experimental and/or observational scientific studies."[69] The Children's Health Protection Advisory Committee also recommends using biomonitoring data and screening for data on developmental toxicants—including information generated from in vivo developmental toxicity tests as well as newer in vitro, in silico, non-mammalian models such as zebrafish, and genomics, and other "omics" technologies.[70]

After identifying the gaps, there are a variety of actions that EPA can take to obtain the necessary information. EPA should utilize its new section 4 authority to order information from entities

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[65] Environmental Working Group, Comment on the Proposed Rule on Procedures for Prioritization of Chemicals for Risk Evaluation Under the Amended Toxic Substances Control Act, at 6 (March 20, 2017), https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0636-0070.

[66] Procedures for Prioritization of Chemicals for Risk Evaluation Under the Toxic Substances Control Act, 40 C.F.R. § 702.3; Procedures for Prioritization of Chemicals for Risk Evaluation Under the Toxic Substances Control Act, 82 Fed. Reg. at 33757.

[67] Procedures for Prioritization of Chemicals for Risk Evaluation Under the Toxic Substances Control Act, 82 Fed. Reg. at 33758 (EPA agrees that it makes sense to view information that can be obtained through testing as ''reasonably available'' in some instances).

[68] Academics, Scientists and Clinicians; Comment on Approaches for Identifying Potential Candidates for Prioritization for Risk Evaluation Under Amended TSCA, Docket EPA-HQ-OPPT-2017-0586, at 7 (Jan. 25, 2018), https://prhe.ucsf.edu/sites/prhe.ucsf.edu/files/wysiwyg/2018%201%2025%20UCSF%20comments%20on%20pre-prioritization%20FINAL.pdf.

[69] *Id.*

[70] Letter from Barbara Morrissey, M.S., Chair, Children's Health Protection Advisory Committee, to Scott Pruitt, Administrator, Environmental Protection Agency (March 30, 2017), https://www.epa.gov/sites/production/files/2017-04/documents/2017.03.30_chpac_tsca_letter.pdf.

that may have or be able to generate that data. EPA could also use its section 26(a)[71] authority during the pre-prioritization period to request information from other agencies, particularly to the extent that information will help EPA identify conditions of use and also better understand the potential aggregate and cumulative risks from a chemical. EPA also has authority to work directly with those agencies to develop research and monitor information.[72] EPA should consider expanding its reporting requirements under sections 8(a) and 8(c) as needed to generate additional data. If necessary, EPA can subpoena information from companies under Section 11(c).[73] To the extent the agency seeks voluntary information, it should take steps to review the information for potential bias and ensure that it has received complete information, rather than selective or partial information cherry-picked to present the chemical in the most favorable light.

b. EPA should primarily screen information for evidence about potential risk

In section 5.2 of the White Paper, EPA delineates how it plans to make determinations with regards to data accessibility, quality, and relevancy.[74] EPA does not explain how it plans to screen for potential risk. The purpose of prioritization is to determine whether a chemical *may* pose an unreasonable risk to human health or the environment based on *potential* hazard or *potential* risk. That means when assessing information availability and data gaps, EPA should be looking to ensure that it has adequate information on key endpoints and populations that might help EPA make determinations about potential risk.

c. Prioritization should be data inclusive and data quality assessments should not rely on EPA's flawed systematic review document

EWG is deeply troubled by EPA's stated intention to rely on its flawed proposed systematic review framework to make data quality assessments and, in some cases, exclude data from consideration based on that framework.

In the White Paper, EPA expressly states that, "EPA intends on surveying the information and checking *quality data elements* in a step-wise approach that ensures responsible and timely completion of the process according to TSCA timelines. The approach is intended to screen out information-deficient candidate chemicals that would hinder EPA's ability of performing scientifically sound risk evaluations. . ."[75] In section 5.2, EPA even more explicitly states that when screening chemicals for prioritization:

> The initial emphasis will be the exclusion of unacceptable data sources based on data quality criteria outlined in the *Application for Systematic Review in TSCA Risk Evaluations* EPA document. Specifically, these criteria identify serious flaws that would make the information unreliable to use for risk evaluation purposes. This increases the efficiency of EPA's systematic review efforts by excluding unacceptable data sources

[71] 15 U.S.C. § 2625(a) ("Upon request by the Administrator, each Federal department and agency is authorized . . . to furnish to the Administrator such information, data, estimates, and statistics, and to allow the Administrator access to all information in its possession as the Administrator may reasonably determine to be necessary for the administration of this chapter.").
[72] 15 U.S.C. § 2609.
[73] 15 U.S.C. § 2610(c).
[74] Environmental Protection Agency, *A Working Approach for Identifying Potential Candidate Chemicals for Prioritization*, at 11-14 (Sept. 28, 2018).
[75] *Id.* at 8. (emphasis added)

> early in the process for those chemical substances that may enter risk evaluation for a high-priority designation.[76]

It would be premature to conduct a systematic review as part of the prioritization process. The purpose of prioritization is to determine the *potential* for risk and prioritize chemicals accordingly. While EPA should assess data availability and identify gaps during prioritization, EPA should not do a thorough data quality assessment or exclude studies at this stage of the risk assessment process.

To EWG's knowledge, this is the first time in a public document that EPA has discussed systematic review in the context of chemical prioritization. EPA's prioritization rule does not discuss systematic review.[77] By contrast, EPA's risk evaluation rule discusses systematic review extensively.[78] EPA's framework for systematic review is entitled "Application of Systematic Review in TSCA *Risk Evaluations*" implying that the document is meant to be used during risk evaluation, rather than prioritization.[79] The only mention of applying systematic review at the prioritization stage in that document is where EPA states that "[t]he first ten chemical substances were not subject to prioritization, the process through which EPA expects to *collect and screen* much of the relevant information about chemical substances that will be subject to the risk evaluation process."[80] Although EPA implies that it will screen information during prioritization, nowhere does EPA say that it will use systematic review to exclude studies at the prioritization stage. EPA should take a data-inclusive approach during the prioritization stage and wait until the risk evaluation stage to do a comprehensive systematic review.

Moreover, *EPA's Application of Systematic Review in TSCA Risk Evaluations* document is deeply flawed. The framework document has yet to undergo peer review. Comments submitted by leading scientists and academic researchers expressed alarm at "EPA's ad hoc and incomplete TSCA systematic review framework, which is inconsistent with current, established, best available empirical methods for systematic review."[81] Comments submitted by NRDC, which EWG joined, criticized that "the TSCA Systematic Review document is less about evaluating the quality of evidence, and more about eliminating it altogether. The document is incomplete, inconsistent with the state of the science, and too flawed to be used."[82] The proposed systematic review framework is a significant departure from other established systematic review frameworks used like the "systematic review and integrated assessment" (SYRINA) of endocrine disrupting chemicals, the Navigation Guide (NavGuide) review method, EPA's IRIS program systematic review (which was recently favorably reviewed by the National Academy of

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[76] *Id.* at 13.
[77] Procedures for Prioritization of Chemicals for Risk Evaluation Under the Toxic Substances Control Act, 82 Fed. Reg. 33753 (July 20, 2017).
[78] Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act, 82 Fed. Reg. 33726 (July 20, 2017).
[79] Environmental Protection Agency, Application of Systematic Review in TSCA Risk Evaluations (May 31, 2018), https://www.epa.gov/sites/production/files/2018-06/documents/final_application_of_sr_in_tsca_05-31-18.pdf (emphasis added).
[80] *Id.* at 19 (emphasis added).
[81] Academics, Scientists, and Clinicians; Comments on the Application of Systematic Review in TSCA Risk Evaluations, at 2 (Aug. 16, 2018), https://prhe.ucsf.edu/sites/prhe.ucsf.edu/files/wysiwyg/2018%2008%2016%20Systematic%20Review%20TSCA%20evaluations%20UCSF%20PRHE%20comments%20EPA_0.pdf.
[82] Natural Resources Defense Council, Comments on the Application of Systematic Review in TSCA Risk Evaluations, at 2 (August 16, 2018), https://www.nrdc.org/resources/nrdc-comments-epa-tsca-systematic-review.

Sciences[83]), and the National Toxicology Program OHAT systematic review. As commenters noted, it fails to take into consideration financial conflicts as a source of bias, uses a qualitative scoring method that is inconsistent with the best available science, and conflates reporting quality with study quality. As such, this framework should not be used at any stage of EPA's TSCA risk assessments.

Relying on EPA's flawed proposed systematic review framework at the prioritization stage would almost certainly result in the exclusion of quality studies. Excluding data could lead some high-priority chemicals to begin risk evaluation missing key health information and other chemicals to potentially earn unwarranted low-priority chemical designation and be spared from risk evaluation all together. It would be better for EPA to take more information into consideration during prioritization and evaluate studies later in the process, using a more scientifically valid systematic review approach.

d. EPA should use caution with regards to the criteria from the alternative strategic plan

EPA indicates throughout the White Paper that it plans to integrate information from New Approach Methodologies (NAMs) in EPA's *Strategic Plan to Promote the Development of Alternative Test Methods* with information from traditional studies.[84] While there is some value to supplementing traditional studies with computer modeling and other NAMs, EPA needs to address several issues in its strategic plan before applying it to prioritization.

As commenters on the strategic plan noted, several definitions in the strategic plan, including "NAMs", "relevance," "reliability," and "equivalent scientific reliability" are vague and need to be clarified.[85] The strategic plan also does not thoroughly address how NAMs will take into account susceptible subpopulations like children, chemical characterization, or characterization of exposure. A plan for using NAMs to specifically address risks to potentially exposed or susceptible subpopulations should be advanced.

The Natural Resources Defense Council noted in its comments on the strategic plan that NAMs should be used differently for data-rich and data-poor chemicals.[86] For chemicals about which much is already known, NAMs can be used to fill remaining data gaps, confirm the evidence already collected, and buttress a chemical's classification. However, for data-poor chemicals, NAMs might fail to capture a hazard. There are limitations to NAMs which should prevent the scientific community from relying solely on them when evaluating toxicity, and therefore, should never be used when determining if a chemical is low-priority. For example, NAMs do not capture the complexity of biological and physiological systems in a living organism—they can only mimic one molecular interaction or part of a pathway. NAMs also cannot account for metabolites and any toxicity caused by metabolism in intact animal systems. High-throughput

[83] National Academies of Sciences, Engineering, and Medicine, Progress Toward Transforming the Integrated Risk Information System (IRIS) Program: A 2018 Evaluation (2018), https://doi.org/10.17226/25086.
[84] *See* Environmental Protection Agency, *A Working Approach for Identifying Potential Candidate Chemicals for Prioritization*, at 6, 10, 16, 17, 18, 26, 27, 28 (Sept. 28, 2018).
[85] Environmental Defense Fund, Comments on EPA Strategic Plan to Promote the Development and Implementation of Alternative Test Methods (Draft), Docket ID EPA-HQ-OPPT-2017-0559 (May 11, 2018).
[86] Natural Resources Defense Council, Comment on Draft Considerations for the Development of the Strategic Plan for Developing and Implementing Alternative Test Methods and Strategies to Reduce, Refine, or Replace Vertebrate Animal Testing for Chemical Substances or Mixtures, Docket ID EPA-HQ-OPPT-2017-0559 , at 3 (Jan. 10, 2018), https://www.nrdc.org/sites/default/files/nrdc-strategic-plan-comments_epa-hq-oppt-2017-0559_2018-01-11_0.pdf.

NAMs may not be able to accurately represent specific vulnerable populations, such as children. Further, in at least one instance, NAMs have demonstrated a high false negative rate compared to animal models, suggesting that many chemicals impacting biological systems could be overlooked and deemed low-risk.[87]

Low-Priority Chemicals

a. EPA should focus its limited resources on identifying high-priority, not low-priority chemicals

The structure and language of section 6 emphasizes high-priority chemical designations. Section 6 creates a regulatory pipeline where chemicals are 1) first designated as high-priority, 2) then undergo risk evaluation, and 3) then are regulated as needed. Low-priority chemicals, by contrast, do not move down this pipeline and are not subject to additional review following a low-priority designation. The law requires EPA to designate at least 20 high-priority and 20 low-priority chemicals by December 2019.[88] It is telling that while Congress created an ongoing designation requirement for *high-priority* chemicals[89] at the end of each risk evaluation, it declined to create any corresponding requirement for the designation of low-priority chemicals. Unlike high-priority chemicals which must be continually designated, EPA has no statutory obligation to identify any more than the first 20 low-priority chemicals.

Given EPA's limited resources, after identifying the first statutorily required 20 low-priority chemicals, EPA should focus on identifying high-priority chemicals.

b. EPA's use of the SCIL list should be a starting point only for identifying low-priority chemicals

EPA has proposed that its Safer Choice Program Safer Chemicals Ingredients List, or SCIL, may be an appropriate starting place for identifying low-priority chemicals. While this may be an appropriate starting point for identifying candidates for low-priority designation, EWG emphasizes that chemicals on the SCIL list should not be considered low-priority by default.

As EPA pointed out in December 2017, the SCIL list was created largely for chemicals that are used in cleaning and related products. EPA may have incomplete data on other uses of the chemicals on that list, as well as the chemicals' full exposure profile. The prioritization process does not allow EPA to designate chemicals based on a narrow subset of issues, but rather requires EPA to look at the chemical as a whole. EPA acknowledges this limitation in the November 2017 discussion draft when it points out that some SCIL chemicals, like strong acids and bases, "may have high acute hazard when assessed under all conditions of use."[90] Statutorily, EPA is also required to consider storage near sources of drinking water, which is not accounted for in the SCIL criteria.

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[87] *Id.* at 6-7.
[88] 15 U.S.C. § 2605(b)(2)(B).
[89] 15 U.S.C. § 2605(b)(3)(C).
[90] Environmental Protection Agency, *Discussion Draft: Possible Approaches and Tools for Identifying Potential Candidate Chemicals for Prioritization*, at 34 (Nov. 14, 2017), https://www.regulations.gov/document?D=EPA-HQ-OPPT-2017-0586-0003.

Most yellow triangle chemicals are unlikely to meet EPA's high bar for low-priority designations since EPA cautions that those chemicals "have some hazard profile issues."[91] Likewise, EPA states that for many green half-circle chemicals, "additional data would strengthen confidence in the chemical's status."[92] Because EPA recognizes that there are data gaps, these chemicals likely do not have the "sufficient information" required for them to be designated as low-priority.

As such, the SCIL list should be considered a starting point only. The law does not allow for shortcuts when it comes to designating low-priority chemicals. While lists like the SCIL may be useful for identifying potential candidates, EWG emphasizes that legally the only way a chemical can be low-priority is if EPA has adequate information to demonstrate that the chemical does not present an unreasonable risk under the conditions of use. EPA should feel confident it can meet that rigorous test before starting the prioritization process on a potential low-priority chemical.

c. EPA should NOT rely on ChAMP, which is plagued by data gaps, to identify low-priority chemicals

EPA proposes using Chemical Assessment and Management Program, or ChAMP, assessments as a basis for low-priority designations for the first time in this White Paper.[93] Previous materials, including at the December 2017 public meeting on prioritization, did not discuss ChAMP as a potential source for identifying low-priority chemicals.

EWG has significant concerns with the use of ChAMP assessments as a means to identify low-priority chemicals. EPA suspended ChAMP evaluations nearly a decade ago,[94] in part due to concerns over lack of transparency and data gaps—especially with regards to use and exposure.[95] ChAMP relied largely on information generated through EPA's voluntary high and medium production volume (HPV and MPV) reporting programs. A 2009 analysis by EWG found that "[t]he HPV challenge has been crippled by lack of data for hundreds of 'orphan' chemicals for which no company agree[s] to submit test data. . . the studies that are volunteered are merely screening studies, often not new, and none of the data has led to any significant health protections."[96]

Because most ChAMP evaluations are now nearly a decade old and contained significant data gaps, it seems unlikely that any ChAMP chemicals would meet the high bar for low-priority designation under TSCA unless new information has been developed. As such, ChAMP is not a good starting place for identifying candidates for low-priority chemical designation.

EPA, not industry stakeholders, must make prioritization decisions

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[91] *Id.* at 33.
[92] *Id.*
[93] Environmental Protection Agency, *A Working Approach for Identifying Potential Candidate Chemicals for Prioritization*, at 15 (Sept. 28, 2018).
[94] *EPA Suspends CHAMP Risk Work to "Ramp" Things Up*, Chemical Watch (June 19, 2009), https://chemicalwatch.com/2373/epa-suspends-champ-risk-work-to-ramp-things-up.
[95] Richard Denison, *ChAMP: Not Exactly a Heavyweight*, Environmental Defense Fund (April 20, 2009), http://blogs.edf.org/health/2009/04/20/champ-not-exactly-a-heavyweight/.
[96] David Andrews, Ph.D. & Richard Wiles, *Off the Books: Industry's Secret Chemicals* (December 2009), https://www.ewg.org/sites/default/files/report/secret-chemicals.pdf.

EWG is concerned by EPA's stated plans to create an "enhanced stakeholder role" for designating additional substances for prioritization. In the White Paper, EPA refers to industry comments that encourage EPA to create a process for stakeholders to "volunteer to sponsor development of information that could be used by EPA to identify candidates that could be designated as low-priority chemicals, beyond the required 20."[97]

Although the statute creates an express mechanism for industry to sponsor a limited number of chemicals to undergo risk evaluation,[98] there is no corresponding statutory mechanism to nominate chemicals for prioritization. Instead, the statute creates a system where only chemicals that clearly meet the high bar for low-priority designation forgo risk evaluation and all other chemicals are, by default, considered high-priority.

EPA's proposal in the White Paper is similar to previous voluntary industry-led programs like the HPV challenge and the Voluntary Children's Chemical Evaluation Program. Environmental and public health groups largely considered those programs to be unsuccessful and ineffective and they failed to generate the chemical information hoped for.

EPA should consider overall Agency priorities, but should also include *all uses* of a chemical in risk evaluations

In section 4.1(a) of the White Paper EPA identifies that as a near-term approach to prioritization, EPA "expects to consider overarching Agency priorities. This may include, but is not limited to, a chemical or group of chemicals that are priorities for the Agency, including chemicals that other EPA program offices have deemed priority for their program and suitable for current prioritization."[99] EPA also plans to consult and coordinate with other federal agencies that may have an interest in particular chemicals.

EWG generally supports this kind of intra and interagency collaboration, especially to the extent that it facilitates data sharing and coordinated risk management. What EPA should not do, however, is then exclude the very exposures regulated by those EPA offices and other agencies from its risk evaluations, as EPA proposes in the problem formulations on the first ten chemicals.[100] As EWG and numerous other groups have commented, excluding key uses from

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[97] Environmental Protection Agency, *A Working Approach for Identifying Potential Candidate Chemicals for Prioritization*, at 16 (Sept. 28, 2018).
[98] *See* 15 U.S.C. § 2605(b)(4)(C)(ii).
[99] Environmental Protection Agency, A *Working Approach for Identifying Potential Candidate Chemicals for Prioritization*, at 7 (Sept. 28, 2018).
[100] *See, e.g.*, Environmental Protection Agency, *Problem Formulation of the Risk Evaluation for Carbon Tetrachloride*, at 13 (Aug. 1, 2018) ("EPA also identified certain exposure pathways that are under the jurisdiction of regulatory programs and associated analytical processes carried out under other EPA-administered environmental statutes – namely, the Clean Air Act (CAA), the Safe Drinking Water Act (SDWA), the Clean Water Act (CWA), and the Resource Conservation and Recovery Act (RCRA) – and which EPA does not expect to include in the risk evaluation. As a general matter, EPA believes that certain programs under other Federal environmental laws adequately assess and effectively manage the risks for the covered exposure pathways. To use Agency resources efficiently under the TSCA program, to avoid duplicating efforts taken pursuant to other Agency programs, to maximize scientific and analytical efforts, and to meet the three-year statutory deadline, EPA is planning to exercise its discretion under TSCA 6(b)(4)(D) to focus its analytical efforts on exposures that are likely to present the greatest concern and consequently merit a risk evaluation under TSCA, by excluding, on a case-by-case basis, certain exposure pathways that fall under the jurisdiction of other EPA-administered statutes. EPA does not expect to include any such excluded pathways as further explained below in the risk evaluation. The provisions of various

the risk evaluations is unlawful, contrary to congressional intent, unscientific, inconsistent with risk assessment best practices, and undermines the public health goals of TSCA.

If EPA is to consider other EPA office and other agency needs, it must also include the uses and exposures falling under those offices' jurisdiction in its chemicals risk assessments. To do otherwise would be hypocritical.

Conclusion

The White Paper does not create a prioritization process that adequately protects public health and the environment. The binning method is resource-intensive, complex, unnecessary, scientifically unsound, and fails to adequately consider risks to vulnerable populations. EPA should instead augment the Work Plan methodology, with a particular emphasis on children's health, to prioritize chemicals. EPA, not industry stakeholders, should make prioritization decisions, and EPA should focus on identifying high-, not low-priority chemicals. EPA should use its various information-gathering authorities under TSCA to fill data gaps with regards to potential risks before prioritizing chemicals.

EWG is happy to discuss these or other comments related to TSCA implementation with EPA.

Sincerely,

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EPA-administered environmental statutes and their implementing regulations represent the judgment of Congress and the Administrator, respectively, as to the degree of health and environmental risk reduction that is sufficient under the various environmental statutes.").