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EWG Comments on EPA Discussion Document: Possible Approaches and Tools for Identifying Potential Candidate Chemicals for Prioritization

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January 25, 2018

From children's health and public health perspectives, the existing chemicals program under the Toxic Substances Control Act section 6 is one of the most important components of EPA's chemical safety program. This section spells out the actions EPA has the authority to take to protect human health and the environment from chemicals already on the market. Historically, however, it was also one of the most broken and unused sections of TSCA. Recent changes to the law (hereinafter "the Lautenberg amendments"), significantly overhauled this section, providing EPA with an unprecedented opportunity to finally address risks from existing chemicals. EWG is alarmed at the recent shift in EPA's implementation of this program away from the public health goals of the law and in favor of industry interests.

Prior to the Lautenberg amendments, the EPA had extremely constrained authority to regulate chemicals that were already on the market. When TSCA was first enacted in 1976, it infamously grandfathered in more than 67,000 existing chemicals. Over its forty-year history, that number ballooned to more than 85,000. Yet, during that same period, EPA only attempted to regulate a handful of chemicals without much success. Most damningly, EPA was not even able to ban asbestos,[1] a potent carcinogen responsible for tens of thousands of deaths each year.[2] As a result, the health of American children, adults and families was put at undue risk to disease and adverse health effects from chemical exposure. Public trust in the EPA significantly eroded.

The Lautenberg amendments require for the first time that EPA finally systematically assesses existing chemicals, and takes steps to protect the public and the environment from potential risks. Prioritization is the first official step in that new process.

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 nearly 25,000 chemicals actively in use on the market today, and scores of other chemicals with legacy uses or that continue to persist in the environment.[3] EPA itself has acknowledged that there are more than 1,000 chemicals that need to be thoroughly evaluated for safety.[4] Given the large number of chemicals that need to be reviewed and likely regulated, it is

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[1] *See Corrosion Proof Fittings v. EPA*, 947 F.2d 1201 (5th Cir. 1991).
[2] Sonya Lunder, *Asbestos Kills 12,000-15,000 People Per Year in the U.S,* Asbestos Nation, http://www.asbestosnation.org/facts/asbestos-kills-12000-15000-people-per-year-in-the-u-s/.
[3] 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 January 25, 2018).
[4] *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 &

imperative that EPA focuses its limited resources on identifying the chemicals that need to undergo safety evaluations, or so-called "high-priority" chemicals.

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 is concerned, however, by the significant changes that were made to that rule when it was finalized in July 2017, and also by some of the new methodologies proposed by the agency in the prioritization methods discussion document. In particular, EWG is concerned by the overall shift in focus at the agency from high- to low-priority chemicals. This was underscored by the amount of time dedicated to identification of low-priority chemicals at the December 11, 2017, public meeting. This is a dramatic departure from the vision of the Lautenberg amendments, which emphasize the prioritization process primarily as a tool to identify the high-priority chemicals in need of thorough safety evaluations.

EWG would like to reiterate its previous comments with regards to prioritization and also provide some additional comments on EPA's most recent discussion document on proposed prioritization methodologies. In particular, EWG would like to comment that:

- EPA's focus should be on the identification of high, not low, priority chemicals.
- The law sets a high bar for the designation of low-priority chemicals.
- There are significant limitations to using EPA's Safer Chemicals Ingredient List, or SCIL, to identify low-priority chemicals, and EPA should not designate a chemical as low-priority solely because it is on the SCIL list.
- EPA's Work Plan criteria have already been publicly vetted and are a logical starting place for prioritization criteria.
- The Lautenberg amendments include some prioritization factors that differ from the Work Plan criteria and should be considered in addition to the Work Plan criteria. In particular, the Lautenberg amendments require EPA to consider all chemical uses and importantly, specific risks to children, pregnant women, and other vulnerable populations.
- EPA should use its various information collecting tools to actively fill data gaps prior to initiating the prioritization process.
- EWG has concerns with some of the other proposed methodologies included in the discussion document and discourages EPA from adopting those methodologies/criteria without providing more information to the public and soliciting additional public comment.

I. EPA must focus its limited resources on the identification of high, not low, priority chemicals

a. Most chemicals will be likely be high-priority due to insufficient data

Pollution Prevention), http://www.epw.senate.gov/public/_cache/files/6072fb1c-06a0-48b5-9dd4-2d894a81e9c0/spw031815.pdf.

The structure and language of section 6 emphasizes high-priority chemical designations. Section 6 creates a regulatory pipeline where chemicals are: 1) designated as high priority; 2) undergo risk evaluation; and 3) 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.[5] It is telling that while Congress created an ongoing designation requirement for *high-priority* chemicals[6] 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 twenty low-priority chemicals. This framework indicates a clear preference for the identification of high-priority chemicals to be evaluated for potential risks over low-priority chemicals that will not undergo further review.

The law also sets a very low bar for a high-priority designations, A high-priority chemical is defined in the law as 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 intended conditions of use, including an unreasonable risk to a potentially exposed or susceptible subpopulation . . . ."[7] This definition makes clear that EPA does not have to understand all of the risks, or confirm all hazards or exposures before designating a chemical as high-priority. Rather, any chemical that *may* present an unreasonable risk because of *potential* hazards or *potential* exposure should be designated as high-priority. This includes when EPA has missing or incomplete information about potential hazards and exposures, including to children and other vulnerable populations.[8] Given the significant data gaps that exist for most chemicals on the market, it follows that most chemicals will receive high-priority chemical designations.

b. To be low-priority, chemicals must meet the high bar set by the statute

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.[9] Because a high-priority chemical is any chemical that "may" pose an unreasonable risk, it follows that EPA must be very confident that a chemical does not present any potential hazard or potential exposure concerns before it can designated as low priority. This includes potential risks to infants, children, pregnant women, workers, or other vulnerable populations.

Most importantly, the law is very clear that EPA can only make low-priority designations on chemicals that are data rich. Specifically, 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

[5] 15 U.S.C. § 2605(b)(2)(B).
[6] 15 U.S.C. § 2605(b)(3)(C).
[7] 15 U.S.C. § 2605(b)(1)(B)(i) (emphasis added).
[8] The statute specifically defines "potentially exposed or susceptible population" 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" 15 U.S.C. § 2602(12).
[9] 15 U.S.C. § 2605(b)(1)(B)(ii) (emphasis added).

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 adequate information. In comments submitted to the agency in December regarding PBTs, 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.[10] Given these significant data gaps, it follows that most chemicals will not meet the information requirements to be designated "low-priority."

c. EPA's Safer Chemicals Ingredient List (SCIL) should be treated as a starting point only

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 points out, the SCIL list was created largely for chemicals that are used in cleaning and related products, and EPA may have incomplete data on other uses of the chemicals on that list, as well as the chemicals' full exposure profile. As discussed later in these comments, 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 seems to acknowledge this limitation in the discussion document 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."[11] Statutorily, EPA is also required to consider storage near sources of drinking water, which is not accounted for in the SCIL criteria.

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."[12] Likewise, EPA states that for many green half-circle chemicals, "additional data would strengthen confidence in the chemical's status."[13] 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 pose an unreasonable risk. EPA should feel confident it can meet that high bar before

[10] 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 (December 21, 2017), https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0724-0006.
[11] Environmental Protection Agency, *Discussion Document: Possible Approaches and Tools for Identifying Potential Candidate Chemicals for Prioritization*, p. 34 (Nov. 14, 2017), https://www.regulations.gov/document?D=EPA-HQ-OPPT-2017-0586-0003.
[12] *Id.* at 33.
[13] *Id.*

starting the prioritization process on a potential low-priority chemical. Additionally, because EPA is only statutorily required to designate 20 low-priority chemicals, the agency should focus its limited resources on identifying high-priority chemicals to undergo risk evaluation.

II. EPA should use the Work Plan methodology, with some updates to reflect new requirements

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. 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.[14] The amendments also say 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.[15] The statute emphasizes the need for timely evaluation of Work Plan chemicals by forbidding deadline extensions on most reviews of these chemicals.[16] It also requires expedited assessment of certain persistent, bioaccumulative, and toxic, or PBT, chemicals identified on the Work Plan.[17]

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.[18]

With regards to prioritization, the committee asserts that "the Work Plan chemicals are, in effect, substances EPA has already prioritized for review."[19] Likewise, the House committee report states that:

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[14] 15 U.S.C. § 2605(b)(3)(B).
[15] 15 U.S.C. § 2605(b)(3)(D).
[16] 15 U.S.C. § 2605(c)(1)(C).
[17] 15 U.S.C. §2605(h).
[18] S. Rep. 114-67, at 9 (2015), https://www.congress.gov/114/crpt/srpt67/CRPT-114srpt67.pdf.
[19] *Id.* at 12.

> 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.[20]

It's not surprising therefore, that when EPA issued its proposed rule on prioritization in January, 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.[21] These nine criteria are nearly identical with the Work Plan Step 1 factors,[22] with the addition of a "catch-all" provision, and EPA acknowledged as much in the proposed rule.[23]

EWG was disappointed that the final rule on prioritization no longer specifically mentions these factors.[24] EWG was particularly disappointed that the final rule no longer mentions biomonitoring, which is a clear indication of exposure and has long been a priority for the organization, [25] and that it no longer explicitly names children's health or children's products as risk factors. Although ultimately dropped, explicit inclusion of these factors in the proposed rule does signal that the agency's early thinking about prioritization was centered on the Work Plan criteria. EWG hopes that this change in language does not mean that the agency is abandoning this criteria in favor of the other less developed proposed methodologies discussed at the December 11 public meeting. EWG urges EPA to continue using the Step 1 Factor criteria described above and strengthen the criteria discussed as follows.

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

At the December 11, 2017, public meeting, EPA officials discussed whether EPA should use the Work Plan criteria as they exist currently, or whether EPA should augment the criteria. This is an odd question because the Lautenberg amendments to TSCA impose new requirements for

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[20] H.R. Rep. 114-176, at 24 (2015), https://www.congress.gov/114/crpt/hrpt176/CRPT-114hrpt176.pdf.
[21] *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.
[22] 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.
[23] 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.").
[24] Procedures for Prioritization of Chemicals for Risk Evaluation Under the Toxic Substances Control Act, 82 Fed. Reg. 33753 (July 20, 2017).
[25] 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.

prioritization that are not reflected in the Work Plan. As such, legally, EPA cannot rely solely on the current Work Plan criteria. Instead, it must take an augmented approach that supplements the Work Plan criteria with the new statutory requirements.

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 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.[26] 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."[27]

Unlike the Work Plan, the statute requires EPA to consider proximity to drinking water sources, as well as production volume. 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."[28]

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.[29] 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

[26] 15 U.S.C. § 2605(b)(1)(A).
[27] 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.").
[28] 15 U.S.C. § 2602(12).
[29] 15 U.S.C. § 2602(4).

chemical substance – not just individual uses or other individual activities – presents an unreasonable risk.[30]

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 factors identified in the statute in what it considers for prioritization designations. 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 FDA or CPSC. 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.[31] Although this

[30] Procedures for Prioritization of Chemicals for Risk Evaluation Under the Toxic Substances Control Act, 82 Fed. Reg. at 33755.

[31] 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,

language was ultimately stricken from the final risk evaluation rule, EPA acknowledges its authority to take these factors into consideration.[32]

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 as 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.[33]

d. EPA should not weaken the Work Plan Criteria, especially with regards to PBTs

EWG is concerned by the assertion by some industry groups that EPA must update the Work Plan criteria, particularly the scoring calculations for PBT chemicals, before using those criteria to prioritize chemicals under TSCA.[34] EPA should actively seek updated data with regards to production volume, toxic releases, hazards and exposure profiles. However, EPA should not update PBT scores, slow down the assessment of PBT chemicals, or change other Work Plan criteria without ample public input. Additionally, EPA should not exclude a chemical from prioritization solely because a manufacturer has indicated that it has lowered its production volume or abandoned particular uses. In fact, the legislative history specifically addresses this issue. In the Senate committee report on the Lautenberg amendments, the committee states that: "The Committee recognizes, however, 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."[35]

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age, gender, genetic traits) and acquired (e.g., pre-existing disease, geography, socioeconomic, cultural, workplace) factors when identifying this population.").

[32] 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.").

[33] 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.

[34] *See, e.g.*, American Chemistry Council, *supra* note 9.

[35] S. Rep. 114-67, at 11 (2015), https://www.congress.gov/114/crpt/srpt67/CRPT-114srpt67.pdf.

III. EPA must fill data gaps before initiating prioritization

Regardless of which methodology EPA adopts to prioritize chemicals, it is imperative that EPA takes steps to ensure it has adequate information both to make prioritization decisions (especially if the substance is a candidate for a low-priority designation), and to complete a risk evaluation. EPA has clear authority to collect information and order testing as part of the prioritization or risk evaluation process.[36] However, as EPA acknowledges in the preamble to the final prioritization rule, once the prioritization process has begun, "it may be difficult or impossible for the Agency to develop or acquire the necessary information, consistent with statutory deadlines for prioritization."[37] As such, EPA should make a concerted effort to gather information *before* it formally initiates prioritization.

As previously explained in these comments, the Lautenberg Act requires EPA to broadly consider all conditions of use, including any reasonably foreseeable uses, when prioritizing and evaluating a chemical.[38] To adequately prioritize and evaluate a chemical under all its conditions of use, EPA will need access to an array of information, including different pathways and routes of exposure, potentially exposed or susceptible populations, aggregate and cumulative exposures, and potential human health and environmental hazards.

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

EWG has previously commented that EPA should also interpret "reasonably available" broadly to include all information that EPA is reasonably aware of—including information published in scientific journals; possessed by to other state, federal and international government bodies; and information that can be directly requested from companies.[40] 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

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[36] 15 U.S.C. § 2603(a)(2).
[37] Procedures for Prioritization of Chemicals for Risk Evaluation Under the Toxic Substances Control Act, 82 Fed. Reg. at 33758.
[38] 15 U.S.C. § 2605(b); 15 U.S.C. § 2602(4).
[39] 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.")..
[40] 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. 6 (March 20, 2017), https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0636-0070.

generate, obtain and synthesize."[41] This would include information already collected by state governments 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.[42]

After reviewing the reasonably available information, EPA should identify any data gaps and take steps to fill them. In determining whether a data gap exists, EPA should not only consider whether information for a particular data point exists, but also the quality, objectivity, and integrity of the information, and the potential for bias. After identifying the gaps, there are a variety of actions that EPA can take to obtain the necessary information. In particular, EPA should utilize its new section 4 authority to order information from entities that may have or be able to generate that data.

In particular, EPA may utilize its order authority to request additional data generated by validated high-throughput technology to generate an array of screening-level information for data-poor chemicals. Validated screening techniques may assist in closing data gaps for a spectrum of endpoints, deciding whether to consider related chemicals as a category, and identifying new areas of potential concern where additional testing may be warranted. Invertebrate and lower vertebrate assays, such those using C. elegans (nematode) and D. rerio (zebrafish), may also provide important developmental and other toxicity information. Other animal testing data using higher vertebrates should be minimized but ordered where appropriate.

EPA could also use its Section 26(a)[43] 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.[44] 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).[45] 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.

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[41] 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.

[42] 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").

[43] 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.").

[44] 15 U.S.C. § 2609.

[45] 15 U.S.C. § 2610(c).

IV. Other methodologies

EWG continues to emphasize that EPA should start with its Work Plan criteria, supplemented by the new statutory requirements, and other risk-based factors as needed. Congress even anticipated that given EPA's experience with the Work Plan, and the time that may be needed to develop other methodologies, that EPA may lean heavily on Work Plan in the early years of implementation. Specifically, the House committee report says that:

> The Committee expects that many, if not all, of the Agency's selections for Agency initiated risk evaluations in the first years after enactment will come from the Work Plan and that risk evaluations for Work Plan chemicals will be completed in the first years.[46]

However, to the extent EPA is still considering the other methods discussed at the December 11, 2017, meeting, EWG offers these brief comments.

a. Canada's chemical management plan

Canada's chemical management plan should be seen as a potential source of data for EPA as it begins to take stock of "reasonably available" information and identify data gaps. EPA should familiarize itself with the data requirements under Canada's program to get a sense of what information the Canadian government likely has, and what information has already been generated by the relevant industry stakeholders. However, it would not be appropriate for EPA to adopt Canada's chemical management plan as is. As EPA acknowledges, EPA has not verified whether the Canadian process meets the specific requirements of the statute and the prioritization rule. Additionally, the Canadian process exempts workers, whereas TSCA specifically requires EPA to consider workers as a potentially exposed or susceptible population.[47]

Furthermore, there are differences between Canada and the U.S. that should give EPA pause. As pointed out by the Environmental Defense Fund in its questions submitted prior to the December 11 public meeting, Canada has a much smaller population than the U.S. and has a much smaller share of the global chemical market. What's more, EDF points out that many of the chemicals reviewed in Canada lacked sufficient data and the agency lacked the authority to request additional data.[48] Given these significant differences in demographics, market share, statutory requirements, and data collection authority, the Canadian chemical management plan is likely not a good model for EPA to adopt.

b. Functional category approaches

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[46] H.R. Rep. 114-176, at 24 (2015), https://www.congress.gov/114/crpt/hrpt176/CRPT-114hrpt176.pdf.

[47] Environmental Protection Agency, *Discussion Document: Possible Approaches and Tools for Identifying Potential Candidate Chemicals for Prioritization*, p. 31 (Nov. 14, 2017), https://www.regulations.gov/document?D=EPA-HQ-OPPT-2017-0586-0003.

[48] Environmental Defense Fund, Public Meeting on Approaches for Identifying Potential Candidates for Prioritization for Risk Evaluation Under Amended TSCA, p. 2-3 (Nov. 27, 2017), http://blogs.edf.org/health/2017/11/29/more-questions-for-epa-on-identifying-chemicals-for-prioritization-under-tsca/.

EWG generally supports the prioritization and risk evaluation of categories of chemicals and recognizes EPA's explicit authority to consider categories under section 26(c).[49] EWG particularly supports the prioritization and evaluation of categories of chemicals to the extent it facilitates the study of cumulative effects of groups of chemicals. To the extent EPA does group chemicals, EWG recommends that EPA take into consideration the approach outlined in the National Academy of Sciences recommendations on phthalates.[50]

However, EWG has concerns with the two functional category approaches proposed in the discussion document. Neither proposed method adequately considers similarities in toxicity or biological activity. Additionally, neither proposed method addresses steps that EPA might take to consider chemicals that are involved in the same adverse outcome pathway. In fact, the only mention of cumulative effects in the entire 103-page document (including two sections on "category" approaches), is in reference to FDA "Cumulative Estimate of Daily Intake" or CEDI estimates.

Although EPA identifies two functional category approaches: 1) use and exposure potential; and 2) chemical structure and function, both approaches heavily emphasize grouping chemicals according to how they are used.

EWG has serious concerns about the inconsistency of this approach with EPA's requirement to prioritize a chemical as a whole under its "conditions of use." Grouping chemicals by "function in industrial process, chemical formulation, or end-use product level,"[51] or by using the uses identified in the FUse database or QSUR model,[52] will not capture all the other known, intended or reasonably foreseeable uses associated with chemicals in that grouping. This concern is compounded by EPA's later statement that "many functional use categories could have large numbers of chemicals."[53] A large grouping of chemicals based solely on use could have widely different downstream, recycling, and disposal uses, as well as varied impacts on vulnerable populations. Although EPA acknowledges that once a chemical enters risk evaluation all uses are considered, it fails to explain how EPA will assure that all uses are adequately considered.

EPA also makes some troubling assumptions about vulnerable populations in the section on exposure. EPA says "children's exposures are accounted for under exposures to consumer products" without additional explanation.[54] In fact, children are exposed to chemicals from many sources, not only consumer products, and not only consumer products that are marketed to children. Additionally, EPA says that "the assumption is that many industrial and commercial operations will have overarching health and safety procedures in place to minimize exposures."[55] EPA should know that workplace controls like personal protective equipment are often

[49] 15 U.S.C. § 2625(c).
[50] Nat'l Acad. Sci., *Phthalates and Cumulative Risk Assessment: The Tasks Ahead* (2008), https://cfpub.epa.gov/ncea/risk/recordisplay.cfm?deid=202508.
[51] Environmental Protection Agency, *Discussion Document: Possible Approaches and Tools for Identifying Potential Candidate Chemicals for Prioritization*, p. 38 (Nov. 14, 2017), https://www.regulations.gov/document?D=EPA-HQ-OPPT-2017-0586-0003.
[52] *Id.* at 48-49.
[53] *Id.* at 39.
[54] *Id.*
[55] *Id.*

inadequately implemented or completely ignored. Given OSHA's weak regulatory authority, it is inappropriate for EPA to take industry assurances about health and safety procedures at face value.

EWG is also concerned about the discussion of identifying alternatives as a possible benefit to the category approach.[56] The availability of substitutes is a non-risk factor that should not be part of the prioritization process. This issue was addressed in the final prioritization rule where EPA specifically said it had stricken references to substitutes from the proposed rule because such considerations were not appropriate at the prioritization stage.[57]

In short, functional category approaches to assess toxicity are not a blanket fix for the lack of adequate safety testing data and EPA should first focus on using its order authority to fill data gaps.

c. Integration of traditional and new approach methods

EWG appreciates the lengthy presentation on this method provided at the December 11, 2017, public meeting and EPA's continued work to validate new approach methods. One key takeaway from the December 11 presentation was that Method 5: H/BER performed as an outlier compared to Method 1-4, predicting fewer high-risk and more low-risk chemicals. Method 5 likely failed to adequately consider exposures to children and other vulnerable populations, and only considered maximum oral exposure—while ignoring dermal and inhalation exposure routes. Applying Method 5 to prioritization would likely be inconsistent with the statutory criteria, particularly with regards to potentially exposed or susceptible populations. Because the other methods were more consistent with one another and with results from the existing TSCA Work Plan, they represent a better starting place under this proposed approach. We generally agree that significant overlap in high bin chemicals across methods highlights good potential candidates for high-priority designation.

The heat map data presented at the December 11 meeting clearly identified certain chemicals that yield the same chemical score when evaluated using traditional approaches or new approach methods, but for other chemicals the results were vastly different. This indicates that new approach methods may only be appropriate for certain chemicals or certain types of chemicals and not others. Correlation between testing methodologies needs to be adequately investigated before the adoption of new approach methods can be relied on to fill data gaps and ensure new approach methods are not used prematurely.

EWG would additionally comment that we support the inclusion of endocrine activity endpoints as suggested, but note that limiting these endpoints to estrogenic and androgenic (or anti-estrogenic and anti-androgenic) activities is a poor representation of the vast biological pathways regulated by the endocrine system—including but not limited to thyroid, neuroendocrine and

[56] *Id.* at 42.
[57] Procedures for Prioritization of Chemicals for Risk Evaluation Under the Toxic Substances Control Act, 82 Fed. Reg. at 33759 ("EPA has stricken the provision in question from the final rule. EPA agrees that the consideration of alternatives is most appropriately considered as part of any risk management rule.").

metabolic effects—and that continued work should be done to validate and include these additional endpoints in new approach methods.

Conclusion

EWG appreciates the opportunity to weigh in on this discussion document and the prioritization process generally. 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,

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