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Gina McCarthy, Administrator
U.S. Environmental Protection Agency

Jim Jones, Assistant Administrator
Office of Chemical Safety and Pollution Prevention
U.S. Environmental Protection Agency

Re: Docket Number EPA-HQ-OPPT-2016-0399

The following comments are submitted on behalf of the Environmental Working Group (EWG), a nonprofit environmental health advocacy organization. EWG has spent over a decade advocating for reforms to strengthen the Toxic Substances Control Act (TSCA). The new requirements under the Frank R. Lautenberg Chemical Safety for the 21st Century Act will for the first time require the Environmental Protection Agency (EPA) to systematically review existing chemicals on the TSCA inventory. This is an unprecedented opportunity to perform robust risk evaluations and promulgate strong regulations to protect all Americans from the most toxic chemicals in our society.

With more than 80,000 chemicals on the TSCA inventory and more than 1,000 chemicals that EPA claims it needs to review for safety,[1] it is imperative that EPA establish a health-protective and efficient process for prioritizing and taking action on the chemicals that may pose the greatest risks to human health – including vulnerable populations – and the environment.

We make the following recommendations:

Procedural Rule
As a starting point, EWG emphasizes that the law requires EPA to establish a risk-based *process* for making prioritization decisions.[2] EWG interprets this to mean that the rule should be procedural and provide a broad framework for making prioritization decisions. If the rule is too detailed on specific scientific considerations, EPA may be bogged down by undue administrative burdens or may not be able to adjust its considerations to keep up with the best available science. As such, more detailed scientific methodologies and factors are better reserved for guidance and policy documents that can be updated more easily to reflect evolving science and understanding of chemical risks. EWG recommends that those considerations be made in the guidance EPA is required to promulgate within two years of enactment and to update every five years.[3] While EPA is not required to solicit public comment on these guidance and policy documents, we encourage it to do so as the public – including industry, advocates, and academics – may have valuable insight on the most current scientific standards.

Adequate Data
Prioritization decisions should be rooted in adequate data, and when adequate data is not available EPA should utilize its order authority. The law requires EPA to take into consideration

all information that is reasonably available.[4] We interpret this broadly to include all information that EPA is reasonably aware of – including information published in scientific journals and information that can be directly requested from companies. In addition to this information, EPA should use its authority under Section 26(a),[5] to request information from other agencies as needed to more adequately understand the potential aggregate and cumulative risks of a chemical. EPA may also work directly with those agencies to develop research and monitoring information, and EWG encourages it to do so.[6] EPA should use its 8(a) authority to require recordkeeping related to production volumes, byproducts, health and environmental effects, and likely exposures.[7] Section 8 also requires manufacturers to maintain, and in some cases submit, records related to adverse events, lists of health and safety studies, and information about substantial risks.[8] All of this information should be considered available to EPA and could help EPA make prioritization decisions.

EWG also encourages EPA to take into consideration information that may have already been collected by state governments or under foreign regulations like 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.

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 . . . ."[9] 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.

The law instructs EPA to consider several factors when determining the potential hazard or potential exposure to a chemical. For example, EPA must consider persistence and bioaccumulation, potentially exposed subpopulations, and storage near potential sources of drinking water.[10] The law also requires that EPA give preference to Work Plan chemicals scoring a 3 for persistence and bioaccumulation, and Work Plan chemicals that are known human carcinogens or have high acute or chronic toxicity.[11] While these are important factors to consider, EWG encourages EPA to use these considerations as starting points only.

When assessing potential exposure for prioritization, EPA should consider potential aggregate exposures as well. This includes potential exposures from not only TSCA-regulated uses, but also uses regulated under other environmental laws and by other agencies like the Food and Drug Administration and Consumer Product Safety Commission. Potential hazard and exposure analysis should also consider all potential routes of exposure – including dermal, oral, and inhalation. When possible, EPA should also consider potential *cumulative* exposures of a chemical in conjunction with other chemicals or stressors that might add to that chemical's environmental or health risks.

When making a prioritization decision, EPA should also consider potential hazards and exposures from the entire life cycle of the chemical from production, to storage, to various uses up and down supply chains – including unintended, but reasonably foreseeable uses – to disposal, or in some cases long-term persistence in the environment or bioaccumulation in the body. In addition to the requirement to consider proximity to drinking water sources, EPA should consider potential risks for communities near places chemicals will be manufactured, processed, stored, or disposed of – even if those facilities do not border drinking water sources. When chemical persistence or presence poses unique threats to a particular community – such as fenceline communities adjacent to vinyl chloride processing facilities – those chemicals should be considered high-priority.

When assessing potential exposures for vulnerable populations, prioritization decisions should take into account who is exposed to a chemical and how. This includes occupational exposures for workers who manufacture and process chemicals, workers exposed to 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, and exposures that may uniquely affect the elderly.

When considering potential risks from different exposures, EPA should not equate low exposures with low risks per se, and low exposure alone should not be the basis for designating a chemical as low-priority. In some cases, particularly with regard 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, 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, European Union's (EU) Globally Harmonized System of Classification and Labelling of Chemicals hazard and toxicity classifications, and the Association of Occupational and Environmental Clinic's Exposure Code List for asthma-causing substances.

EPA should consider designating *categories* of chemicals as high-priority to more quickly and efficiently work through the backlog of chemical substances that EPA must review. EPA clearly has the authority to make these groupings under Section 26, which states that "any action authorized or required to be taken by the Administrator under any provision of this chapter with respect to a chemical substance or mixture may be taken by the Administrator in accordance with that provision with respect to a category of chemical substances or mixtures."[12] Other states like California, have cited in public testimony[13] that this approach has helped to streamline their chemical review processes, and we encourage EPA to do the same where chemicals exhibit similar characteristics and potential risks. EPA should initially focus on developing and expanding categories of chemicals for those similar to regulated substances. When counting the number of chemicals under review or with completed reviews, categories should count as one chemical.

EWG recognizes that one of the great challenges EPA faces in prioritizing chemicals is the lack of comprehensive safety testing. In the absence of sufficient information on environmental or human health impact, the agency should consider the chemical in question to be a high-priority for review. The American Chemistry Council has also previously suggested this approach of categorizing a chemical as high-priority in the absence of adequate data.[14] For chemicals lacking sufficient data the agency should act quickly and utilize its order authority to request additional testing.

Low-Priority Designations

The definitions of high- and low-priority chemicals mandate that EPA err on the side of designating chemicals as high-priority. The law requires all low-priority designations to be "based on information *sufficient* to establish" that the chemical would not meet the standard for a high-priority chemical.[15] Taking the inverse of the definition of a high-priority chemical – a chemical which "may present an unreasonable risk" – a low-priority chemical must not present an unreasonable risk. If there is not sufficient data to show that a low-priority chemical would not present an unreasonable risk, then by definition it *may* present such a risk and must be designated as high-priority. When EPA does not have sufficient data to make a low-priority designation, EWG recommends using order authority given under section 4(a)(2)[16] to order such information, or to designate the chemical as high-priority and then order the information as part of the risk evaluation process.

EWG also notes that while EPA is required to repopulate its list of high-priority chemicals as it completes risk evaluations,[17] there is no corresponding requirement for low-priority designations. EPA must only designate 20 low-priority chemicals within three-and-a-half years of enactment and then "continue to designate priority substances . . . at a pace consistent with the ability of the Administrator to complete risk evaluations in accordance with the deadlines under paragraph 4(G)."[18] This means that the pace of further designations are tied to EPA's ability to complete evaluations of *high-priority* chemicals, but that there is no statutory minimum number of low-priority designations beyond the first 20. As such, EPA should only designate a chemical as low-priority if it feels truly confident, based on sufficient information, that the chemical will not pose an unreasonable risk of injury to health or the environment.

The law also allows EPA to revise low-priority designations based on new information.[19] EPA should develop a process to periodically review chemicals placed on the low-priority list to ensure the most current science still supports that designation. For example, if production volumes increase significantly or if a compound becomes detectable in biomonitoring studies, the prioritization designation should be reevaluated.

Prioritize Chemicals, Not Uses

During the public meeting on Aug. 10, several commenters seemed to encourage an approach that would allow EPA to prioritize uses of chemicals rather than the whole chemical. This would potentially result in high- and low-priority uses for one chemical. EWG strongly disagrees with this approach. EPA already has a significant backlog of chemicals to review and prioritizing uses

rather than substances would substantially increase the number of reviews EPA must perform. Instead, EPA should prioritize the whole chemical and, where appropriate, regulate uses differently after it is has completed a risk evaluation and promulgates risk management rules.

Transparent Process

EWG appreciated the public meetings organized on Aug. 9 and 10, and the opportunity to submit these comments. We look forward to continued input during the 90-day comment periods[20] required for each prioritization decision, and encourage EPA to consider the 90-day comment period as a minimum. Should EPA need more time to consider public input on a prioritization decision, it should extend that comment period.

EPA should also be transparent and consider public comment even where not required under the law. For example, in addition to EPA's prioritization decisions, up to 50 percent of the chemicals EPA reviews may be assessed at the request of manufacturers.[21] While EPA is not required to seek public input on decisions to accept or reject manufacturer requests, EWG encourages EPA to be transparent in its decision-making processes. Likewise, if a third party submits a draft evaluation for a chemical using the guidance under Section 26(l)(5),[22] EPA should publish the draft and be transparent about its process for accepting or rejecting that draft evaluation and/or its basis as part of a prioritization decision.

Finally, Section 26(j)(5) requires EPA to make public, along with each prioritization designation, "an identification of the information, analysis, and basis used to make this designation."[23] In addition to merely identifying the information used, EPA should make the information available to interested parties through the Freedom of Information Act. EPA should also limit the use of confidential business information (CBI) in these disclosures so that the information is accessible and understandable to the public. Furthermore, EPA has discretion under Section 14(f) to require manufacturers to resubstantiate a CBI claim once a chemical has been designated as high-priority.[24] In the interest of transparency, we encourage EPA to rigorously exercise this discretion following high-priority designations.

Thank you for the opportunity to comment, and we look forward to continuing to work with EPA on TSCA implementation.

Sincerely,

Melanie Benesh, J.D.
Legislative Attorney

Johanna Congleton, MSPH, Ph.D.
Senior Scientist

David Andrews, Ph.D.
Senior Scientist

[1] Jim Jones, Assistant Admn'r, EPA Office of Chemical Safety & Pollution Prevention, Testimony before Senate Comm. on Env't & Pub. Works (Mar. 18, 2015), http://www.epw.senate.gov/public/_cache/files/6072fb1c-06a0-48b5-9dd4-2d894a81e9c0/spw031815.pdf.
[2] 15 U.S.C. § 2605(b)(1)(A)(emphasis added).
[3] 15 U.S.C. § 2625(l)(1)-(2).
[4] 15 U.S.C. § 2625(k).
[5] 15U.S.C. § 2625(a).
[6] 15 U.S.C. § 2609.
[7] 15 U.S.C. § 2607(a).
[8] 15 U.S.C. § 2607(c)-(e).
[9] 15 U.S.C. § 2605(b)(1)(B)(i)(emphasis added).
[10] 15 U.S.C. § 2605(b)(1)(A).
[11] 15 U.S.C. § 2605(b)(2)(D).
[12] 15 U.S.C. § 2625(c)(1).
[13] Gina Solomon, Deputy Sec'y for Health & Sci. at Cal. Envtl. Prot. Agency, Oral Comment at EPA Public Meeting on Section 6 Risk Evaluation (Aug. 9, 2016).
[14] American Chemistry Council, American Chemistry Council Prioritization Screen Approach (2011), https://www.americanchemistry.com/Prioritization-Document/.
[15] 15 U.S.C. § 2605(b)(1)(B)(ii)(emphasis added).
[16] 15 U.S.C. § 2603(a)(2).
[17] 15 U.S.C. § 2605(b)(3)(C).
[18] 15 U.S.C. § 2605(b)(2)(C).
[19] 15 U.S.C. § 2605(b)(3)(B).
[20] 15 U.S.C. § 2605(b)(1)(C)(ii).
[21] 15 U.S.C. § 2605(b)(4)(E)(ii).
[22] 15 U.S.C. § 2625(l)(5).
[23] 15 U.S.C. § 2625(j)(5).
[24] 15 U.S.C. § 2613(f)(1).