AMERICAN PUBLIC HEALTH ASSOCIATION
For science. For action. For health.

September 18, 2017

The Honorable Scott Pruitt
Administrator
U.S. Environmental Protection Agency
Office of Pollution Prevention and Toxics
1200 Pennsylvania Avenue, NW
Washington, DC 20460-0001

RE: Comments on the Scopes of Risk Evaluations for the First 10 Chemicals Evaluated under Section 6 of the Toxic Substances Control Act, as Amended[1]

Dear Administrator Pruitt:

On behalf of the American Public Health Association, a diverse community of public health professionals who champion the health of all people and communities, I appreciate the opportunity to comment on the scopes of risk evaluations for 10 chemicals that the U.S. Environmental Protection Agency is currently conducting under the amended Toxic Substances Control Act.

APHA has called for the restructuring of TSCA and we urge EPA to seize this opportunity to strengthen the risk evaluations conducted by the agency and the risk management steps these evaluations support.[2] The recommendations listed below apply across the first 10 chemicals that EPA will evaluate; therefore, we have submitted this comment in duplicate to each docket for consideration by the agency.

The scope of a risk evaluation for a chemical substance can determine whether the evaluation adequately captures the full range of exposures and risks associated with it.[3] The following recommendations, based largely on recent reports from the National Academy of Science, will

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[1]The 10 chemicals and their docket numbers are: asbestos (EPA-HQ-OPPT-2016-0736), 1-bromopropane (EPA-HQ-OPPT-2016-0741), carbon tetrachloride (EPA-HQ-OPPT-2016-0733), 1,4-dioxane (EPA-HQ-OPPT-2016-0723), cyclic aliphatic bromide cluster (EPA-HQ-OPPT-2016-0735), methylene chloride (EPA-HQ-OPPT-2016-0742), N-methylpyrrolidone (EPA-HQ-OPPT-2016-0743), perchloroethylene (EPA-HQ-OPPT-2016-0732), pigment violet 29 (EPA-HQ-OPPT-2016-0725), and trichloroethylene (EPA-HQ-OPPT-2016-0737).

[2] APHA, *Policy Statement 20077: Calling on Congress to Restructure the Toxic Substances Control Act of 1976*, https://apha.org/policies-and-advocacy/public-health-policy-statements/policy-database/2014/07/08/13/04/calling-on-the-us-congress-to-restructure-the-toxic-substances-control-act-of-1976 (last accessed September 12, 2017).

[3] National Research Council, *Science and Decisions: Advancing Risk Assessment*, 2009, Washington, DC: National Academies Press (hereafter, "Science and Decisions") at 68-69.

help ensure that EPA does not overlook critical information about hazard, exposure, or risk as it moves forward in developing draft risk evaluations for the first 10 chemicals, and that the agency conducts its evaluations in a manner that is both protective of public health and transparent.

EPA should assess aggregate exposures within and across populations resulting from all current and legacy uses of a chemical substance to avoid underestimating risk. A chemical substance may have many current uses and legacy uses that remain ongoing and thus contribute to exposure and associated human health risks. EPA must assess exposures resulting from *all* current and legacy uses of a chemical and consider these together to adequately assess exposure and characterize risk. For example, asbestos is widely prevalent in the environment due largely to legacy uses,[4] and risk evaluations that assess only exposures from current uses will fail to characterize the risks these chemicals pose. Furthermore, while EPA has proposed to assess exposure in three populations (occupational and occupational non-users, consumers and bystanders, and the general population), individuals may be members of more than one of these populations and the agency must sum exposures across contexts to understand the true level of exposure experienced by such individuals. For example, workers may be exposed to trichloroethylene used in industry (an example of occupational exposure) and present in ambient air they inhale and drinking water they ingest (examples of general population exposure).[5] EPA cannot narrow the scope of its evaluations to a subset of uses or exposure pathways without jeopardizing the validity of its conclusions.

EPA should conduct hazard identification by following systematic review processes that integrate animal, human, and mechanistic evidence. The scope of a risk evaluation should include all of the hazards associated with exposure to a chemical, and EPA should not exclude associations from consideration in the risk evaluation until the agency has conducted a systematic review that identifies all of the relevant scientific information. In August 2017, NAS recommended that EPA conduct risk evaluations by identifying any existing systematic reviews for a chemical substance, determining if the reviews are of high quality, and for those that are, building upon the reviews by incorporating any more recent studies that may have become available since the review was conducted.[6] EPA should heed this recommendation.

EPA should follow recommendations from NAS to identify vulnerable subpopulations based on established risk factors that increase susceptibility or exposure. In many cases, low-income communities and/or communities of color live, work or attend school near chemical manufacturing, processing, distribution, or disposal sites and face elevated exposures and/or increased susceptibility due to the synergistic effects of exposures to multiple chemicals and

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[4] ATSDR, *Toxicological Profile for Asbestos*, 2001, https://www.atsdr.cdc.gov/toxprofiles/tp61.pdf (last accessed September 12, 2017) at 3-4.
[5] EPA, *Scope of Risk Evaluation for Trichloroethylene*, https://www.epa.gov/sites/production/files/2017-06/documents/tce_scope_06-22-17.pdf (last accessed September 12, 2017) at 32-34.
[6] National Academies of Sciences, Engineering, and Medicine, *Application of Systematic Review Methods in an Overall Strategy for Evaluating Low-Dose Toxicity from Endocrine-Active Chemicals*, 2017, Washington, DC: National Academies Press at 10.

social and economic stressors.[7] In addition, children are uniquely vulnerable due to their developing metabolisms and organ systems; physical factors such as lower body weights; and certain behaviors that may increase their exposure.[8] Pregnant women are also vulnerable, and numerous toxicants are known to cross the placenta, exposing the fetus.[9] NAS has identified multiple factors that may indicate disparate exposure or susceptibility,[10] and EPA should use these factors to assess the risks faced by vulnerable subpopulations. If EPA lacks information on these factors as they relate to a specific chemical, the agency should use health-protective defaults to fill data gaps (see below).

EPA should use health-protective defaults if the agency lacks information specific to a chemical, and health-protective methods to quantify risk when characterizing risk. A lack of information specific to a chemical under evaluation is a common challenge in risk assessment, and historically risk assessors have used defaults to bridge these data gaps.[11] For example, EPA routinely applies safety or uncertainty factors of 10 to account for inter- and intra-species variability.[12] We support the use of health-protective defaults, but NAS has found that a factor of 10 may be inadequate to account for the myriad sources of variability in susceptibility; default factors of 25 or 50 may be more appropriate.[13] It is especially important to apply additional uncertainty or safety factors that account for early-life exposures during gestation, infancy and childhood.[14] NAS also recommends that EPA quantify risk rather than concluding only that exposure is greater or less than a level of concern.[15]

EPA should require that claims of confidential business information be fully substantiated by industry and not used to conceal critical information from the public. NAS has stressed the importance of transparency in risk assessment.[16] If a risk evaluation relies upon information that is withheld from public disclosure as CBI, transparency is limited. EPA should require that any claim of CBI is fully substantiated so that critical information is not withheld without adequate justification. The agency also should exercise its considerable discretion to disclose information that otherwise might warrant CBI protection when the agency determines that such information is relevant to a risk evaluation.

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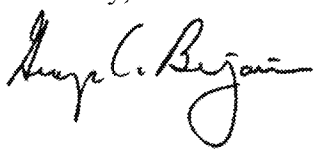
[7] Science and Decisions at 213.
[8] National Research Council, *Pesticides in the Diets of Infants and Children*, 1993, Washington, DC: National Academies Press at 23-24.
[9] Application of Systematic Review Methods at 41.
[10] Science and Decisions at 110.
[11] National Research Council, *Risk Assessment in the Federal Government: Managing the Process*, 1983, Washington, DC: National Academies Press at 51.
[12] EPA, A Review of the Reference Dose and Reference Concentration Processes, https://www.epa.gov/sites/production/files/2014-12/documents/rfd-final.pdf (last accessed September 12, 2017) at 4-42.
[13] Science and Decisions at 109 and 168.
[14] California Environmental Protection Agency, Technical Support Document for Cancer Potency Factors: Methodologies for Derivation, Listing of Available Values, and Adjusted to Allow for Early Life Stage Exposures, 2009, https://oehha.ca.gov/media/downloads/crnr/tsdcancerpotency.pdf (last accessed September 12, 2017).
[15] Science and Decisions at 138.
[16] Science and Decisions at 71.

The Lautenberg Act requires that EPA make risk determinations and protect against "unreasonable risk." The recommendations outlined above will help ensure that the agency conducts risk evaluations that fulfill this mandate and are protective of public health, based on the best available science and transparent to all stakeholders. Please contact me with any questions regarding our comments.

Sincerely,



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