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

August 10, 2018

The Honorable Andrew Wheeler
Acting Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460-0001

Re: Comments on Problem Formulation Documents for Risk Evaluations Conducted under the Toxic Substances Control Act as Amended;[1] Comments on "Application of Systematic Review in TSCA Risk Evaluations" Guidance Document[2]

Dear Acting Administrator Wheeler:

On behalf of the American Public Health Association, a diverse community of public health professionals that champions the health of all people and communities, I appreciate the opportunity to comment on: (1) problem formulation documents for risk evaluations that the U.S. Environmental Protection Agency is conducting under the Toxic Substances Control Act as amended and (2) EPA's "Application of Systematic Review in TSCA Risk Evaluations" guidance document.

TSCA is EPA's primary source of authority for evaluating and managing the health and environmental risks presented by approximately 85,000 industrial chemicals.[3] Unfortunately, the problem formulation documents indicate that the agency intends to conduct risk evaluations that are incomplete and likely to underestimate risk. Specifically, the agency plans to *ignore* numerous exposures to these chemicals. By considering only some exposures and not others, EPA likely will conclude that the total level of exposure to a chemical is lower than it truly is.

[1] APHA has submitted these comments to the dockets for nine chemicals: 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 (HBCD) (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). APHA has submitted separate comments to the docket for asbestos (EPA-HQ-OPPT-2016-0736).
[2] APHA also has submitted these comments to the docket for the "Application of Systematic Review in TSCA Risk Evaluations" guidance document (EPA-HQ-OPPT-2018-0210).
[3] EPA, *About the TSCA Chemical Substance Inventory* (last updated Sept. 14, 2016), https://www.epa.gov/tsca-inventory/about-tsca-chemical-substance-inventory.

The agency then may determine incorrectly that this lower level of exposure does not present an unreasonable risk of injury to health or the environment, even when the true level of exposure does present such a risk. The decision to ignore chemical exposures is unlawful and lacks scientific credibility. EPA should include all exposures to these chemicals in its risk evaluations.

In addition, the Systematic Review Guidance describes how the agency intends to identify, evaluate, and integrate scientific information for TSCA risk evaluations. The guidance will be pivotal to the conduct and ultimately the scientific credibility of these evaluations. Yet the guidance is inconsistent with the best available science and has not been peer reviewed by independent experts. The current draft diverges from established techniques in use in the scientific community. I urge the agency to comply with its own Peer Review Handbook, to arrange for peer review of the guidance by the National Academy of Science, and to revise the guidance based on the results of this peer review prior to relying upon it to conduct systematic reviews for TSCA risk evaluations.

EPA's Exclusions of Exposures from the Risk Evaluations Are Unlawful and Lack Scientific Credibility

EPA's problem formulation documents indicate several ways in which the agency intends to ignore exposures to the chemicals. First, TSCA requires EPA to "conduct risk evaluations…to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment…*under the conditions of use*." TSCA § 6(b)(4)(A) (emphasis added). In general, "the conditions of use" of a chemical include the manufacture, distribution in commerce, processing, use, and disposal of the chemical. EPA has decided to ignore conditions of use and resulting exposures, either by declaring that certain activities are not conditions of use or by acknowledging that the activities are conditions of use but nonetheless declaring that they will not be included in the risk evaluation. These actions by the agency lack both legal and factual support.

Second, EPA has decided to exclude entire exposure pathways, such as inhalation of a chemical in ambient air or ingestion of a chemical in drinking water, from the risk evaluations. These exclusions rely on a flawed analysis of TSCA and other environmental statutes. Furthermore, EPA admits the exclusions will disregard important risks of injury to health.

<u>Exclusions of Conditions of Use</u>

The exclusion of certain activities from the risk evaluations is unlawful. As noted above, TSCA requires EPA to evaluate the risks presented by "a chemical substance" under "the conditions of use." The language of the statute clearly directs the agency to evaluate the risk presented by a chemical substance in total and does not provide for picking and choosing among conditions of use when conducting a risk evaluation. Even if EPA did possess the authority to include only some conditions of use and not others, however, the agency still has failed to support its exclusions with information provided in the problem formulation documents.

In many cases, it appears that EPA has obtained information via unverified communications with companies that once engaged and still may be engaged in activities that constitute conditions of use. These include manufacturers, processors, distributors, commercial users, and companies involved in disposal of one or more of the chemicals. It does not appear that EPA has taken

meaningful steps to verify information provided by companies or their representatives. This is inappropriate due to the obvious conflicts of interest with respect to risk evaluations for chemicals that once were or still are important to their businesses. For example, EPA has concluded that "domestic manufacture of HBCD has ceased" based primarily on assurances provided by two recent manufacturers of the flame retardant.[4] The agency does not indicate how it verified these assurances or how it will ensure that the purported cessation will continue in the future.

EPA relies on information from entities even after concluding that the information is not credible. For example, the agency relies on information from "several racing authorities" to conclude that dioxane is no longer used as a fuel additive in car racing.[5] Even though the racing authorities "could not provide credible information on…whether [dioxane] is currently used at all," the agency nonetheless determined that "fuels and fuel additives" are not a condition of use for the purposes of the 1,4-dioxane risk evaluation and will be excluded.[6]

Even if the information provided by a company is accurate, the company remains free to resume any activity at any point in the future absent a regulation stating otherwise. Such an activity therefore remains a "reasonably foreseeable" condition of use under the statute. Furthermore, accurate information that may be provided by one company or subset of companies cannot be assumed to represent the activities of all current or future firms within an industry. Yet EPA makes this assumption. The agency has excluded domestic manufacture of expanded polystyrene (EPS) resin and extruded polystyrene (XPS) masterbatch from the HBCD evaluation based on reports by "all *major* North American manufacturers…of EPS resin" and comments by "*major* producers" of XPS masterbatch (emphasis added), respectively.[7] These reports cover only manufacturers or producers that the agency considers "major." They cannot represent the activities of any other manufacturers of EPS resin or XPS masterbatch, including any future manufacturers.

At a minimum, if EPA is told that manufacture, import, and processing of a chemical has ceased, the agency should demand legally binding certification of such cessation from *every* previous manufacturer, importer, and processor of the chemical. Furthermore, the agency should promulgate a significant new use rule under TSCA § 5(a) so that, if and when manufacture, import, or processing of the chemical does occur in the future, the activity must be reported to EPA.

<u>Exclusions of Exposure Pathways</u>

In addition to ignoring conditions of use, EPA intends to disregard entire pathways of exposure to chemicals. By disregarding these pathways, EPA will narrow the scopes of the risk

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[4] EPA, *Problem Formulation for Cyclic Aliphatic Bromides Cluster (HBCD)* 20 (May 2018), https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/cyclic-aliphatic-bromides-cluster-hbcd-cluster-problem (hereafter, "Problem Formulation for HBCD").
[5] EPA, *Problem Formulation of the Risk Evaluation for 1,4-Dioxane* 18 (May 2018), https://www.epa.gov/sites/production/files/2018-06/documents/14-dioxane_problem_formulation_5-31-18.pdf (hereafter, "Problem Formulation for 1,4-Dioxane").
[6] *Id*.
[7] Problem Formulation for HBCD at 21.

evaluations further. For example, even if domestic manufacture of 1,4-dioxane is included in the scope of the risk evaluation, inhalation of 1,4-dioxane in ambient air or ingestion of 1,4-dioxane in drinking water as a result of releases by domestic manufacturers will be excluded. In addition, for every chemical except pigment violet 29, EPA argues it can ignore exposures resulting from disposal.[8] By excluding pathways, the agency will ignore potential exposure to more than 68 million pounds of industrial chemicals released each year.[9] EPA's rationale for excluding pathways disregards TSCA and, by the agency's own admission, ignores unreasonable risks of injury to health.

According to the agency, exposure pathways will be excluded when they fall under "other environmental statutes, administered by EPA, which adequately assess and effectively manage exposures and for which long-standing regulatory and analytical processes already exist[.]"[10] There are key differences between the requirements imposed by "other environmental statutes" and the requirements imposed by TSCA. For example, EPA intends to exclude inhalation of methylene chloride in ambient air.[11] The agency claims that, because methylene chloride is listed as a hazardous air pollutant under the Clean Air Act, this pathway is "adequately assess[ed] and effectively manage[d]" under another statute and need not be considered under TSCA.[12] This is incorrect. EPA manages hazardous air pollutants by requiring source categories to reduce emissions based on what is achievable using certain technologies. The agency does not require source categories to eliminate all emissions, and the remaining emissions can present significant risks. In the case of methylene chloride in ambient air, there is no reason to believe that exposure and risk are effectively managed. As the agency acknowledges, "levels of methylene chloride in the ambient air are widespread and shown to be increasing."[13] EPA is required to evaluate the risk presented by chemicals under TSCA. This includes any risks to vulnerable populations. The agency cannot escape this requirement by ducking behind unrelated statutes that impose separate requirements to protect public health.

EPA admits that excluding exposure pathways will neglect unreasonable risks of injury to health presented by the chemicals. For example, the agency said it intends to exclude exposure to 1,4-dioxane in drinking water because drinking water contaminants may be regulated under the Safe Drinking Water Act.[14] (Notably, the agency does not regulate 1,4-dioxane under the Safe Drinking Water Act, nor has it proposed to do so.) EPA acknowledges that "[t]he general population may ingest 1,4-dioxane via contaminated drinking water."[15] EPA reports that 341

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[8] *See, e.g.*, EPA, *Problem Formulation of the Risk Evaluation for Carbon Tetrachloride (Methane, Tetrachloro-)* 50-51 (May 2018), https://www.epa.gov/sites/production/files/2018-06/documents/ccl4_problem_formulation_05-31-18.pdf.

[9] Environmental Defense Fund, *Pruitt EPA Illegally and Dramatically Undermines Authority to Limit Dangerous Chemicals under Reformed Chemical Safety Law* (Jun. 1, 2018), http://blogs.edf.org/health/2018/06/01/pruitt-epa-illegally-and-dramatically-undermines-authority-to-limit-dangerous-chemicals-under-reformed-chemical-safety-law.

[10] EPA, *Problem Formulation of the Risk Evaluation for Methylene Chloride (Dichloromethane, DCM)* 46 (May 2018), https://www.epa.gov/sites/production/files/2018-06/documents/mecl_problem_formulation_05-31-18.pdf.

[11] *Id.* at 54.

[12] *Id*.

[13] *Id*. at 39.

[14] Problem Formulation for 1,4-Dioxane at 31.

[15] *Id*. at 43.

water systems have measured 1,4-dioxane at concentrations associated with an excess cancer risk greater than or equal to one in one million.[16] This level of risk "has often been considered a "benchmark" above which EPA has concerns for exposure to the general population" — that is, the agency has considered this level of risk to be unreasonable.[17] Because EPA is excluding drinking water exposure to 1,4-dioxane from the risk evaluation, however, this unreasonable risk will be ignored.

EPA's Use of the Systematic Review Guidance Would Violate TSCA Science Standards

EPA's Systematic Review Guidance describes how EPA intends to identify, evaluate and integrate scientific information used in TSCA risk evaluations. The guidance will shape, for example, whether and to what extent the agency considers a study finding that exposure to a chemical was associated with a particular adverse health effect. TSCA requires EPA to "use scientific information, technical procedures, measures, methods, protocols, methodologies, or models, employed in a manner *consistent with the best available science*" and to "consider as applicable…the extent of independent verification or *peer review* of the information or of the procedures, measures, methods, protocols, methodologies, or models." § 26(h) (emphasis added). Yet the guidance is not consistent with the best available science nor has it been peer reviewed by independent experts. EPA's reliance on this version of the guidance would violate TSCA.

The guidance is not consistent with best practices for systematic review. The guidance includes hundreds of pages of data quality criteria that EPA will use to assign numeric scores to individual studies.[18] The agency says it may disregard a study based on the numeric score assigned to it.[19] This is an outdated approach. NAS discourages the use of numeric scoring in systematic review, noting that "[i]n recent years, systematic review teams have moved away from scoring systems to assess the quality of individual studies," in part because scoring systems have not been validated and different systems can produce radically different results.[20] Notably, systematic reviews conducted by EPA's Integrated Risk Information System do not utilize numeric scoring,[21] and neither should systematic reviews conducted under TSCA.

Surprisingly, EPA has not subjected the guidance to peer review. This is a major omission. In addition to ignoring TSCA's requirement to consider the extent of peer review of the scientific information and technical procedures used by the agency, relying on the guidance when it has not been peer reviewed would harm the scientific credibility of the TSCA program. As EPA's

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[16] *Id.* at 31.
[17] EPA, *New Chemicals Decision-Making Framework: Working Approach to Making Determinations under Section 5 of TSCA* 4 (November 2017), https://www.epa.gov/sites/production/files/2017-11/documents/new_chemicals_decision_framework_7_november_2017.pdf.
[18] EPA, *Application of Systematic Review in TSCA Risk Evaluations* 30 (May 2018), https://www.epa.gov/sites/production/files/2018-06/documents/final_application_of_sr_in_tsca_05-31-18.pdf.
[19] *Id*. at 33.
[20] Institute of Medicine, *Finding What Works in Health Care: Standards for Systematic Reviews* 132 (2011), https://www.nap.edu/catalog/13059/finding-what-works-in-health-care-standards-for-systematic-reviews (hereafter, "NAS Systematic Review Report").
[21] NAS, *Progress Toward Transforming the Integrated Risk Information System (IRIS) Program* 43-52 (2018), https://www.nap.edu/catalog/25086/progress-toward-transforming-the-integrated-risk-information-system-iris-program.

own Peer Review Handbook states, "Peer review enhances the credibility and acceptance of the decision based on the work product," which in this case is the decision to regulate or not regulate a chemical under TSCA based on a risk evaluation and determination.[22] EPA should seek peer review of the guidance by NAS, which has published several reports on the conduct of systematic review for chemical exposure and its application by federal agencies.[23]

EPA Must Evaluate Risks to Workers and Other Vulnerable Subpopulations and Ensure Adequate Protections

TSCA requires EPA to determine whether a chemical presents an unreasonable risk of injury to the general population and/or to "potentially exposed or susceptible subpopulations." § 6(b)(4)(A). A potentially exposed or susceptible subpopulation is any "group of individuals within the general population…who, due to either greater susceptibility or greater exposure, may be at greater risk than the general population…such as infants, children, pregnant women, workers, or the elderly." § 3(12). It is well understood, for example, that pregnant women, children, and infants are uniquely susceptible to chemical exposures.[24] TSCA imposes a duty on EPA to ensure that vulnerable subpopulations are protected from chemical risks, and it is imperative that the agency conduct risk evaluations, make risk determinations, and promulgate risk management regulations in accordance with this duty.

In particular, TSCA provides new tools to protect workers from occupational exposures to a wide variety of chemicals encountered while on the job. Workers face significant risk of harm from chemical exposures but they are not adequately protected by regulations of the Occupational Safety and Health Administration. OSHA has adopted comprehensive health standards on just a few dozen chemicals since the agency was established in 1971, and most of these standards were issued before 1990.[25] Furthermore, tens of millions of workers are not covered by the Occupational Safety and Health Act. EPA's duty to protect workers and other vulnerable subpopulations under TSCA fills in gaps in the law that have allowed workers to go unprotected from chemical hazards.

Conclusion

TSCA now provides an opportunity to evaluate and manage the health and environmental risks presented by tens of thousands of industrial chemicals that to date have received scant attention from EPA. Seizing this opportunity will require the agency to conduct risk evaluations that

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[22] EPA Science and Technology Council, *Peer Review Handbook* 21 (2015), https://www.epa.gov/sites/production/files/2016-03/documents/epa_peer_review_handbook_4th_edition.pdf.

[23] *See, e.g.*, NAS, *Progress Toward Transforming the Integrated Risk Information System (IRIS) Program* 43-52 (2018), https://www.nap.edu/catalog/25086/progress-toward-transforming-the-integrated-risk-information-system-iris-program; NAS Systematic Review Report.

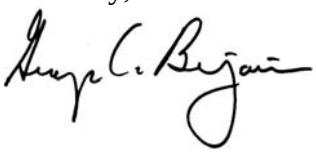
[24] Project TENDR: Targeting Environmental Neuro-Developmental Risks, *The TENDR Consensus Statement*, 124 Environmental Health Perspectives A118 (2016), https://ehp.niehs.nih.gov/ehp358; Patricia D. Koman, et al., *Examining joint effects of air pollution exposure and social determinants of health in defining "at-risk" populations under the Clean Air Act: susceptibility of pregnant women to hypertensive disorders of pregnancy*, 10 World Medical and Health Policy 1 (2018).

[25] U.S. Government Accountability Office, *Workplace Safety and Health: Multiple Challenges Lengthen OSHA's Standard Setting* (April 2012), https://www.gao.gov/assets/590/589825.pdf.

include all exposures, to use the best available science, and to ensure adequate protections for vulnerable subpopulation. We therefore respectfully request that EPA reexamine its problem formulation documents and Systematic Review Guidance prior to completing the draft risk evaluations for the chemicals it currently is evaluating.

Thank you for taking our comments into consideration. Please feel free to contact me with any questions regarding our views on EPA's proposals.

Sincerely,



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