UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Comments of Safer Chemicals Healthy Families on Risk Evaluation Scoping Documents for Ten Chemical Substances under the Toxic Substances Control Act

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1,4-Dioxane. Docket ID No.: EPA-HQ-OPPT-2016-0723.

1-Bromopropane. Docket ID No.: EPA-HQ-OPPT-2016-0741.

Asbestos. Docket ID No.: EPA-HQ-OPPT-2016-0736.

Carbon Tetrachloride. Docket ID No.: EPA-HQ-OPPT-2016-0733.

Cyclic Aliphatic Bromide Cluster (Hexabromocyclododecane or HBCD). Docket ID No.: EPA-HQ-OPPT-2016-0735.

Methylene Chloride. Docket ID No.: EPA-HQ-OPPT-2016-0742.

N-Methylpyrrolidone (NMP). Docket ID No.: EPA-HQ-OPPT-2016-0743.

Pigment Violet 29 (Anthra[2,1,9-def:6,5,10-d'e'f]diisoquinoline-1,3,8,10(2H,9H)-tetrone). Docket ID No.: EPA-HQ-OPPT-2016-0725.

Trichloroethylene (TCE). Docket ID No.: EPA-HQ-OPPT-2016-0737.

Tetrachloroethylene (also known as Perchloroethylene). Docket ID No.: EPA-HQ-OPPT-2016-0732.

INTRODUCTION AND SUMMARY

Safer Chemicals, Health Families (SCHF), Earthjustice, Natural Resources Defense Council (NRDC), Environmental Health Strategy Center, Toxic-Free Future and Asbestos Disease Awareness Organization (ADAO) submit these comments on the scoping documents developed by the Environmental Protection Agency (EPA) on the initial 10 chemicals selected for risk evaluations under the newly enacted Frank R. Lautenberg Chemical Safety for the 21st Century Act (LCSA). These organizations are committed to enhancing the safety of chemicals used in homes, workplaces and products and strongly support effective and health-protective implementation of the LCSA.

Through LCSA, Congress amended the Toxic Substances Control Act (TSCA) to establish a new framework for conducting timely, comprehensive and science-based risk evaluations for chemicals of concern. The law provides that EPA's evaluations must be strictly risk-based and must result in a definitive determination of whether the evaluated substance as a whole presents an unreasonable risk of injury to health and the environment across its life cycle, without regard to cost and other non-risk factors.

Congress wanted EPA to launch the risk evaluation process expeditiously. Accordingly, in section 6(b)(2)(A) of TSCA, it directed EPA to assure that evaluations are initiated within six months of the law's enactment on 10 substances drawn from the 2014 TSCA Workplan list. EPA designated these 10 substances on December 19, 2016,[1] and following a public meeting and comment period, released draft scoping documents on June 22. Soon thereafter, EPA announced that it was developing problem formulation documents on the 10 chemicals and would release them for further comment by the end of the year. It also requested comments on the scoping documents in order to inform its approach to problem formulation.[2]

These comments address general issues common to the 10 chemicals as well as several chemical-specific issues. We are submitting our comments to all ten of the EPA dockets. The comments build on earlier submissions by these groups, including our March 15 comments on the scoping process and our July 24 letter to the Agency providing initial reactions to the 10 scoping documents. We have coordinated with a number of other public health and scientific organizations in developing comments on the scoping documents and generally support their recommendations.

The main messages and key recommendations in our comments are as follows:

- Problem formulation can fill gaps in scoping documents and enhance their depth of analysis but cannot be used to remove uses, exposures and hazards from the risk evaluation scope
- EPA should use problem formulation to provide more detail on the potentially exposed and susceptible subpopulations it will consider and how risks to these subpopulations will be determined
- Problem formulations should also describe EPA's strategies for assessing risks from aggregate and cumulative exposures
- Ongoing use and disposal of chemical products that are no longer being manufactured fall within the TSCA definition of "conditions of use" and must be included in problem formulations and assessed in risk evaluations
- Chemicals with ozone depletion and global warming potential pose environmental and health risks that fall within the scope of TSCA risk evaluations
- EPA risk evaluations should not reassess uses of trichloroethylene (TCE), methylene chloride (MC) and N-Methylpyrrolidone (NMP) that were fully assessed in its proposed section 6(a) rules, although these exposure pathways should be included in its determinations of aggregate exposure to these chemicals
- In the course of TSCA risk evaluations, EPA should not revisit definitive findings in IRIS assessments since these assessments represent the Agency's authoritative, peer reviewed determinations on the health effects of the chemicals they address
- In evaluating workplace risks, EPA should recognize and account for the uneven use and effectiveness of engineering controls, labeling and personal protective equipment in preventing occupational exposure and determine risks to workers in situations where these measures are not in place or ineffective
- EPA should not exclude from the 1,4-dioxane evaluation its production as a byproduct or impurity, which is a significant source of contamination of water sources and cancer risk

[1] 81 Federal Register 91927
[2] 82 Fed. Reg. 31,592 (July 7, 2017).

- In order to apply these general principles and fill other gaps in its scoping documents, these documents must be expanded and strengthened in several specific respects during problem formulation
- EPA should not prejudge the absence of adverse effects for particular end-points at the scoping stage but should defer such conclusions until the systematic review phase of its risk evaluation as the law requires
- Problem formulations should highlight aspects of use and exposure where available information is insufficient and request or require submission of this information by industry and other interested parties
- EPA needs to take stronger steps to limit CBI treatment of critical information during the risk evaluation process so that transparency and public participation in that process are not impaired

I. PROBLEM FORMULATION CAN FILL GAPS IN SCOPING DOCUMENTS AND ENHANCE THEIR DEPTH OF ANALYSIS BUT CANNOT BE USED TO REMOVE USES, EXPOSURES AND HAZARDS FROM THE RISK EVALUATION SCOPE

The 10 chemicals undergoing risk evaluations have widespread and substantial exposure and multiple adverse health effects. Comprehensive and health protective assessments of their safety are essential to safeguard communities and vulnerable populations and to set a precedent for strong and effective implementation of the new law. For this reason, our groups made a significant investment in characterizing the use and exposure profiles of several of the 10 chemicals and provided extensive submissions to the Agency to help inform its scoping documents for these chemicals.

The scoping documents represent a considerable amount of work in a short period of time and provide a helpful starting point for the 10 evaluations. However, the July 7 Federal Register notice announcing the availability of the scoping documents acknowledges that the Agency was unable to process all the information gathered during the scoping process and that the scoping documents were not as "refined or specific" as EPA had hoped. We agree with this assessment and believe that the scoping documents contain serious gaps, lack sufficient information on use and exposure, impose questionable limitations on the risk scenarios to be examined and fail to provide a roadmap to key elements of assessment methodology. These shortcomings reduce the utility of the scoping documents in laying the groundwork for well-informed and rigorous risk evaluations.

Given their limitations, we believe that expanding and strengthening the scoping documents through a problem formulation process is appropriate in this instance. However, neither LCSA nor the recently promulgated risk evaluation process rule refers to or authorizes problem formulation. Because it has no basis in the law, we oppose using problem formulation to narrow the scope of risk evaluations by deleting conditions of use, exposure pathways or health or environmental end-points identified in the June scoping documents. Section 6(b)(4)(D) of amended TSCA provides that, "not later than 6 months after the initiation of a risk evaluation," EPA must "publish the scope of the risk evaluation to be conducted, including the hazards, exposures, conditions of use and the potentially exposed or susceptible subpopulations the Administrator expects to consider." EPA met this requirement in its June scoping documents. The law provides no basis for EPA to remove uses, hazards or exposures from a risk

evaluation after its scope has been established in accordance with section 6(b)(4)(D).[3] Since problem formulation is not a recognized step in the risk evaluation process or a substitute for scoping under LCSA, it cannot be used narrow a risk evaluation's scope after-the-fact.

We do support, however, using problem formulation to provide more detail on the conditions of use, potentially exposed and susceptible subpopulations, and exposure pathways that EPA will evaluate as well as further explanation of the methodologies that EPA will use in its analysis of these and other risk assessment elements. This will help better structure the risk evaluations, assure that all relevant information is considered, and characterize more fully the conditions of use to be evaluated – without narrowing the risk evaluation scope.

II. EPA SHOULD USE PROBLEM FORMULATION TO PROVIDE MORE DETAIL ON THE POTENTIALLY EXPOSED AND SUSCEPTIBLE SUBPOPULATIONS IT WILL CONSIDER AND HOW RISKS TO THESE SUBPOPULATIONS WILL BE DETERMINED

One area that would benefit from greater elaboration during problem formulation is the identification of potentially exposed or susceptible subpopulations that require consideration in risk evaluations under TSCA section 6(b)(4)(F). The scoping documents provide nearly identical general "boilerplate" descriptions of such subpopulations. Further particulars on the size, geographic location, demographic characteristics and exposure profile of each subpopulation EPA has identified would provide helpful assurance that the risks to that subpopulation will be characterized with the rigor that TSCA requires.

It is also critical for EPA to spell out the methodology it intends to use to determine the nature and magnitude of the risks that chemicals pose to each subpopulation. Such subpopulations are often comprised of low income and/or people of color and exposed to a disproportionate share of pollution, environmental hazards, and social and economic stressors. Multiple exposures to chemical and non-chemical stressors collectively increase the risk of harm, combined with synergistic effects with other health stressors such as limited access to quality health care.[4,5] EPA's risk evaluations need to fully account for these factors and its problem formulations should explain how it intends to do so.

In regard to greater susceptibility, the following are well-known factors that increase biologic sensitivity or reduce resilience to exposures,[6,7] and should be considered consistently for all 10 chemicals to identify susceptible subpopulations:

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[3] EPA's final risk evaluation rule, in contrast to its proposal, would permit the Agency to select which conditions of use to include in risk evaluation scopes as opposed to including all such uses. 82 Fed. Reg. 33,726 (July 20, 2017). Our groups argued in their comments on the proposal that the law required the Agency to address all conditions of use in its risk evaluations, as was recognized in the Agency's original proposal. Along with several other groups, we are challenging EPA's contrary interpretation in its petition for judicial review of the risk evaluation rule. Regardless of the outcome of this challenge, we believe that EPA has no basis to narrow the risk evaluation to exclude conditions of use once they have been included in its scope.

[4] Morello-Frosch R, Zuk M, Jerrett M, Shamasunder B, Kyle AD. Understanding the cumulative impacts of inequalities in environmental health: Implications for policy. Health Aff. 2011;30(5):879–87.

[5] Vesterinen HM, Morello-Frosch R, Sen S, Zeise L, Woodruff TJ. Cumulative effects of prenatal-exposure to exogenous chemicals and psychosocial stress on fetal growth: Systematic-review of the human and animal evidence. Meliker J, editor. PLoS One. 2017 Jul 12;12(7):e0176331.

[6] Morello-Frosch R, Zuk M, Jerrett M, Shamasunder B, Kyle AD. Understanding the cumulative impacts of inequalities in environmental health: Implications for policy. Health Aff. 2011;30(5):879–87.

Intrinsic/ endogenous factors

- Genetic polymorphisms/ genetics/ genetic makeup
- Health status/ nutritional status/ disease status/ pre-existing conditions
- Prenatal life stage
- Age

Extrinsic factors

- Multiple exposures/ co-exposures
- Race/ ethnicity
- Socioeconomic status (SES)

For example, the prenatal life stage is the most sensitive to developmental and reproductive toxicants, and women of childbearing age should be considered as a susceptible subpopulation for any chemical with such hazards. However, women of reproductive age are not identified as a potential susceptible subpopulation in the scoping documents for pigment violet 29, TCE, NMP, PERC, or HBCD, even though EPA will consider reproductive and developmental toxicity hazards for these chemicals. This omission should be corrected during problem formulation.

III. PROBLEM FORMULATION MUST DESCRIBE EPA'S STRATEGIES FOR ASSESSING RISKS FROM AGGREGATE AND CUMULATIVE EXPOSURES

Problem formulation should also address more fully how EPA intends to address the risks resulting from cumulative and aggregate exposures to each of the 10 chemicals. The scoping documents provide minimal discussion of this essential aspect of risk evaluation design.

Section 6(b)(4)(F)(ii) requires risk evaluations to describe whether aggregate or sentinel exposures to a chemical were considered and the basis for that consideration. To properly apply either or both of these approaches in a risk evaluation, EPA must determine in advance what methodology it will employ and then incorporate it in the risk evaluation design in sufficient detail to describe the key data sources it will use to assess exposure and how they will be used. The scoping documents fail to do this. EPA should remedy this gap in problem formulation.

We believe aggregate exposure assessment will be required for all of the 10 chemicals.[8] The focus of the new law is on determining risk based on all relevant pathways and sources of exposure for the general population and vulnerable subpopulations throughout a chemical's life cycle. Thus, under section 6(b)(4)(F)(i), EPA must "integrate and assess available information on hazards and exposures for *the conditions of use* of the chemical substance" and, under section 6(b)(4)(F)(iv), must "take into account, where relevant, the likely duration, intensity, frequency and number of exposures under *the conditions of use* of the chemical substance." This emphasis on integrating risk and exposure factors across a chemical's conditions of use necessarily requires the Agency to identify all sources of exposure that may affect the general population or specific subpopulations and to determine the overall levels, frequency

[7] National Research Council. Science and Decisions: Advancing Risk Assessment. Washington, D.C.: National Academies Press; 2009.

[8] When analyzing aggregate exposures, "sentinel exposure" may be considered simultaneously, where appropriate. However, these are not mutually exclusive and EPA should not incorporate sentinel to the exclusion of aggregate.

and duration of exposures by each population or subpopulation resulting from this combination of pathways.[9]

EPA has applied the tools of "aggregate exposure assessment" successfully in several programs. For example, the 1996 Food Quality Protection Act (FQPA) directs EPA to examine aggregate exposures when issuing or renewing tolerances for pesticides in food and EPA has longstanding guidance for doing aggregate risk and exposure assessments to meet this requirement.[10]

During problem formulation, EPA should develop a roadmap for each of the 10 chemicals showing what steps it is taking to gather the necessary information for aggregate exposure assessment and how it will calculate or estimate the combined exposures resulting from multiple pathways or uses for the general population and potentially exposed or susceptible subpopulations.

Problem formulations should also address whether and how EPA will use "cumulative risk" methodologies for the first 10 risk evaluations. This, too, is an area that EPA has addressed in several guidance documents.[11] The Agency defines "cumulative risk" as "the combined risks from aggregate exposures (i.e., multiple route exposures) to multiple agents or stressors" and has explained that:

> "In cumulative risk assessments that examine risks posed by multiple chemicals, exposure assessments evaluate a population's chemical exposures through multiple routes of exposure over time. Such assessments may encompass multiple exposure timeframes in which the timing and intensity of exposures to different chemicals are examined relative to each other. It is also important to determine whether the exposures to multiple chemicals can lead to toxicokinetic interactions or toxicodynamic interactions. In addition to providing information about multiple chemical exposures in the general population, these exposure assessments identify potentially susceptible or vulnerable subpopulations in the study area and potentially unique pathways of exposure in those subpopulations."[12]

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[9] Exposures from TSCA-exempt uses such as personal care products or biocides should also be included in scoping documents and risk evaluations because of the need to account for their contribution to aggregate risk, even though regulatory authority over these products is not available under TSCA but derives from other laws administered by EPA or agencies such as FDA. This is now standard practice in implementing the Food Quality Protection Act (FQPA). The scoping documents contain limited and incomplete information on exposures to the listed chemicals from non-TSCA uses.

[10] https://www.epa.gov/sites/production/files/2015-07/documents/aggregate.pdf

[11] E.g., *Guidance on Cumulative Risk Assessment of Pesticide Chemicals That Have a Common Mechanism of Toxicity*. U.S. Environmental Protection Agency, Office of Pesticide Programs, Washington, DC. (2002) Available at http://www.epa.gov/oppfead1/trac/science/cumulative_guidance.pdf; *Framework for Cumulative Risk Assessment,* U.S. Environmental Protection Agency, Office of Research and Development, National Center for Environmental Assessment, Washington, DC. EPA/600/P-02/001F (2004). Available at http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=54944.

[12] EPA National Center for Environmental Assessment, *Concepts, Methods and Data Sources for Cumulative Health Risk Assessment of Multiple Chemicals, Exposures and Effects: A Resource Document,* at xxviii (August 2007).

The importance of examining risks posed by multiple chemicals with overlapping pathways of exposure and common adverse health effects was also underscored by the National Academy of Sciences (NAS) in its Phthalates and Cumulative Risk report.[13]

We recommend that, in its problem formulations, EPA should commit to perform cumulative risk assessments whenever a population or subpopulation exposed to the subject chemical is also exposed to other chemicals that have similar health effects. In this situation, total risk to the relevant population or subpopulation will be a function not just of exposure to the subject chemical in isolation but of combined exposure to that chemical and other chemicals which have additive or synergistic health effects.

A compelling case for examining cumulative risks will exist where EPA is in parallel conducting risk evaluations on multiple chemicals within a class that have similar chemical structures, conditions of use and adverse health effects. An example of such a grouping is the four solvents (TCE, PERC, MC and NMP) among the initial 10 chemicals: not only is it likely that workers and consumers are exposed to all or some of these solvents simultaneously but their common hazards (i.e. neurotoxicity, reproductive toxicity) are likely to magnify the risks of such concurrent exposures. The problem formulations for these four chemicals should recognize the need to examine the cumulative risks they present and describe how EPA will evaluate cumulative risk scenarios.

IV. ONGOING USE AND DISPOSAL OF CHEMICAL PRODUCTS THAT ARE NO LONGER BEING MANUFACTURED FALL WITHIN THE TSCA DEFINITION OF "CONDITIONS OF USE" AND MUST BE ASSESSED IN RISK EVALUATIONS

Several of the 10 chemicals – asbestos, perchloroethylene (PERC), TCE, MC, carbon tetrachloride (CTC) and hexabromocyclododecane (HBCD) – contribute to ongoing exposure and risk as a result of historical manufacturing and processing activities that have been discontinued. In many cases, the current and foreseeable risks associated with these activities are significant. Nonetheless, the scoping documents provide limited information about these risk and exposure scenarios and take the position that they are outside the scope of risk evaluations except possibly as a source of information about aggregate exposure. Each scoping document contains this statement:

> "EPA interprets the mandates under section 6(a)-(b) to conduct risk evaluations and any corresponding risk management to focus on uses for which manufacture, processing, or distribution in commerce is intended, known to be occurring, or reasonably foreseen (i.e., is prospective or on-going), rather than reaching back to evaluate the risks associated with legacy uses, associated disposal, and legacy disposal, and interprets the definition of "conditions of use" in that context. For instance, the conditions of use for purposes of section 6 might reasonably include the use of a chemical substance in insulation where the manufacture, processing or distribution in commerce for that use is prospective or on-going, but would not include the use of the chemical substance in previously installed insulation, if the manufacture, processing or distribution for that use is not prospective or on-going. In other words, EPA interprets the risk evaluation process of section 6 to focus on the continuing flow of chemical

[13] National Research Council. Committee on the Health Risks of Phthalates, Board on Environmental Studies and Toxicology, Division on Earth and Life Studies. 2008. Phthalates and cumulative risk assessment: the task ahead. Washington, D.C.: National Academies Press.

substances from manufacture, processing and distribution in commerce into the use and disposal stages of their lifecycle. That said, in a particular risk evaluation, EPA may consider background exposures from legacy use, associated disposal, and legacy disposal as part of an assessment of aggregate exposure or as a tool to evaluate the risk of exposures resulting from non-legacy uses."[14]

We believe that EPA is incorrectly interpreting the provisions of LCSA. The definition of "conditions of use" in section 3(4) covers the "circumstances . . . under which a chemical substance is . . . known or reasonably foreseen to be . . . used or disposed of." Where a chemical is performing an ongoing *in situ* function as a result of previous manufacturing and processing activity, that function comprises a current "use" of the chemical that is "known" to be occurring.

For example, although asbestos may no longer be sold as insulation, the asbestos insulation installed in millions of US buildings continues to perform insulating functions and thus is a current ongoing "use" of asbestos. Installed asbestos-containing building materials (ACBMs) represent one of the largest sources of asbestos accessible to the general public in the US, and the largest asbestos-exposed population consists of people who occupy buildings and homes with ACBMs. Maintenance and construction activities involving ACBMs are also frequent and widespread and account for the largest present-day increase in mesothelioma illness and death in the US.[15]

Similarly, the Healthy Building Network estimates there are 66-132 million pounds (30,000-60,000 metric tons) of HBCD in insulation in existing buildings.[16] These ongoing insulation uses are and will continue to be critical sources of ongoing exposures. HBCD is also present in cars and furniture as a flame retardant and its use in these long-lived consumer articles will contribute to ongoing exposures for years to come.[17]

Equally important, the disposal of building materials or consumer products containing asbestos or HBCD is an ongoing occurrence as buildings are torn down or remodeled and cars and furniture are replaced. Thus, the resulting releases into the environment and communities comprise a "circumstance . . . under which [these chemicals] are . . . known or reasonably foreseen to be . . . disposed of." As "conditions of use" within the TSCA definition, these activities and the risks they present are likewise required to be addressed in risk evaluations under section 6(b). For both chemicals, the immediate and long-term exposures associated with disposal of *in situ* building materials and products are likely to be widespread and significant well into the future.

To exclude from risk evaluations ongoing and future exposures from *in situ* uses of discontinued products would create a sizable gap in the life-cycle assessments of risk that Congress directed EPA to conduct under the new law. This would deprive the public, scientists and regulators of a comprehensive

[14] EPA, *Scope of the Risk Evaluation for Asbestos*, June 2017, at 8.
[15] US CDC study, "Malignant Mesothelioma Mortality – United States 1999 to 2005."
[16] Safer Chemicals, Healthy Families et al. Comments to the U.S. Environmental Protection Agency (EPA) on the Scope of its Risk Evaluation for the TSCA Work Plan Chemicals: CYCLIC ALIPHATIC BROMIDE CLUSTER or HEXABROMOCYCLODODECANE (HBCD). March 15, 2017. https://healthybuilding.net/uploads/files/saferchemicals-hbcd.pdf
[17] For chemicals like TCE and PERC, the uses that contributed to widespread contamination of groundwater and drinking water may in fact be uses for which these chemicals are still being sold, requiring EPA to include them in its risk evaluations even under its narrow interpretation of the law.

picture of one of the largest sources of continuing and future risk. One consequence would be that EPA would lack the scientific basis to ban resumption of the sale and distribution of discontinued products containing asbestos, HBCD and similar chemicals despite the unreasonable risks that they present. In addition, decision-makers would be unable to reduce ongoing exposures and impose safeguards against unsafe disposal because they would lack a meaningful risk evaluation to inform these actions. Just as TSCA provides authority to evaluate the risks associated with ongoing exposures from discontinued activities, so it gives EPA the authority under section 6(a) to reduce these risks, yet the Agency would be stymied by the absence of a risk evaluation that provides a basis for such regulation.[18]

In short, EPA must characterize and assess ongoing exposures from the use and disposal of discontinued products and determine the risks they present as part of its risk evaluations on the initial 10 chemicals. The scoping documents provide virtually no discussion of these sources of exposure to the 10 chemicals. Nothing in the law allows EPA to exclude these risks from its evaluations. EPA must correct this omission during problem formulation.

V. OZONE DEPLETION AND GLOBAL WARMING POTENTIAL POSE ENVIRONMENTAL AND HEALTH RISKS THAT FALL WITHIN THE SCOPE OF TSCA RISK EVALUATIONS

In earlier submissions, SCHF and its members highlighted data showing the high ozone depleting potential of MC, CTC and 1-Bromopropane (1-BP).[19] The scoping documents do not address these properties of the three chemicals. Nor do they examine the global warming potential (GWP) of any of the 10 chemicals. These omissions conflict with the express purpose of risk evaluations under section 6(b)(4)(A): to "determine whether a chemical substance presents an unreasonable risk of injury to health *or the environment"* (emphasis added). They also fail to meet the Agency's obligation under section 6(b)(4)(F)(i) to "integrate and assess information . . . that is relevant to specific risks of injury to health *or the environment"* (emphasis added). Ozone depletion and global warming potential clearly pose risks to the environment and they are also recognized risk factors for human health.[20,21] Nothing in the law allows EPA to exclude these risks from its evaluations.

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[18] For some chemicals like lead and asbestos, other laws administered by EPA address handling and disposal of *in situ* materials. The Agency may be able to refer the findings of its risk evaluations to the programs implementing these laws under TSCA section 9(b) in lieu of further regulation under section 6. However, there are no existing laws that address ongoing exposure from use and disposal of discontinued products containing HBCD, perfluorinated chemicals and other substances and therefore the availability of the protections afforded under section 6 of TSCA may be critical to addressing their risks.

[19] See Comments of Safer Chemicals Healthy Families on Risk Evaluation Scoping Documents for Ten Chemical Substances under the Toxic Substances Control Act, March 15, 2017.

[20] The human health risks of ozone depletion are well recognized by the Agency and documented, at least in part, on EPA's webpage, "Health and Environmental Effects of Ozone Layer Depletion:" "Ozone layer depletion increases the amount of UVB that reaches the Earth's surface. Laboratory and epidemiological studies demonstrate that UVB causes non-melanoma skin cancer and plays a major role in malignant melanoma development. In addition, UVB has been linked to the development of cataracts, a clouding of the eye's lens." https://www.epa.gov/ozone-layer-protection/health-and-environmental-effects-ozone-layer-depletion (Accessed 9-18-17)

[21] The human health risks of global warming were well recognized and documented, at least in part, by the agency prior to the arrival of Administrator Pruitt, as outlined in the legacy pages at: https://19january2017snapshot.epa.gov/climate-impacts/climate-impacts-human-health_.html While that page is being updated, "…to reflect EPA's priorities under the leadership of President Trump and Administrator Pruitt," the Agency still notes, "Climate change is having direct and indirect impacts on the health of people. More extreme

The EPA Office of Air and Radiation (OAR) has considerable expertise in both ozone depletion and global warming and has assessed some (but not all) of the 10 chemicals from the perspective of these concerns. OAR can help OCSPP draw on this prior work for its TSCA risk evaluations and perform new assessments for those chemicals whose ozone depletion and global warming impacts have not previously been examined. By addressing these impacts in TSCA risk evaluations, EPA will fulfill the law's goal of providing a comprehensive picture of environmental and health risks across the chemical's life cycle. In particular cases, it may also highlight contributors to ozone depletion and global warming that have been overlooked and may warrant restriction. Whether these impacts can be adequately addressed under the Clean Air Act (CAA) or under TSCA need not be determined in the risk evaluation itself and can be deferred to the later evaluation of risk management options under section 6(a).

VI. EPA RISK EVALUATIONS SHOULD NOT REASSESS USES OF TCE, MC AND NMP THAT WERE FULLY ASSESSED IN ITS PROPOSED SECTION 6(a) RULES

EPA has proposed to ban certain uses of TCE, MC and NMP under section 6(a) of amended TSCA.[22] As the basis for these proposed rules, EPA conducted comprehensive exposure and risk assessments on the targeted uses of the three chemicals. These assessments were subject to public comment and peer review both during their development and again as part of the rulemaking process.

In its scoping documents for the three chemicals, EPA indicates that it intends to rely on the completed assessments and will not "reassess" the targeted uses.[23] We strongly agree with this approach. It would be counterproductive for the Agency reopen these assessments for yet another round of public input and to redo the extensive analysis they contain simply so industry commenters can have another bite at the apple on findings they dislike. Moreover, we believe that the next step in the rulemakings is for EPA to issue final rules as quickly as possible. These rules, once issued, should close the book on the targeted uses and enable EPA to focus its risk evaluations on uses that have not yet been assessed. In its more comprehensive risk evaluations, however, EPA should incorporate its earlier assessments so that the exposures they describe can be accounted for in determining aggregate exposure to the three chemicals.

VII. EPA SHOULD NOT REVISIT DEFINITIVE FINDINGS IN IRIS ASSESSMENTS, WHICH REPRESENT THE AGENCY'S AUTHORITATIVE PEER-REVIEWED DETERMINATIONS OF THE HEALTH EFFECTS OF CHEMICALS

Five of the 10 chemicals – TCE, MC, CTC, PERC and 1,4-dioxane – have been assessed under the EPA Integrated Risk Information System (IRIS). The IRIS process is the Agency's authoritative mechanism for reviewing available studies, characterizing the health effects of chemicals and identifying concentrations below which these chemicals are not likely to cause adverse effects. IRIS assessments typically reflect

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weather events, heat waves, spread of infectious diseases and detrimental impacts on air and water quality are having impacts on our health." https://www.epa.gov/climate-research/human-health-and-climate-change-research (accessed 9-18-17).

[22] Trichloroethylene (TCE); Regulation of Use in Vapor Degreasing under TSCA Section 6(a), 82 Fed. Reg. 7432 (Jan. 19, 2017); Trichloroethylene; Regulation of Certain Uses under TSCA § 6(a), 81 Fed. Reg. 91592 (Dec. 16, 2016) and Methylene Chloride and N-Methylpyrrolidone; Regulation of Certain Uses under TSCA Section 6(a), 82 Fed. Reg. 7464 (Jan. 19, 2017).

[23] See, e.g., EPA. *Scope of the Risk Evaluation for Trichloroethylene,* June 2017, at 33.

years of work by EPA scientists, multiple rounds of public comment, inter and intra-agency consultation, and extensive peer review, often by the Agency's independent Science Advisory Board (SAB) or the National Academy of Sciences (NAS).

Where EPA is conducting a TSCA risk evaluation of a chemical that has already been assessed under IRIS, the conclusions of the IRIS assessment should be presumed to be applicable to the TSCA evaluation as a definitive statement by the Agency of the best available science. To revisit IRIS findings would be inefficient and resource-intensive at a time when the Agency is struggling with workforce and budget reductions. It would also make the three-year statutory deadline for completing risk evaluations even more challenging by greatly expanding the scope of EPA's work effort. Most significantly, reopening IRIS findings would prolong scientific uncertainty on issues that have been addressed and resolved through an authoritative, transparent and inclusive EPA process. Like other Agency actions, IRIS assessments often give rise to differences of opinion and some stakeholders may be disappointed by the outcome. But this does not mean that EPA should reinvent the wheel and provide another bite at the apple on scientific determinations that have been made after thorough deliberation and a robust process.

In sum, the problem formulation documents on the 10 chemicals should make clear that EPA's risk evaluations will rely on previous IRIS assessments in determining health effects that those assessments address.

VIII. IN EVALUATING WORKPLACE RISKS, EPA SHOULD RECOGNIZE THE UNEVEN USE AND EFFECTIVENESS OF ENGINEERING CONTROLS, LABELING AND PERSONAL PROTECTIVE EQUIPMENT IN PREVENTING OCCUPATIONAL EXPOSURE

Several scoping documents indicate that, in its approach to occupational exposure analysis, EPA will "[c]onsider and incorporate applicable engineering controls and/or personal protective equipment into exposure scenarios."[24] These measures are certainly relevant factors in analyzing occupational exposures. However, it is essential that EPA not presume that they will be effective in preventing exposure in all workplaces and for all employees. In many cases, they may in fact provide limited protection, particularly for short-term poorly trained workers in small shops and workers whose English language skills are challenged.

In its proposed section 6(a) rules for TCE, MC and NMP, EPA explained at some length why label warnings and instructions are not uniformly read, comprehended or followed and thus provide limited protection. This was not a mere opinion on EPA's part but the result of an examination of nearly fifty studies.[25] Based on this review, EPA's conclusions as described in its initial TCE rulemaking were as follows:

> "The Agency determined that warning labels and instructions alone could not mitigate the risks to the extent necessary so that TCE no longer presents the identified unreasonable risks to users. The Agency based this determination on an analysis of 48 relevant studies or meta-analyses, which found that consumers and professionals do not consistently pay attention to

[24] See, for example, US EPA (2017). Scope of the Risk Evaluation for Cyclic Aliphatic Bromides Cluster. Pg. 45

[25] OPPT summarized these studies in a paper entitled
The Effectiveness of Labeling on Hazardous Chemicals and Other Products (March 2016)(Ref. 33 in rulemaking docket).

> labels; consumers and professional users often do not understand label information; consumers and professional users often base a decision to follow label information on previous experience and perceptions of risk; even if consumers and professional users have noticed, read, understood, and believed the information on a hazardous chemical product label, they may not be motivated to follow the label information, instructions, or warnings; and consumers and professional users have varying behavioral responses to warning labels, as shown by mixed results in studies."[26]

In the TCE vapor degreasing proposal, EPA further concluded that comprehension of warnings would be unusually challenging because of the complexity of the information conveyed:

> "EPA found that presenting information about TCE on a label would not adequately address the identified unreasonable risks because the nature of the information the user would need to read, understand, and act upon is extremely complex. It would be challenging to most users to follow or convey the complex product label instructions required to explain how to reduce exposures to the extremely low levels needed to minimize the risk from TCE. Rather than a simple message, the label would need to explain a variety of inter-related factors, including but not limited to the use of local exhaust ventilation, respirators and assigned protection factor for the user and bystanders, and time periods during pregnancy with susceptibility of the developing fetus to acute developmental effects, as well as effects to bystanders**.** *It is unlikely that label language changes for this use will result in widespread, consistent, and successful adoption of risk reduction measures by users and owners.*[27]

Similarly, EPA cautioned that "there are many documented limitations to successful implementation of respirators", including these well-known problems: [28]

> "Not all workers can wear respirators. Individuals with impaired lung function, due to asthma, emphysema, or chronic obstructive pulmonary disease for example, may be physically unable to wear a respirator. Determination of adequate fit and annual fit testing is required for a tight fitting full-face piece respirator to provide the required protection. Also, difficulties associated with selection, fit, and use often render them ineffective in actual application, preventing the assurance of consistent and reliable protection, regardless of the assigned capabilities of the respirator. Individuals who cannot get a good face piece fit, including those individuals whose beards or sideburns interfere with the face piece seal, would be unable to wear tight fitting respirators. In addition, respirators may also present communication problems, vision problems, worker fatigue and reduced work efficiency (63 FR 1156, January 8, 1998). According to OSHA, 'improperly selected respirators may afford no protection at all (for example, use of a dust mask against airborne vapors), may be so uncomfortable as to be intolerable to the wearer, or may hinder vision, communication, hearing, or movement and thus pose a risk to the wearer's safety or health. (63 FR 1189-1190).'"

EPA based these conclusions on expert analyses by OSHA, which has extensive experience with respirators under its workplace standards.

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[26] 81 FR at 91601.
[27] 82 FR 7441 (emphasis added)
[28] 82 FR 7445

The problem formulation documents should explicitly recognize that industrial hygiene controls do not necessarily provide reliable and effective protection from exposure and that the adequacy of these controls needs to be examined on a case-by-case basis in the context of the specific establishments where the chemical is used, the makeup of the worker population in these establishments and the diligence of employers in implementing workplace controls. During problem formulation, EPA should elaborate on how these considerations will be applied for the 10 chemicals.

More generally, when considering occupational exposures, EPA needs to recognize and account for differences in levels of exposure, workplace practices and susceptibility that result in significant gradations in risk, even within a single workplace. In workplaces where chemicals and chemical products are used, exposures typically occur most intensely among a highly exposed subgroup, rather than uniformly across the population of workers. In a vehicle repair shop, for example, chemical-intensive tasks on brakes, engines, and drive-train components are performed by a subset of workers who experience high levels of exposure to aerosolized degreasing solvents, whereas other workers in the same shop who perform diagnostic or electrical work, for example, experience little or no exposure to these solvents. To effectively characterize the "conditions of use" among workers, EPA must account for the levels and duration of exposure—and therefore risk—that occurs within highly exposed subgroups as a consequence of actual workplace conditions, rather than relying on an "average" estimated exposure across a population of workers, based on an assumption of "intended" use.

IX. EPA SHOULD NOT EXCLUDE FROM THE 1,4-DIOXANE EVALUATION ITS PRODUCTION AS A BYPRODUCT OR IMPURITY, WHICH IS A SIGNIFICANT SOURCE OF CONTAMINATION OF WATER SOURCES

The scoping document for 1,4-dioxane takes the unusual approach of precluding any consideration of this substance's manufacture as a byproduct or impurity in EPA's risk evaluation:

> "In the case of 1,4-dioxane, EPA anticipates that production of 1,4-dioxane as a by-product from ethoxylation of other chemicals and presence as a contaminant in industrial, commercial and consumer products will be excluded from the scope of the risk evaluation. These 1,4-dioxane activities will be considered in the scope of the risk evaluation for ethoxylated chemicals. EPA believes its regulatory tools under TSCA section 6(a) are better suited to addressing any unreasonable risks that might arise from these activities through regulation of the activities that generate 1,4-dioxane as an impurity or cause it to be present as a contaminant than they are to addressing them through direct regulation of 1,4-dioxane"[29]

This is a deeply flawed approach that will weaken the 1,4-dioxane risk evaluation and result in inadequate risk reduction during any subsequent rulemaking under section 6(a).

1,4-dioxane is a probable carcinogen that has contaminated drinking water and groundwater in multiple parts of the country, eliciting expressions of concern from many public officials and communities. A recent analysis of data from EPA-mandated monitoring indicates that water supplies for more than 7

[29] Scope of the Risk Evaluation for 1,4-Dioxane, at 8 (June 2017)

million Americans in 27 states contain 1,4-dioxane at levels above those that EPA and other agencies believe present an acceptable cancer risk.[30]

1,4-dioxane's presence in drinking water and groundwater is linked to several pathways of release into the environment. In addition to its manufacture as a chemical product, 1,4-dioxane is a byproduct of plastic production and other chemical manufacturing processes utilizing ethoxylation. Due to its production as a byproduct, it is present as an impurity in several industrial, commercial and consumer products. 1,4-dioxane often is found in the wastewater discharged by industrial facilities and POTWs. Its presence in wastewater is likely attributable not only to intentional production and use activities but to the use and disposal of products in which it is present as an impurity.

If 1,4-dioxane's manufacture as a byproduct and presence in products and waste streams as an impurity are excluded from EPA's risk evaluation, it will have no basis for accounting for these sources of environmental release and will be unable to characterize their contribution to levels of the chemical found in drinking water, surface water and ground water. This will make its assessment of the extent and causes of water contamination incomplete and undermine its ability to conduct an informed evaluation of the options for reducing contamination and risk. Any action it later decides to take under section 6 will thus be based on inadequate information and analysis and, as a result, may be ineffective and under-protective.

Manufacture as a byproduct is plainly within the definition of "conditions of use" in section 3(4) of TSCA. There is no basis in this provision or other parts of the law for differentiating between manufacture as a byproduct and purposeful production and including one in a risk evaluation but excluding the other. And in this instance, there's no evidence (and EPA does not claim) that exposure to and release of 1,4-dioxane as a byproduct and impurity are inconsequential from a risk standpoint.[31]

While EPA suggests that it might be more efficient or effective to address byproduct production of 1,4-dioxane in a separate section 6(a) rulemaking for ethoxylated chemicals, this seems far-fetched. If EPA assesses the contribution of these chemicals to 1,4-dioxane water contamination in the current risk evaluation, it will have a sound basis to regulate their production and use under section 6(a) if they are found to present an unreasonable risk of injury.[32] Otherwise, there is no telling when EPA might mitigate water contamination resulting from byproduct production of 1,4-dioxane production. Thus far, EPA has offered no indication when, if ever, it will make a high-priority designation for ethoxylated chemicals and assess their contribution to the presence of 1,4-dioxane in the environment.

We recommend that during problem formulation, EPA add 1,4-dioxane production as a byproduct and impurity to the scope of its risk evaluation.

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[30] Environmental Working Group, HIDDEN CARCINOGEN TAINTS TAP WATER, CONSUMER PRODUCTS NATIONWIDE (September 2017).

[31] Under our interpretation of section 6(b), EPA could not exclude a condition of use from the risk evaluation scope based on low risk in any event.

[32] Section 6(a) does not limit EPA to regulating purposeful production of a chemical subject to a risk evaluation. It can regulate production by other means so long as it has been assessed in that evaluation and found to present an unreasonable risk.

X. BASED ON THE GENERAL PRINCIPLES OUTLINED ABOVE AND OTHER GAPS IN ITS SCOPING DOCUMENTS, EPA SHOULD AUGMENT THESE DOCUMENTS IN SEVERAL SPECIFIC RESPECTS DURING PROBLEM FORMULATION

Applying the general approaches outlined in these comments and in light of several omissions we identified in individual scoping documents, we recommend that EPA bolster those documents during problem formulation as follows:

1-Bromopropane (nPB)

- In our initial comments to EPA, we specifically identified nPB as being imported by companies whose primary business is supplying the cosmetics industry.[33] While the EPA has noted that authorities such as the State of California have included nPB on lists of chemicals banned in cosmetics, the potential for nPB directly or indirectly (through residues remaining from cleaning manufacturing equipment) to be present in cosmetic products is not addressed as a potential use for further assessment.
- As discussed in detail in Part V of these comments, EPA failed to address the ozone depletion potential of nPB.
- While the scoping document includes references to those exposed to nPB from use of the chemical in consumer products, as well as those co-located with dry cleaning facilities utilizing the chemical, it does not clearly identify people who may be further exposed from chemical residuals, such as those wearing clothing cleaned with nPB or their children. This pathway is not discussed, even though the scoping document for PERC includes it from the similar use of PERC in dry cleaning.

Asbestos

- EPA's scoping document claims that public comments were not received on various imported asbestos containing products available in the United States: "Products available from several online retailers and distributers include brake blocks, aftermarket friction products, roof and non-roof coatings, and gaskets, most of which are imported. No public comments were received regarding these uses." However, we submitted detailed comments highlighting all of these items and more, including other building products. [34]
- EPA's failure to include a lengthy list of legacy uses, as further discussed in Part IV of these comments, is especially problematic for asbestos which was extensively sold and distributed and remains widely present and in use in our buildings and cities.
- The recycling of legacy materials, notably asphalt shingles containing asbestos, is a unique and ongoing use of the substance, and in particular is worthy of additional consideration by the EPA, as discussed in our initial comments.[35]

[33] EPA-HQ-OPPT-2016-0741-0027 at PDF Pages 25, 27, 31.
[34] EPA-HQ-OPPT-2016-0736-0064 at PDF Pages 19, 25-27
[35] EPA-HQ-OPPT-2016-0736-0064 at PDF Pages 21-22

- There is evidence that asbestos has been present in significant levels in some talc products as the result of colocation of asbestos and talc deposits, as we discussed in our initial comments.[36] This use and ongoing exposure are not addressed in the scoping document.

- The scoping document fails to look at the risks of exposure to those who are upstream to the process of utilizing asbestos in chlor-alkali processing. This would include miners and packaging workers (who, while likely abroad, are still being exposed as a result of the substance's uses in the US considered by the EPA), as well as transportation workers, first responders, and community members who may be exposed in the shipment and transfer of asbestos to the chlor-alkali facilities.

- The absence in the scoping document of total import volumes for asbestos is troubling because it deprives the public of an understanding of the aggregate quantities of asbestos present in the US. In fact, the Asbestos Disease Awareness Organization, along with the Environmental Working Group, released a statement on September 19 that, based on data from the Department of Commerce and US International Trade Commission, 705 metric tons of raw asbestos were imported in 2016, compared to 343 metric tons in 2015. This significant increase in imports is important information that should be given prominence in the problem formulation document for asbestos.

Carbon Tetrachloride (CTC)

- As discussed in detail in Part V of these comments, EPA failed to address the ozone depletion potential and global warming potential of CTC in its scoping document. This is particularly problematic for CTC, as its use as a feedstock or intermediary was exempted from the Montreal Protocol on the false assumption that CTC production would be phased out. In actuality, CTC production is poised for an increase due to its use in HFO manufacture, as we discussed on our initial comments.[37]

- As discussed in detail in Part III of these comments, EPA failed to describe with any specificity how it will look at aggregate and cumulative exposures. In the CTC scoping document, EPA seems to specifically discredit the need for this consideration. The Agency highlights the fact that some individuals may be exposed to CTC through vapor intrusion of ground sources of CTC into their home, but then states that, ". . . this route is not likely to be significant given the agency's identified conditions of use . . ." Clearly, whether the CTC inhaled by a resident is from the vapor intrusion or from an adhesive product, they face potential health risks from it. The Agency must consider all uses and sources of exposure in the risk evaluation in order to accurately assess the human health risk and fulfill its statutory obligations.

Cyclic Aliphatic Bromides Cluster (HBCD)

- As detailed in Part IV of these comments, EPA must not exclude the ongoing use and disposal from past introduction of HBCD in a variety of products. Significant exposures will continue to occur as products incorporating HBCD move through their lifecycle, and these exposures must be considered in the risk evaluation.

[36] EPA-HQ-OPPT-2016-0736-0064 at PDF Pages 18-19
[37] EPA-HQ-OPPT-2016-0733-0023 at PDF pages 4-5, 19

N-Methylpyrrolidone (NMP)

- As we documented in our initial comments to the EPA, NMP has been used in the manufacturing of coating for the insides of aluminum spray cans.[38] Even products not including deliberate addition of NMP may therefore be contaminated with NMP, and this exposure pathway should be considered by the Agency.

- As detailed in Part II of these comments, EPA failed to provide specifics on susceptible subpopulations. While the Agency acknowledges that reproductive effects are to be assessed, considering the well-documented reproductive toxicity of NMP, the Agency needs to better detail how the risks to women of childbearing age will be addressed.

Methylene Chloride (MC)

- While the scoping document includes a use categorization for "other consumer products" including novelty "Drinking Bird" items, we identified an additional item,[39] a "Novelty Christmas Bubbling Night Light" labeled as containing MC but not previously included in EPA's "Preliminary Information on Manufacturing, Processing, Distribution, Use, and Disposal: Methylene Chloride." These consumer-oriented uses that are attractive to children illustrate the need to be comprehensive in the determination of "reasonably foreseeable" uses.

XI. EPA MAY NOT PREJUDGE THE ABSENCE OF ADVERSE EFFECTS FOR PARTICULAR END-POINTS AT THE SCOPING STAGE AND SHOULD DEFER SUCH CONCLUSIONS UNTIL THE SYSTEMATIC REVIEW STAGE OF ITS RISK EVALUATION

In some scoping documents, EPA has decided that the subject chemical does not raise concerns for particular endpoints and, therefore, it will not address these end-points in its risk evaluation. Examples are given in the table below where EPA concludes that HBCD, NMP and pigment violet 29 are not genotoxic:

Chemical	Example Text from EPA Scoping Document
HBCD	"Available data suggest that HBCD is not genotoxic. Existing assessments have also concluded, based on genotoxicity information and a limited lifetime study, that HBCD is not carcinogenic (NICNAS, 2012; EINECS, 2008; TemaNord, 2008; OECD, 2007). Unless new information indicates otherwise, EPA does not expect to conduct additional in-depth analysis of genotoxicity or cancer hazards in the risk evaluation of HBCD at this time."[40]
NMP	"NMP is not mutagenic, based on results from bacterial and mammalian *in vitro* tests and *in vivo* systems and is not considered to be carcinogenic (RIVM, 2013; OECD, 2007; WHO, 2001). Unless new information indicates otherwise, EPA does not expect to conduct additional in-depth analysis of genotoxicity and cancer hazards in the NMP risk evaluation."[41]

[38] EPA-HQ-OPPT-2016-0743-0031 at PDF page 18
[39] https://www.amazon.com/Bubble-Nightlight-Novelty-Christmas-Bubbling/dp/B00PV61HXC/
[40] EPA, *Scope of the Risk Evaluation for Cyclic Aliphatic Bromides Cluster, June 2017, at*. 36
[41] EPA, *Scope of the Risk Evaluation for N-Methylpyrrolidone,* June 2017*, at* 36

Pigment violet 29	"Testing for carcinogenicity of Pigment Violet 29 has not been conducted. However, negative genotoxicity results, structure-activity considerations and the expectation of negligible absorption and uptake of Pigment Violet 29 (based on very low solubility), indicate carcinogenicity of Pigment Violet 29 is unlikely. Unless new information indicates otherwise, EPA does not expect to conduct additional, in-depth analyses of genotoxicity and cancer hazards in the risk evaluation of Pigment Violet 29."[42]

EPA cannot reach such definitive conclusions at the scoping stage. The required course under the law is to proceed with a systematic review of the relevant data (a process that EPA strongly endorses) and withhold any conclusions about particular end-points until this review is complete.

In the case of HBCD, for example, a more thorough review would reveal two recent studies indicating carcinogenic potential. One suggests that HBCD could "enhance progression of prostate cancer by modulating growth and migration of LNCaP prostate cells,"[43] and the other concludes the genotoxicity of HBCD is dose-dependent and related to DNA repair.[44] These new studies are examples of the need for EPA to assure that it has fully considered all the available data through the systematic review process in order to avoid premature and possibly incorrect decisions to drop particular end-points at the scoping stage.

XII. PROBLEM FORMULATIONS SHOULD HIGHLIGHT ASPECTS OF USE AND EXPOSURE WHERE AVAILABLE INFORMATION IS INSUFFICIENT AND REQUEST OR REQUIRE SUBMISSION OF THIS INFORMATION BY INDUSTRY

Our own research on the 10 chemicals and the scoping documents themselves confirm that there are significant gaps in the use and exposure information available to EPA and that they will weaken the quality of EPA's risk evaluations unless filled. Although the timeframe for completing risk evaluations is compressed, there is still a window for augmenting the information-base used to conduct them. To take advantage of this opportunity, EPA should include in each problem formulation document a description of information on use and exposure that is lacking and a request that industry and other interested parties submit or obtain that information as expeditiously as possible.

EPA should also signal its readiness to use its mandatory information collection authorities under TSCA to fill data-gaps where voluntary submissions are not timely or adequate. The LCSA expands these authorities and streamlines the process for exercising them, removing the barriers to information development that hamstrung EPA under the old law. For example, section 4 now authorizes EPA to issue orders where necessary to "perform a risk evaluation." Such orders can be used to require industry to develop new information on the frequency, levels and duration of exposure for a chemical's conditions of use. Alternatively, EPA can use its subpoena authority under section 11 to obtain such information that already exists but has not been provided to EPA. EPA should specify in the problem formulation document its roadmap and timetable for filling data gaps using these authorities.

[42] EPA, *Scope of the Risk Evaluation for Pigment Violet 29*, June 2017, at 29.
[43] Seung-Hee Kim, et al, 2016. Influence of hexabromocyclododecane and 4-nonylphenol on the regulation of cell growth, apoptosis and migration in prostatic cancer cells. Toxicology in Vitro. 32:240-247. April 2016.
[44] Rui Jing Li, et al. Hexabromocyclododecane-induced Genotoxicity in Cultured Human Breast Cells through DNA Damage. Letter to Editor. Biomedical and Environmental Sciences. 30(4): 296-300.

Where the database available for a risk evaluation is incomplete, it is critically important that EPA not equate the absence of data with the absence of risk. For example, if EPA lacks data to assess a chemical's carcinogenicity, its risk evaluation needs to clearly state that cancer risk has not been addressed, that the chemical may or may not present such a risk, and that this end-point is outside the scope of its evaluation because of the absence of data. EPA should make the same disclaimers for conditions of use that cannot be adequately characterized, even by using default assumptions or extrapolation methods, because basic information about the nature of the use and scope and extent of exposure is unavailable.

XIII. EPA NEEDS TO LIMIT REDACTION FROM SCOPING AND PROBLEM FORMULATION DOCUMENTS OF CRITICAL INFORMATION CLAIMED CBI SO THAT TRANSPARENCY AND PUBLIC PARTICIPATION IN THE RISK EVALUATION PROCESS ARE NOT IMPAIRED

The scoping documents omit critical exposure and use information that has been claimed as confidential business information (CBI) that must be withheld from disclosure under TSCA. In some cases, the information is as basic as the total volume of the chemical manufactured and imported in the US. For example, the scoping documents fail to provide total manufacture/import volumes for asbestos, HBCD and pigment violet 29. Not only is this information obtainable in the public domain but it is fundamental to public understanding of the risks posed by these chemicals and, therefore, to informed public participation in the risk evaluation process.[45]

During problem formulation, EPA should make a concerted effort to limit the redaction of CBI-claimed production, use and exposure data that are essential for the transparency of the risk evaluation process. Several tools can be used for this purpose.

First, section 14(b)(3) of TSCA declares that "information not protected from disclosure" includes:

> "any general information describing the manufacturing volumes, expressed as specific aggregated volumes or . . . expressed in ranges."
>
> "a general description of a process used in the manufacture or processing and industrial, commercial or consumer functions and uses of a chemical, substance, mixture or article containing a chemical substance or mixture . . ."

This provision compels the disclosure of much of the information in scoping documents claimed CBI.

Alternatively, section 14(d)(7) provides that the Administrator may disclose information otherwise warranting CBI protection if he or she "determines that disclosure is relevant in a proceeding under this Act." The risk evaluations that EPA is conducting on the 10 chemicals under section 6(b)(2)(A) of TSCA represent a "proceeding" under TSCA. Information submitted by industry on the 10 chemicals is plainly "relevant" to these evaluations because it will inform how EPA assesses exposures and related risks

[45] For asbestos, SCHF and Environmental Health Strategy Center were able to use US government data accessible through the Panjiva database to determine annual asbestos imports over an extended period. As noted above, a more recent analysis of import data by the Asbestos Disease Awareness Organization shows that asbestos imports doubled in 2016, a startling finding that should be central to EPA's risk evaluation because of its implications for exposure to asbestos in the US.

associated with manufacture, processing and downstream commercial and consumer use. Thus, EPA can and should decide to disclose all information on the 10 chemicals notwithstanding any CBI claims.

Finally, to the extent these grounds for disclosure do not apply, EPA should use its authority under section 14(f)(1)(C) to require immediate substantiation of CBI claims for information for which "disclosure would be important to assist the Administrator in conducting risk evaluations . . . under section 6." This provision should be applied broadly to accomplish disclosure of all information that would be of value to the public in commenting on risk evaluations.

CONCLUSION

Our groups appreciate the opportunity to comment on the 10 scoping documents and look forward to continued dialogue with the Agency as it develops problem formulation documents and proceeds with risk evaluations on the 10 chemicals.

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