

# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

## Comments of Safer Chemicals Healthy Families, Earthjustice, Environmental Health Strategy Center and Natural Resources Defense Council on Draft Scoping Documents for Seven High-Priority Substances Under the Toxic Substances Control Act (TSCA)

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Safer Chemicals Healthy Families (SCHF), Earthjustice, Environmental Health Strategy Center and Natural Resources Defense Council (NRDC) submit these comments on the April 23, 2020 Environmental Protection Agency (EPA) notice of the availability of seven draft scoping documents for risk evaluations under section 6(b)(4)(D) of the Toxic Substances Control Act (TSCA).<sup>1</sup> Our organizations are national and grassroots groups committed to assuring the safety of chemicals used in our homes, workplaces and the many products to which our families and children are exposed each day. We took a leadership role during the TSCA legislative process, advocating the most protective and effective legislation possible to reduce the risks of toxic chemicals in use today.

Our comments provide cross-cutting recommendations to improve the scoping documents and upcoming risk evaluations. We also address the draft scoping documents for formaldehyde and phthalate esters.

### Recommendations to Improve Scoping Documents and Risk Evaluations

The seven chemicals are among a group of 20 substances that EPA designated as high priority under TSCA on December 20, 2019. High-priority designation triggers EPA's obligation under TSCA to conduct a risk evaluation under TSCA. Scoping documents are the first step in that process. Under TSCA section 6(b)(4)(D), their role is to provide stakeholders and the public with a clear roadmap to the risk evaluation by describing the "hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations the Administrator expects to consider." Section 702.41(c) of EPA's 2017 risk evaluation framework rule elaborates on the elements scoping documents must contain. If draft scopes do not contain these elements, the public will have limited ability to comment on the data and analytic approach EPA will use to conduct its risk evaluations.

Measured against TSCA and EPA regulations, the 20 draft scoping documents are woefully inadequate. As we underscored in our May 13, 2020 comments, they lack many required elements, including a description of human health hazards from acute and chronic exposures to the high priority chemicals, the results of EPA's systematic reviews of available data, and the Potentially Exposed or Susceptible Subpopulations (PESS) that EPA intends to address. Moreover, the scopes fail to explain how EPA will analyze exposure and hazard data and integrate different lines of evidence for the chemical at hand. Instead, they consist mainly of boilerplate

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<sup>1</sup> 85 Federal Register 22734 (April 23, 2020)

methodologies with little relevance to the specific chemical to be evaluated. These limitations deprive the public of adequate notice of how EPA will conduct the upcoming risk evaluations and impede meaningful public comment. Thus, our groups have urged EPA to publish revised and expanded scopes and provide an additional 30 days for public comment.

In these comments, we underscore an important additional failing of the draft scopes. EPA is nearing completion of the initial 10 risk evaluations required under TSCA and its draft evaluations have been subject to public comment and peer review by the Science Advisory Committee on Chemicals (SACC). The SACC has provided 8 reports which raise serious concerns about EPA's drafts; we have raised similar issues in our comments. It is now clear that the initial 10 evaluations are seriously flawed from a legal, policy and scientific perspective and do not represent a viable model for future evaluations. Yet the scopes fail to provide any "lessons learned" from these evaluations, do not acknowledge or address the issues raised by SACC and commenters, and fail to describe any changes in approach that EPA intends to make for the upcoming evaluations.

If EPA is taking to heart the deficiencies in the first 10 evaluations and planning improvements in the next 20, the scoping process is the right time to outline these improvements and engage the public. On the other hand, if EPA sees no need to improve its risk evaluations, that raises troubling questions about the Agency's responsiveness to peer review recommendations and indicates that the next 20 evaluations will be as flawed as the first 10. The 10 evaluations depart from the requirements of TSCA, fail to apply the best available science and use all available information, and understate exposure and risk. By perpetuating this problematic approach in its second round of evaluations, EPA would further undermine the public health and environmental protection goals of amended TSCA.

Below, we summarize the shortcomings in EPA's initial evaluations and recommend critical steps to improve the completeness, protectiveness, and legal viability of the next 20. Our concerns and recommendations are as follows:

**Data Gaps.** Like the 10 initial chemicals, most of the 20 proposed high-priority chemicals lack data for hazard endpoints that should be addressed in a comprehensive risk evaluation. The scopes fail to identify these data gaps or outline steps to fill them. While time is short because EPA failed to address data gaps during the prioritization process, the Agency should now use its section 4 authority to require as much testing as possible. These requirements should include health and environmental effects testing as well as monitoring of workplace exposure levels, environmental releases, and presence in environmental media. For data-gaps that EPA is unable to address on a timely basis, the risk evaluations should apply an additional Uncertainty Factor (UF) for database uncertainty, an approach called for by EPA guidelines and routinely used by the Integrated Risk Information System (IRIS) but absent from the first 10 evaluations. (pp. 7-9)

**Systematic Review.** The TSCA systematic review protocol used in the initial risk evaluations is deeply flawed and has compromised their quality, validity, and protectiveness. The SACC has raised numerous concerns about the TSCA protocol, and it is now undergoing review by the National Academy of Sciences (NAS). Given the many concerns that have been raised and lack of a completed peer review, it would be a serious mistake to use the TSCA protocol in the next round of risk evaluations. Yet based on the draft

scopes, this is exactly what EPA is doing. EPA should abandon the TSCA protocol and instead apply one of the established methodologies for systematic review that are consistent with the definition developed by the Institute of Medicine (IOM), such as the National Toxicology Program (NTP) OHAT method or the Navigation Guide Systematic Review Method developed by the University of California San Francisco. These methodologies embody recognized principles of systematic review and have been endorsed by NAS and other peer review bodies. (pp. 9-13)

**Peer Review.** Assistant Administrator Dunn has announced that EPA will use a different peer review process for the 20 new evaluations than it used for the first 10 and that the SACC will no longer be reviewing individual evaluations. Any attempt to scale back peer review of the upcoming evaluations would be a serious mistake. Although the SACC process has not been perfect, it has been an essential vehicle for independent scrutiny of EPA's draft evaluations. Strengths of the process include the involvement of recognized experts, stakeholder input on EPA's charge questions, direct interaction between SACC members and EPA staff, transparent public meetings, opportunities for the public to submit written comments and make oral presentations, and preparation of a detailed report providing SACC's findings and recommendations. Since the risk evaluations qualify as Highly Influential Scientific Assessments (HSIA) under EPA and OMB guidelines, a robust peer review process containing these basic elements is essential for the next 20 evaluations. (pp. 13-16)

**Environmental Releases and General Population Exposure.** For each of the 10 initial evaluations, EPA has excluded all environmental release pathways that contribute to human exposure, including air, drinking water, groundwater and soil. EPA's rationale for disregarding these pathways is that they "are covered under the jurisdiction of other environmental statutes administered by EPA." Because of these exclusions, none of the evaluations addresses exposure by the general population and the contribution of this exposure to overall risk. This approach undermines TSCA's comprehensive multi-media risk evaluation framework and has been rejected by the SACC because it results in an incomplete and underprotective picture of risk and exposure. The upcoming 20 evaluations must address all environmental releases without regard to other EPA-implemented laws. (pp. 16-18)

**Combining Risks Across Routes and Pathways of Exposure.** Subpopulations with greater exposures than the general population are PESSs under TSCA and the law requires EPA to determine whether their higher exposures present an unreasonable risk of injury. However, in most of the first 10 risk evaluations, EPA failed to combine dermal and inhalation exposure to derive composite risk estimates even though it recognized that these two routes of exposure often occur simultaneously for workers and consumers. EPA also failed to account for the risks to subpopulations exposed to a chemical by multiple pathways (consumer, occupational and environmental). People who are exposed to chemicals on the job and at home and from the ambient environment are PESSs under TSCA. The 20 upcoming risk evaluations must identify such subpopulations, estimate overall exposure for each and determine whether the total risk to the subpopulation is unreasonable. (pp. 18-20)

**Risks to Susceptible Subpopulations.** The TSCA definition of PESS also includes subpopulations at greater risk because of their greater susceptibility to the health effects of chemicals. For the initial 10 chemicals, EPA's evaluations identify several conditions that increase susceptibility, such as life-stage, sex, genetic polymorphisms, race/ethnicity, preexisting health status, lifestyle factors, and/or nutrition

status. However, identifying these PESSs is only the first step under TSCA. EPA must also determine whether the chemical presents an unreasonable risk to the PESS – a step that EPA has not taken for the initial 10 chemicals. In the upcoming evaluations, EPA must assess the degree of increased risk to each susceptible subpopulation and then determine whether this increased risk is unreasonable. Where there are uncertainties in this analysis, EPA should account for them by applying a UF beyond the default intraspecies 10X factor, as EPA has elsewhere done for other susceptible groups such as infants and children. (pp. 20-21)

**Assumed Use of Personal Protective Equipment.** Most of EPA’s initial risk evaluations assume the use of Personal Protective Equipment (PPE) in determining whether risks to workers are unreasonable. This approach lacks any legal basis, departs from established federal workplace protection policy and practice, and is contrary to the realities of worker exposure to chemicals. As SACC recommended, consistent with the established OSHA hierarchy of controls, EPA should base unreasonable risk determinations for workers on measured or estimated exposure levels in the absence of PPE. If these levels present an unreasonable risk, the necessary measures to protect workers against this risk should be addressed in the subsequent rulemaking under TSCA section 6(a). (pp. 21-23)

**Legacy Uses.** In the initial 10 evaluations, EPA took the position that the TSCA definition of “conditions of use” does not include “legacy activities” – i.e. the ongoing use of substances, mixtures and articles that are no longer manufactured, processed or distributed in commerce and the disposal of these legacy products. However, the Ninth Circuit has now held that EPA’s interpretation violates the plain language of TSCA. In upcoming risk evaluations for the 20 high-priority substances, EPA must address all ongoing uses of legacy products and associated disposal activities. There is no evidence in the draft scopes that EPA is systematically attempting to identify these products and activities. (pp. 23-24)

**Discontinued Conditions of Use.** In its initial evaluations, EPA has interpreted TSCA to exclude discontinued manufacturing, processing and use activities from the definition of “conditions of use.” However, under section 3(4) of TSCA, “conditions of use” include not simply intended or known uses but the “circumstances under which a chemical substance is . . . reasonably foreseen to be manufactured, processed, distributed in commerce, used or disposed of.” It is clearly “reasonably foreseen” that long-standing and significant uses of a chemical that have been phased out may re-enter commerce in the absence of any legal restriction. The goals of TSCA would be defeated if manufacturers of unsafe chemicals could avoid scrutiny simply by ceasing production for specific uses before EPA completes a risk evaluation and then later re-entering the marketplace free from any restriction or determination of risk. Recently discontinued uses that may resume should be addressed in the upcoming 20 evaluations. (pp.24-25)

**Reasonably Available Use, Exposure and Toxicity Information.** The SACC has been highly critical of the adequacy of the information EPA has used to assess exposure in the initial 10 evaluations and called for EPA to “obtain better data and documentation” from industry “on conditions of use, exposures, and potential for worker exposures.” However, the 20 scopes do not indicate that EPA will take any additional steps to obtain use and exposure data that are not available in public sources. For all the 20 high-priority chemicals, EPA should immediately put in place a comprehensive process for obtaining

information and data from industry, backstopped by TSCA information collection authorities. (pp. 25-27)

**Unreasonable Cancer Risk to Workers.** In its first 10 evaluations, EPA used a cancer risk of  $1 \times 10^{-4}$  as the benchmark for determining unreasonable risk to workers. This contrasts with the more protective benchmark of  $1 \times 10^{-6}$  that EPA has used for consumers. The SACC has stated that EPA has not provided an “adequate explanation and justification” for applying a less stringent risk standard to workers than other subpopulations. In fact, workers are specifically identified as a PESS in section 3(12) of the law. Thus, there is no basis for affording them *less* protection than other subpopulations by denying them the benefit of well-established EPA benchmarks for unacceptable cancer risk. In the 20 upcoming evaluations, EPA should treat any increased cancer risk to workers exceeding  $1 \times 10^{-6}$  as unreasonable, thereby triggering risk management under section 6 of TSCA. (pp. 27-29)

**Chronic Health Risks to Consumers.** The initial 10 evaluations have only addressed acute exposure scenarios for consumers and disregarded evidence of repeated exposure and chronic health risks. This is a significant shortcoming given the large population of consumers exposed to several of the first 10 chemicals and the importance of addressing whether these consumers are at risk of cancer and other serious chronic health effects identified by EPA. In its report on the trichloroethylene (TCE) evaluation, the SACC “disagreed with EPA’s decision not to characterize chronic risks for consumers,” indicating that “[s]everal Committee members suggested that some consumers are likely to be exposed more frequently and more pervasively to emissions from [consumer] products” than EPA assumed and pointing to the widespread presence of TCE in indoor air as evidence of such continuous exposure. For chemicals with similar consumer exposure profiles, EPA’s upcoming evaluations should base risk determinations on the assumption of chronic consumer exposure and assess whether consumers are at risk of cancer and other chronic health effects. (pp. 29-30)

**Reliance on Data Summaries Where Actual Reports Are Unavailable.** Some of the initial EPA evaluations rely on industry-generated studies that were conducted outside the US under the European Union REACH program and are described in “robust summaries” made available by the European Chemicals Agency (ECHA). These summaries are prepared by industry and are considerably less detailed than actual study reports. Thus, before relying on the summaries to support a finding of no unreasonable risk, EPA must obtain and independently evaluate the underlying studies. In addition, EPA must adopt a uniform policy of treating REACH-generated studies and data provided for use in a risk evaluation as “health and safety studies submitted under [TSCA]” and therefore subject to section 14(b)(2)(A), which expressly prohibits EPA from withholding such studies as confidential business information (CBI). This will assure the public a meaningful opportunity to comment on the scientific basis for EPA’s proposed determinations of risk. (pp. 30-32)

**Occupational Non-Users.** A persistent area of concern in the first 10 evaluations is EPA’s differentiation between directly exposed workers and the category of “occupational non-users” (ONUs), which EPA generally treats as having lower exposure and risk. This is a false dichotomy, and inconsistent with the state of the science for industrial exposure assessment. Instead, experts make a more meaningful distinction between near-field and far-field exposure and differentiate among jobs by whether they may be near or far from the source of exposure. Consistent with this approach, EPA

should replace the broad ONU category with more refined groupings of near- and far-field workers and, within each grouping, conduct a more detailed exposure analysis which reflects job responsibilities and exposure scenarios specific to different types of workers and chemicals. (pp. 32-34)

**All Conditions of Use.** In its initial 10 evaluations, EPA excluded undisputed conditions of use based on the claim that it had discretion under TSCA to pick and choose the conditions it would evaluate and that its risk evaluation framework rule authorized it to exercise such discretion. However, the Ninth Circuit's decision in *Safer Chemicals v. United States EPA*, 943 F.3d 397 (9th Cir. 2019) holds that EPA's risk evaluation framework rule does not grant the agency discretion to exclude conditions of use from the scope of risk evaluations. Accordingly, EPA must address all conditions of use in the upcoming 20 evaluations. (pp. 34-35)

**IRIS Assessments** 14 of the 20 high-priority chemicals have been assessed under the EPA Integrated Risk Information System (IRIS). The IRIS process has been 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. 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 receive substantial weight as a previous statement by the Agency of the "best available science." EPA should modify IRIS findings only where there is a strong justification, such as the availability of new data that inform the weight of the scientific evidence. Such additional data should be assessed using peer reviewed and accepted systematic review methodologies. EPA should explain departures from IRIS assessments in its risk evaluations. (p. 35)

### **Comments on Scoping Documents for Formaldehyde and Phthalate Esters**

- Formaldehyde is the subject of a draft IRIS assessment that, contrary to previous EPA commitments, has been withheld from public comment and peer review. Continued suppression of the draft IRIS report would enable the TSCA program to reach less protective conclusions about formaldehyde's health effects without informing the public of the IRIS determinations and how and why EPA has rejected these findings. Rather than pursuing this untenable course, EPA should immediately release the draft IRIS assessment for public comment and submit it to the NAS for peer review. If TSCA scientists have questions or concerns about the scientific basis for the IRIS findings, they can be framed for public comment and reflected in the charge for NAS review. Following NAS review, EPA's risk evaluation should respond to NAS recommendations and explain and justify any departures from the draft IRIS assessment. (pp. 35-37)
- EPA should combine the five phthalates listed as high priority with the two phthalates for which industry has requested risk evaluations into a single category and then conduct a cumulative risk assessment on this category. Category treatment is clearly warranted under section 26(c) of TSCA. More than a decade ago, the National Research Council (NRC) reviewed the evidence on phthalates and found that because people are exposed to multiple phthalates at the same time, and phthalates contribute to one or more common adverse health outcomes, "a cumulative risk assessment should be conducted that evaluates the combined effects of exposure." The NRC

further found that “[c]umulative risk assessment based on common adverse outcomes is a feasible and physiologically relevant approach to the evaluation of the multiplicity of human exposures and directly reflects EPA’s mission to protect human health.” EPA should follow these recommendations. (pp. 37-38)

## **I. EPA Must Identify Data-Gaps on the 20 High-Priority Candidates and Require Testing under TSCA Section 4 to Fill Them**

**Importance of Comprehensive Data for Risk Evaluations.** Under section 6(b)(4) of TSCA, the goal of risk evaluations is to “determine whether a chemical substance presents an unreasonable risk to injury to health or the environment, . . . including an unreasonable risk to a potentially exposed or susceptible subpopulation . . . , under the conditions of use.” To achieve this goal, TSCA risk evaluations must “look comprehensively at the hazards associated with the chemical.” S. Rep. No. 94-698, 114<sup>th</sup> Cong, 1<sup>st</sup> Sess. (2015) at 2. This requires extensive hazard and exposure information across all a chemical’s conditions of use and health endpoints.

We have consistently emphasized that, to assure that EPA has sufficient information for informed risk evaluations, efforts to identify and fill data gaps must begin while a chemical is being considered for prioritization. EPA’s proposed prioritization framework rule included a pre-prioritization process designed to achieve this goal.<sup>2</sup> These provisions were unfortunately eliminated from the final rule. However, in its September 27, 2018 *Working Approach for Identifying Potential Candidate Chemicals for Prioritization*,<sup>3</sup> EPA reemphasized that “[i]dentifying information gaps and needs before a chemical enters prioritization is an important component of pre-prioritization and prioritization [and] the Agency has authorities under TSCA sections 4, 8 and 11 to gather information and request data to fill data gaps.”

EPA has an obligation to use these TSCA tools for chemicals undergoing risk evaluations. Under section 26(k) of TSCA, EPA “shall take into consideration information relating to a chemical substance or mixture, including hazard and exposure information, under the conditions of use, that is reasonable available to the Administrator.” EPA’s risk evaluation framework rule defines reasonably available information as “information that EPA possesses or can reasonably generate, obtain, and synthesize for use in risk evaluations, considering the deadlines specified in TSCA section 6(b)(4)(G) for completing such evaluation.” 40 C.F.R §702.33. The preamble to the rule underscores that information that either exists or “can be obtained through testing” is “reasonably available” and that the Agency may be obligated to require “data [to be] generated in response to EPA data gathering, including testing, authorities” to meet its obligation to consider reasonably available information.<sup>4</sup>

**Data Gaps in the First 10 Evaluations.** The lack of adequate data for risk determinations was painfully evident in EPA’s first draft evaluation, for Pigment Violet 29 (PV29). The December 2018 draft concluded that this chemical does not present an unreasonable risk of injury but based this sweeping conclusion on limited hazard and exposure information. Our groups strongly faulted the draft evaluation for giving PV29

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<sup>2</sup> 82 Fed. Reg. 4825 (January 17, 2017).

<sup>3</sup> <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2018-0659-0001>

<sup>4</sup> 82 Fed. Reg. 33726, 33732 (July 20, 2017).

a clean bill of health without supporting data.<sup>5</sup> The SACC agreed, highlighting multiple data deficiencies and recommending several additional studies to characterize hazard and exposure.<sup>6</sup> EPA ultimately agreed to require limited PV 20 testing under a section 4 order<sup>7</sup> but stopped short of requiring the studies that we and SACC deemed necessary for a supportable risk determination.

Other draft risk evaluations reveal data-gaps for critical endpoints like endocrine effects, immunotoxicity, developmental neurotoxicity and ecotoxicity.<sup>8</sup> In addition, as the SACC has observed, the draft evaluations frequently lack reliable information on human exposure and environmental release. As a result, EPA's risk estimates have heavily relied on modeling predictions and limited monitoring data that have a high level of uncertainty.

**Data Gaps on the 20 High-Priority Chemicals.** The EPA support documents for the 20 high-priority candidates reveal multiple data-gaps for human health endpoints.<sup>9</sup> For example, 1,1-dichloroethane lacks reproductive, respiratory sensitization and immunotoxicity data; 1,2-dichloroethylene lacks data on carcinogenicity, reproductive and developmental toxicity and neurotoxicity; phthalic anhydride lacks reproductive, neurotoxicity and immunotoxicity data; dicyclohexyl phthalate lacks immunotoxicity, neurotoxicity and carcinogenicity data; and triphenyl phosphate lacks carcinogenicity data.

The support documents reveal even more basic data gaps for assessing environmental risks. As EPA admits, "there are very few publicly available assessments . . . with cited environmental hazard data" for the 20 chemicals and it "used a read-across approach to identify additional environmental hazard data . . . to fill in potential data gaps."<sup>10</sup> EPA guidelines for ecological risk assessment typically call for studies of acute and chronic effects in a range of invertebrates, aquatic species, and terrestrial species.<sup>11</sup> However, according to EPA's support documents, there is a virtual absence of chronic toxicity studies in any taxa for 1,1-Dichloroethane, Tris(2-chloroethyl) phosphate, 1,2-Dichloroethylene, Phthalic Anhydride, Di-isobutyl Phthalate and dicyclohexyl phthalate.

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<sup>5</sup> Comments of Safer Chemicals Healthy Families, Earthjustice, Environmental Health Strategy Center, Natural Resources Defense Council, and the undersigned groups on EPA's Draft Risk Evaluation for C.I. Pigment Violet 29 under the Amended Toxic Substances Control Act (January 14, 2019) EPA-HQ-OPPT-2018-0604.

<sup>6</sup> TSCA Science Advisory Committee on Chemicals Meeting Minutes and Final Report No. 2019-01, *A Set of Scientific Issues Being Considered by the Environmental Protection Agency Regarding: Peer Review for EPA Draft Risk Evaluation of C.I. Pigment Violet 29*, available at <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2018-0604-0088>, September 18, 2019 (PV29 SACC Report).

<sup>7</sup> EPA-HQ-OPPT-2020-0070-0002.pdf

<sup>8</sup> For example, developmental neurotoxicity data are unavailable for 1,4 dioxane, methylene chloride, trichloroethylene and perchloroethylene. HBCD lacks sufficient data to determine its immunotoxicity, male reproductive effects, carcinogenicity and developmental neurotoxicity.

<sup>9</sup> <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/supporting-information-proposed-high-priority-chemical>.

<sup>10</sup> See, e.g., [https://www.epa.gov/sites/production/files/2019-08/documents/ethylene\\_dibromide\\_106-93-4\\_high-priority\\_proposeddesignation\\_082319.pdf](https://www.epa.gov/sites/production/files/2019-08/documents/ethylene_dibromide_106-93-4_high-priority_proposeddesignation_082319.pdf), at 16.

<sup>11</sup> EPA, Overview of the Ecological Risk Assessment Process in the Office of Pesticide Programs, January 23, 2004, available at <https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/ecological-risk-assessment-pesticides-technical>



Remarkably, the scopes for the 20 chemicals lack any discussion of these data-gaps even though EPA identified them in its prioritization support documents. Once again, therefore, the risk evaluations will move forward without any up-front assessment of the sufficiency of available data and a process to fill gaps using EPA's section 4 authority. While time is short because EPA failed to address data gaps during the prioritization process, the Agency should now use its section 4 authority to require as much testing as possible. *These requirements should include health and environmental effects testing as well as monitoring of workplace exposure levels, environmental releases and presence in environmental media.*

**UF for Data-Base Deficiencies.** Where time-constraints preclude requiring studies on critical endpoints, the resulting uncertainties must be accounted for in the risk evaluation. EPA guidance calls for application of an Uncertainty Factor (UF) where the absence of adequate data creates uncertainty in determining a chemical's health effects:<sup>12</sup>

The database UF is intended to account for the potential for deriving an underprotective RfD/RfC as a result of an incomplete characterization of the chemical's toxicity. In addition to identifying toxicity information that is lacking, review of existing data may also suggest that a lower reference value might result if additional data were available. Consequently, in deciding to apply this factor to account for deficiencies in the available data set and in identifying its magnitude, the assessor should consider both the data lacking and the data available for particular organ systems as well as life stages.

The size of this UF can vary between 3 and 10. EPA guidance advises that "the size of the database factor to be applied will depend on other information in the database and on how much impact the missing data may have on determining the toxicity of a chemical and, consequently, the POD."<sup>13</sup>

None of the 10 initial TSCA risk evaluations has applied a UF for data-base deficiencies although it is standard practice in IRIS assessments and the EPA guidance calling for this UF is agency-wide in application. The decision of the TSCA program to deviate from this EPA guidance has never been explained or justified. For several of the 10 chemicals, IRIS assessments and often the TSCA evaluations call out data gaps for such critical endpoints as immunotoxicity and developmental neurotoxicity. However, while IRIS has applied UFs of up to 10X, OPPT has not.<sup>14</sup> *Since there are significant data-gaps for many of the 20 high-priority chemicals, EPA must apply a data base UF in its upcoming risk evaluations, consistent with established EPA policy and practice.*

## **II. EPA Must Abandon its Flawed TSCA Systematic Review Protocol and Apply Scientifically Valid and Peer Reviewed Systematic Review Methodologies**

The scopes for the 20 high-priority chemicals state that:

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<sup>12</sup> RD and RC Review at 4-44

<sup>13</sup> Id. at 4-45.

<sup>14</sup> For example, in its assessment of perchloroethylene (PCE), IRIS pointed to "uncertainties associated with database deficiencies on neurological, developmental, and immunological effects" and applied a 10X UF.

“To further develop this draft scope document, EPA conducted a comprehensive search to identify and screen multiple evidence streams (i.e., chemistry, fate, release and engineering, exposure, hazard) and the search and screening results are provided in Section 2.1.....EPA is using the systematic review process described in the *Application of Systematic Review in TSCA Risk Evaluations* document (U.S. EPA, 2018a) to guide the process of searching for and screening reasonably available information, including information already in EPA’s possession, for use and inclusion in the risk evaluation.”<sup>15</sup>

EPA’s continued reliance on the TSCA “systematic review” process<sup>16</sup> for the upcoming 20 evaluations is deeply troubling in light of the many concerns about this process expressed by commenters and the SACC and the ongoing National Academy of Sciences (NAS) review of the controversial TSCA protocol .

**Flaws in the TSCA Systematic Review Criteria.** Our organizations have previously commented that the TSCA protocol represents a deeply flawed and unscientific approach to systematic review that will compromise the quality, validity and protectiveness of the 10 initial risk evaluations.<sup>17</sup> These concerns were summarized in a recent peer-reviewed commentary published in the *American Journal of Public Health*.<sup>18</sup>

“Systematic review” is a well-established approach for evaluating and integrating scientific evidence to arrive at judgments about hazard, exposure and risk. The EPA framework risk evaluation rule recognizes the need for a systematic review process in determining chemical risks under TSCA.<sup>19</sup> However, the TSCA protocol departs radically from accepted scientific principles for systematic review adopted by the IOM,<sup>20</sup> the NTP,<sup>21</sup> and EPA’s Integrated Risk Information System (IRIS)<sup>22</sup> and endorsed by the NAS<sup>23</sup> and other peer review bodies.

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<sup>15</sup> Draft Scope of the Risk Evaluation for Formaldehyde, April 2020 at 10 (emphasis added)

<sup>16</sup> 83 Fed. Reg. 26998 (June 11, 2018); *Application of Systematic Review in TSCA Risk Evaluations*, available at [https://www.epa.gov/sites/production/files/2018-06/documents/final\\_application\\_of\\_sr\\_in\\_tsca\\_05-31-18.pdf](https://www.epa.gov/sites/production/files/2018-06/documents/final_application_of_sr_in_tsca_05-31-18.pdf)

<sup>17</sup> Comments of Safer Chemicals Healthy Families et al. on *Application of Systematic Review in Risk Evaluations under Section 6 of the Amended Toxic Substances Control Act*, August 16, 2018, Docket ID EPA-HQ-OPPT-2018-0210. We incorporate these comments by reference.

<sup>18</sup> Singla V, Sutton P, Woodruff TW. (2019) The Environmental Protection Agency Toxic Substances Control Act Systematic Review Method May Curtail Science Used to Inform Policies, With Profound Implications for Public Health. *Am J Public Health*. doi: 10.2105/AJPH.2019.305068

<sup>19</sup> 82 Fed. Reg. 33726 33734 (July 20, 2017).

<sup>20</sup> Institute of Medicine. *Finding What Works in Health Care. Standards for Systematic Review*. Washington, D.C.: The National Academies Press.; 2011.

<sup>21</sup> National Toxicology Program. *Handbook for Conducting a Literature-Based Health Assessment Using OHAT Approach for Systematic Review and Evidence Integration*. In: U.S. Department of Health and Human Services, editor.: Office of Health Assessment and Translation, Division of National Toxicology Program, National Institute of Environmental Health Sciences; 2015.

<sup>22</sup> National Research Council. *Review of EPA's Integrated Risk Information System (IRIS) Process*. Washington, DC: National Academies Press; 2014.

<sup>23</sup> National Research Council. *Review of EPA's Integrated Risk Information System (IRIS) Process*. Washington, DC: National Academies Press; 2014; National Research Council. *Review of the Environmental Protection Agency’s State-of-the-Science Evaluation of Non Monotonic Dose–Response Relationships as They Apply to Endocrine Disruptors*.

The TSCA approach applies a rigid scoring system to grade the “quality” of studies on chemicals. This system could result in many studies being arbitrarily classified as “poor” or “unacceptable” based on a small number of reporting or methodology limitations that do not negate their overall value for assessing health and environmental risks. The consequence will be that important evidence of public health impacts -- particularly epidemiological studies demonstrating harm in human populations – will be either disregarded or given limited weight in risk evaluations. Other systematic review methodologies do not use numerical scoring systems for assessing study quality and the NAS recommends strongly against such scoring.

The TSCA approach also focuses on one limited aspect of systematic review – study quality – but fails to address other critical elements that the Agency itself recognizes are essential for science-based risk judgments. EPA’s July 2017 risk evaluation framework rule defines systematic review as a comprehensive, consistent and transparent process to “identify and evaluate each stream of evidence” and “to integrate evidence as necessary and appropriate based on strengths, limitations, and relevance.”<sup>24</sup> Yet the TSCA document lacks any protocol for these important tasks. Experts agree that systematic review methods need to be established in advance of individual evaluations to eliminate the potential for bias and to assure that evidence reviews are conducted using consistent, well-defined criteria. EPA’s failure to take this necessary step *before conducting risk evaluations* has severely compromised the scientific validity of the 10 initial TSCA risk evaluations.

Recent draft risk evaluations have also been based on a “hierarchy of preferences,” a new concept that was not part of the original TSCA systematic review document and has likewise not been subject to peer review or public comment. The 1-BP evaluation briefly explains this approach as follows:<sup>25</sup>

“EPA’s approach uses a hierarchy of preferences that guide decisions about what types of data/information are included for further analysis, synthesis and integration into the environmental release and occupational exposure assessments. EPA prefers using data with the highest rated quality among those in the higher level of the hierarchy of preferences (i.e. data>modeling>occupational exposure limits or release limits).”

EPA does not explain why some types of studies should receive preference over others in determining the weight of evidence for a particular endpoint and on what basis these studies should be assigned to a “higher level.” Thus, there are no objective criteria for determining which evidence to rely on and which to exclude, undermining transparency and consistency in the systematic review process and encouraging subjective judgments.

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Washington, DC: National Academies Press; 2014; 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. Washington, DC: 2017.

<sup>24</sup> 40 C.F.R. 704.33.

<sup>25</sup> Draft Risk Evaluation for 1-Bromopropane, August 2019, at 45, available at [https://www.epa.gov/sites/production/files/2019-08/documents/01.1bp\\_draft\\_risk\\_evaluation\\_hero\\_links\\_external.pdf](https://www.epa.gov/sites/production/files/2019-08/documents/01.1bp_draft_risk_evaluation_hero_links_external.pdf).

**SACC Concerns.** In its peer review of the Draft Risk Evaluation of PV29, the EPA SACC highlighted the following areas of concern with the TSCA systematic review method:

- “The Agency rationale for developing the TSCA SR should include a comparison to other SR approaches and describe the rationale for major differences.”<sup>26</sup>
- “The Committee discussed the need to publish peer reviewed pre-established protocols for each of the Agency’s reviews prior to performing the actual risk assessment. The protocol for PV29 was created concurrently with the review, which is contrary to best practices for systematic reviews.”<sup>27</sup>
- “The Committee noted that the TSCA SR weighted scoring system may be inappropriate if there is disagreement in the weighting of different metrics. For example, a certain study characteristic that may be a “fatal flaw” would be weighted equally to other more minor elements. The “Agency should provide justification for using a weighted scoring system and the rationale for the specific metrics used for differential weighting in its evaluation of studies.”<sup>28</sup>
- “Regarding data integration, the Committee discussed the benefits of including a more thorough and inclusive data integration discussion in the TSCA SR for PV29 ... there is a need in the Evaluation for a thorough description and outline for how all evidence and data are integrated into a final weight of evidence conclusion”<sup>29</sup>

These concerns were forcefully underscored in the SACC review of the 1,4-dioxane risk evaluation:<sup>30</sup>

“Committee members did not find the systematic review to be a transparent and objective method to gather the relevant scientific information, score its quality, and integrate the information. Several Committee members brought up examples of references that were not in the systematic review bibliography and/or not considered in the Data Quality evaluation step, but which were used at different stages in the Evaluation. Several Committee members found that it was difficult to determine whether the relevant information was properly evaluated and considered in the Evaluation.”

The SACC “noted problems with both the systematic review design and consistent implementation of its protocols,” elaborating that:<sup>31</sup>

“Signs that the systematic review design has issues include the need for “backward reference searching” or “targeted supplemental searches,” which shouldn’t be required if the initial search finds all the relevant references. Similarly, the Committee noted a high fraction of studies where the initial quality score was later changed, indicating that the data quality evaluation protocol is not clearly defined and possibly inconsistently implemented by different reviewers. The

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<sup>26</sup> PV 29 SACC Report at 26.

<sup>27</sup> Id. at 27.

<sup>28</sup> Id. at 26-7.

<sup>29</sup> Id. at 27.

<sup>30</sup> 1,4-Dioxane and HBCD SACC Report, at 30.

<sup>31</sup> Id. at 31.

automated gray literature search found mostly several off-topic documents and also missed other useful documents.”

The SACC report further indicated that “[s]everal Committee members recommended simplifying the scoring system or adopting an existing peer-reviewed method, such as the method used by the National Toxicology Program’s Center for the Evaluation of Risks to Human Reproduction (NTP-CERHR).”<sup>32</sup>

**Path Forward.** EPA has not addressed these SACC concerns in the scopes or elsewhere. Moreover, with the initial systematic review protocol in a state of flux following revisions during the initial risk evaluations, it is not even clear what methodologies EPA is using to review data on the 20 high-priority chemicals. The scopes fail to shed any light on the review protocols EPA is using and do not provide any of the underlying documentation for these reviews. The scopes also fail to address the ongoing NAS review of the TSCA protocol and how the NAS conclusions and recommendations might affect the ongoing evaluations should they cast doubt on the scientific validity of the EPA approach.

*In the face of the serious concerns of SACC and others and the ongoing NAS review, EPA should not use the TSCA systematic review protocol for the upcoming 20 risk evaluations. Instead, it must apply one of the established methodologies for systematic review that are consistent with the definition developed by the Institute of Medicine (IOM), such as the National Toxicology Program (NTP) OHAT method or the Navigation Guide Systematic Review Method developed by the University of California San Francisco. These methodologies embody recognized principles of systematic review and have been endorsed by NAS and other peer review bodies.*

### **III. The 20 Evaluations Should Undergo Robust Peer Review in Accordance with EPA and OMB Guidelines for Highly Influential Scientific Assessments**

Under EPA’s risk evaluation framework rule, scoping documents must describe EPA’s plan for peer review. 40 CFR § 702.41(c)(6). However, the scopes for the 20 chemicals merely state that “[p]eer review will be conducted in accordance with EPA’s regulatory procedures for chemical risk evaluations, including using EPA’s Peer Review Handbook and other methods consistent with Section 26 of TSCA (See 40 CFR 702.45).”<sup>33</sup> This hardly constitutes a peer review plan: among other issues, it fails to describe the peer review body EPA will convene, the review process it will conduct and its timeline, how the reviewers will be selected and opportunities for public participation.

**Elimination of SACC Role.** This lack of specificity is of particular concern because Assistant Administrator Dunn has announced that EPA will use a different peer review process for the 20 new evaluations than it used for the first 10 and that, under this new process, the SACC will no longer be reviewing individual evaluations.<sup>34</sup> The elimination of the SACC’s peer review role would be a serious mistake.

Although the SACC process has not been perfect, it has been an essential vehicle for independent scrutiny of EPA’s draft evaluations. Strengths of the process include the involvement of recognized experts,

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<sup>32</sup> Id.

<sup>33</sup> Draft Formaldehyde Scoping Document at 62.

<sup>34</sup> <https://insideepa.com/daily-news/epa%E2%80%99s-dunn-says-some-tsca-deadlines-may-slide-get-quality-reviews>

stakeholder input on EPA's charge questions, direct interaction between SACC members and EPA staff, transparent public meetings, opportunities for the public to submit written comments and make oral presentations, and preparation of a detailed report providing SACC's findings and recommendations. The SACC has taken its responsibilities seriously, offering hard hitting and independent advice to EPA and highlighting weaknesses and flaws in the draft evaluations that bear on whether they use the best available science, are protective of health and the environment, and achieve the goals of TSCA. This feedback has been invaluable to Congress, the public and EPA itself during early implementation of TSCA's new mandate for comprehensive risk evaluations on chemicals of concern.

It may be possible to retain the important benefits of SACC review while reducing the time commitments of individual SACC members. However, any effort to scale back and narrow the scope of peer review would be unwise and unjustified.

Like the first 10 evaluations, the next 20 will be comprehensive and complex. The 20 high-priority chemicals are high-visibility substances with significant health and environmental impacts that have previously received considerable scientific and regulatory scrutiny in the US and globally. Evaluations of these chemicals will necessarily address multiple health and ecological endpoints, combine hazard information with exposure analysis, and determine the risks presented by numerous conditions of use. The chemical-specific and general science issues presented will be important and in some cases novel. The evaluations will have far-reaching regulatory consequences because they will be used to determine whether the 20 chemicals present an unreasonable risk of injury and should be restricted under section 6(a) of TSCA. Many fundamental questions and concerns that surfaced during the SACC reviews of the initial 10 chemicals will likely remain unresolved and the next 20 chemicals will present similar challenges. Robust peer review will continue to be critically important.

**Peer Review Requirements for HISAs.** Under OMB's 2005 Final Information Quality Bulletin for Peer Review, the TSCA risk evaluations qualify as Highly Influential Scientific Assessments (HISAs) because they not only will have "a clear and substantial impact on important public policies" but will be "novel, controversial, or precedent-setting or ha[ve] significant interagency interest."<sup>35</sup> OMB requires a robust independent peer review process for such assessments, noting that that the "intensity of peer review should be commensurate with the significance of the information being disseminated and the likely implications for policy decisions" and that "the need for rigorous peer review is greater when the information contains precedent-setting methods or models, presents conclusions that are likely to change prevailing practices, or is likely to affect policy decisions that have a significant impact."<sup>36</sup>

EPA's Peer Review Handbook uses the same definition of HISAs, emphasizing that "[t]he more far-reaching or significant the impacts of a scientific assessment, the more appropriate it is to categorize the product as an HISA." The Handbook advises that HISAs "are expected to undergo rigorous external peer review with opportunities for public participation."<sup>37</sup>

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<sup>35</sup> 70 Fed. Reg. 2664, 2671 (January 14, 2005).

<sup>36</sup> Id at 2668.

<sup>37</sup> U.S. Environmental Protection Science and Technology Council. Agency Peer Review Handbook 4th Edit on;

Because they are HSIAAs, the peer review process must include certain minimum elements:

- According to EPA’s Peer Review Handbook, a “charge is a set of focused questions that identifies the scientific and technical issues on which the Agency would like feedback and invites suggestions for improving the document as a whole. . . . Preparing a good charge is time well-spent, as the charge is crucial for an effective peer review.”<sup>38</sup> Public input is often invaluable in shaping the charge and the EPA SAB and individual EPA offices normally seek comments on draft charge questions before finalizing them. Because the TSCA risk evaluations are precedent setting, framing the right set of charge questions will be critical. Interested parties should have the opportunity to weigh in on the draft charge. Significantly, EPA’s risk evaluation framework rule emphasizes that “EPA plans to take public comment on the charge questions given to peer reviewers.”<sup>39</sup> The recent SACC reviews followed this practice and it should be continued for the next round of risk evaluations.
- The EPA Peer Review Handbook recommends “that the process [for HSIAAs] should include a public meeting, whenever feasible and appropriate, . . . [at which] interested members of the public can make oral presentations on scientific issues.”<sup>40</sup> The SACC reviews of the 10 initial evaluations occurred in multi-day meetings and allowed interested parties to provide written comments and oral statements to the reviewers. The SAB implements a similar public participation process for its review of IRIS assessments. The SACC model should be followed for the next 20 risk evaluations. EPA should provide for submission of written public comments to the reviewers and afford an opportunity for oral statements by interested parties. . . Ample meeting time should be scheduled to enable panel members to fully discuss the scientific issues among themselves.
- The Federal Advisory Committee Act (FACA) requires peer review panels to be “fairly balanced in terms of the points of view represented and the functions to be performed” and protected from “inappropriate[] influence[] by the appointing authority or by any special interest.” 5 U.S.C. app. 2 § 5(b)(2)- (3). Consistent with FACA, the OMB Handbook underscores the importance of assuring that external peer reviewers lack conflicts of interest and are impartial:<sup>41</sup>

The National Academy of Sciences defines “conflict of interest” as any financial or other interest that conflicts with the service of an individual on the review panel because it could impair the individual’s objectivity or could create an unfair competitive advantage for a person or organization. This standard provides a useful benchmark for agencies to consider in selecting peer reviewers. Agencies shall make a special effort to examine prospective reviewers’ potential financial conflicts, including significant investments, consulting arrangements, employer affiliations and grants/contracts.

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October 2015, at 43, 55, available at <https://www.epa.gov/osa/peer-review-handbook-4th-edition-2015>

<sup>38</sup> Handbook, at 82.

<sup>39</sup> 82 Fed. Reg. 33744

<sup>40</sup> Handbook, at 86.

<sup>41</sup> 70 Fed. Reg. 2670

Financial ties of potential reviewers to regulated entities (e.g., businesses), other stakeholders, and regulatory agencies shall be scrutinized when the information being reviewed is likely to be relevant to regulatory policy. The inquiry into potential conflicts goes beyond financial investments and business relationships and includes work as an expert witness, consulting arrangements, honoraria and sources of grants and contracts.

Historically, EPA's practice for major peer reviews has been to seek public comment on the qualifications of candidate reviewers, including whether they should be barred from serving because of conflicts of interest or bias. EPA has accomplished this by publishing a notice identifying candidate reviewers and soliciting public input.

- Peer review reports are most useful to the Agency and public when they are the outgrowth of dialogue among panel members and, as a result, distill key panel recommendations and capture common themes, areas of agreement and disagreement, and the views of panel members with shared areas of expertise. By contrast, where panel members submit their individual responses to charge questions with no give-and-take and group discussion, the resulting report is often a collection of unsynthesized opinions. Once reports are submitted, it is critical for the Agency to respond to the panel's recommendations and revise its scientific work product to reflect the panel's feedback. As explained in the EPA Handbook, "[t]he credibility of the final influential work product is likely to be enhanced if the public understands how the Agency addressed the specific concerns raised by the peer reviewers."<sup>42</sup>

These peer review principles and practices were largely followed by the SACC for the first 10 evaluations and should be retained for the next 20, whether the peer reviews are performed by the SACC itself or some other body.

#### **IV. EPA Must Include All Environmental Pathways in TSCA Risk Evaluations**

For each of the 10 initial evaluations, EPA has excluded all environmental release pathways that contribute to human exposure, including air, drinking water, groundwater and soil. EPA's rationale for disregarding these pathways is that they "are covered under the jurisdiction of other environmental statutes, administered by EPA, which adequately assess and effectively manage those exposures, i.e., CAA, SDWA, CWA, and RCRA." Because of these exclusions, none of the evaluations addresses exposure levels for the general population and the risk these exposures present.<sup>43</sup> This approach is contrary to the comprehensive multi-media scope of TSCA and has been squarely rejected by the SACC.

**TSCA's Comprehensive Risk Evaluation Framework.** Under section 6(b)(4)(A), TSCA risk evaluations must determine "whether a chemical substance presents an unreasonable risk of injury to health or the environment" – a requirement that entails examining all sources of exposure to the substance. Similarly, section 6(b)(4)(A) provides that a risk evaluation must determine the substance's risks under "the conditions of use." This broad term spans the entire life cycle of a chemical and is defined under section

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<sup>42</sup> Handbook, at 87.

<sup>43</sup> US EPA. 2018. "Problem Formulation of the Risk Evaluation for 1,4-Dioxane." P 42. Available at [https://www.epa.gov/sites/production/files/2018-06/documents/14-dioxane\\_problem\\_formulation\\_5-31-18.pdf](https://www.epa.gov/sites/production/files/2018-06/documents/14-dioxane_problem_formulation_5-31-18.pdf); Draft Risk Evaluation for 1,4-Dioxane, at 156.



3(4) to mean “the circumstances . . . under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of.” These “circumstances” clearly include air emissions and releases to water that result in pathways of human exposure and risk, whether they might be addressed under other laws or not.

If Congress had intended a blanket exemption of environmental releases from risk evaluations under section 6(b), it surely would have said so explicitly, given the far-reaching impact of such an exemption. But as the legislative history of the original law confirms, Congress recognized that then-existing environmental laws were “clearly inadequate” to address the “serious risks of harm” to public health from toxic chemicals. H.R. Rep. No. 94-1341, 94<sup>th</sup> Cong., 2d Sess. at 7 (1976); see S. Rep. No. 94-698, 94<sup>th</sup> Cong., 2d Sess. (1976) at 3 (“[W]e have become literally surrounded by a manmade chemical environment. . . . [T]oo frequently, we have discovered that certain of these chemicals present lethal health and environmental dangers.”). While other federal environmental laws focused on specific media, such as air or water, none gave EPA authority to “look comprehensively” at the hazards of a chemical “in total.” S. Rep. No. 94-698, at 2. Congress designed TSCA to fill these “regulatory gaps,” *id.* at 1, through a comprehensive approach to chemical risk management that considered “the full extent of human or environmental exposure,” H.R. Rep. No. 94-1341, at 6.

In amending TSCA in 2016, Congress sought to promote “effective implementation” of the 1976 law’s objectives. See S. Rep. No. 114-67, 114<sup>th</sup> Cong., 1<sup>st</sup> Sess. (2015) at 2. At the time it strengthened TSCA, Congress affirmed that the intent of the original law—to give EPA “authority to look at the hazards [of chemicals] in total,” S. Rep. No. 94-698, at 2—remained “intact.” S. Rep. No. 114-67, at 7. Indeed, in a statement accompanying the law’s passage, its Senate Democratic sponsors underscored that, with the expanded authorities conferred by Congress, TSCA should not be “construed as a ‘gap filler’ statutory authority of last resort” but “as the primary statute for the regulation of toxic substances.”<sup>44</sup>

**SACC Rejection of EPA Approach.** EPA’s position that other environmental laws should displace TSCA risk evaluations arbitrarily assumes that these laws provide equivalent protection of public health and the environment and that there is no added benefit in evaluating the risks presented by environmental pathways of exposure under TSCA. But in its review of the 1,4-dioxane draft, the SACC questioned this basis for failing to consider environmental pathways of exposure and consumer uses:<sup>45</sup>

“Some Committee members stated that omission of consumers and the general United States (U.S.) population is inappropriate, unless risk assessments *have been* completed at this point in time. Exposure scenarios that include consumers are important given the known presence of 1,4-Dioxane in plastics, other commercially available products, surface water, drinking water, groundwater, and in sediments. The Committee also had concerns that the omission of these multiple routes of exposure puts workers who inhale or ingest 1,4-Dioxane outside the workplace at even greater risk.”

The SACC added that:<sup>46</sup>

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<sup>44</sup> Congressional Record – Senate 3517 (June 7, 2016).

<sup>45</sup> 1,4-Dioxane and HBCD SACC Report, at 20.

<sup>46</sup> *Id.*

“The Committee discussed that if each program office of the EPA says others are assessing the risks and thus not including them in their assessment, the U.S. public will be left with no overall assessment of risks. If risks have been assessed by other program offices of EPA then the Agency should present them as part of the underlying data to support this TSCA Evaluation—if not, the Agency must gather the data for an assessment or include an assessment based on the assumption of near-worst-case exposures.”

The SACC underscored that “[g]eneral human population and biota exposure must be assessed for inhalation, ingestion, and dermal routes [and that] [d]ifferent sub-populations may have different extents of exposure, but each route must be assessed.”<sup>47</sup> EPA’s narrower approach, it said, “strayed from basic risk assessment principles by omitting well known exposure routes such as water consumption by all occupationally and non-occupationally-exposed humans as well as similar exposures to other biological receptors.”<sup>48</sup>

Although some of the scopes are worded broadly, it appears that EPA intends to continue to exclude most environmental releases from its upcoming evaluations. For example, the formaldehyde scope states that “EPA plans to analyze exposure levels for indoor air, ambient air (consumer activities affecting colocated/co-residence populations), sediment, soil, and terrestrial biota associated to exposure to formaldehyde.”<sup>49</sup> However, the scope also cautions that EPA plans to “avoid duplicating efforts taken pursuant to other Agency programs.”<sup>50</sup> Thus, it indicates that EPA will not address air emissions because formaldehyde is a Hazardous Air Pollutant (HAP), will be excluding drinking water because formaldehyde is “currently addressed in the SDWA regulatory analytical process for public water systems,” and will be excluding land disposal because it is subject to RCRA.<sup>51</sup> As described above, these exclusions are unjustified under TSCA.

*Under TSCA, EPA must comprehensively evaluate environmental releases and general population exposure. The 20 risk evaluations must address all environmental releases without regard to other EPA-implemented laws.*

## **V. EPA Should Combine Risks Across Routes and Pathways of Exposure**

**Aggregating Exposure Across Dermal and Inhalation Routes.** In the initial 10 evaluations, EPA consistently failed to aggregate exposure and risks across routes and pathways of exposure. The scopes provide no indication that EPA will modify this approach in the 20 upcoming evaluations.

For several of the initial 10 chemicals, EPA recognized that dermal and inhalation exposure occur simultaneously for workers and consumers in many use scenarios. Nonetheless, with no credible justification, it failed to combine these two routes of exposure to derive composite risk estimates. This failure resulted in a significant understatement of risk for several of these chemicals, as EPA recognized in its draft evaluation for methylene chloride.<sup>52</sup>

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<sup>47</sup> Id.

<sup>48</sup> Id.

<sup>49</sup> Formaldehyde Scoping Document at 47.

<sup>50</sup> Id at 40.

<sup>51</sup> Id., Appendix H.

<sup>52</sup> Methylene Chloride Risk Evaluation at 304.

In its report on the draft evaluation for 1-bromopropane (1-BP), the SACC recommended that EPA estimate “cumulative exposures, which involves both dermal and inhalation contact with 1-BP” because “dermal exposure to 1-BP would most likely correspond with simultaneous inhalation exposure” and “vapor and dermal exposures are not separable.”<sup>53</sup> EPA should similarly use combined dermal and inhalation exposures to determine risks in the upcoming 20 evaluations.

**Aggregating Exposure Across Pathways.** General population exposure to several of the 10 chemicals stems from their presence in ambient and indoor air, in drinking water, and at waste management facilities and contaminated sites. These sources of exposure are additive for many subpopulations and should be considered in combination when determining overall risk. However, by ignoring the collective contribution of environmental pathways of exposure, EPA has not only violated TSCA but failed to determine total risks to these subpopulations. No individual environmental law enables EPA to combine exposure across environmental media. TSCA is the only environmental law authorizing EPA to evaluate risks from all environmental pathways. If TSCA is not used for this purpose, the cross-media risks of chemicals will go unaddressed.

Combining exposures across pathways is also a necessary step in protecting workers and users of consumer products. For many workers, job-related exposures will be magnified by environmental exposures and, often, residential exposures. For example, in the home environment, workers may use household products containing the same chemicals to which they are exposed during their weekday work. For these subpopulations, risks would be a function of the total contribution of each activity and pathway to total exposure. However, the initial 10 evaluations have looked at each exposure pathway in isolation from others, thus ignoring the large number of people with concurrent exposure in the workplace, from the ambient environment and at home. The SACC report on the 1-BP evaluation faulted this approach, indicating that:

“The Committee found that the draft risk evaluation failed to consider cumulative or aggregate exposures. It was pointed out that a worker who is occupationally exposed may also be exposed through other conditions of use in the home. Yet, these exposures are decoupled in the draft risk evaluation. The Committee was concerned that 1-BP off-gassing from insulation in home and schools is inadequately assessed, thereby underestimating exposures.”<sup>54</sup>

In such cases, EPA should identify subpopulations with elevated risks because of the convergence of multiple exposure pathways and estimate the increased risks they face. In this way, EPA would meet its obligation under TSCA to define PESS and protect them from unreasonable risks.

*TSCA requires EPA to consider all exposures associated with a chemical’s known, intended and reasonably foreseen conditions of use.<sup>55</sup> It also requires EPA to separately evaluate whether there are unreasonable risks to subpopulations that face greater exposures than the general public, including people who are exposed by multiple routes and pathways, both on the job and at home and from the ambient*

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<sup>53</sup> TSCA Science Advisory Committee on Chemicals Meeting Minutes and Final Report No. 2019-03, Peer Review for the United States Environmental Protection Agency (EPA) Draft Risk Evaluation for 1-Bromopropane (1-BP) (SACC Report on 1-BP), December 12, 2019, <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2019-0235-0061>, at 47, 73.

<sup>54</sup> SACC Report on 1-BP Evaluation at 16.

<sup>55</sup> 15 U.S.C. §§ 2602(4), 2606(b)(2).

environment.<sup>56</sup> The 20 upcoming risk evaluations must identify such subpopulations, estimate overall levels of exposure for each and determine whether the total risk to the subpopulation is unreasonable.

## **VI. EPA Must Determine Risks to Subpopulations with Greater Susceptibility to the Health Effects of Chemicals**

PESs are defined in section 3(12) of TSCA as groups within the general population who are at greater risk because of higher levels of exposure or greater susceptibility. In addition to subpopulations with elevated exposures due to multiple routes and pathways, the first 10 evaluations do not adequately account for subpopulations more likely to be harmed by exposure because they are more susceptible to a chemical's adverse health effects.

The 10 evaluations have identified PESs at increased risk because of life-stage, sex, genetic polymorphisms, race/ethnicity, preexisting health status, lifestyle factors, and/or nutrition status. However, identifying these PESs is only the first step under TSCA. EPA must also determine whether the chemical presents "an unreasonable risk to a potentially exposed or susceptible subpopulation."<sup>57</sup> EPA has not made this determination for any of the many subpopulations it has identified in its first 10 evaluations. To do so, it must analyze how much *more susceptible* these subpopulations are to a chemical than the general population. It must then calculate non-cancer Margins of Exposure (MOEs) and cancer risk estimates that account for this greater likelihood of harm. Without such an analysis, EPA cannot address whether risks to PESs (as opposed to average workers and consumers) are unreasonable and quantify the additional increment of risk to which these subpopulations are exposed.

In several evaluations, EPA has attempted to account for the enhanced susceptibility of PESs by applying a default intraspecies uncertainty/variability factor (UF) of 10. As the Agency explains: "EPA identified lifestage, biological sex, genetic polymorphisms, race/ethnicity, preexisting health status, and lifestyle factors and nutrition status as factors affecting biological susceptibility" and concluded that "most but not all of these factors are expected to be covered by the inclusion of a 10x UFH."<sup>58</sup> However, this UF is customarily used by EPA to account for normal expected variations in sensitivity within the healthy population.<sup>59</sup> Thus, EPA guidance provides that "a 10-fold factor may sometimes be too small because of factors that can influence large differences in susceptibility, such as genetic polymorphisms."<sup>60</sup> In cases where risks are more than 10 times greater for susceptible subgroups than healthy adults, a larger UF would be warranted.

*To provide adequate protection to PESs, EPA must analyze how much more susceptible a PESS is to a chemical and then determine whether this increased risk is unreasonable. Where there are uncertainties in*

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<sup>56</sup> 15 U.S.C. §§ 2602(12), 2606(b)(2).

<sup>57</sup> 15 USC § 2605(b)(4)(A).

<sup>58</sup> PCE Evaluation at 402.

<sup>59</sup> For instance, in its draft Pigment Violet 29 risk evaluation EPA used an intraspecies UF of 10 despite finding "no evidence of increased susceptibility for any single group relative to the general population." Draft Risk Evaluation for C.I. Pigment Violet 29 (Anthra[2,1,9-def:6,5,10-d'e'f']diisoquinoline- 1,3,8,10(2H,9H)-tetrone) (Nov. 2018), found at [https://www.epa.gov/sites/production/files/2018-11/documents/draft\\_pv29\\_risk\\_evaluation\\_public.pdf](https://www.epa.gov/sites/production/files/2018-11/documents/draft_pv29_risk_evaluation_public.pdf) (PV29 Risk Evaluation).

<sup>60</sup> EPA-630-P02-002F, A Review of the Reference Dose and Reference Concentration Processes, at 4-44(Dec. 2002) <https://www.epa.gov/risk/review-reference-dose-and-reference-concentration-processes-document>. (RD and RC Review).

*this analysis, EPA should account for them by applying a UF beyond the default intraspecies 10X factor, as EPA has elsewhere done for other susceptible groups such as infants and children.<sup>61</sup> How big this UF should be will require further analysis of the particular susceptibilities of the PESS to a chemical.*

## **VII. EPA’s Determinations of Unreasonable Risk to Workers Should Not Assume the Use of Personal Protective Equipment to Reduce Exposure**

All of EPA’s initial draft risk evaluations proposed to determine that risks to workers are not unreasonable where the assumed use of Personal Protective Equipment (PPE) would reduce exposures to “acceptable” levels. This approach lacks any legal basis, departs from established federal workplace protection policy and practice, and is contrary to the realities of worker exposure to unsafe chemicals.

To reduce worker risks below levels of concern, the EPA draft evaluations assume that “workers and occupational non-users wear respirators for the entire duration of the work activity throughout their career” and “are properly trained and fitted on respirator use.” According to EPA, “similar assumptions apply to the use of gloves and their expected elimination of any dermal exposure.”<sup>62</sup> However, EPA offers no evidence that these assumptions correspond to actual workplace practice and in fact recognizes that the opposite is the case.

Thus, the 1-BP draft risk evaluation acknowledges that “[f]ew literature sources indicate the use of respirators in 1-BP conditions of use” (p. 57) and notes that “none of the workers surveyed at a Chinese facility wore PPE” (p.59) and that “small commercial facilities performing dry cleaning and spot cleaning are unlikely to have a respiratory protection program” (p. 24). The 1.4-dioxane evaluation likewise recognizes that “[t]he use of a respirator would not necessarily resolve inhalation exposures since it cannot be assumed that employers have or will implement comprehensive respiratory protection programs for their employees” (p. 53). Similarly, EPA emphasizes that “[d]ata about the frequency of effective glove use – that is, the proper use of effective gloves – is very limited in industrial settings” (p. 293). And it adds that gloves provide effective protection only “if proven impervious to the hazardous chemical, and if worn on clean hands and replaced when contaminated or compromised.” (p. 180).

The Agency recognized in its TSCA rulemaking to ban methylene chloride in paint removers that respirators are often not feasible and may be used intermittently by workers even where legally required:<sup>63</sup>

“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

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<sup>61</sup> EPA, Consideration of the FQPA Safety Factor and Other Uncertainty Factors In Cumulative Risk Assessment of Chemicals Sharing a Common Mechanism of Toxicity, February 28, 2002, available at <https://www.epa.gov/sites/production/files/2015-07/documents/apps-10x-sf-for-cra.pdf>; Assessing susceptibility from early-life exposure to carcinogens. Environ Health Perspect. 2005;113(9):1125-33. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1280390/>

<sup>62</sup> Draft Risk Evaluation for HBCD, June 2019, available at [https://www.epa.gov/sites/production/files/2019-07/documents/hbcd\\_draft\\_risk\\_evaluation\\_062719\\_hero\\_link\\_0.pdf](https://www.epa.gov/sites/production/files/2019-07/documents/hbcd_draft_risk_evaluation_062719_hero_link_0.pdf), at 381.

<sup>63</sup> 82 Fed. Reg. 7432, 7445 (January 19, 2007).

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).’”

Effective use of PPE requires clear and understandable hazard warnings and directions for safe use together with adequate employee training and oversight. Yet based on numerous studies, EPA has concluded that “consumers and professionals do not consistently pay attention to labels for hazardous substances; consumers, particularly those with lower literacy levels, 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; [and] 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.”<sup>64</sup> EPA has also noted that label warnings and directives will only be effective if the “employer provides appropriate PPE and an adequate respiratory protection program.”<sup>65</sup>

Thus, the SACC questioned EPA’s assessment of worker exposure to PV29, noting that “the analysis in the Evaluation does not discuss or account for the fact that downstream commercial users may be oblivious to chemical risks and lack even rudimentary industrial hygiene measures.”<sup>66</sup> Similarly, in reviewing the 1,4-dioxane evaluation, the SACC concluded that the “consensus of the Committee believes that PPE may not be consistently and properly worn, as EPA assumed”<sup>67</sup> and noted that “[g]love use should not always be assumed to be protective” and, if worn improperly, gloves “could actually lead to higher exposures.”<sup>68</sup> The SACC emphasized that, “[b]ecause respirators are inherently uncomfortable and potentially unreliable for long-term use, the use of respirators for more than relatively short terms is not considered appropriate in typical industrial hygiene practice.” As it concluded, “8-hour use of PPE should not be used in the risk characterization of inhaled 1,4-Dioxane. Risk estimates should be presented without the use of PPE as reasonable worst case.”<sup>69</sup>

In the case of HBCD, the SACC noted that “it was unreasonable to assume workers would wear PPE for entire 8-hour shifts due to underlying medical conditions, facial hair, discomfort, and other issues” and added that:<sup>70</sup>

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<sup>64</sup> Id.

<sup>65</sup> 82 Fed. Reg. at 7473-4.

<sup>66</sup> SACC Report on PV29 at 37.

<sup>67</sup> SACC Report on 1,3-dioxane and HBCD, at 86.

<sup>68</sup> Id. at 55.

<sup>69</sup> Id. at 53.

<sup>70</sup> Id at 118.

“[M]any members of the Committee believed EPA should place more emphasis on the limited likelihood that respiratory protection will be adopted without specific occupational exposure guidelines for HBCD . . . Dust exposures in the construction trades (especially residential construction) continue to represent an occupational health concern because of the many small-to-medium size operators and the use of temporary (and, not infrequently, undocumented) workers. Workers in these small-to-medium enterprises may not be likely to adopt personal protective equipment (PPE) controls, so EPA’s characterization of reasonable risk relying on use of PPE is not sufficiently supported by the practical realities of many workplaces.”

Because of the limitations of PPE, OSHA and NIOSH manage chemical risks using the “hierarchy of controls,” under which hazard elimination, substitution, engineering and administrative controls are all prioritized over the use of PPE.<sup>71</sup> As explained by NIOSH, “[t]he hierarchy of controls normally leads to the implementation of inherently safer systems” because chemical regulation and substitution are “more effective and protective” than PPE. EPA’s own risk evaluation for 1,4-dioxane likewise recognizes that “[t]he most effective controls are elimination, substitution, or engineering controls [and that] “[r]espirators, and any other personal protective equipment. . . , should only be considered when process design and engineering controls cannot reduce workplace exposure to an acceptable level” (p 52). Thus, the SACC review of the HBCD evaluation stressed that “[m]any Committee members were concerned with the reliance on PPE or engineering controls to reduce risk, as that is contrary to the hierarchy of controls.”<sup>72</sup>

The draft scopes do not address whether and how EPA will account for the use of PPE in the upcoming evaluations. This is a surprising omission given the unfavorable attention this issue received in public comments and SACC reports on the first 10 evaluations. *Based on this negative feedback, EPA should no longer base unreasonable risk determinations for workers on the assumption that they will be adequately protected by the use of PPE. Instead, consistent with OSHA and NIOSH practice and the hierarchy of controls, EPA should base these determinations on measured or estimated exposure levels in the absence of PPE. How to reduce exposure to substances presenting unreasonable risks to workers should be addressed during the risk management phase.*

### **VIII. The 20 Risk Evaluations Must Address Legacy Uses of Chemicals and Associated Disposal Activities**

In its recent decision addressing challenges to the risk evaluation rule, the U.S. Court of Appeals for the Ninth Circuit ruled that EPA’s exclusion of legacy activities was a violation of the plain language of TSCA:

“EPA’s contention that TSCA can reasonably be read to refer to the future use of a product, and disposals associated with such use, only when the product will also be manufactured in the future for that use—and not when the product is no longer manufactured for the relevant use—is without merit. TSCA’s “conditions of use” definition plainly addresses conditions of use of chemical substances that will be used or disposed of in the future, regardless of whether the substances are still manufactured for the particular use.”

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<sup>71</sup> OSH, Ctrs. for Disease Control & Prevention, updated Jan. 13, 2015, <https://www.cdc.gov/niosh/topics/hierarchy/>.

<sup>72</sup> SACC Report on 1,4-dioxane and HBCD, at 73.

*Safer Chemicals, Healthy Families v USEPA*, 943 F.3d 397, 425 (9th Cir. 2019).

EPA's April 23 Federal Register notice recognizes that, "as a result of the Ninth Circuit Court of Appeals' decision in *Safer Chemicals, Healthy Families v. U.S. EPA*, 943 F.3d 397, 425 (9th Cir. 2019), EPA will no longer exclude legacy uses or associated disposal from the definition of 'conditions of use.'" <sup>73</sup> The Agency states that, where "intended, known, or reasonably foreseen, these activities will be considered uses and disposal, respectively, within the definition of 'conditions of use.'"

This recognition is not reflected in the draft scopes, however. Nowhere do they indicate that EPA has attempted to identify legacy activities that would be considered TSCA "conditions of use" and included them in its plan for determining exposures and risks. The public should have an opportunity to weigh in on whether EPA has correctly identified all legacy uses and disposal activities, but this is impossible given the Agency's silence on the issue. *For each of the 20 chemicals, EPA must identify ongoing uses of legacy products and associated disposal activities and outline a methodology for assessing their risks.*

### **IX. Discontinued Manufacturing, Processing and Use Activities Comprise TSCA "Conditions of Use" If Their Resumption Is Reasonably Foreseen**

EPA has also interpreted TSCA to exclude discontinued manufacturing, processing and use activities from the definition of "conditions of use" and therefore from the scope of risk evaluations. For example, as described in the asbestos Problem Formulation, EPA is not addressing the risks of a long list of industrial and construction materials containing asbestos that are no longer active commercial products.<sup>74</sup> Similarly, EPA is not evaluating the risks of domestic production of HBCD, which recently ceased, along with a host of recently discontinued uses.<sup>75</sup> Because these uses will be outside the scope of EPA's risk evaluations, they will not be subject to an unreasonable risk determination and thus could not be prohibited or restricted under section 6(a). This will open the door to their resumption in the future, notwithstanding the dangers these uses would then pose to workers, consumers and the environment.

The voluntary decisions of some manufacturers to phase out specific uses do not represent formal and legally enforceable commitments and do not tie the hands of these manufacturers in the future. For example, the recent phase-out of previously well-established HBCD uses is most plausibly explained by the regulatory and public scrutiny HBCD has received. This factor could wane in importance in the future, particularly if the final EPA risk evaluation concludes, as the draft does, that HBCD does not present an unreasonable risk to health or the environment.

EPA provides no justification for its assertion that the TSCA definition of "conditions of use" does not apply to recently discontinued uses. As defined in section 3(4), this term includes not simply intended or known uses but the "circumstances under which a chemical substance is . . . reasonably foreseen to be manufactured, processed, distributed in commerce, used or disposed of." It is clearly "reasonably

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<sup>73</sup> 85 Fed. Reg. 22734.

<sup>74</sup> Asbestos Problem Formulation at 19-20.

<sup>75</sup> These include use as a chemical intermediate, plastic material and resin manufacturing component in the manufacture of vehicles and other transportation equipment, and as a flame retardant in high impact polystyrene (HIPS) for electrical and electronic appliances, consumer and commercial textiles, floor coverings, adhesives, coatings, children's products including toys and car seats, and furniture. HBCD Risk Evaluation at, at 31, 39; HBCD Problem Formulation, at 24-26.



foreseen” that long-standing and significant uses of a chemical that have been phased out may re-enter commerce in the absence of any legal restriction. The goals of TSCA would be defeated if manufacturers of unsafe chemicals could avoid scrutiny simply by ceasing production for specific uses before EPA completes a risk evaluation of those uses and then later re-entering the marketplace free from any restriction or determination of unreasonable risk. This scenario is particularly troubling where the voluntary product phase-out is likely in response to agency risk concerns and intended to avoid the consequences of an adverse risk finding and subsequent regulatory action.<sup>76</sup>

Although the 2016 TSCA amendments removed the phrase “will present” from section 6(a), the statement of Democratic sponsors at the time of enactment makes clear that this change –

“...does not reflect an intent on the part of Congressional negotiators to remove EPA’s authority to consider future or reasonably anticipated risks in evaluating whether a chemical substance or mixture presents an unreasonable risk to health or the environment. In fact, a new definition added to TSCA explicitly provides such authority and a mandate for EPA to consider conditions of use that are not currently known or intended but can be anticipated to occur . . .”<sup>77</sup>

For example, resumption of a discontinued use can be “reasonably anticipated” if the use fills an important commercial need, the chemical offers favorable properties in comparison with substitutes and the use is continuing outside the US.

*In the upcoming risk evaluations, EPA should treat recently discontinued manufacturing, processing and use activities as “conditions of use” based on the presumption that their reintroduction into commerce is “reasonably foreseeable.” These activities should then be assessed to determine whether they present unreasonable risks of injury and, if so, should be banned or restricted under section 6(a).*

#### **X. EPA Should Establish a Comprehensive Process for Obtaining Toxicological, Use and Exposure Data from Industry on the 20 High-Priority Chemicals**

The 20 scopes do not describe additional steps EPA plans to take to obtain toxicological, use and exposure data that are not available in public information sources. This is unfortunate in light of the paucity of information EPA used in the first 10 evaluations.

The SACC has been highly critical of the adequacy of the information EPA used to assess exposure in its these evaluations. As stated in its report on the 1,4-dioxane draft:<sup>78</sup>

“EPA’s characterization of **occupational inhalation exposure** . . . is **not** adequately supported in this draft Evaluation. The information used to evaluate worker exposure was generally lacking in

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<sup>76</sup> In the case of asbestos, EPA promulgated a significant new use rule (SNUR) requiring notification of EPA in advance of the reintroduction of certain discontinued asbestos-containing products. 84 FR 17345 (April 25, 2019). However, SNURs have drawbacks compared to risk evaluations and rulemaking under section 6. SNURs do not include findings of unreasonable risk. They are also fundamentally notification requirements. The activities they define as “significant new uses” are not prohibited. Companies seeking to conduct these activities must notify EPA at least 90 days before initiating them. The Agency can then determine that the notified uses may or do present an unreasonable risk and should be restricted using EPA’s authorities under section 5(e) or section 5(f). However, EPA has discretion under these provisions and may or may not take regulatory action.

<sup>77</sup> Cong. Record – Senate 3515 (June 7, 2016).

<sup>78</sup> SACC Report on 1,4-dioxane and HBCD, at 21.

its ability to present a coherent picture of this critical element of risk. Reliance on meager air monitoring data that were presented without context failed to provide the needed confidence that exposures were being reasonably evaluated” (emphasis in original).

According to its PV29 report, the SACC “considered EPA’s characterization of Environmental Releases and Exposures . . . as cursory and dependent upon sweeping generalizations that are often unsubstantiated.”<sup>79</sup> Regarding its occupational exposure assessment, SACC urged EPA to “clearly acknowledge that there are few data to support a confident conclusion that workers would not be exposed” to PV29 and “recommended that the Agency obtain and incorporate into the Evaluation better data and documentation from the manufacturer on conditions of use, exposures, and potential for worker exposures.”<sup>80</sup> The SACC concluded that:<sup>81</sup>

“Despite the compound having been in manufacture for decades, the Committee could find no basic information on the number of exposed workers and whether medical monitoring has historically been conducted. Implicit in the Evaluation is that “absence of evidence is evidence of absence.” The Committee could not determine whether the population size or level of attentiveness were sufficient to have revealed health effects even if they exist. No evidence was provided to indicate that EPA queried other Federal or state OSHAs for information on PV29 or requested occupational hygiene or environmental release-related data from the manufacturer that are typically collected and archived.”

The SACC findings underscore the inadequacy of EPA’s reliance on voluntary industry submissions that are often unrepresentative, incomplete, and poorly documented and thus insufficient to fill large gaps in EPA’s understanding of use and exposure. Industry is likely in possession of unpublished toxicology and human health studies and possesses considerable information on occupational exposure and environmental release that is not generally available to EPA. But EPA’s haphazard information collection process offers no assurance that it will obtain the great bulk of this information. Thus, EPA must establish a comprehensive process to obtain information from industry on workplace exposure, environmental release, chemical fate and toxicity for risk evaluation chemicals. This process must be implemented immediately for the 20 high-priority chemicals. Otherwise, risk evaluations on these chemicals will have the same information gaps as the first 10 evaluations.

*We recommend that, for each of the 20 high-priority chemicals, EPA issue an information request to all manufacturers and processors specifying the toxicological, use and exposure information necessary for upcoming risk evaluations, The Agency should develop a standardized format for submitting this information. Because industry may not fully comply with this voluntary request, EPA should backstop it with subpoenas under TSCA section 11 where necessary. Use of the subpoena authority can obtain information on an expedited timeframe that accommodates TSCA risk evaluation deadlines*

To support future risk evaluations, EPA should add all new high-priority chemicals to its TSCA section 8(d) rule (40 CFR Part 716). This rule requires manufacturers, processors and distributors to report “health and safety studies” on listed chemicals. The rule defines “health and safety study” broadly to include

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<sup>79</sup> SACC Report on PV29, at 16.

<sup>80</sup> Id at 20

<sup>81</sup> Id at 35.

studies of health and environmental effects as well as of human exposure and environmental release.<sup>82</sup> Reporting under the rule would be particularly useful to capture information on exposure and release: the definition of health and safety study explicitly includes “[a]ssessments of human and environmental exposure, including workplace exposure, and impacts of a particular chemical substance or mixture on the environment, including surveys, tests, and studies.” and “[m]onitoring data, when they have been aggregated and analyzed to measure the exposure of humans or the environment to a chemical substance or mixture.”<sup>83</sup> This is a critical area of analysis in TSCA risk evaluations and one where EPA may receive limited and undocumented information unless it uses its reporting authority.

Another essential step for future evaluations is to expand the scope of CDR reporting (40 CFR Part 711) for high-priority listing candidates. Because EPA needs more comprehensive use and exposure information on these chemicals to support risk evaluations, the reporting threshold should be lowered from 25,000 pounds at any single site to 2,500 pounds or even less for particular chemicals. For high-priority listing candidates, EPA should also add a processor reporting component to the CDR rule so it captures information on downstream conditions of use and exposure. Unfortunately, EPA rejected our recommendation to make these changes as part of the recent CDR revisions and thus they will not be implemented for the 2020 reporting cycle.<sup>84</sup> We strongly recommend including in revisions for future reporting cycles.

#### **XI. EPA Should Use a Benchmark of $1 \times 10^{-6}$ to Determine Whether Cancer Risks to Workers and Consumers are Unreasonable under TSCA**

In its first 10 evaluations, EPA used a cancer risk of  $1 \times 10^{-4}$  as the benchmark for determining unreasonable risk to workers. This contrasts with the more protective benchmark  $1 \times 10^{-6}$  EPA has used for consumers. The SACC has stated that EPA has not provided an “adequate explanation and justification” for this lower level of protection for workers.<sup>85</sup> The scopes are silent on how EPA will define unreasonable cancer risk in the next 20 evaluations.

The draft TCE evaluation describes how EPA has previously approached cancer risks under the laws it administers as follows:<sup>86</sup>

“Standard cancer benchmarks used by EPA and other regulatory agencies are an increased cancer risk above benchmarks ranging from 1 in 1,000,000 to 1 in 10,000 (i.e.,  $1 \times 10^{-6}$  to  $1 \times 10^{-4}$ ) depending on the subpopulation exposed. Generally, EPA considers  $1 \times 10^{-6}$  to  $1 \times 10^{-4}$  as the appropriate benchmark for the general population, consumer users, and non-occupational PESS.”

Thus, as EPA notes, in applying CAA “residual risk” standards for air toxics, it uses a two-step approach that includes a “presumptive limit on maximum individual lifetime [cancer] risk (MIR) of approximately 1 in 10 thousand” and consideration of whether emissions standards provide an ample margin of safety to

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<sup>82</sup> 40 CFR § 716.3.

<sup>83</sup> Id. For example, section 8(d) requirements would encompass exposure monitoring data collected by employers – whether required by OSHA or developed voluntarily – which must be retained for 30 years under OSHA regulations. 29 C.F.R. 1910.1020(D)(7)(ii).

<sup>84</sup> 85 Fed. Reg. 20122 (April 9, 2020).

<sup>85</sup> SACC 1,4-Dioxane and HBCD Report at 23.

<sup>86</sup> TCE Risk Evaluation at 376.

protect public health “in consideration of all health information, including the number of persons at risk levels higher than approximately 1 in 1 million, as well as other relevant factors.”<sup>87</sup> EPA likewise uses a risk range of  $1 \times 10^{-4}$  to  $1 \times 10^{-6}$  to set cleanup goals at CERCLA hazardous waste sites.<sup>88</sup> In fact, EPA has used a  $1 \times 10^{-6}$  cancer standard to evaluate risk and determine CERCLA remedies at sites where carcinogens are present.<sup>89</sup>

Despite reserving discretion to make case-by-case decisions within this range, EPA has identified  $1 \times 10^{-6}$  as its goal for public health protection. Thus, in its air toxics standard for radionuclides, EPA stressed that it “should reduce risks to less than  $1 \times 10^{-6}$  for as many exposed people as reasonably possible.”<sup>90</sup> Similarly, in guidance for setting health-based water quality criteria under the Clean Water Act (CWA), EPA explained that it:<sup>91</sup>

“intends to use the  $10^{-6}$  risk level, which the Agency believes reflects an appropriate risk for the general population. EPA’s program office guidance and regulatory actions have evolved in recent years to target a  $10^{-6}$  risk level as an appropriate risk for the general population. EPA has recently reviewed the policies and regulatory language of other Agency mandates (e.g., the Clean Air Act Amendments of 1990, the Food Quality Protection Act) and believes the target of a  $10^{-6}$  risk level is consistent with Agency-wide practice.”

In the CERCLA program, EPA guidance provides that, while “remedies should reduce the risks from carcinogenic contaminants such that the excess cumulative individual lifetime cancer risk for site-related exposures falls between  $10^{-4}$  and  $10^{-6}$ ,” the Agency “has expressed a preference for cleanups achieving the more protective end of the risk range (i.e.,  $10^{-6}$ ).”<sup>92</sup>

However, EPA’s 10 risk evaluations deviate from this approach for worker exposures, maintaining that risks smaller than  $1 \times 10^{-4}$  will be considered “reasonable” under TSCA because, “consistent with case law and 2017 NIOSH guidance,” this risk level applies to “industrial and commercial work environments subject to Occupational Safety and Health Act (OSHA) requirements.”<sup>93</sup>

OSHA precedent does not control decision-making under TSCA, a separate law with different purposes and wording. The cancer risk threshold applied by NIOSH and OSHA is rooted in the Supreme Court’s *Benzene* decision, which interpreted the OSH Act as requiring “a threshold finding that a place of employment is unsafe—in the sense that *significant* risks are present and can be eliminated or lessened by a change in practices.” *Indus. Union Dep’t, AFL-CIO v. API*, 448 U.S. 607, 642 (1980) (emphasis added). The Court grounded this interpretation in an examination of the language, structure and legislative history of the OSH Act.

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<sup>87</sup> 54 Fed. Reg. 38044, 38045 (September 14, 1989).

<sup>88</sup> EPA, *Rules of Thumb For Superfund Remedy Selection*, August 1997, found at <https://semspub.epa.gov/work/HQ/174931.pdf>. (CERCLA Guidance).

<sup>89</sup> See Record of Decision, Bofors Nobel Superfund Site at 12 (Sept. 1990) (methylene chloride).

<sup>90</sup> 54 Fed. Reg. 51654, 51686 (Dec. 15, 1989).

<sup>91</sup> EPA, *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health* p. 2-6 (2000), <https://www.epa.gov/sites/production/files/2018-10/documents/methodology-wqc-protection-hh-2000.pdf>.

<sup>92</sup> CERCLA Guidance at 9.

<sup>93</sup> TCE Risk Evaluation at 376.

TSCA, by contrast, is anchored in the concept of “unreasonable risk” (a term that implies a lower risk threshold than the OSH Act concept of “significant risk”). No provision of TSCA provides that workers should receive less protection than other exposed subpopulations or that well-established EPA benchmarks for unacceptable cancer risks would be inapplicable to workers. Indeed, workers are specifically identified as a “potentially exposed or susceptible subpopulation” that EPA is required to protect in section 3(12) of TSCA, indicating that Congress was particularly concerned by the levels of toxic chemicals in the workplace and the special vulnerability of some employee populations to their adverse health effects. Moreover, contrary to EPA’s claims, NIOSH does not recommend that workers be left exposed to a 1 in 10,000 risk of cancer. Instead, the NIOSH guidance cited by EPA states “for most carcinogens, there is no known safe level of exposure ... [and] NIOSH will continue to recommend that employers reduce worker exposure to occupational carcinogens as much as possible through the hierarchy of controls, most importantly elimination or substitution of other chemicals that are known to be less hazardous ...”<sup>94</sup>

In contrast to the OSH Act, TSCA provides protections to workers not just from chemical exposure in the workplace but from air emissions and other environmental releases as well as exposures to consumer products. As discussed above, while draft EPA risk evaluations have assessed worker exposure in isolation from other pathways, this approach understates risks; instead, EPA should combine exposures from all relevant pathways and determine an aggregate risk reflecting the contribution of each source. This is a further reason why setting a higher cancer risk threshold for workers than other populations is unjustified under TSCA.

*In the upcoming 20 risk evaluations, EPA must apply to workers the same benchmarks for determining unreasonable cancer risks that it uses for other populations. For all exposed populations, EPA should consider any increased cancer risk exceeding  $1 \times 10^{-6}$  to be unreasonable and to require action under TSCA.*

## **XII. EPA Should Address Chronic Health Risks to Consumers**

Routinely, the initial 10 evaluations have only addressed acute exposure scenarios for consumers and disregarded evidence of repeated exposure and chronic health risks. As we have explained in our comments, this approach is flawed in two ways.

First, as we showed in our comments on the TCE and PCE evaluations, EPA has failed to consider indoor air concentrations of these chemicals (some at extremely high levels) which indicate that consumer exposure is not episodic but continuous. It has also failed to consider the likelihood of chronic exposure from consumption of contaminated drinking water and long-term environmental exposure from the presence of chemicals in ambient air and at waste sites. For PCE and other chemicals, detection in human blood, urine and breath samples and in human breast milk provides further evidence of long-term continuous exposure.

Second, for chemicals like TCE, PCE, methylene chloride and NMP that are found in consumer products, EPA has assumed one-time or very intermittent product use. However, most consumer products containing these chemicals are used regularly by hobbyists, household cleaners, home renovators, artists,

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<sup>94</sup> Christine Whittaker et al., NIOSH, Current Intelligence Bull. 68, NIOSH Chemical Carcinogen Policy 20 (July 2017), <https://www.cdc.gov/niosh/docs/2017-100/pdf/2017-100.pdf>.

and do-it-yourself vehicle mechanics. Moreover, while EPA's draft assumes use of a single product type during a day, many consumers likely use different products containing these chemicals on the same day or over time. Thus, even apart from other evidence that consumers have chronic exposure, intensive users of consumer products are plainly exposed to the chemicals on a recurring basis.

In its report on the TCE evaluation, the SACC "disagreed with EPA's decision not to characterize chronic risks for consumers." As it explained:<sup>95</sup>

"Several Committee members suggested that some consumers are likely to be exposed more frequently and more pervasively to emissions from these products than indicated by the Westat survey data (U.S. EPA, 1987). Firstly, certain high-exposed consumers (hobbyists, home businesses, etc.) are likely to use more than one trichloroethylene-containing product on the same day and/or multiple and consecutive days. Secondly, the Westat survey was unlikely to capture the true distribution of use frequency for high-end users (i.e., oversampling these subpopulations would have been required to obtain a reliable estimate of use patterns for these individuals). Thirdly, it is likely that contributions to indoor air concentrations (and, therefore, exposures) persist for longer periods of time than assumed by EPA from sources such as carpet spot cleaners and fabric sprays (see also, for example, Doucette et al., 2018; Gorder and Dettenmaier, 2011)"

*These considerations are relevant to other chemicals with similar consumer use profiles. For chemicals in the group of 20 high-priority substances with such profiles, EPA should base its risk determinations on the assumption of chronic consumer exposure and assess whether consumers are at risk of chronic health effects.*

### **XIII. EPA Should Not Rely on Studies Conducted by Manufacturers Outside the US Without Obtaining and Disclosing the Full Studies and All Underlying Data**

Some of the EPA draft evaluations rely on industry-generated studies conducted outside the US under the European Union (EU) Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) program. These studies are described in "robust summaries" made available by the European Chemical Agency (ECHA). These summaries are prepared by industry and are not actual study reports. While ECHA posts these summaries on its website, it does not evaluate either the summaries or underlying studies for quality and reliability. Thus, neither ECHA nor any other government agency has vouched for the accuracy of the summaries, validity of the study findings or methods by which the studies were conducted.

Before determining that a chemical does not present an unreasonable risk for a particular endpoint based on the summaries, it is critical that EPA obtain and independently evaluate the underlying studies supporting this determination. Moreover, all data, including ECHA robust summaries, must be subject to a credible and peer-reviewed systematic review process in order to assess their reliability and risk of bias.

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<sup>95</sup> TSCA Science Advisory Committee on Chemicals Meeting Minutes and Final Report No. 2020-4 Peer Review for EPA Draft Risk Evaluation for Trichloroethylene (TCE), June 1, 2020, at 58.

EPA should also adopt a uniform policy of treating REACH-generated studies and underlying data used in a risk evaluation as “health and safety studies submitted under [TSCA]” for purposes of section 14(b)(2)(A), which expressly prohibits EPA from withholding such studies as confidential business information (CBI). As this provision recognizes, disclosure of the data underlying the Agency’s risk evaluations will assure the public a meaningful opportunity to comment on the scientific basis for EPA’s proposed determinations of risk.

Unfortunately, EPA did not follow this approach for REACH studies that it relied on in its PV29 evaluation. Because the data owners demanded confidentiality, EPA initially disclosed to the public only ECHA summaries but not actual studies. After strong objections to this lack of transparency by our groups and members of Congress, EPA belatedly released some, but not all, of the studies and continued to withhold critical data claimed by industry to comprise CBI. These actions violated TSCA and undermined the public’s ability to comment on the draft PV29 evaluation.<sup>96</sup>

Equally troubling is how EPA’s used ECHA summaries to evaluate the environmental effects of 1-BP. EPA attempted to obtain the full ECHA studies with no success. Nonetheless, it still “decided to use the experimental data . . . [g]iven that the ECHA environmental test data results are in the public domain” while admitting that the “full studies summarized in ECHA have not been evaluated for data quality, according to [the EPA] systematic review criteria.”<sup>97</sup> Other than the ECHA studies, EPA acknowledged that it had “only a single acute fish toxicity study identified during the literature search process ((Geiger et al., 1988)).” Yet EPA justified using the ECHA summaries on the basis of a “qualitative” evaluation of the reported findings.”<sup>98</sup> Needless to say, since EPA never obtained or reviewed the ECHA studies, the public had no opportunity to comment on the full basis for EPA’s proposed determination that 1-BP does not present an unreasonable risk to the environment.

On the other hand, EPA appropriately refused to rely on industry-sponsored reproductive toxicity studies on N-methyl Pyrrolidone (NMP) which industry had claimed confidential. In its December 11, 2019 letter to NMP Producers Group, EPA explained:<sup>99</sup>

“EPA has reviewed summaries of these two unpublished two-generation studies (RIVM, 2013; OECD, 2007b) but data in these reports are not publicly available and EPA does not have

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<sup>96</sup> In its PV29 Report, the SACC expressed concern about basing its reviews on data withheld from the public:

“It is possible that in the future, CBI data could turn out to be the crucial information needed to confidently estimate the dose response function needed to establish a benchmark dose (BMD) and benchmark dose level (BMDL). Without these being public, the Committee would not be able to publicly publish their analysis, and in the public report the BMD and BMDL estimates would appear without justification (or with analysis text redacted). The Committee found this situation uncomfortable and very un-scientific. This said, the Committee understands that in this situation, these data would be deemed as critically important and EPA would negotiate with the data owner for public release.”

SACC Report on PV29 at 59.

<sup>97</sup> Risk Evaluation on 1-BP at 141.

<sup>98</sup> Id.

<sup>99</sup> Letter from Mark A. Hartman, EPA, to Kathleen Roberts, NMP Producers Group, re: EPA Request for Submission of NMP Study Reports (Dec. 11, 2019), <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2019-0236-0043>

complete access to the full reports. EPA is therefore unable to evaluate study quality or incorporate quantitative information from these studies into the dose-response assessment.”

EPA also recognized that “the studies in question would be subject to limitations on protections from disclosure under TSCA section 14 . . . . Irrespective of whether the group submits the studies to EPA on its own accord, or EPA obtains the studies in some other manner, a CBI claim under TSCA for the health and safety information contained in these studies is likely to be denied in light of the limitations in TSCA 14(b)(2).”

*For the 20 high-priority substances, EPA should only rely on actual studies, not ECHA summaries, to support determinations of no unreasonable risk and should follow a uniform policy of disclosing these studies to the public as required by TSCA. If companies will not agree to disclosure of the studies, EPA should require testing under section 4 of TSCA so there is no doubt about public access to the data under section 14 of TSCA.*

#### **XIV. EPA Should Abandon the Poorly Defined Category of Occupational Non-Users (ONUs) In Favor of a More Realistic Framework for Exposure Analysis**

A persistent area of concern in the first 10 evaluations is EPA’s differentiation between directly exposed workers and the category of “occupational non-users” (ONUs), which EPA generally treats as having lower exposure and risk. EPA defines occupational users as workers that directly handle a chemical and occupational non-users (ONUs) as workers who do not directly handle the chemical but perform work in an area where PCE is present.<sup>100</sup> (p. 29, footnote 1). EPA’s methodology of dividing occupations into whether the worker’s job description includes direct contact with the chemical is a false dichotomy, and inconsistent with the state of the science for industrial exposure assessment. In fact, the term “ONU” or “occupational non-user” does not appear on a search of PubMed – the NIH medical library of over 10,000 scientific journals – or on a ‘google’ search, other than in EPA TSCA documents.

Instead, experts make a more meaningful distinction between near-field and far-field exposure, and divide jobs by whether they may be near or far from the source of exposure.<sup>101</sup> There are existing principles of exposure assessment that allows the assessor to evaluate exposures to the near and far field workers (see citations for examples).<sup>102</sup> The near-field/far-field distinction is the state of the science

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<sup>100</sup> See, e.g., EPA risk evaluation for perchloroethylene (TCE) at 29, FN1.

<sup>101</sup> LeBlanc M, Allen JG, Herrick RF, Stewart JH. Comparison of the near field/far field model and the advanced reach tool (ART) model V1.5: exposure estimates to benzene during parts washing with mineral spirits. *Int J Hyg Environ Health*. 2018 Mar;221(2):231-238. doi: 10.1016/j.ijheh.2017.10.016. Epub 2017 Oct 31.

Keil CB, Nicas M. Predicting room vapor concentrations due to spills of organic solvents. *AIHA J (Fairfax, Va)*. 2003 Jul-Aug;64(4):445-54. PubMed PMID: 12908858.

Lee EG, Lamb J, Savic N, Basinas I, Gasic B, Jung C, Kashon ML, Kim J, Tischer M, van Tongeren M, Vernez D, Harper M. Evaluation of Exposure Assessment Tools under REACH: Part I-Tier 1 Tools. *Ann Work Expo Health*. 2019 Feb 16;63(2):218-229. doi: 10.1093/annweh/wxy091.

<sup>102</sup> LeBlanc M, Allen JG, Herrick RF, Stewart JH. Comparison of the near field/far field model and the advanced reach tool (ART) model V1.5: exposure estimates to benzene during parts washing with mineral spirits. *Int J Hyg Environ Health*. 2018 Mar;221(2):231-238. doi: 10.1016/j.ijheh.2017.10.016. Epub 2017 Oct 31.

Keil CB, Nicas M. Predicting room vapor concentrations due to spills of organic solvents. *AIHA J (Fairfax, Va)*. 2003 Jul-Aug;64(4):445-54. PubMed PMID: 12908858.



because it has logic – workers whose job brings them near to the chemical are considered to share the same exposures as other near-field workers, whether or not they are specifically tasked with directly contacting the material.

In fact, it is often the case that the workers tasked with directly working with the chemical are not the highest exposed, because they are the most protected, working in a fume hood or behind a shield, or with proper fitted and functioning PPE. It may be the other workers in the near-field that are not necessarily tasked with directly contacting the chemical that may be at increased risk – workers that EPA classifies as ONUs. For example, janitorial staff that clean up spills, workers that repair leaks, lab workers in neighboring stations, administrative staff in nearby open offices, truck drivers that transport the chemical if there is an accidental spill or leak, etc. EPA does not expect these workers to handle the chemical as part of the normal course of their workday, but the reality – which EPA ignores – is that they perform work in an area near where the chemical is present. That is, their exposure is that of ‘near-field workers’, but EPA wrongly classifies them in its ONU category, for which EPA assigns ‘far-field’ exposures. Using this classification, EPA then applies risk-lowering assumptions – i.e. that there is no dermal exposure and that central tendency exposure estimates should be used for risk determinations – that are likely incorrect for many near-field workers.

The SACC recognized this in its report on the methylene chloride evaluation: “The Agency should consider exploring different categories of ONUs (e.g., workers who do not handle methylene chloride directly, but whose job requires them to be in the same area as users; cleaning staff that can be exposed after hours to residues present in the work area, or office/managerial workers that could be incidentally exposed when visiting a work area but are not at risk from exposure routinely) because their potential exposure risk likely varies.”<sup>103</sup> The SACC further explained that:<sup>104</sup>

“ONUs are likely a heterogeneous population of workers, and some could be exposed more than just occasionally to high concentrations. This possibility should be included explicitly as a source of uncertainty. As recommended earlier, EPA should consider the different categories of ONUs potentially at risk.”

Real world examples of near-field workers who experience elevated exposures to solvents (wrongly classified by EPA as ‘far-field’ ONUs) are provided in the comments of the Toxics Use Reduction Institute (TURI) on the methylene chloride evaluation. For example:<sup>105</sup>

“... occupational non-users can have levels of exposure similar to that of occupational users. Concerns about this category of workers are exacerbated by the fact that they may work in close proximity to methylene chloride yet may not be provided with personal protective equipment

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Lee EG, Lamb J, Savic N, Basinas I, Gasic B, Jung C, Kashon ML, Kim J, Tischer M, van Tongeren M, Vernez D, Harper M. Evaluation of Exposure Assessment Tools under REACH: Part I-Tier 1 Tools. *Ann Work Expo Health*. 2019 Feb 16;63(2):218-229. doi: 10.1093/annweh/wxy091.

<sup>103</sup> SACC report on methylene chloride risk evaluation, at. 31

<sup>104</sup> Id at 44.

<sup>105</sup> Comments of the Massachusetts Toxics Use Reduction Institute (TURI) on EPA's Draft Toxic Substances Control Act (TSCA) Risk Evaluation: Methylene chloride. December 2019. Docket Number EPA-HQ-OPPT-2019-0437-0070. Available at <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2019-0437-0070>

(PPE). For example, at one of the furniture refinishing facilities visited by program staff, paint stripping was performed in an open room with work areas separated by plastic lining dividers. In addition, a break room was located in close proximity to the work stations.”

TURI program staff also emphasize that they “have observed that an individual using methylene chloride directly may be equipped with PPE, while an individual doing another task, such as sanding, may be standing close to the methylene chloride user separated only by a plastic barrier. This individual generally lacks respiratory protection.”<sup>106</sup>

TURI program staff warn that they have, “also heard anecdotally about methylene chloride being used outside a fume hood in research and educational environments.”<sup>107</sup>

TURI’s observations are relevant to several other risk evaluation chemicals.

*Thus, a simplistic categorization of all non-production workers as ONUs who have uniformly lower levels of exposure is unjustified and understates risks to many workers. EPA should replace this broad category with more refined groupings of near- and far-field workers and, within each grouping, conduct a more detailed exposure analysis which reflects job responsibilities and exposure scenarios specific to different types of workers and chemicals. Implementing this approach will require EPA to undertake additional outreach to obtain “reasonably available” information – as required by TSCA -- about real world near and far-field exposure scenarios for specific chemicals.*

## **XV. EPA Cannot Exclude Conditions of Use from Risk Evaluations**

In its initial 10 evaluations, EPA excluded undisputed conditions of use based on the claim that it had discretion under TSCA to pick and choose the conditions it would evaluate and that its risk evaluation framework rule authorized it to exercise such discretion. Thus, in the draft risk evaluation for 1,4-dioxane, EPA chose not to address the risks it posed as a constituent of consumer products because it was present in these products as a byproduct and EPA planned to address these byproduct uses in a future evaluation of another class of compounds. Similar, EPA declined to evaluate all consumer product uses of carbon tetrachloride on the ground that the risks of these uses could be deemed *de minimis* without any further analysis. Our groups’ position has consistently been that TSCA unambiguously direct EPA in address all a chemical’s conditions of use in its evaluations and these and other exclusions are unlawful.

The Ninth Circuit’s decision in *Safer Chemicals v. United States EPA*, 943 F.3d 397 (9th Cir. 2019) holds that EPA’s risk evaluation framework rule does not grant the agency discretion to exclude conditions of use from the scope of risk evaluations. The Court found that the Rule was “not ambiguous” on this point. *Safer Chems.*, 943 F.3d at 418. Petitioners challenged the Rule as granting EPA discretion to exclude conditions of use from risk evaluations. The Court ruled that “the challenged provisions unambiguously do not grant EPA the discretion Petitioners contend.” *Id.* at 419.

“The phrase “the conditions of use within the scope of” an evaluation simply refers to the conditions of use that are applicable to any particular substance—and that therefore are included in the scope of that substance’s evaluation—without excluding any conditions of use in forming that list. Likewise, the phrase that refers to the conditions of use “that the EPA plans to consider”

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<sup>106</sup> *Id.*

<sup>107</sup> *Id.*

simply refers to the Agency’s role in determining what the conditions of use are for a particular substance.”

*Id.* While the preamble to the Rule stated that EPA did retain discretion to exclude conditions of use, the Court found that “because the scope provisions are not ambiguous on their face, reference to the preamble discussion would be improper.” *Id.* at 420. EPA must thus comply with the final regulations promulgated in the Rule as interpreted by the Court. See 15 U.S.C. § 2605(b)(4)(C) (requiring EPA to conduct risk evaluations “in accordance with [the Rule]”).

Accordingly, EPA should address all conditions of use in the upcoming 20 evaluations.

#### **XVI. EPA Should Not Revisit Definitive Findings in IRIS Assessments Unless There Are New Data That Inform Its Evaluation of the Weight of the Evidence**

At this time, 14 of the 20 high-priority candidates have been assessed under the EPA Integrated Risk Information System (IRIS).<sup>108</sup> 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 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). The IRIS program recently received a favorable review from the NAS.<sup>109</sup>

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 receive substantial weight as a previous statement by the Agency of the “best available science.” a requirement under section 26(h) of TSCA for all science-based decisions under the law. EPA should modify IRIS findings only where there is a strong justification, such as the availability of new data that inform the weight of the scientific evidence. Such additional data should be reviewed by the TSCA program, in consultation with IRIS scientists, to assess whether they might inform the determination of the weight of the evidence for the relevant endpoints. This review should be conducted using a peer-reviewed systematic review methodology as described above, not the TSCA systematic review method. Where the TSCA program concludes that a new weight of evidence determination is warranted based on new data or other considerations, the draft evaluation should explain why EPA is revisiting previous IRIS conclusions.

#### **XVII. EPA’s Risk Evaluation for Formaldehyde Under TSCA Should be Based on the Draft IRIS Assessment and This Assessment should be Immediately Released for Public Comment and Peer Review**

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<sup>108</sup> The 14 chemicals with IRIS assessments are: 1,4-Dichlorobenzene (1,4-dichlorobenzene); 1,2-Dichloroethane; trans-1,2-Dichloroethylene; o-Dichlorobenzene; 1,1,2-Trichloroethane; 1,2-Dichloropropane; 1,1-Dichloroethane; Dibutyl phthalate (DBP) (1,2-Benzene- dicarboxylic acid, 1,2- dibutyl ester); Butyl benzyl phthalate (BBP) - 1,2-Benzene- dicarboxylic acid, 1- butyl 2(phenylmethyl) ester; Di-ethylhexyl phthalate (DEHP) - (1,2-Benzene- dicarboxylic acid, 1,2- bis(2-ethylhexyl) ester); Ethylene dibromide; 1,3-Butadiene; Formaldehyde; and Phthalic anhydride.

<sup>109</sup> National Academies of Sciences, Engineering, and Medicine. 2018. Progress Toward Transforming the Integrated Risk Information System (IRIS) Program: A 2018 Evaluation. Washington, DC: The National Academies Press. <https://doi.org/10.17226/25086>.

Formaldehyde, one of the 20 high-priority chemicals, is the subject of a draft IRIS assessment that has not been released for public comment and peer review. EPA Assistant Administrator Dunn has stated that “the work done for IRIS will inform the TSCA process” on formaldehyde but has not affirmed that TSCA staff will rely on this work or that the Agency will publicly release either the IRIS draft or OPPT’s analysis of the key IRIS conclusions.<sup>110</sup> Continued suppression of the draft IRIS assessment would depart from the Assistant Administrator’s declaration that “[e]nsuring greater public transparency of chemical information is a top priority, and the EPA is actively working to achieve this across all areas of TSCA implementation.”<sup>111</sup>

Formaldehyde is a chemical of high concern. It has been linked to several types of cancer and other adverse health effects and has multiple uses with the potential for widespread consumer and worker exposure. Protecting public health from formaldehyde exposure has been critical to the missions of several EPA offices for many years. To meet this agency-wide need, formaldehyde has been a priority of the IRIS program since 1997 and IRIS scientists have devoted thousands of hours to reviewing and analyzing its voluminous data-base.

An earlier IRIS assessment of formaldehyde was reviewed by the NAS in 2011. Following that review, EPA began revising the assessment in response to the NAS recommendations. A new draft assessment was reportedly completed nearly two years ago and reaffirmed previous conclusions by IRIS and other expert bodies that exposure to formaldehyde is causally linked to nasal cancers and leukemias, as well as other adverse effects. EPA then prepared to release the draft for public comment and peer review by the NAS. However, these efforts were blocked by senior EPA management and work on the assessment was abandoned. A March 4 General Accounting Office (GAO) report raised concerns about this decision,<sup>112</sup> yet EPA has never explained why it opposes public comment and peer review of a definitive draft report by its leading scientists that is directly relevant to its public health protection responsibilities under TSCA.

Continued suppression of the draft IRIS report would enable the TSCA program to produce a more favorable assessment of formaldehyde’s health effects without informing the public of the IRIS determinations and how and why OPPT has reached different conclusions. This would be contrary to EPA’s responsibilities under TSCA Section 26(h) and (i) to use all relevant scientific information “in a manner consistent with the best available science” and to base its decisions under TSCA section 6 on “the weight of the scientific evidence.” Should the TSCA risk evaluation include weaker findings of risk than the IRIS draft, the credibility of the TSCA program would be irreparably damaged and its risk determinations for this chemical would be legally compromised.

Rather than pursuing this untenable course, EPA should immediately release the draft IRIS assessment for public comment and submit it to the NAS for peer review. If TSCA scientists have questions or concerns about the scientific basis for the IRIS findings, they can be framed for public comment and reflected in the charge for NAS review. The public comments and NAS guidance that EPA receives could then inform how it uses the IRIS determinations in the TSCA risk evaluation. This would avoid an open-ended reanalysis of the formaldehyde database that fails to leverage the extensive work IRIS has already done. If these steps

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<sup>110</sup> <https://www.epa.gov/newsreleases/reaching-another-tsca-milestone-epa-identifies-40-chemicals-prioritize-risk-evaluation>

<sup>111</sup> <https://chemicalwatch.com/register/result?o=76748&layout=main&productID=1>

<sup>112</sup> <https://www.gao.gov/assets/700/697212.pdf>

occur early in the risk evaluation process, they will conserve EPA resources and enhance the credibility of its ultimate evaluation – which otherwise will be fatally compromised by persistent questions about EPA’s commitment to transparency and scientific integrity.

### **XVIII. EPA Should Combine the Five Phthalates Listed as High-Priority with the Two Phthalates for Which Industry Has Requested Risk Evaluations into a Single Category Subject to a Cumulative Risk Assessment**

Five of the high-priority substances are ortho-phthalates: Butyl benzyl phthalate (BBP), Dibutyl phthalate (DBP), Dicyclohexyl phthalate, Di-ethylhexyl phthalate (DEHP) and Di-isobutyl phthalate (DIBP). In addition, EPA has granted manufacturer requests to conduct TSCA risk evaluations on two additional phthalates, diisodecyl phthalate (DIDP) and diisononyl phthalate (DINP).<sup>113,114</sup>

Phthalates are widely found in food, everyday products, and air and dust in the indoor environment. The U.S. population, including pregnant women and children, is “co-exposed to many phthalates simultaneously,” and these phthalates can “cause a wide range of toxicities.”<sup>115</sup> More than a decade ago, the National Research Council (NRC) reviewed the evidence on phthalates and found that because people are exposed to multiple phthalates at the same time, and phthalates contribute to one or more common adverse health outcomes, “a cumulative risk assessment should be conducted that evaluates the combined effects of exposure.”<sup>116</sup> The NRC further found that “[c]umulative risk assessment based on common adverse outcomes is a feasible and physiologically relevant approach to the evaluation of the multiplicity of human exposures and directly reflects EPA’s mission to protect human health.”<sup>117</sup>

Section 26(c) of TSCA gives EPA authority treat chemicals as a “category” in implementing the law:

“Any action authorized or required to be taken by the Administrator under any provision of this chapter with respect to a chemical substance or mixture may be taken by the Administrator in accordance with that provision with respect to a category of chemical substances or mixtures.”

This section defines “category of chemical substances” as:

“a group of chemical substances the members of which are similar in molecular structure, in physical, chemical, or biological properties, in use, or in mode of entrance into the human body or into the environment, or the members of which are in some other way suitable for classification as such for purposes of this chapter...”

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<sup>113</sup> Exxon Mobil Chemical Company and American Chemistry Council High Phthalates Panel (2019) Manufacturer Request for Risk Evaluation of Diisodecyl Phthalate (DIDP); Docket ID: EPA-HQ-OPPT-2018-0435

<sup>114</sup> Exxon Mobil Chemical Company and American Chemistry Council High Phthalates Panel (2019) Manufacturer Request for Risk Evaluation of Diisononyl Phthalate (DINP); EPA-HQ-OPPT-2018-0436

<sup>115</sup> Gennings, C., Hauser, R., Koch, H. M., Kortenkamp, A., Liroy, P. J., Mirkes, P. E., & Schwetz, B. A. (2014). *Report to the U.S. Consumer Product Safety Commission by the Chronic Hazard Advisory Panel on Phthalates and Phthalate Alternatives*. Retrieved from U.S. Consumer Product Safety Commission website: <http://www.cpsc.gov/PageFiles/169902/CHAP-REPORT-With-Appendices.pdf> pg. 1; pg. 3

<sup>116</sup> National Research Council (U.S.), & Committee on the Health Risks of Phthalates. (2008). *Phthalates and cumulative risk assessment: the task ahead*. Retrieved from <http://site.ebrary.com/id/10274055>

<sup>117</sup> *Id.* pg. 11-12

Since EPA has agreed to conduct manufacturer-requested risk evaluations for DIDP and DINP, it should combine these substances with the five phthalates listed as high-priority and treat all seven phthalates as a “category” under TSCA section 26(c). The seven phthalates merit treatment as a category because they are similar in molecular structure, toxicity, use and exposure.

Creating this category would require EPA to conduct a single cumulative risk evaluation for the seven phthalates. In this evaluation, EPA should address all conditions of use and associated exposures for members of the category. Otherwise, risk will be underestimated for potentially exposed and susceptible subpopulations such as children with exposure to multiple phthalates. To accurately account for real-life risks, EPA needs to aggregate exposures across pathways using its methodologies for aggregate exposure assessment. The contribution to aggregate exposure from non-TSCA-regulated uses of phthalates in food and medical devices should be accounted for so total exposure is not underestimated. These category-wide exposure estimates should then be the basis for determining whether the category as a whole presents an unreasonable risk of injury for those health effects common to category members. Like other chemicals proposed for high-priority listing, the phthalates have data-gaps for health endpoints. To the extent studies can be completed while the risk evaluation is underway, EPA should immediately require testing under section 4 to fill these gaps and strengthen the basis for risk determinations for the category.

### **Conclusion**

We appreciate this opportunity to comment on EPA’s scoping documents for the upcoming risk assessment for the 20 newly listed high priority chemicals.

If you have any questions, please contact Bob Sussman, SCHF counsel, at [bobsussman1@comcast.net](mailto:bobsussman1@comcast.net).

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