UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Comments of Safer Chemicals Healthy Families, Natural Resources Defense Council, and Environmental Health Strategy Center on Proposed High-Priority Substance Designations Under the Toxic Substances Control Act (TSCA)

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Docket No. EPA-HQ-OPPT-2019-0131

Safer Chemicals Healthy Families (SCHF), Natural Resources Defense Council, and Environmental Health Strategy Center submit these comments on the August 23, 2019 proposal by the Environmental Protection Agency (EPA) to designate 20 chemicals as high-priority substances under section 6(b)(1) of the Toxic Substances Control Act (TSCA).[1] 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. They 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.

High-priority designation under section 6(b)(1) of TSCA is the primary tool in the law for selecting chemicals for risk evaluations to determine whether they present unreasonable risks to human health and the environment. Chemicals found to present unreasonable risks in these evaluations must then be banned or otherwise restricted under section 6(a). Section 6(b)(2)(B) of TSCA requires EPA to designate at least 20 high-priority substances within 3.5 years of enactment of the 2016 TSCA amendments—or by December 31, 2019. EPA's proposal would satisfy this obligation.

TSCA sets a low bar for listing chemicals as high priority. Under section 6(b)(1)(B)(i), a substance will qualify as high priority if it "may present an unreasonable risk of injury to health or the environment because of a potential hazard and a potential route of exposure under the conditions of use." Based on the EPA support documents in the docket, the 20 substances proposed for high-priority listing appear to meet this standard.

Once EPA finalizes its proposed listings, the 20 chemicals will enter the risk evaluation process. Our comments address how these risk evaluations should be conducted to comply with the law and assure full protection of public health and the environment. EPA is now proceeding with the first 10 risk evaluations required under TSCA section 6(b)(2)(A). The six draft evaluations released by the Agency to-date raise numerous legal, policy and scientific concerns and do not provide a viable model for future evaluations. Our groups and other commenters have identified several flaws in the draft evaluations. The peer reviews conducted by the independent Science Advisory Committee on Chemicals (SACC) have likewise been strongly critical of EPA's approach. In these comments, we summarize the serious shortcomings in EPA's initial draft evaluations and recommend critical steps to improve the quality, completeness, protectiveness and legal viability of the upcoming evaluations on the 20 chemicals.

[1] 84 Federal Register 44300

The principal points in our comments are as follows:

Recommendations to Improve Risk Evaluations

- 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. While time is short because EPA has delayed in filling these data gaps, the Agency should nonetheless 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.

- The TSCA systematic review protocol EPA has used in its initial risk evaluations is deeply flawed and unscientific and is compromising the quality, validity and protectiveness of these evaluations. EPA should abandon this protocol immediately and not use it in the next round of risk evaluations. Instead, it should adopt one of the methodologies for systematic review developed by the Institute of Medicine (IOM), National Toxicology Program (NTP) and EPA's Integrated Risk Information System (IRIS). These methodologies follow recognized principles of systematic review and have been endorsed by the National Academy of Sciences (NAS) and other peer review bodies.

- The initial EPA risk evaluations have excluded significant pathways of exposure and conditions of use. SACC was troubled by these exclusions and warned that they are resulting in serious underestimates of real-world exposure and risk. Moreover, a recent appellate court decision holds that EPA's framework risk evaluation rule provides no justification to pick and choose which exposure pathways and uses EPA will address. Going forward, risk evaluations must include *all* exposure pathways and uses**.**

- All of EPA's initial six draft risk evaluations propose 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. 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 should be addressed in the subsequent rulemaking under TSCA section 6(a).

- EPA's position in risk evaluations on the initial 10 chemicals has been 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 ongoing risk evaluations for asbestos and HBCD and upcoming risk evaluations for the 20 high-priority substances, EPA must address all ongoing uses of legacy products and associated disposal activities.

- 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. However, as defined in 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.

- The SACC has been highly critical of the adequacy of the information EPA has used to assess exposure in its draft risk evaluations and called for EPA to "obtain better data and documentation" from industry "on conditions of use, exposures, and potential for worker exposures." The SACC concerns underscore EPA's continuing failure to establish a systematic process to obtain the information from industry that is necessary for complete and reliable TSCA risk evaluations. This is a significant shortcoming given that industry is likely in possession of unpublished toxicology and human health studies unavailable to EPA and possesses considerable information on occupational exposure and environmental release that the Agency does not have. For the 20 high-priority candidates, EPA should immediately put in place an effective process for obtaining comprehensive information and data from industry, backed up by expanded reporting requirements under TSCA information collection authorities.

- Some of the EPA draft evaluations rely on industry-generated studies conducted outside the US under REACH and described in ECHA "robust summaries." These ECHA summaries are prepared by industry and are not actual study reports. Thus, before relying on the summaries to support a finding of no unreasonable risk, it is critical that EPA obtain and independently evaluate the underlying studies themselves. In addition, EPA should 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]," thereby triggering 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.

- 14 of the 20 high-priority candidates have been assessed under the EPA Integrated Risk Information System (IRIS). The IRIS process is the Agency's authoritative mechanism for reviewing available studies, characterizing the health effects of chemicals, and identifying concentrations below which these chemicals are not likely to cause adverse effects. Where EPA is conducting a TSCA risk evaluation of a chemical that has already been assessed under IRIS, the conclusions of the IRIS assessment should be presumed to be applicable to the TSCA evaluation as a definitive statement by the Agency of the "best available science." EPA should modify IRIS findings only where additional data have become available that inform the weight of the

scientific evidence. Such additional data should be assessed using peer reviewed and accepted systematic review methodologies.

Other Comments on the Proposed High-Priority Listings

- EPA's risk evaluation for formaldehyde under TSCA should be based on its draft IRIS assessment and this assessment should be immediately released for public comment and peer review.
- EPA should combine the five phthalates proposed for high-priority listing 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.

Listing Mercury as a High-Priority Substance

- The United States is a Party to the Minamata Convention on Mercury. The Convention entered into force on August 16, 2017. Under the Convention, the United States has obligations related to reducing mercury use in product manufacturing and in industrial processes.
- Designating mercury as high priority would enable the US to carry out these obligations and also serve the objectives of TSCA.

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

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, 114th Cong, 1st Sess. (2015) at 2. This requires extensive hazard and exposure information across all of a chemical's conditions of use and health endpoints.

To assure that EPA has sufficient information for informed risk evaluations, efforts to develop additional data must begin while a chemical is being considered for prioritization, if not sooner. As EPA emphasized in its September 27, 2018 *Working Approach for Identifying Potential Candidate Chemicals for Prioritization* (Working Approach) under TSCA,[2] selection of chemicals for high-priority listing should be based on the "sufficiency" of the available hazard and exposure information for conducting a robust risk evaluation. Accordingly, "[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."

[2] https://www.regulations.gov/document?D=EPA-HQ-OPPT-2018-0659-0001

EPA has an obligation to use these tools on chemicals under consideration for high-priority listing. 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 reasonably 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.[3]

Data Gaps in the First 10 Evaluations. The consequences of conducting risk evaluations without adequate data were painfully evident in EPA's first draft evaluation, for Pigment Violet 29 (PV29). The December 2018 draft concludes that this chemical does not present an unreasonable risk of injury but bases this sweeping conclusion on limited hazard and exposure information that is inadequate to demonstrate the absence of risk. Comments by SCHF, NRDC, Earthjustice and other groups strongly faulted the draft evaluation for giving PV29 a clean bill of health without supporting data.[4] The SACC agreed, highlighting multiple data deficiencies and recommending several additional studies to provide a basis for characterizing hazard and exposure.[5]

EPA's initial draft risk evaluations for other substances reveal data gaps for critical endpoints like endocrine effects, developmental neurotoxicity and ecotoxicity.[6] 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 and could well understate actual exposure and risk. Because of these limitations, the initial draft evaluations are incomplete in important areas, as SACC has emphasized in its peer reviews.

Data Gaps on the 20 High-Priority Candidates. As we have previously recommended, the following studies comprise a minimum dataset that EPA and other expert bodies have deemed necessary for definitive determinations of risk:

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[3] 82 Fed. Reg. 33726, 33732 (July 20, 2017).

[4] 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.

[5] 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).

[6] 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.

- Acute mammalian toxicity
    - Oral
    - Dermal
    - Inhalation
- Respiratory sensitization
- Skin sensitization
- Eye irritation/ corrosivity
- Skin irritation/ corrosivity
- Carcinogenicity
- Mutagenicity/ genotoxicity
- Immunotoxicity
- Reproductive toxicity
- Developmental toxicity
- Developmental neurotoxicity
- Neurotoxicity
- Repeated dose toxicity
- Endocrine activity
- Toxicokinetics

For these endpoints, EPA risk assessment guidelines and other authoritative sources identify the studies necessary to reach informed conclusions about a chemical's potential hazards.[7]

Compared to this minimum dataset, many of the 20 proposed high-priority chemicals lack data for hazard endpoints that should be addressed in a TSCA risk evaluation.

One example is 1,3,4,6,7,8-Hexahydro-4,6,6,7,8,8,-hexamethylcyclopenta[g]-2-benzopyran (HHCB), a fragrance that is commonly used in detergents and other consumer and personal care products and has been found in adipose tissue, blood, breast milk, and umbilical cord blood. A 2015 review of HHCB found no data on major health effects, [8] and EPA's support document for its proposal confirms that respiratory sensitization, carcinogenicity, and immunotoxicity data remain lacking.[9] Similarly, in its 2014 Work Plan assessment of HHCB's environmental effects, EPA concluded that "[t]he inability to assess potential risks

[7] See, e.g., Office of Pollution Prevention & Toxics, *EPA's Safer Choice Program Master Criteria for Safer Ingredients*, Version 2.1 September 2012, available at https://www.epa.gov/sites/production/files/2013-12/documents/dfe_master_criteria_safer_ingredients_v2_1.pdf; ECHA (2018) Guidance for the identification of endocrine disruptors in the context of Regulations (EU) No 528/2012 and (EC) No 1107/2009. Pg. 31-32. Available: https://www.efsa.europa.eu/en/efsajournal/pub/5311; EPA. Guidelines for Developmental Toxicity Risk Assessment. Available at https://www.epa.gov/sites/production/files/2014-11/documents/dev_tox.pdf; EPA, Guidelines for Reproductive Toxicity Risk Assessment, June 1996, available at https://www.epa.gov/sites/production/files/2014-11/documents/guidelines_repro_toxicity.pdf; EPA 2005. Guidelines for Carcinogen Risk Assessment. Pg. 84-85. Available from: https://www.epa.gov/sites/production/files/2013-09/documents/cancer_guidelines_final_3-25-05.pdf

[8] https://www.womensvoices.org/wp-content/uploads/2016/04/1222-05-5-HHCB-aka-Galaxolide-GS-546-v-1-2-Certified-April-2015-3.pdf

[9] https://www.epa.gov/sites/production/files/2019-08/documents/134678-hexahydro-466788-hexamethylcyclopentag-2-benzopyran_1222-05-5_high-priority_proposeddesignation_082219_correct.pdf

to terrestrial invertebrates and plants is a major uncertainty associated with this assessment."[10] Since these data gaps were identified several years ago, EPA has had ample opportunity to fill them using its section 4 authority, yet has failed to do so.

Yet another example of data insufficiency is information on endocrine effects. The Center for Environmental Health (CEH) conducted a literature review of existing studies to identify what is known about the endocrine disruption potential of the 20 high-priority candidates. For many of these compounds, data indicating endocrine disruption is already available, such as for the five phthalates. However, additional data are necessary for other compounds with less publicly available data (such as p-dichlorobenzene, 1,2-dichloroethane, trans-1,2-dichloroethylene, o-dichlorobenzene, and ethylene dibromide). Studies on these compounds are limited but suggest endocrine activity which should be further investigated. For two compounds, 1,1-dichloroethane and phthalic anhydride, no endocrine data at all are publicly available. The studies required for a definitive evaluation of endocrine disruption potential are described in the Revised Guidance Document 150 on Standardized Test Guidelines for Evaluating Chemicals for Endocrine Disruption from the Organization for Economic Cooperation and Development (OECD); all chemicals should undergo the studies listed in Conceptual Framework Levels 2-5.

The support documents for the 20 high-priority candidates reveal additional data gaps for human health endpoints.[11] For example, 1,1-dichloroethane lacks reproductive, respiratory sensitization and immunotoxicity data; 1,2-dichloroethylne 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. Moreover, even where the support documents indicate that data are available for an endpoint, this does not necessarily mean that EPA can access studies that are sufficient to determine whether the chemical presents an unreasonable risk for that endpoint. For example, only a few in vitro assays may exist to inform whether the chemical is genotoxic/mutagenic; data on reproductive/developmental toxicity may be from screening studies that would be considered inadequate under EPA risk assessment guidelines; or neurotoxicity studies may fail to address developmental neurotoxic effects. In these instances, lack of data will hamper EPA's ability to make definitive risk determinations.

The EPA support documents reveal additional data gaps for assessing environmental risks. If anything, these data gaps are more extensive than in the human health effects domain, as evidenced by EPA's admission that "there are very few publicly available assessments . . . with cited environmental hazard data" for the 20 chemicals and that it "used a read-across approach to identify additional environmental hazard data . . . to fill in potential data gaps."[12] EPA guidelines for ecological risk assessment typically call

[10] https://www.regulations.gov/document?D=EPA-HQ-OPPT-2012-0722-0024

[11] https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/supporting-information-proposed-high-priority-chemical.

[12] See, e.g., https://www.epa.gov/sites/production/files/2019-08/documents/ethylene_dibromide_106-93-4_high-priority_proposeddesignation_082319.pdf, at 16.

for studies of acute and chronic effects in a range of invertebrates, aquatic species, and terrestrial species.[13] 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. This is particularly troubling in view of the SACC's conclusions that "the environmental fate, exposure, and effects assessment was inadequate" for 1,4-dioxane[14] and that the PV29 assessment was weakened by the "limited nature of the dataset describing [its] potential environmental hazards."[15] EPA's next round of risk evaluations will suffer from the same problems unless additional environmental effects testing is conducted.

Considerable testing could now be underway under section 4 if, as our groups have repeatedly urged, EPA had moved quickly after the TSCA amendments took effect in 2016 to fill data gaps on chemicals that were likely candidates for high-priority listing based on the 2014 Work Plan list or other indicators of concern. Because EPA sat on its hands, however, it will be challenging to complete long-term studies on the 20 high-priority candidates by the 3.5-year deadline in TSCA section 6(b)(4)(G) for finalizing risk evaluations. However, it is still possible to initiate and complete shorter-duration studies in time for their inclusion in these risk evaluations. *We urge EPA to expeditiously use its section 4 order authority to require such studies. These requirements should include health and environmental effects testing as well as monitoring of workplace exposure levels, environmental releases and presence in environmental media.*

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

EPA is using "systematic review" criteria developed by the TSCA program[16] to evaluate the quality of available data on the initial 10 chemicals undergoing risk evaluations. 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 risk evaluations.[17] These

[13] 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

[14] TSCA Science Advisory Committee on Chemicals Meeting Minutes and Final Report No. 2019-02 *Peer Review for EPA Draft Risk Evaluations for 1,4-Dioxane and Cyclic Aliphatic Bromide Cluster (HBCD),* November 1, 2019, at 18 (1,4-Dioxane and HBCD SACC Report), available at https://www.regulations.gov/document?D=EPA-HQ-OPPT-2019-0238-0063.

[15] PV29 SAAC Report, at 16.

[16] 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

[17] 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.

concerns were summarized in a recent peer-reviewed commentary published in the *American Journal of Public Health*.[18]

"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.[19] However, the TSCA protocol departs radically from accepted scientific principles for systematic review adopted by the IOM,[20] the NTP[21] and EPA's Integrated Risk Information System (IRIS)[22] and endorsed by the NAS[23] and other peer review bodies.

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."[24] 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

[18] 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

[19] 82 Fed. Reg. 33726, 33734 (July 20, 2017).

[20] Institute of Medicine. Finding What Works in Health Care. Standards for Systematic Review. Washington, D.C.: The National Academies Press.; 2011.

[21] 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.

[22] National Research Council. Review of EPA's Integrated Risk Information System (IRIS) Process. Washington, DC: National Academies Press; 2014.

[23] 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. 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.

[24] 40 C.F.R. 704.33.

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 evaluation*s 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:[25]

> "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.

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."[26]
- "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."[27]
- "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."[28]
- "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

[25] 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.
[26] PV29 SACC Report at 26.
[27] Id. at 27.
[28] Id. at 26-7.

Evaluation for a thorough description and outline for how all evidence and data are integrated into a final weight of evidence conclusion."[29]

The SACC also strongly recommended that EPA move forward with National Academy of Sciences (NAS) review of its TSCA systematic review method – a commitment on which EPA is dragging its feet, months after agreeing to seek NAS guidance.

These concerns were forcefully underscored in the SACC review of the 1,4-dioxane risk evaluation:[30]

> "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:[31]

> "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 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)."[32]

In the face of the serious concerns of SACC and others, EPA should abandon the TSCA systematic review protocol immediately and not use it in the next round of risk evaluations. Instead, it must adopt one of the recognized systematic review methodologies developed by IOM, NTP and EPA's IRIS program and endorsed by the NAS and other peer review bodies.

III. EPA Must Include All Pathways of Exposure and Conditions of Use in TSCA Risk Evaluations

[29] Id. at 27.
[30] 1,4-Dioxane and HBCD SACC Report, at 30.
[31] Id. at 31.
[32] Id.

The initial EPA risk evaluations have excluded significant pathways of exposure and conditions of use that contribute to overall risk. For example, EPA's draft evaluation of 1,4-dioxane only addresses one dimension of exposure – risks to workers engaged in the chemical's manufacture, processing and use. The evaluation expressly excludes use of personal care and cleaning products containing 1,4-dioxane as an impurity and consumption of contaminated drinking water.[33] These are well-documented and widespread sources of exposure that put many millions of Americans at risk of harm from a multi-site, multi-species carcinogen.

In the case of 1-bromopropane (1-BP) and methylene chloride,[34] EPA excludes air emissions from its draft evaluations and thus does not address general population exposure and risk. Both methylene chloride and 1-BP are highly volatile and there is considerable evidence that their air emissions are significant and widespread, impacting both the general population and vulnerable subpopulations. These emissions also add to other sources of exposure by workers and consumers who are already at high risk of adverse health effects.

EPA bases these exclusions on the rationale that releases of chemicals to air and water are being addressed and regulated under the Safe Drinking Water Act (SDWA) and the Clean Air Act (CAA) and need not be considered in TSCA risk evaluations.[35] This rationale is contrary to the comprehensive multi-media scope of TSCA.

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 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 or not they might be addressed under other laws.

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, 94th Cong., 2d Sess. at 7 (1976); see S. Rep. No. 94-698, 94TH Cong., 2d Sess. (1976) at 3 ("[W]e have become literally surrounded by a manmade chemical

[33] Draft Risk Evaluation for 1,4-Dioxane, June 2019, available at https://www.epa.gov/sites/production/files/2019-06/documents/1_14-dioxane_draft_risk_evaluation_06-27-2019.pdf.
[34] Draft Risk Evaluation for 1-Bromopropane; Risk Evaluation for Methylene Chloride (October 2019), available at https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/draft-risk-evaluation-methylene-chloride
[35] 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; Draft Risk Evaluation for 1,4-Dioxane, at 156.

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, 114th Cong., 1st 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."[36]

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:[37]

> "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:[38]

> "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*."[39] EPA's narrower approach, it said, "strayed

[36] Congressional Record – Senate 3517 (June 7, 2016).
[37] 1,4-Dioxane and HBCD SACC Report, at 20.
[38] Id.
[39] Id. (emphasis added).

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."[40]

EPA has defended its selective exclusion of pathways of exposure and uses from TSCA risk evaluations as a reasonable interpretation of TSCA and its framework risk evaluation rule. But in its recent decision addressing challenges to the rule, the U.S. Court of Appeals for the Ninth Circuit found that the rule did not authorize EPA's approach. It explained that "we do not interpret the language in the Rule to say anything about exclusion of conditions of use" and that "[w]e therefore conclude that the challenged provisions unambiguously do not grant EPA the discretion" to remove such conditions from the scope of risk evaluations. *Safer Chemicals, Healthy Families v USEPA*, No. 17-72260 (9th Cir. Nov. 14, 2019), at 43.

Based on the court's holding, EPA's initial risk evaluations cannot be squared with TSCA and any exclusion of environmental releases and uses from risk evaluations for the next 20 chemicals would be unlawful.

IV. 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 six draft risk evaluations propose 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.

For example, in its risk evaluations for 1,4-dioxane, 1-BP and methylene chloride, EPA uses a risk benchmark of 1 x 10^{-4} to determine whether cancer risks to workers are unreasonable.[41] In each case, EPA calculates cancer risks above the benchmark for several workplace exposure scenarios in the absence of respirators and gloves but then determines that use of PPE would lower the risk below the benchmark. If finalized, EPA's determinations of no unreasonable risk would mean that these workers receive no protection against cancer risk under section 6(a) of TSCA. EPA uses the same approach in assessing non-cancer risks to workers from exposure to HBCD, methylene chloride and NMP. For these chemicals, EPA determines whether the Margin of Exposure (MOE) during worker exposure scenarios is greater than a so-called "benchmark" MOE, which purports to provide "adequate protection" against adverse effects. These evaluations find that numerous worker categories (and some occupational

[40] Id.

[41] Given that EPA has previously used a risk range of 1 x 10^{-4} to 1 x 10^{-6} as a trigger for regulatory action, the selection of the upper end of this range to define unreasonable risk is arbitrary and unprotective. As explained in the draft evaluation for 1,4-dioxane, "[s]tandard 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., 1x10^{-6} to 1x10^{-4}) depending on the subpopulation exposed. Generally, EPA considers 1 x 10-6 to 1x 10-4 as the appropriate benchmark for the general population, consumer users, and non-occupational potentially exposed or susceptible subpopulations (PESS)" (p. 155). However, EPA then asserts that 1 x 10^{-4} should be the unreasonable risk threshold for occupational exposure based on OSHA precedent. EPA does not explain why this precedent should control decision-making under TSCA, a different law, or why workers should receive less protection than other exposed subpopulations.

bystanders) have unprotective MOEs in the absence of PPE but would be adequately protected if PPE is used. For HBCD, the assumption of PPE use means that *no* worker populations will face unreasonable risks and therefore EPA will not regulate HBCD under section 6(a) to protect workers.

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."[42] 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 trichloroethylene (TCE) use in vapor degreasing that respirators are often not feasible and may be used intermittently by workers even where legally required:[43]

> "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-facepiece respirator to provide the required protection. Also, difficulties associated with selection, fit, and use often render them ineffective in actual application, preventing the assurance of consistent and reliable protection, regardless of the assigned capabilities of the respirator. Individuals who cannot get a good facepiece fit, including those individuals whose beards or sideburns interfere with the facepiece seal, would be unable to wear tight fitting respirators. In addition, respirators may also present communication problems and vision problems, increase worker fatigue, and reduce work efficiency … 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

[42] 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, at 381.
[43] 82 Fed. Reg. 7432, 7445 (January 19, 2017).

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.'"

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." Id. 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."[44]

These conditions are not likely for the chemicals addressed in the first six risk evaluations. A full OSHA standard is in place for only one of these chemicals (methylene chloride) but it does not reflect the minimum level of protection required by current scientific understanding, and monitoring data cited by EPA indicates that exposure limits are routinely exceeded. As for the claimed legal obligation of employers to consider all relevant data and control exposure accordingly, OSHA regulations give employers wide latitude to interpret evidence of workplace risks and to select worker protection measures they deem appropriate in the absence of specific PPE requirements.[45] Moreover, the draft evaluations document exposure by large worker populations at hundreds of facilities, many of which are small businesses with minimal industrial hygiene programs.

Thus, the SACC questioned EPA's PPE assumptions for PV29, noting that "[t]he 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."[46] 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"[47] 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."[48] 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."[49]

[44] 82 Fed. Reg. at 7473-4.
[45] OSHA's PPE standard requires employers to assess the hazards workers face but to provide PPE only when the employer deems such measures "necessary." 29 C.F.R. § 1910.132(a).
[46] SACC Report on PV29 at 37.
[47] SACC Report on 1,3-dioxane and HBCD, at 86.
[48] Id. at 55.
[49] Id. at 53.

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:[50]

> "[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.[51] 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."[52]

As it finalizes the initial 10 risk evaluations and moves ahead with the next 20 evaluations, EPA should abandon its unprecedented, untenable and unlawful approach of basing unreasonable risk determinations for workers on the assumption that they will be adequately protected from harmful exposure 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. If these levels present an unreasonable risk, the necessary measures to protect workers must be addressed in the subsequent rulemaking under TSCA section 6(a) to eliminate that risk.*

V. Risk Evaluations Must Address Legacy Uses of Chemicals and Associated Disposal Activities

[50] Id at 118.
[51] OSH, Ctrs. for Disease Control & Prevention, updated Jan. 13, 2015, https://www.cdc.gov/niosh/topics/hierarchy/.
[52] SACC Report on 1,4-dioxane and HBCD, at 73.

In the preamble to its final risk evaluation rule, EPA asserted that the TSCA definition of "conditions of use" does not include what the Agency termed "legacy activities" – i.e. ongoing use of substances, mixtures and articles that are no longer manufactured, processed or distributed in commerce and the disposal of these legacy products.[53] 82 Fed. Reg. at 33729–30. Based on its interpretation, EPA has excluded legacy activities from the scope of ongoing TSCA risk evaluations.

Thus, in its Problem Formulation for asbestos, EPA advised that the risk evaluation for this substance would not address the risks of insulation and other asbestos-containing materials that are now installed in buildings across the US and are performing ongoing uses in these structures.[54] Similarly, the draft evaluation for HBCD does not address ongoing exposure and related risks from the continued presence of many legacy HBCD-containing articles and products in thousands of homes, schools and businesses where they perform continuing flame retardant, insulating and other functions.[55] As the SACC noted, the exclusion of discontinued products is "problematic as some HBCD-treated textiles, as well as treated high impact polystyrene (HIPS) products remain in use in U.S. homes, vehicles and businesses, or have been disposed of properly or improperly, and thus serve as a source for human and wildlife exposure. This HBCD contributes to the existing and future sediment and biota HBCD concentrations."[56]

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."

Safer Chemicals, Healthy Families v USEPA, No. 17-72260 (9th Cir. Nov. 14, 2019), at 53.

The Ninth Circuit decision requires EPA to expand the scope of its ongoing risk evaluations for asbestos and HBCD to include ongoing uses of legacy products and associated disposal activities. These legacy activities must also be addressed in the upcoming risk evaluations for the 20 high-priority substances.

[53] 82 Fed. Reg. at 33729–30.
[54] Problem Formulation of the Risk Evaluation for Asbestos (May 2018) at 8.
[55] HBCD Risk Evaluation at, at 31, 39; HBCD Problem Formulation, at 24-26
[56] SACC Report on 1,4-dioxane and HBCD, at 102.

VI. Discontinued Manufacturing, Processing and Use Activities Comprise TSCA "Conditions of Use" and Should be Addressed in Risk Evaluations

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.[57] Similarly, EPA is not evaluating the risks of domestic production of HBCD, which recently ceased, along with a host of recently discontinued uses.[58] 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.

While EPA may believe that industry has agreed not to resume selling asbestos or HBCD-containing products for uses that have been phased out, these promises are informal and unenforceable and do not tie the hands of manufacturers in the future. Indeed, 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 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 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.[59]

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[57] Asbestos Problem Formulation at 19-20.

[58] 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.

[59] 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

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 . . ."[60]

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

In both current and upcoming risk evaluations, EPA should treat 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).

VII. EPA Should Establish a Systematic Process for Obtaining Existing Toxicological and Exposure Data from Industry on the 20 High-Priority Candidates Using its TSCA Reporting Authorities

The SACC was highly critical of the adequacy of the information EPA used to assess exposure in its draft risk evaluations. As stated in SACC's report on the 1,4-dioxane draft:[61]

> "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 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, SAAC "considered EPA's characterization of Environmental Releases and Exposures . . . as cursory and dependent upon sweeping generalizations that are often

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.

[60] Cong. Record – Senate 3515 (June 7, 2016).

[61] SACC Report on 1,4-dioxane and HBCD, at 21.

unsubstantiated."[62] 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."[63] SACC concluded that:[64]

> "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 EPA's continuing failure to establish a systematic process to obtain information from industry on workplace exposure, environmental release, chemical fate and toxicity for risk evaluation chemicals. This is a significant gap given that industry is likely in possession of unpublished toxicology and human health studies and possesses considerable information on occupational exposure and environmental release that is unavailable to EPA. The Comprehensive Data Reporting (CDR) rule and other mandatory TSCA reporting requirements do not call for the submission of this information for high-priority chemicals. If industry voluntarily provides such information selectively or (as in the case of PV29) in summary form with no documentation, the quality and credibility of the EPA risk evaluations will suffer.

We recommend that, for each of the 20 high-priority candidates, EPA issue an information request to all manufacturers and processors specifying the toxicological and exposure information necessary for TSCA risk evaluations, with a focus on the data needed to evaluate risks to potentially exposed or susceptible subpopulations. The Agency should also develop a standardized format for submitting this information.

Because industry may not fully comply with this voluntary request, EPA should put in place mandatory reporting mechanisms as a backstop. For example, 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 studies of health and environmental effects as well as of human exposure and environmental release.[65] 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,

[62] SACC Report on PV29, at 16.
[63] Id at 20.
[64] Id at 35.
[65] 40 CFR § 716.3.

when they have been aggregated and analyzed to measure the exposure of humans or the environment to a chemical substance or mixture."[66] 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.

40 CFR § 716.105 provides an expeditious mechanism for adding chemicals to the section 8(d) health and safety data reporting rule. EPA should use this mechanism to subject the 20 high-priority candidates to reporting immediately.

Another essential step 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 of a chemical substance at any single site to 2,500 pounds or even less for particular chemicals. For high-priority chemicals, EPA should also add a processor reporting component to the CDR rule so it obtains accurate and complete information on downstream conditions of use and exposure. These revisions should be made as part of the ongoing rulemaking to modify the CDR rule so they are implemented for the 2020 reporting cycle.[67]

In particular instances, these expanded reporting requirements may not provide sufficient information for TSCA risk evaluations. In these cases, EPA should use its subpoena authority under TSCA section 11 to efficiently obtain more information from individual manufacturers and processors to support risk evaluations.

VIII. EPA Should Not Make Findings of No Unreasonable Risk Based 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 REACH and described in ECHA "robust summaries." These ECHA 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 either the accuracy of the summaries or the validity of the study findings they describe and the methods with which the studies were conducted. Before determining that a chemical presents no unreasonable risk for a particular endpoint based on the summaries, it is critical that EPA obtain and independently evaluate the underlying studies themselves. Moreover, all data, including ECHA robust summaries, must be subject to a credible and peer-reviewed systematic review process in order to assess reliability and risk of bias.

In addition, EPA should 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]" for purposes of section

[66] Id. For example, section 8(d) requirements might 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).

[67] 84 Fed. Reg. 17692 (April 25, 2019). We have separately submitted these recommendations to the CDR rulemaking docket.

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 is legally required and will assure the public a meaningful opportunity to comment on the scientific basis for EPA's proposed determinations of risk.

It would be unfortunate if EPA were to repeat its treatment of REACH studies on PV29. 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.[68]

Equally troubling is how EPA 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."[69] 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."[70] 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.

In the future, 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.

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

[68] 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.

[69] Risk Evaluation on 1-BP at 141.

[70] Id.

14 of the 20 high-priority candidates have been assessed under the EPA Integrated Risk Information System (IRIS).[71] 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.[72]

Where EPA is conducting a TSCA risk evaluation of a chemical that has already been assessed under IRIS, the conclusions of the IRIS assessment should be presumed to be applicable to the TSCA evaluation as a definitive statement by the Agency of the "best available science," a requirement under section 26(h) of TSCA for all science-based decisions under the law. Reopening IRIS findings would harm the public by prolonging uncertainty on issues that have been addressed and resolved through an authoritative, transparent and inclusive EPA process. To revisit IRIS findings would also be inefficient and resource-intensive at a time when the Agency is struggling with workforce and budget constraints and is straining to manage its TSCA workload.

For some IRIS assessments performed several years ago, significant new data have subsequently become available. However, this should not be an open-ended basis to reopen previous IRIS hazard findings. Rather, to update and incorporate new evidence, the new data should be reviewed, in consultation with scientists in the IRIS program, to assess whether they might inform the previous IRIS determination of the weight of the evidence for particular endpoints. This review should be conducted using one of the peer-reviewed systematic review methodologies described above.

X. 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

Formaldehyde, one of the 20 high-priority candidates, 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 provided no indication 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. Continued suppression of the draft IRIS assessment would depart from the Assistant Administrator's declaration that "[e]nsuring greater public

[71] The 14 chemicals with IRIS assessments are: Lp-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.

[72] 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.

transparency of chemical information is a top priority, and the EPA is actively working to achieve this across all areas of TSCA implementation."

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 database.

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, 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 exonerate formaldehyde from the serious health effects found in 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 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.

XI. EPA Should Combine the Five Phthalates Proposed for High-Priority Listing with the Two Phthalates for Which Industry Has Requested Risk Evaluations into a Single Category Subject to a Cumulative Risk Assessment

Five of the proposed high-priority substances are phthalates: Butyl benzyl phthalate (BBP), Dibutyl phthalate (DBP), Dicyclohexyl phthalate, Di-ethylhexyl phthalate (DEHP) and Di-isobutyl phthalate (DIBP). In addition, EPA has received manufacturer requests to conduct TSCA risk evaluations on two additional phthalates, diisodecyl phthalate (DIDP) and diisononyl phthalate (DINP).[73,74]

Phthalates are chemicals 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."[75] 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."[76] 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."[77]

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…"

Should EPA decide to conduct the manufacturer-requested risk evaluations for DIDP and DINP, EPA should treat all seven phthalates as a "category" under TSCA section 26(c) and conduct a single

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[73] 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

[74] 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

[75] Gennings, C., Hauser, R., Koch, H. M., Kortenkamp, A., Lioy, 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

[76] 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

[77] Id. at 11-12.

cumulative risk evaluation for the entire group of chemicals. The seven phthalates merit treatment as a category because they are similar in molecular structure, toxicity, use and exposure.

In a cumulative risk evaluation for the seven phthalates, EPA should address all conditions of use and associated exposures. This broad scope is necessary both for chemicals selected for risk evaluations based on manufacturer requests and those designated high priority. Otherwise, risk will be underestimated for potentially exposed and susceptible subpopulations such as children. To accurately account for real-life risks, EPA needs to aggregate exposures across exposure pathways using its methodologies for aggregate exposure assessment. 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.

XII. EPA Should List Mercury and Its Compounds as High Priority Substances

The United States is a Party to the Minamata Convention on Mercury. The Convention entered into force on August 16, 2017. Under the Convention, the United States has obligations related to reducing mercury use in product manufacturing and in industrial processes. For example, under Article 4 of the Convention, the United States must reduce mercury use in the manufacture of switches and relays,[78] and under Article 5 of the Convention take measures to phase out mercury use in the production of polyurethane "as fast as possible."[79] Moreover, the United States has obligations to discourage new mercury product types[80] and discourage new uses of mercury in manufacturing processes,[81] and has reporting obligations related to each of these control measures.[82] Exercising these responsibilities requires actions under various provisions of TSCA.

Nonetheless, EPA removed mercury and mercury compounds from the 2014 TSCA Work Plan for Chemical Assessments. At that time, the Agency maintained that "their hazards are already well characterized"[83] and that EPA planned to take additional risk management measures anyway, both because of the high hazard these chemicals present and because of the government's Minamata Convention on Mercury obligations.[84]

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[78] See http://www.mercuryconvention.org/Portals/11/documents/submissions/USA%20declaration_Art%204%20para%202.pdf, p. 5.
[79] See Minamata Convention on Mercury, Annex B, Part II.
[80] See Article 4, Paragraph 6.
[81] See Article 5, Paragraph 7.
[82] See Article 21.
[83] See e.g., https://www.epa.gov/mercury/health-effects-exposures-mercury.
[84] See https://www.epa.gov/sites/production/files/2015-01/documents/tsca_work_plan_chemicals_2014_update-final.pdf, p. 7.

This decision to remove mercury and mercury compounds from the 2014 Workplan was made before the 2016 TSCA revisions were enacted. Now, under the current TSCA statutory scheme, EPA must designate mercury as a high-priority chemical, conduct a risk evaluation under TSCA section 6(b) and determine that it presents an unreasonable risk of injury to health or the environment, before taking the necessary regulatory actions under TSCA section 6(a). Accordingly, in its comments on EPA's prioritization framework rules, NRDC emphasized the need to prioritize mercury and other chemicals covered by binding international agreements as high-priority substances under TSCA where implementing action under TSCA is necessary to carry out US responsibilities under these agreements. EPA concurred, as reflected in the Response to Comment document on the final rule:

> Comment: One commenter (0054) suggested that EPA consider its international obligations in selecting a chemical for prioritization, as achieving compliance with these obligations may necessitate prioritization of a particular chemical substance under TSCA.
>
> EPA Response: EPA agrees that it should take into consideration relevant international actions, such as multilateral environmental agreements, global and regional partnerships, and bilateral or international commitments. EPA is of the view that it should give particular attention to those chemicals for which the United States has accepted international obligations and to chemicals for which significant global or regional action has been taken or is expected to be taken.

There is a compelling basis to select mercury and mercury compounds for high-priority designation and risk evaluation under TSCA at this time. Even apart from the Minamata Convention, mercury is already a priority of EPA and other federal agencies. EPA's mercury activities under the TMDL program,[85] and the recent work of EPA and US Customs to improve the tracking of mercury and mercury compound trading within North America, are indicative of the importance of mercury within the federal government.[86] The federal government has also enacted a mercury export ban,[87] mandated the construction of a facility to permanently sequester mercury in lieu of placing the mercury in commerce, and records/publicizes mercury fish consumption advisories.[88] Strong support for addressing mercury is also evident from state agencies.[89]

In addition, the science underlying the risks posed by mercury is extraordinarily strong and substantial.[90] As EPA indicated in the 2014 Workplan Update, the chemicals are already "well characterized." And under TSCA as revised, a separate and detailed supply, use, and trade reporting system is now in place,

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[85] See https://www.epa.gov/tmdl/impaired-waters-and-mercury.
[86] See http://www3.cec.org/islandora/en/item/11769-enhancing-alignment-north-american-trade-statistics-elemental-mercury-and-en.pdf.
[87] See https://www.epa.gov/mercury/questions-and-answers-mercury-export-ban-act-meba-2008.
[88] See https://www.epa.gov/sites/production/files/2015-06/documents/technical-factsheet-2011.pdf.
[89] See e.g., ECOS Resolution 16-2 at https://www.ecos.org/documents/resolution-16-2-reducing-mercury-in-the-environment/, and http://www.newmoa.org/prevention/mercury/imerc/about.cfm.
[90] See http://www.who.int/mediacentre/factsheets/fs361/en/: http://cwm.unitar.org/cwmplatformscms/site/assets/files/1254/mercury_timetoact.pdf; https://www.nrdc.org/sites/default/files/hea_15062401a.pdf. See also footnote 6.

under final rules published by EPA on June 27, 2018.[91] These rules will require the electronic submission of data from both mercury (and mercury compound) manufacturers and processors by July 1, 2019.[92] Accordingly, approximately six months before EPA's final prioritization decisions are made (by the end of December 2019), the Agency will have a mercury-specific database that includes information for identifying conditions of use and potential exposure scenarios.[93] Based upon these data, the Agency is required to issue an inventory of mercury supply, trade, and use by April 1, 2020, which would further inform EPA's scoping and risk evaluation processes following the priority designation.

In sum, EPA should recognize that mercury and mercury compounds are a candidate for high priority listing and risk evaluation because EPA can only carry out the US government's obligations as a Party to the Minamata Convention on Mercury by applying the TSCA prioritization and risk evaluation process to these substances, and because they fully meet TSCA'S criteria for high-priority chemicals.

Conclusion

We appreciate this opportunity to comment on EPA's August 23, 2019 notice proposing 20 chemicals for high-priority listing under section 6(b) of TSCA.

If you have any questions, please contact Bob Sussman, SCHF counsel, at bobsussman1@comcast.net.

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[91] See 83 FR 30054-77 (June 27, 2018).

[92] See 40 CFR 713.17, as published at 83 FR 30076-77 (June 27, 2018).

[93] In petitions for review currently pending before the United States Court of Appeals for the Second Circuit, NRDC and the State of Vermont are challenging several exemptions to the mercury reporting rule promulgated by EPA. *See Natural Resources Defense Council, Inc. v. United States Environmental Protection Agency, et al.* (Case No. 18-2121); *State of Vermont v. United States Environmental Protection Agency, et al.* (Case No. 18-2670). Those exceptions, NRDC and Vermont contend, unlawfully exempt from reporting (1) manufacturers and importers of mercury-added products in which the mercury is in a component of the larger product; and (2) manufacturers and importers of mercury already reporting to the EPA's Chemical Data Reporting database. Although NRDC and Vermont believe the mercury reporting rule's exceptions are unlawful under TSCA, the rule will contribute to the quantity and quality of information available to EPA, regardless of whether the exceptions are upheld. A successful outcome in the litigation will further strengthen the available data on mercury supply and uses.