UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Comments of Safer Chemicals Healthy Families et al. on Risk Evaluation Problem Formulation Documents for Ten Chemical Substances under the Toxic Substances Control Act

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

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

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

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

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

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

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

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

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

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

Safer Chemicals Healthy Families (SCHF) and the undersigned groups submit these comments on the problem formulations developed by the Environmental Protection Agency (EPA) on the initial 10 chemicals selected for risk evaluations under the newly enacted Frank R. Lautenberg Chemical Safety for the 21st Century Act (LCSA).[1]

SCHF leads a coalition of national and grassroots organizations 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. SCHF and its partners took a leadership role during the LCSA legislative process, advocating the most protective and effective legislation possible to reduce the risks of toxic chemicals in use today.

These comments address crosscutting legal and policy issues common to the 10 chemicals as well as several chemical-specific issues. We are submitting our comments to all ten of the EPA dockets. The comments

[1] 83 Federal Register 26998 (June 11, 2018).

build on earlier SCHF submissions, including our September 19, 2017 comments on the EPA scoping documents on the 10 chemicals. Many SCHF partner organizations are also commenting on the problem formulations and we support these comments.

Organizations joining these comments are:

Alaska Community Action on Toxics
Alliance of Nurses for Healthy Environments
Asbestos Disease Awareness Organization
Center for Environmental Health
Clean and Healthy New York
Clean Production Action
Clean Water Action (National)
Clean Water Action (Connecticut)
Colorado PIRG (CoPIRG)
Earthjustice
Environmental Health Strategy Center
Healthy Building Network
League of Conservation Voters
Learning Disabilities Association of America
Maryland PIRG
Natural Resources Defense Council
Science and Environmental Health Network
Texas PIRG (TexPIRG)
Toxic-Free Future
U.S. PIRG
United Steelworkers
WashPIRG
WE ACT for Environmental Justice
Women for a Healthy Environment

OVERVIEW

Through LCSA, Congress amended the Toxic Substances Control Act (TSCA) to establish a new framework for conducting timely, comprehensive and science-based risk evaluations for chemicals of concern. The law provides that EPA's evaluations must be strictly risk-based and must result in a definitive determination of whether the evaluated substance as a whole presents an unreasonable risk of injury to health and the environment across its life cycle, without regard to cost and other non-risk factors. In conducting risk evaluations, EPA must address risks not only to the general population but also to "potentially exposed or susceptible subpopulations," including the elderly, children, pregnant women and workers.

On December 19, 2016,[2] as required by section 6(b)(2)(A) of TSCA, EPA selected 10 chemicals for initial risk evaluations. These precedent-setting evaluations address substances with widespread exposure and known health hazards. How EPA evaluates the risks of these chemicals will be critical to whether the public and policymakers are fully informed about the threats they pose to health and the environment. This in turn will determine whether EPA follows through with effective risk reduction measures under section 6(a) of TSCA that protect at-risk populations. The initial evaluations will also lay the groundwork for overall TSCA implementation and thus determine whether EPA establishes the robust and protective chemical risk management program that LCSA calls for.

Unfortunately, the 2017 scoping documents and more recent problem formulations make it increasingly apparent that the initial 10 evaluations will fall far short of the expectations of Congress and the requirements of the law. Through a combination of questionable exclusions and loopholes, failure to require necessary testing, deviations from accepted scientific methods and refusal to accept previous peer reviewed determinations of risk, the Agency is on a path to produce evaluations that ignore important exposure

[2] 81 Federal Register 91927

pathways and at-risk populations, disregard evidence of adverse effects and reach misleading and incomplete conclusions that understate risks and weaken public health protection.

The many shortcomings of the scoping documents and problem formulations are compounded by the June 11 TSCA document for applying "systematic review" methods in the TSCA risk evaluations. As explained in our separate comments on this document, it would require data on the 10 chemicals to be reviewed using an arbitrary set of numerical criteria for study quality that has not been peer reviewed and is in conflict with other systematic review approaches used within EPA and by other federal agencies that have been endorsed by authoritative bodies like the National Academy of Sciences (NAS). Application of the TSCA systematic review document will unjustifiably restrict the body of evidence that informs EPA judgments about risk and hamper the Agency's ability to use the most relevant and meaningful data for decision-making on the 10 chemicals.

Because the 10 risk evaluations are likely to deviate dramatically from the goals of the law and take a large step backward in protecting public health, EPA should put them on hold, rethink how they are being conducted, and reinitiate them in accordance with the law and principles of sound science.

SUMMARY OF KEY POINTS

As described more fully in the body of these comments, we have the following fundamental concerns about the approach to risk evaluation reflected in EPA's scoping documents and problem formulations:

- Congress intended the scope of risk evaluations to be defined within six months after their initiation. Problem formulations are not an authorized step in the risk evaluation process and cannot be used to revisit issues of scope after the Agency has issued a scoping document in accordance with section 6(b)(4)(D). The problem formulations on the 10 chemicals are unlawful under TSCA because they go far beyond the scoping documents in excluding uses, exposures and hazards from the risk evaluations. (Section I, page 6)
- In direct contrast to the scoping documents, all the problem formulations provide that EPA will not consider environmental exposure pathways that could be addressed under other laws administered by EPA. This approach would remove all environmental exposure pathways – a significant contributor to human health risk for many chemicals – from the TSCA risk evaluation process. This dramatic narrowing of TSCA's scope is contrary to the plain language of the law and will defeat the central purpose of TSCA reform – to conduct comprehensive risk evaluations on ubiquitous chemicals that examine the impacts on health and the environment of all of the diverse pathways and modes of release that may result in harm. (Section II, pages 7-12)
- In an extension of this approach, several of the problem formulations indicate that EPA will not evaluate the risks of general population exposure to the 10 chemicals. However, if the presence of a chemical in environmental media – and therefore exposure to the chemical by the general population – is attributable to its "conditions of use," there is no basis for excluding this background level of exposure from EPA's risk evaluation. Moreover, EPA cannot perform its obligation under the law to "integrate and assess" information on exposure if it ignores the contribution of general population exposure to the

overall risk that a chemical poses to subpopulations that have additional sources of exposure. (Section III, pages 12-13)

- More broadly, neither the scoping documents nor the problem formulations shed any light on how EPA risk evaluations will account for multiple pathways of exposure by the general population or subpopulations. Instead, it appears that EPA will examine each source of exposure in isolation and will not consider either the combined effect of multiple exposures or the contribution of environmental releases to overall exposure and risk. This is a violation of TSCA. (Section IV, pages 13-14)
- Despite the deep concerns of commenters, the problem formulations reaffirm EPA's exclusion from its risk evaluations of ongoing use and disposal of chemical products that are no longer being manufactured (so-called "legacy uses"). This use and disposal clearly falls within the TSCA definition of "conditions of use" and its exclusion violates the plain language of the law. As the case of asbestos illustrates, discontinued products may be ubiquitous in the built environment and their contribution to current and future exposure and risk may greatly dwarf that of the few products that remain in commerce. To ignore this source of risk would deprive the public, scientists and regulators of important information about threats to public health and prevent policymakers from taking meaningful action to protect at-risk populations. (Section V, pages 14-16)
- Further narrowing the scope of risk evaluations, EPA has determined that it will not address recently discontinued uses of chemicals. The goals of TSCA would be defeated if manufacturers of unsafe chemicals could circumvent 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 of particular concern where the product phase-out is in response to agency scrutiny and intended to avoid the consequences of an adverse risk finding and subsequent regulatory action. Although EPA claims that discontinued uses are not "conditions of use" as defined in TSCA, the future resumption of these uses can be "reasonably foreseen" and thus would satisfy the statutory definition. By including such uses in its risk evaluation, EPA could then ban or restrict them permanently under section 6(a), providing certainty to the marketplace and long-term public health protection. (Section VI, pages 16-18)
- Our groups have repeatedly called for EPA to identify data gaps that limit its ability to reach definitive conclusions about the health and environmental effects of the 10 chemicals. However, the problem formulations make a minimal effort to identify the absence of data on the 10 chemicals and address how lack of information will impact the conclusions reached in the risk evaluations. In the face of material data gaps, an unqualified conclusion that a chemical does not "present an unreasonable risk of injury" to health could not be defended under TSCA and would misinform the public about the chemical's safety. Thus, EPA should be explicit about the health and environmental end-points that lack adequate data and exclude these end-points from its determinations of unreasonable risk. It should also use its TSCA authorities to require manufacturers to conduct testing to develop adequate data for a defensible risk evaluation so that future assessments can be informed by a comprehensive dataset. (Section VII, pages 18-23)
- The problem formulations indicate that conditions of use that present *de minimis* risks will not be further analyzed or addressed in risk evaluations. However, EPA has provided no general criteria for

determining levels of exposure that are insignificant. Nor has it provided any information to demonstrate that the uses it plans to drop lack meaningful exposure potential, either in themselves or in relation to their contribution to overall exposure. EPA may have some latitude to devote greater effort to some exposure scenarios than others, but this does not excuse ignoring particular conditions of use based on the unsubstantiated claim that their risks are negligible. (Section VIII, pages 23-24)

- As the asbestos risk evaluation illustrates, EPA has also dropped from consideration significant health end-points known to be linked to exposure to the chemical. This omission is likewise contrary to TSCA's comprehensive approach to evaluating risk. (Section IX, pages 24-25)
- Six of the 10 chemicals – asbestos (and Libby amphibole asbestos), trichloroethylene (TCE), methylene chloride (MC), carbon tetrachloride (CTA), perchloroethylene (PERC) and 1,4-dioxane – have been assessed under the EPA Integrated Risk Information System (IRIS). The IRIS process is the Agency's authoritative mechanism for reviewing available studies and characterizing the health effects of chemicals. The problem formulations, however, indicate that EPA will revisit the interpretation of studies already evaluated in IRIS using its highly questionable TSCA "systematic review" method that has not been peer reviewed. This may lead to departures from IRIS determinations of the "best available science" and "weight of the evidence." Reopening IRIS findings would harm the public by prolonging uncertainty on issues that have been addressed and resolved through an authoritative and transparent process. In rare cases where significant new data (since the IRIS assessment) are available, the EPA TSCA program should rely on the IRIS program to review, assess, and if appropriate incorporate any new information using a systematic review method that is consistent with the state of the science. (Section X, pages 25-28)
- EPA has proposed to ban certain uses of TCE and N-methylpyrrolidone (NMP) under TSCA section 6(a) based on comprehensive exposure and risk assessments of these uses, including its peer reviewed IRIS assessments on TCE. However, the problem formulations indicate that EPA intends to reopen these completed assessments and delay regulatory action despite serious threats to public health. This is unjustified and unnecessary. EPA should finalize the proposed rules without delay. (Section XI, pages 28-29)
- Occupational exposure is significant for nearly all of the 10 chemicals and should be a major focus of EPA's risk evaluations. The problem formulations indicate that when evaluating occupational risks, the Agency will heavily weigh applicable workplace standards. Although these standards may be relevant, EPA should not presume that they are fully protective of workers or that their existence can be equated with the absence of unreasonable risk. OSHA and EPA apply differing standards of protection by law; several OSHA standards are obsolete and do not reflect best available science; OSHA standards do not cover all workers with exposure to regulated chemicals; compliance with OSHA standards is uneven and variable; and as EPA has recognized, some of the industrial hygiene strategies embodied in OSHA standards – such as labels and respirators – are known to be of limited effectiveness in protecting workers. EPA should explicitly recognize these considerations in determining whether risks to workers are unreasonable under TSCA. (Section XII, pages 29-32)

I. The Problem Formulations Have No Basis in the Law and Improperly Narrow the Scope of the 10 Risk Evaluations

Section 6(b)(4)(D) of amended TSCA provides that, "not later than 6 months after the initiation of a risk evaluation," EPA must "publish the scope of the risk evaluation to be conducted, including the hazards, exposures, conditions of use and the potentially exposed or susceptible subpopulations the Administrator expects to consider." There is no authorization in the law for issuing a "problem formulation" document at a later point in time to further refine, expand or narrow the scope of the risk evaluation. Nor is this step identified in EPA's final risk evaluation framework rule issued under TSCA section 6(b)(4)(B).

Nonetheless, when it released its scoping documents for the 10 chemicals in June 2017, EPA announced that it was also developing problem formulations.[3] It justified this step on the basis that it had been unable to process all the information gathered during the scoping process and the scoping documents were not as "refined or specific" as EPA had hoped. Although the problem formulations may have performed a useful role under these unique circumstances, we do not support repeating this step for additional risk evaluations that EPA conducts. The intent of Congress was to provide clear notice to the public of the scope of risk evaluations within six months after they are initiated. This goal will be undermined if EPA retains the discretion to revisit issues of scope throughout the risk evaluation process and to continuously modify the hazards, uses and exposures that its evaluations will address.[4] Thus, problem formulation should be a one-time activity, limited to the special case of the first 10 chemicals, and not part of the risk evaluation process in the future.

We are also concerned that the problem formulations on the 10 chemicals go far beyond the scoping documents in excluding uses, exposures and hazards from the risk evaluations. Not only are these exclusions not justified under TSCA[5] but they narrow the evaluation significantly after its scope had been established in accordance with section 6(b)(4)(D). Since problem formulation is not a recognized step in the risk evaluation process or a substitute for scoping under LCSA, it cannot be used to narrow a risk evaluation's scope after-the-fact. Thus, the additional exclusions established in the problem formulations are unlawful.

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[3] 82 Fed. Reg. 31,592 (July 7, 2017).

[4] Thus, instead of taking comments on proposed scoping documents and addressing them in final scoping documents issued six months after a risk evaluation is initiated, EPA is now requesting comments on scope issues 20 months into the risk evaluation process. EPA plans to release draft risk evaluations by the end of 2018. Thus, it will be unable to review the comments and modify the evaluations without delaying their completion. In practice, this creates a high likelihood that the comments will be ignored. EPA admits as much by acknowledging that it plans to respond to the comments only when the risk evaluations are final.

[5] EPA's final risk evaluation rule, in contrast to its proposal, would permit the Agency to select which conditions of use to address in risk evaluations. 82 Fed. Reg. 33726 (July 20, 2017). SCHF and several of its partner organizations argued in their comments on the proposal that the law requires the Agency to address all conditions of use in its evaluations. Along with several other groups, SCHF is challenging EPA's contrary interpretation in its petition for judicial review of the risk evaluation rule. *Safer Chemicals Healthy Families v. EPA*, 17-72260 (9th Cir.) Regardless of the outcome of this challenge, we believe that EPA has no basis to narrow the risk evaluation to exclude conditions of use once they have been included in its scope.

II. EPA's Extreme Approach of Removing All Environmental Exposure Pathways from Risk Evaluations Is Contrary to the Plain Language and Structure of TSCA and Will Defeat the Central Purpose of TSCA Reform

In direct contrast to the scoping documents, all 10 of the problem formulations provide that EPA will not evaluate the risks of "exposure pathways that are under the jurisdiction of regulatory programs and associated analytical processes carried out under other EPA-administered environmental statutes – namely, the Clean Air Act (CAA), the Safe Drinking Water Act (SDWA), the Clean Water Act (CWA), and the Resource Conservation and Recovery Act (RCRA)."[6] EPA's rationale for this blanket exclusion is that it "believes that certain programs under other Federal environmental laws adequately assess and effectively manage the risks for the covered exposure pathways." As the Agency explains, "[t]he provisions of various EPA-administered environmental statutes and their implementing regulations represent the judgment of Congress and the Administrator, respectively, as to the degree of health and environmental risk reduction that is sufficient under the various environmental statutes."

Since the laws cited by EPA potentially apply to all releases into the environment, the effect of EPA's approach would be to remove environmental exposure pathways in their entirety from the TSCA risk evaluation process. This extreme approach is without any basis in the text of the law and will defeat the central purpose of TSCA reform – to conduct comprehensive risk evaluations on ubiquitous chemicals that examine the impacts on health and the environment of all of the diverse pathways and modes of release that may result in harm. Environmental media – air, surface water, groundwater, drinking water and waste – are known and pervasive sources of exposure for many substances. Any risk evaluation that fails to account for their contribution to total exposure will provide the public with a misleading and incomplete account of their potential to harm human health and fail to identify critical opportunities for risk reduction.

A. TSCA Risk Evaluations Must Examine Total Risk and Consider All Contributors to Exposure and Conditions of Use

Risk evaluations under TSCA section 6(b)(4)(A) must determine "whether a chemical substance presents an unreasonable risk of injury to health or the environment." These evaluations must therefore examine the totality of risks presented by the substance, taking into account all contributors to exposure, including not just its presence in the workplace or consumer products but its releases into the environment. Indeed, under the plain language of the statute, EPA's focus expressly includes risks to the *environment* in addition to human health. "Environment" is defined in section 3(6) to include "air, water and land and the interrelationship which exists among and between air, water and land and all living things." If EPA excludes the chemical's presence in environmental media (air, water and soil) and the impacts on the environment of that presence on humans and other living things, then it cannot meet its obligation to determine environmental risks.

Section 6(b)(4)(A) also provides that a risk evaluation must also determine the substance's risks under "the conditions of use." This broad term spans the entire life cycle of a chemical. It is defined under

[6] See, e.g., Problem Formulation of the Risk Evaluation for Carbon Tetrachloride (May 2018) at 13.

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." The "circumstances" to which the definition applies clearly include air emissions and water discharges from industrial facilities as well as releases to environmental media during disposal. For EPA to exclude all such environmental releases from its risk evaluations would remove from the application of the law a large category of "conditions of use" that Congress directed EPA to address.[7]

B. Environmental Exposure Pathways Are Central to Chemical Prioritization, Risk Evaluation and Regulation under Section 6 of TSCA

Other provisions in section 6 confirm the need to consider environmental releases as part of chemical prioritization and risk evaluation. For example, storage near significant sources of drinking water is a factor that EPA must examine in its process for designating chemicals as high- or low-priority under section 6(b)(1)(A). Similarly, under both this provision and section 6(b)(2)(D), chemicals with significant potential for persistence, bioaccumulation and toxicity (PBTs) must receive preference in the selection of substances for high-priority listing. PBTs are of concern because of their presence in environmental media and potential to concentrate in animals and humans as they are distributed in air, water and soil taken up the food chain. If EPA does not consider environmental release pathways of PBTs in evaluating their risks, it would be pointless to designate them as high-priority since the ensuing evaluation could not meaningfully address the contribution of environmental exposure pathways to total risk.

Paralleling the expansive definition of "conditions of use," the regulatory authorities in section 6(a) of the law empower EPA to take a broad array of actions to restrict chemical exposures and releases in order to eliminate unreasonable risks to health and the environment. Under the original law, EPA in fact used section 6(a) on a number of occasions to curtail environmental releases of toxic chemicals.[8] Indeed, section 6(a)(6)(A) authorizes EPA to impose a "requirement prohibiting or otherwise regulating any manner or method of disposal of such substance or mixture, or of any article containing such substance or mixture, by its manufacturer or processor or by any other person who uses, or disposes of, it for commercial purposes." The authority to regulate disposal (a broad concept that can include virtually any release of wastes into air, water or land) would be meaningless if EPA did not use risk evaluations under section 6(b) to identify disposal activities that present an unreasonable risk of injury and are subject to restriction under section 6(a).

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[7] As SCHF and its co-petitioners have argued in their brief in *Safer Chemicals Healthy Families v. EPA,* the statute gives EPA no discretion to exclude any conditions of use from risk evaluations, let alone the broad universe of environmental releases that occur during manufacture, processing, use, distribution in commerce and disposal of a chemical substance.

[8] Of the 6 existing chemicals EPA regulated under section 6 under the original law, the prevention of environmental releases was the basis for three of these regulatory actions. In 1978, EPA banned nonessential uses of fully halogenated chlorofluoroalkanes as propellants in aerosol spray containers because of concerns that these chemicals were destroying the upper atmosphere's ozone layer. In 1980, EPA promulgated a rule prohibiting Vertac Chemical Company and others from removing for disposal certain wastes containing 2,3,7,8-tetrachlorodibenzo-p-dioxin (TCDD) stored at Vertac's Jacksonville, Arkansas, facility. The rule also required any persons planning to dispose of TCCD contaminated wastes to notify EPA 60 days before their intended disposal. In 1994, EPA promulgated a rule to eliminate emissions of hexavalent chromium from comfort cooling towers.

C. TSCA Legislative History Demonstrates that the Law Was Intended to Address Environmental Releases that May Be Within the Purview of Other Laws

If Congress had intended a blanket exemption for environmental releases from risk evaluations under section 6(b) and regulation under section 6(a), it surely would have said so explicitly given the far-reaching impact of such an exemption. Not only is there no such exemption in the law, but its legislative history and structure demonstrate that Congress intended TSCA to provide a comprehensive framework for identifying and managing chemical risks, including those that derive from environmental exposure pathways and could be addressed under other environmental laws.

The comprehensive scope of TSCA was underscored in the legislative history of the original law. 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, at 7 (1976); see S. Rep. No. 94-698, at 3 ("[W]e have become literally surrounded by a manmade chemical environment. … [T]oo frequently, we have discovered that certain of these chemicals present lethal health and environmental dangers."). While other federal environmental laws focused on specific media, such as air or water, none gave EPA authority to "look comprehensively" at the hazards of a chemical "in total." S. Rep. No. 94-698, at 2. Congress designed TSCA to fill these "regulatory gaps," S. Rep. No. 94-698, 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."[9] Excluding all pathways of chemical exposure through air, water and soil from risk evaluations would be directly contrary to these Congressional expectations.

D. TSCA Section 9(b) Provides that EPA Must Decide Whether TSCA or Another Law is the Best Vehicle for Risk Management Only After Evaluating the Risks of a Chemical's Environmental Releases under TSCA

In the 1976 law, Congress recognized the need to coordinate use of TSCA with implementation of other environmental laws. However, it chose to do so not by excluding environmental releases from the purview of TSCA – the approach EPA is pursuing now. Instead, it established a framework for determining, on a case-by-case basis, whether the risks of particular chemicals are best addressed under these laws or under TSCA. Thus, section 9(b)(1) of TSCA provides that EPA may use TSCA regulatory authorities if it "determines, in [its] discretion, that it is in the public interest to protect against [a particular] risk by action taken under this Act" but should use other environmental laws if it determines

[9] Congressional Record – Senate 3517 (June 7, 2016).

that "a risk to health or the environment . . . could be reduced to a sufficient extent by actions taken under" these laws.

In 2016, Congress underscored the chemical-specific focus of this analysis by revising section 9(b)(2) so that, in deciding whether to regulate under TSCA or another law, EPA must "consider . . . all relevant aspects of the risk" in question and make a "comparison of the estimated costs and efficiencies" of addressing the risk under TSCA and other laws. Commenting on this language, the law's Senate Democratic sponsors explained that it allowed EPA to regulate under other laws in lieu of TSCA only where the "Administrator has already determined that a risk to health or the environment associated with a chemical substance or mixture could be eliminated or reduced to a sufficient extent by additional actions taken under other EPA authorities."[10]

This approach presupposes that EPA has already used the TSCA risk evaluation process to identify the risks of a chemical and the exposure pathways contributing to those risks and thus has an informed basis to determine whether they "could be eliminated or reduced to a sufficient extent" under another law. If EPA has not examined the specific pathways of environmental exposure and their contribution to total risk under TSCA, then it cannot conduct the analysis that section 9(b) requires because it will be unable to evaluate the relative strengths of using TSCA or another law to eliminate the risk. By presuming that other laws are *always* superior to TSCA in identifying and reducing the risks of chemicals in environmental media, EPA's blanket exclusion of environmental releases thus turns section 9(b) on its head.

E. Contrary to EPA, There is No Basis to Conclude that Other Environmental Laws are Equivalent in Scope and Protectiveness to TSCA

EPA's position that other environmental laws should displace TSCA risk evaluations for *all* chemicals arbitrarily assumes that these laws provide equivalent protection of public health and the environment and that there is no added benefit in addressing environmental pathways of exposure under TSCA. But in reality these other laws vary greatly in the degree of protection they afford against chemical risks and the extent of their application to unsafe chemicals. These limitations are precisely why Congress gave EPA comprehensive authority over chemical risks under TSCA in 1976 and strengthened that authority in 2016.

The 2016 TSCA amendments establish a risk-basic framework for EPA's decisions on chemical safety and set a high standard of protection of health and the environment. 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, *without consideration of costs or other non-risk factors*" (emphasis added). This determination must be for both the general population and "potentially exposed or susceptible subpopulations." Once an unreasonable risk is identified, TSCA section 6(c)(1) requires EPA to issue a rule under section 6(a) to address the risk. Section 6(a), in turn, directs that this rule must restrict the chemical "to the extent necessary so that the chemical substance no longer presents such risk" – again assuring protection of potentially exposed or susceptible subpopulations. As EPA has recognized, it

[10] Id.

cannot lower this level of protection based on consideration of costs and benefits.[11] Although the rule must be accompanied by an economic analysis, the restrictions it imposes must be sufficient to eliminate the unreasonable risk identified in the evaluation. Indeed, the 2016 TSCA revisions were explicitly designed to remove the cost-benefit framework required under the old law because it had impeded meaningful regulation of unsafe chemicals.[12]

TSCA's strict risk-based framework for chemical risk management is not mirrored in most environmental laws that govern releases to air, water and soil and disposal of waste. For example, the standard-setting process to establish discharge limits for chemical and other pollutants under the Clean Water Act (CWA) is technology-based and does not allow for consideration of risk.[13] The same is true of several provisions of the Clean Air Act (CAA) that regulate emissions from new and modified stationary sources of pollution and mobile sources.[14] In addition, the primary CAA mechanism for controlling industrial emissions of air toxics calls for EPA to set standards requiring Maximum Achievable Control Technology (MACT), an approach that does not take into account risks to health, although any "residual risks" can be addressed in a second stage of rulemaking.[15]

Even statutes that do allow for consideration of risks also direct EPA to weigh cost and other economic factors. The Safe Drinking Water Act (SDWA), for example, requires cost-benefit balancing in setting limits for drinking water contaminants, the very approach rejected in the 2016 TSCA amendments.[16] The Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), which governs the remediation of contaminated sites, focuses on health protection but also directs EPA to take into account costs and technical achievability.[17] And importantly, most of these laws do not include TSCA's explicit protections for potentially exposed or susceptible subpopulations at higher risk than the general population. In short, the bulk of EPA-implemented environmental laws lack the high level of protectiveness and exclusive focus on eliminating unreasonable risks that Congress demanded in its recent TSCA revisions.

Equally important, in comparison to TSCA, the scope of regulation under other federal environmental laws is limited: these laws generally apply to only a subset of the substances that may present risks to health or the environment and only a subset of the facilities whose environmental releases contribute to these risks. For example, air toxics emission requirements in the CAA only address 189 Hazardous Air Pollutants (HAPs) designated by Congress in the 1990 CAA amendments[18] and only large industrial emitters that meet the CAA definition of "major source" are subject to emission limits.[19] Similarly, CERCLA cleanups encompass a statutory list of hazardous substances[20] and disposal requirements under

[11] See proposed rule banning TCE use in vapor degreasing, 82 Fed. Reg. 7432, 7439-41 (Jan. 19, 2017).
[12] S. Rep. No. 114-67, at 4.
[13] 33 U.S.C. §1317.
[14] 42 U.S.C. §§7411,7475.
[15] 42 U.S.C. §7412.
[16] 42 U.S.C. §300g-1
[17] 42 U.S.C. §9621.
[18] 42 U.S.C. §7412(b).
[19] 42 U.S.C. §7412(a)(1).
[20] 42 U.S.C. §9601(14).

the Resource Recovery and Conservation Act (RCRA) only apply to those wastes that EPA has designated as "hazardous."[21] Industrial discharge limits under the CWA only apply to regulated "toxic" pollutants[22] and the CWA's water quality framework involves a complex mix of state and federal standards that vary across regions, may not address all pollutants that threaten human health and often do not result in uniform levels of protection. These basic gaps in coverage are painfully evident as EPA and states struggle to address widespread contamination and threats of harm to human health resulting from the extensive use and environmental release of Per- and polyfluoroalkyl substances (PFAS). Despite their significant risks, PFAS chemicals are not regulated as HAPs under the CAA, drinking water contaminants under the SDWA, hazardous substances under CERCLA or toxic pollutants under the CWA.

While EPA may have authority to expand the reach of its environmental laws to include previously unregulated toxics, it cannot do so without first evaluating the risks of these chemicals. With limited exceptions, however, EPA has no obligation under its environmental laws to assess the risks of unregulated chemicals or even to update its understanding of the hazard and exposure profile of those substances that are regulated. In practice, moreover, EPA's other regulatory programs have limited resources and many competing priorities, including those required by specific statutory provisions and/or court orders. Thus, there is little likelihood that previously unaddressed chemical risks will be evaluated by these programs. Indeed, many existing environmental standards are decades old and no longer reflect the best available science but EPA's environmental media programs lack the bandwidth and inclination to update them based on current understanding of risks to human health and the environment. For all these reasons, by precluding the use of TSCA to determine the health and environmental impacts of chemical releases to air, water and soil, EPA is effectively closing the door to any meaningful evaluation of these impacts – and, thus, to the use of TSCA or other laws to restrict those releases that are found to be unsafe.

In sum, exclusion of all environmental releases from TSCA risk evaluations is contrary to the wording, intent and purposes of the law and will inevitably mean that serious threats to health and the environmental are neither identified nor addressed.

III. There is No Legal or Technical Justification for Excluding General Population Exposure from EPA's Risk Evaluations

Several of the problem formulations indicate that EPA will not evaluate the risks of general population exposure. As stated in the PERC problem formulation:

> EPA does not plan to consider and analyze general population exposures in the risk evaluation for PERC. EPA has determined that the existing regulatory programs and associated analytical processes have addressed or are in the process of addressing potential risks of TCE that may be present in various media pathways (e.g., air, water, land) for the general population. For these cases, EPA believes that the TSCA risk evaluation should focus not on those exposure pathways,

[21] 42 U.S.C. §6921.
[22] 42 U.S.C. §1317(a).

but rather on exposure pathways associated with TSCA uses that are not subject to those regulatory processes.[23]

This approach is unjustified for the reasons discussed above. If the presence of a chemical in environmental media – and therefore exposure to the chemical by the general population – is attributable to its "conditions of use", there is no basis for excluding this background level of exposure from EPA's risk evaluation. The claim that this exclusion is justified because "existing regulatory" programs apply to environmental releases is unsupported by the law: in accordance with section 9(b), EPA must first determine the risk resulting from environmental releases through a TSCA risk evaluation and then determine whether the risk is best addressed under TSCA or other EPA-administered environmental laws.

The goal of risk evaluations under section 6(b)(4)(A) is to determine the risks presented by a chemical as a whole, not the risks of individual uses and pathways in isolation. Moreover, section 6(b)(4)(F) directs EPA to take into account "the likely duration, intensity, frequency and number of exposures under the conditions of use of the chemical substance" and to "integrate and assess available information on hazards and exposures for the conditions of use." This integrating analysis cannot be performed if some pathways of exposure are excluded simply because they involve environmental media and could be subject to other laws. As the House Report for original TSCA emphasized, "[i]ntelligent standards for regulating exposures to a chemical in the workplace, the home or elsewhere in the environment cannot be set unless the full extent of human or environmental exposure is considered."[24]

The background levels of a chemical in the environment may present an unreasonable risk to the general population in their own right or they may add to other sources of exposure to present an overall risk to specific populations that is unreasonable. In either event, EPA cannot discharge its obligations under the law unless it determines and takes into account the background levels of a chemical to which the general population is exposed.

IV. EPA's Continues to Fail to Explain What Methodology It Will Use to Account for Multiple Exposure Pathways that Increase Overall Risk

The law's clear requirements for evaluating and protecting against risks to "potentially exposed or susceptible subpopulations" further underscore EPA's obligation to consider all contributors to exposure and risk, including a chemical's presence in environmental media. In order to determine whether a subpopulation may be at greater risk because it has greater exposure than the general population, the Agency must first quantify general population exposure and then determine how this exposure is increased because of exposures in the workplace, through products, as a result of environmental releases or because of other pathways that affect a particular subpopulation. To protect these subpopulations, EPA's focus must be on whether the total risk they face, considering all sources of exposure, is unreasonable. If one or more contributors to exposure are ignored, groups who are at

[23] Problem Formulation of the Risk Evaluation for Perchloroethylene (May 2018) at 73.
[24] House Rept. No. 94-1341, supra, at 6.

greater risk than the general population because of multiple exposure pathways will be inadequately protected.

Recognizing the need to account for the impact of multiple sources of exposure, TSCA section 6(b)(4)(F)(ii) requires risk evaluations to describe whether aggregate or sentinel exposures to a chemical were considered and the basis for that consideration. To properly apply either or both of these approaches in a risk evaluation, EPA must determine in advance what methodology it will employ and then incorporate it in the risk evaluation design in sufficient detail to describe the key data sources it will use to assess exposure and how they will be used.

EPA has not done this. Disappointingly, neither the scoping documents nor the problem formulations shed any light on how EPA risk evaluations will account for multiple pathways of exposure by the general population or subpopulations. Instead, it appears that EPA will examine each source of exposure in isolation and will not consider either the combined effect of multiple exposures or the contribution of environmental releases to overall exposure and risk. This is a violation of TSCA.

V. Ongoing Use and Disposal of Chemical Products that are No Longer Being Manufactured Fall Within the TSCA Definition of "Conditions of Use" and Cannot Be Excluded from Risk Evaluations

Among the 10 chemicals are substances, such as asbestos and HBCD, that contribute to ongoing exposure and risk as a result of historical manufacturing and processing activities that have been discontinued. In many cases, the current and foreseeable risks associated with these activities are significant. Nonetheless, the problem formulations, like the scoping documents, take the position that they are outside the scope of risk evaluations. As stated in EPA'S asbestos problem formulation:

> In the case of asbestos, legacy uses, associated disposals, and legacy disposals will be excluded from the problem formulation and risk evaluation, as they were in the Scope document. These include asbestos containing materials that remain in older buildings or are part of older products but for which manufacture, processing and distribution in commerce are not currently intended, known or reasonably foreseen. EPA is excluding these activities because EPA generally interprets the mandates under section TSCA § 6(a)-(b) to conduct risk evaluations and any corresponding risk management to focus on uses for which manufacture, processing or distribution is intended, known to be occurring, or reasonably foreseen, rather than reaching back to evaluate the risks associated with legacy uses, associated disposal, and legacy disposal, and interprets the definition of conditions of use in that context. [25]

EPA is incorrectly interpreting the provisions of LCSA. The definition of "conditions of use" in section 3(4) includes the "circumstances . . . under which a chemical substance is . . . known or reasonably foreseen to be . . . used or disposed of." Where a chemical is performing an ongoing *in situ* function as a result of

[25] Problem Formulation of the Risk Evaluation for Asbestos (May 2018) at 8.

previous manufacturing and processing activity, that function comprises a current "use" of the chemical that is "known" to be occurring.[26]

For example, although asbestos may no longer be sold as insulation, the asbestos insulation installed in millions of US buildings continues to perform insulating functions and thus is a current ongoing "use" of asbestos. Installed asbestos-containing building materials (ACBMs) represent one of the largest sources of asbestos accessible to the general public in the US, and the largest asbestos-exposed population consists of people who occupy buildings and homes with ACBMs. Maintenance and construction activities involving ACBMs are also frequent and widespread and account for the largest present-day increase in mesothelioma illness and death in the US.[27]

Similarly, the Healthy Building Network estimates there are 66 million- 132 million pounds (30,000-60,000 metric tons) of HBCD in insulation in existing buildings.[28] These ongoing insulation uses are and will continue to be critical sources of ongoing exposures. HBCD is also present in cars and furniture as a flame retardant and its use in these long-lived consumer articles will contribute to ongoing exposures for years to come.[29]

Equally important, the disposal of building materials or consumer products containing asbestos or HBCD is an ongoing occurrence as buildings are torn down or remodeled and cars and furniture are replaced. Thus, the resulting releases into the environment and communities comprise a "circumstance . . . under which [these chemicals] are . . . known or reasonably foreseen to be . . . disposed of." As "conditions of use" within the TSCA definition, these activities and the risks they present are likewise required to be addressed in risk evaluations under section 6(b). For both chemicals, the immediate and long-term exposures associated with disposal of *in situ* building materials and products are likely to be widespread and significant well into the future.[30]

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[26] SCHF and its co-petitioners are challenging EPA's position that ongoing use and disposal of discontinued products are not TSCA "conditions of use" in *Safer Chemicals Healthy Families v. EPA*, 17-72260 (9th Cir.) In addition to being used and disposed of, legacy products that perform functions in the built environment can be considered "distributed in commerce" as this term is defined in TSCA section 3(5). The definition includes "to hold, or the holding of, the substance, mixture or article after its introduction in commerce" – language that plainly applies to *in situ* products. Likewise, the definition includes the "introduction or delivery for introduction into commerce" of the substance, mixture or article. This description would apply to legacy products that are repurposed or sold for recycling.

[27] US CDC study, "Malignant Mesothelioma Mortality – United States 1999 to 2005."

[28] Safer Chemicals, Healthy Families et al. Comments to the U.S. Environmental Protection Agency (EPA) on the Scope of its Risk Evaluation for the TSCA Work Plan Chemicals: CYCLIC ALIPHATIC BROMIDE CLUSTER or HEXABROMOCYCLODODECANE (HBCD). March 15, 2017. https://healthybuilding.net/uploads/files/saferchemicals-hbcd.pdf

[29] It is unclear whether EPA intends to exclude installed HBCD-containing building and construction materials from its risk evaluation. The problem formulation states that the evaluation will address "commercial/consumer use" of "building/construction materials" but this could be interpreted to apply to materials that are available for use in ongoing construction projects and not those already installed. See Problem Formulation for Cyclic Aliphatic Bromides Cluster (HBCD) (May 2018) at 29.

[30] EPA also excludes disposal from the asbestos and HBCD risk evaluations based on its overall determination that the release of chemicals to environmental media should not be addressed under TSCA. Oddly, disposal of HBCD construction and demolition waste is listed as a condition of use EPA plans to address in one part of its problem

To exclude from risk evaluations ongoing and future exposures from *in situ* uses of discontinued products would create a sizable gap in the life-cycle assessments of risk that Congress directed EPA to conduct under the new law. This would deprive the public, scientists and regulators of a comprehensive picture of one of the largest sources of continuing and future risk. Since *in situ* sources of exposure form a critical component of the background levels of asbestos and other chemicals to which the general population is exposed, EPA's assessment of risks to particular subpopulations from more specific exposure pathways would also be incomplete and understated.

In addition, decision-makers would be unable to reduce ongoing exposures and impose safeguards against unsafe use and disposal and "legacy" products because they would lack a meaningful risk evaluation to inform these actions. Just as TSCA provides authority to evaluate the risks associated with ongoing exposures from discontinued activities, so it gives EPA the authority under section 6(a) to reduce these risks, yet the Agency would be stymied by the absence of a risk evaluation that provides a basis for such regulation.[31]

In short, EPA must characterize and assess ongoing exposures from the use and disposal of discontinued products and determine the risks they present as part of its risk evaluations on the initial 10 chemicals. Its continuing failure to do so is a clear violation of TSCA.

VI. Uses Discontinued under the Threat of Regulatory Action Fall Within the TSCA Definition of "Conditions or Use" and Must be Addressed in TSCA Risk Evaluations

A number of the problem formulations indicate that certain chemical uses have been discontinued and therefore will not be addressed in the risk evaluation for that chemical.

The problem formulation for HBCD illustrates this approach. Based on representations by industry, EPA asserts that HBCD use in the production of flame retardants, EPS resins, high impact polystyrene, XPS master batch, motor vehicle upholstery, consumer textiles, and military, institutional and aviation textile applications has ceased. According to EPA, these uses are no longer "intended, known or reasonably foreseen" and therefore do not comprise TSCA "conditions of use" that will be addressed in the HBCD risk evaluation.[32] EPA also indicates that because HBCD is no longer being manufactured in the US, domestic production will likewise not be addressed.

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formulation (page 29) but then identified as an exposure pathway that will not be considered later in the same document (page 52).

[31] For some chemicals like lead and asbestos, other laws administered by EPA address handling and disposal of *in situ* materials and the Agency may be able to refer the findings of its risk evaluations to the programs implementing these laws under TSCA section 9(b) in lieu of further regulation under section 6. However, there are no existing laws that address ongoing exposure from use and disposal of discontinued products containing HBCD, perfluorinated chemicals and other substances and therefore the availability of the protections afforded under section 6 of TSCA may be critical to addressing their risks. Obviously, if these risks are not identified and evaluated under TSCA section 6(b), there will be no basis for reduction them through regulation under section 6(a).

[32] Problem Formulation of the Risk Evaluation for Cyclic Aliphatic Bromides Cluster (HBCD), at 24-25.

EPA has not disclosed the industry communications it is relying on but it appears they are informal and non-binding and have not been verified by the Agency. Nor has EPA indicated that it has contacted all HBCD producers and users to confirm that the uses in question have been fully eliminated. Thus, there is no assurance that these HBCD uses no longer exist and, if so, will not be revived in the future. Indeed, the most likely explanation for the phase-out of previously well-established HBCD uses is the regulatory and public scrutiny HBCD has received, a consideration that could wane in importance in the future, particularly if the risks presented by these uses are not evaluated or restricted by EPA.

EPA has also narrowed the scope of the asbestos risk evaluation by excluding now discontinued but historically significant asbestos-containing products and failing to address mining of asbestos in the US. Instead, EPA has proposed a significant new use rule (SNUR) so that it is notified of the reintroduction of discontinued products before it occurs.[33] However, while EPA has the ability to ban or restrict a new use after receiving notification under a SNUR, the SNUR does not itself comprise a finding of unreasonable risk nor does it provide any assurance that the use would be regulated once the Agency receives a significant new use notice (SNUN). With the exclusion of discontinued asbestos uses, the EPA risk evaluation will be limited to the small number of asbestos products that remain in commerce, providing a grossly incomplete picture of the threat to health from past and potential future uses of asbestos.

We disagree with EPA that discontinuance of a previously widespread use necessarily places it beyond the reach of section 6 risk evaluation and management authorities. EPA provides no justification for its assertion that the TSCA definition of "conditions of use" does not apply to such 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. Moreover, section 6(a) provides that EPA must regulate a chemical where "manufacture, processing, distribution in commerce, use or disposal" presents an unreasonable risk but does not stipulate that these activities must be currently occurring to warrant restriction. Indeed, the purpose of section 6(a) rules – to impose the measures "necessary so that the chemical substance no longer presents [an unreasonable] risk" – is equally applicable to ongoing commercial activities and to historical uses that could resume and require restrictions so they do not cause harm to health and the environment.

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 EPA retained its authority to address anticipated future risks:

> "Existing TSCA as in effect before the date of enactment of Frank R Lautenberg Chemical Safety for the 21st Century Act includes the authority, contained in several sections (see, for example, section 6(a)), for EPA to take regulatory actions related to chemical substances or mixtures if it determines that the chemical substance or mixture 'presents or will present' an unreasonable risk to health or the environment. The Frank R. Lautenberg Chemical Safety for the 21st Century

[33] 83 Fed. Reg. 26922 (June 11, 2018).

> Act includes language that removes all instances of 'will present' from existing TSCA and the amendments thereto. *This 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 . . . "*[34]

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 product phase-out is in response to agency risk concerns and intended to avoid the consequences of an adverse risk finding and subsequent regulatory action. In these cases, the best interpretation of TSCA is to treat the possible reintroduction of a discontinued use as "reasonably anticipated," to address that use in the risk evaluation and to then ban or restrict it permanently under section 6(a) if it is determined to present an unreasonable risk.

We do not believe a SNUR is an adequate substitute for evaluation and regulation of a discontinued chemical use under section 6. SNURs are fundamentally notification requirements and do not themselves require an assessment or determination of risk. 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. While the Agency must review the new use and ban or restrict it under sections 5(e) or 5(f) upon determining that the use does or may present an unreasonable risk, the Agency may or may not choose to take these actions. Thus, the door will not be closed to reintroduction of the use. Moreover, EPA's review of a SNUN and decision to regulate the new use lack the elements of openness and accountability that apply during section 6 risk evaluations and rulemakings. Thus, these decisions will receive limited public and judicial review.

A comprehensive risk evaluation under section 6, by contrast, enables the Agency to make a definitive risk determination for plausible future risk scenarios in a transparent process that provides clarity to industry and the public and closes the door to the resumption of unsafe uses. If there is a role for a SNUR, it is to perform the limited stop-gap function of assuring that EPA is notified of significant changes in use while its risk evaluation and follow-up rulemaking are underway so that these uses are not re-established in the marketplace before EPA has addressed their risks under section 6 and restricted them if warranted.

VII. EPA Should Not Make Determinations of Unreasonable Risk for Endpoints that Lack Adequate Information and Should Use its Section 4 Authorities to Require Industry to Fill These Data gaps

[34] Cong. Record – Senate 3515 (June 7, 2016) (emphasis added).

Our groups have repeatedly called for EPA to identify data gaps that limit its ability to reach definitive conclusions about the health and environmental effects of the 10 chemicals.[35] We have urged EPA to take steps to fill these data gaps early in the risk evaluation process using its expanded TSCA information development authorities so that sufficient information is available for an informed evaluation. EPA itself has emphasized the need for comprehensive data on hazard and exposure before it initiates evaluations although it has backed away from a systematic information collection process at the pre-prioritization stage for risk evaluation candidates.[36] Basing risk evaluations on adequate data is not only necessary to meet EPA's obligation under section 26(k) to consider all "reasonably available information" but furthers section 2(b)(2), which declares that "[i]t is the policy of the United States" that "adequate data should be developed with respect to the effect of chemical substances and mixtures on health and the environment."

It is therefore disappointing that the problem formulations, like the earlier scoping documents, make minimal efforts to identify significant data gaps for the 10 chemicals, to set in motion development of additional information, and to address how these data gaps will impact the conclusions reached in the risk evaluations. Indeed, EPA seems ready to find that substances do not present an unreasonable risk of injury even where available data are lacking entirely or are insufficient under Agency guidelines to determine that a substance lacks adverse effects.[37]

Pigment violet 29 is a case in point. The problem formulation for this substance indicates that, based on the absence of significant evidence of hazard, EPA "expects to be able to reach conclusions about particular conditions of use, hazards, or exposure pathways without further analysis."[38] Yet nowhere does EPA address whether it has sufficient information to reach such conclusions for major health end-points. EPA's Design for the Environment (now known as Safer Choice) Program and risk evaluation

[35] See, e.g., Comments of Safer Chemicals Healthy Families on Proposed Procedures for Chemical Risk Evaluations under the Amended Toxic Substances Control Act Submitted via Regulations.gov (March 20, 2017), Docket ID EPA-HQ-OPPT-2016-0654

[36] In the discussion paper EPA prepared for its December 11, 2017 public meeting on prioritization, EPA stated that:

> Prior to designating a chemical as a high-priority for risk evaluation, it is important for EPA to ensure the reasonably available information is sufficient to conduct a scientifically robust risk evaluation. In many cases, EPA believes it would be difficult to require the development of necessary chemical substance information, evaluate that information, and incorporate that information into analyses and decisions within the statutory timeframes associated with the prioritization and risk evaluation processes. Therefore, it will be useful for EPA to identify information needs and determine whether any of these needs should be addressed before initiating the prioritization process.

DISCUSSION DOCUMENT: Possible Approaches and Tools for identifying Possible Candidate Chemicals for Prioritization at 7. Despite this recognition, EPA's final prioritization framework rule deleted a pre-prioritization process that would have expressly provided a process for identifying and filling data gaps before risk evaluations are initiated. *Procedures for Prioritization of Chemicals for Risk Evaluation under the Toxic Substances Control Act.* 82 Fed. Reg. 33753 (July 20, 2017).

[37] The EPA responses to comments on the scoping documents indicate that: "when OPPT does find existing data are not adequate, OPPT will use all available authorities to fill data gaps necessary to conduct fit-for-purpose assessments." This is not, however, the approach reflected in the problem formulations.

[38] Problem Formulation of the Risk Evaluation for Pigment Violet 29 (May 2018) at 7.

guidelines and REACH requirements in the EU identify the studies deemed necessary for an informed risk evaluation. The database for pigment violet 29 is deficient when measured against these authoritative sources. Illustrating these deficiencies, the table below compares the test data available on pigment violet 29 with the requirements for a DfE/Safer Choice human health hazard trait assessment. [39]

DfE Hazard Trait	**Empirical Data Available for Pigment Violet 29?[40]**
Acute mammalian toxicity	Yes. In vivo oral, dermal and inhalation acute toxicity studies are available, though the inhalation studies are deemed to be unsuitable by ECHA.[41]
Respiratory sensitization	No
Skin sensitization	Yes, in vivo study
Eye irritation/ corrosivity	Yes, in vivo study
Skin irritation/ corrosivity	Yes, in vivo study
Carcinogenicity	No
Mutagenicity/ genotoxicity	Yes. In vitro gene mutation and mammalian cells genetic toxicity studies available.
Reproductive and developmental toxicity	Yes, screening study
Developmental neurotoxicity	No
Neurotoxicity	No
Repeated dose toxicity	No
Endocrine activity	No

Thus, EPA could not reach scientifically defensible conclusions that pigment violet 29 lacks the potential to cause carcinogenicity, reproductive and developmental toxicity, developmental neurotoxicity, neurotoxicity, repeated dose toxicity or endocrine effects.

[39] SCHF is grateful to scientists at the University of California San Francisco for preparing this table, which is included in comments on the problem formulations filed on behalf of a group of academics, scientists, and clinicians.

[40] Information from: US EPA (May 2018) Problem Formulation of the Risk Evaluation for Pigment Violet 29. European Chemicals Agency (ECHA). (2017). Perylene-3, 4; 9, 10-tetracarboxydiimide. Helsinki, Finland. Available: https://echa.europa.eu/registration-dossier/-/registered-dossier/10330

[41] ECHA states: "Unsuitable test system, as the inhalation hazard test is insufficient for non-volatile substances." Available: https://echa.europa.eu/registration-dossier/-/registered-dossier/10330/7/3/3/?documentUUID=34aa4522-b714-47b0-9bee-af8052fff73d

Pigment violet 29 is not the only one of the 10 chemicals with significant data gaps. 1,4-dioxane, MC, PERC and TCE also lack data for important end-points:

1,4 Dioxane. For this chemical, there is little or no information on the potential for developmental toxicity or developmental neurotoxicity. This is especially problematic given that the chemical is a well-known neurotoxic agent. This critical data gap was identified by ATSDR in its 2012 Tox Profile.[42]

MC. MC is a known human neurotoxicant, associated with depression of the central nervous system, and severe dose-dependent neurotoxic effects including headaches, slowed reaction time, decreased alertness, impaired movements, loss of consciousness, coma, seizures, and death. (It has been shown in animal studies to cross the placenta, and in humans it has been detected in breast milk.[43]) Yet, the chemical has not been adequately tested for developmental neurotoxicity. This is especially alarming given the widespread use and population exposure to this deadly neurotoxic chemical. Chemicals that are neurotoxic should be presumed to be developmentally neurotoxic. That is, compared with adult exposures, they are much more damaging and at much lower levels when exposures take place during early fetal development.[44] The failure to test and appropriately regulate these chemicals has led to debilitating neurodevelopmental disorders such as autism, learning deficits, and behavioral problems – all with disastrous impacts on affected individuals, families, and society.

PERC. This chemical is considered by EPA to be both neurotoxic and a developmental toxicant, yet it has never been tested for developmental neurotoxicity. This is a major data gap, given that developmental neurotoxic effects such as learning impairments and behavioral problems are often overlooked in routine tests such as the ones EPA considered, which focus on crude frank toxicity such as reduced body or organ weights, stillbirths and deaths (see Perc problem formulation, p. 52). Lead, mercury, and other developmental neurotoxic chemicals have all been shown to have virtually no safe level when exposures occur prenatally during critical windows of neurodevelopment.[45] For this reason, the EPA pesticide office began requiring pesticide registrants to submit developmental neurotoxicity testing – which includes subtle but important endpoints like motor activity, learning and memory, and auditory startle response – for the organophosphates and other pesticides known to be neurotoxic.[46] In an EPA fact sheet issued last month, EPA emphasizes why specific developmental neurotoxicity tests are important:[47]

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[42] Agency for Toxic Substances and Disease Registry (ATSDR). 2012. Toxicological profile for 1,4 Dioxane. Atlanta, GA: U.S. Department of Health and Human Services, Public Health Service. P. 143. https://www.atsdr.cdc.gov/toxprofiles/tp.asp?id=955&tid=199

[43] ATSDR Medical Management Guidelines for Methylene Chloride. Updated 2014. https://www.atsdr.cdc.gov/MMG/MMG.asp?id=230&tid=42

[44] Grandjean P, Landrigan PJ. Developmental neurotoxicity of industrial chemicals. Lancet. 2006 Dec 16;368(9553):2167-78. Review.

[45] Grandjean P, Landrigan PJ. Developmental neurotoxicity of industrial chemicals. Lancet. 2006 Dec 16;368(9553):2167-78. Review.

[46] EPA OPPTS 870.6300 Developmental neurotoxicity study. 1996. EPA 712-C-96-239.

[47] EPA Science Brief. Evaluating Developmental Neurotoxicity. July 2018. https://www.epa.gov/sites/production/files/2018-07/documents/dnt_factsheet_07_23_18_final.pdf

- The developing nervous system can be particularly sensitive to exposure to environmental chemicals.
- Less than 1% of chemicals in the environment have been fully evaluated for their potential to be developmental neurotoxicants, or their impact on the developing nervous system.
- Due to a lack of data, it is not possible to understand the extent or potential contribution of environmental chemicals in neurodevelopmental disease, nor predict the potential developmental neurotoxicity risk for individual chemicals.

The failure to address the risks of developmental neurotoxicity posed by PERC represents a serious data gap in EPA's assessment, particular for the low-dose risks.

TCE. Trichloroethylene was evaluated well over a decade ago, in 2004, by the EU, which at the time identified the need for developmental neurotoxicity testing to be conducted for TCE:

> The developmental toxicity of inhaled trichloroethylene at non-maternally toxic levels (up to 1,800 ppm) has been investigated in rats, mice and rabbits in conventional studies. No evidence of developmental toxicity was reported. In contrast, the results of a series of non-standard oral studies in rats raised some concerns about the potential for trichloroethylene to induce developmental neurotoxicity at dose levels in the range of 30-110 mg/kg/day. However, these studies were of limited scope and were considered not to provide sufficient basis on which to draw clear conclusions about the hazardous properties of trichloroethylene. To be able to draw clear conclusions regarding developmental neurotoxicity, further testing according to the draft OECD TG 426 Developmental Neurotoxicity guideline would be required."[48]

The 2011 IRIS assessment comes to similar conclusions, also identifying the potential for developmental neurotoxicity and noting this data gap:

> In summary, an overall review of the weight of evidence in humans and experimental animals is suggestive of the potential for developmental toxicity with TCE exposure. A number of developmental outcomes have been observed in the animal toxicity and the epidemiological data, as discussed below. These include adverse fetal/birth outcomes including death (spontaneous abortion, perinatal death, pre- or post-implantation loss, resorptions), decreased growth (low birth weight, SGA [small for gestational age], IUGR [intrauterine growth restriction], decreased postnatal growth), and congenital malformations, in particular cardiac defects. Postnatal developmental outcomes include developmental neurotoxicity, developmental immunotoxicity, and childhood cancer.[49]

The TCE problem formulation identifies the risk of neurotoxicity and developmental toxicity separately, noting evidence from both human studies and animal studies, including psychomotor effects from TCE exposures.[50] Yet, there is no study that specifically targets the sensitive and critical endpoint of

[48] European Union 2004, Risk Assessment Report for Trichloroethylene, p. 241. https://echa.europa.eu/documents/10162/83f0c99f-f687-4cdf-a64b-514f1e26fdc0

[49] EPA 2011, Toxicological Review of Trichloroethylene for IRIS, available at: http://www.epa.gov/iris/supdocs/0199index.html, p. 4-556

[50] EPA 2018 TCE Problem Formulation p. 45. See also the EPA IRIS 2011 Toxicological Review of Trichloroethylene.

developmental neurotoxicity. The failure to address the risks of developmental neurotoxicity posed by TCE represents a serious data gap in EPA's assessment, particular for the low-dose risks.

In the face of material data gaps, an unqualified conclusion that a chemical does not "present an unreasonable risk of injury" to health could not be defended under TSCA and would misinform the public about the chemical's safety.[51] Thus, EPA's risk evaluations should be explicit about the health and environmental end-points that lack adequate data and should exclude these end-points from its determinations of unreasonable risk. It should also use its TSCA authorities to require manufacturers to conduct testing to develop adequate data for a defensible risk evaluation so that future assessments can be informed by a comprehensive dataset. EPA's lack of interest in using section 4 of the law to generate data necessary for risk evaluation is deeply troubling in light of the clear intent of the 2016 TSCA amendment to provide the Agency with the tools to require more testing by industry to support priority setting and risk evaluations under section 6.

VIII. Where EPA Believes that Particular Conditions of Use Present *De Minimis* Risks, It Cannot Drop These Uses with no Additional Analysis, But Rather Must Explain and Document Why Their Risks Are Insignificant

The problem formulations also indicate that EPA "expects to be able to reach conclusions about particular conditions of use, hazards or exposure pathways without further analysis" and will not further address them in its risk evaluations.[52] For example, EPA indicates that it will devote no further attention to multiple uses of carbon tetrachloride (CTC) that it asserts pose only *de minimis* risks:

> Because industrial, commercial, and consumer use of such products (solvents for cleaning/degreasing, adhesives/sealants, and paints/coatings) would present only de minimis exposure or otherwise insignificant risk, EPA has determined that these conditions of use do not warrant evaluation, and EPA does not expect to consider or evaluate these conditions of use or associated hazards or exposures in the risk evaluation for carbon tetrachloride.[53]

Nowhere has EPA provided general criteria for determining levels of exposure or risk that are "insignificant" for purposes of TSCA risk evaluations. Nor has the Agency explained why it considers carbon tetrachloride-containing solvents with potential consumer, industrial and commercial exposure to be so inconsequential that they can be determined not to present "unreasonable risks" without any product-specific analysis of use and release scenarios.[54] Since carbon tetrachloride is a carcinogen, even

[51] EPA has recognized that "OPPT does not believe that absence of data equals no risk." EPA's Responses to Public Comments Received on the Scope Documents for the First Ten Chemicals for Risk Evaluation under TSCA (May 2018) at 13. However, the problem formulations suggest that the Agency is not applying this principle in its evaluations of individual chemicals.

[52] This statement appears in the Introduction to all of the Problem Formulations. See, e.g., Problem Formulation of the Risk Evaluation for Carbon Tetrachloride at 13.

[53] Id., at 21.

[54] EPA's initial use summary found products with up to 2.5% CTC and SCHF's submission to EPA of publically available product information included products with 1% CTC. See Safer Chemicals, Healthy Families,

low concentrations cannot be assumed to be safe without some understanding of the conditions and levels of exposure. Moreover, even if the risk from a specific product is small in itself, multiple products and exposure pathways may result in aggregate levels of exposure that present significant risks to one or more worker or consumer subpopulations. As noted above, TSCA requires EPA to examine chemical risks holistically, taking into account all uses and pathways of exposure, and cannot summarily eliminate an entire class of products from consideration. EPA may have some latitude to devote greater effort to some exposure and risk scenarios than others, but this does not excuse ignoring particular conditions of use based on the unsubstantiated claim that they present *de minimis* risks.

It is also troubling that, despite numerous critical comments, EPA continues to ignore the presence of 1,4-dioxane as an impurity in products on the ground that "contamination of industrial, commercial and consumer products are not intended conditions of use for 1,4-dioxane and will not be evaluated."[55] EPA's position is legally unsupportable. Production of a chemical as a byproduct or impurity is plainly a "circumstance . . . under which a chemical substance . . . is known . . . to be manufactured" and thus falls squarely within the definition of "conditions of use" in section 3(4) of TSCA. There is no basis in this provision or other parts of the law for differentiating between manufacture as a byproduct/impurity and purposeful production and including the latter in a risk evaluation but excluding the former. In the case of 1,4-dioxane, EPA has made no effort to argue that byproduct/impurity production poses *de minimis* risks and such a position could not be defended given the evidence that 1,4-dioxane's detection in drinking water and groundwater is linked in part to its presence as a contaminant in products and waste streams released into the environment. Plainly, EPA must add 1,4-dioxane production as a byproduct and impurity to the scope of its risk evaluation.

IX. EPA Cannot Drop Significant Hazards from Risk Evaluations

The asbestos problem formulation provides another example of an EPA decision "not to further analyze" a potential source of risk. EPA has chosen to limit its asbestos evaluation to lung cancer and mesothelioma.[56] Yet the asbestos scoping document is clear that several other cancers have been linked to asbestos: [57]

> Mortality studies of asbestos workers have revealed increases in cancer mortality at one or more sites other than the lung, the pleura or the peritoneum. Cancer of the larynx and ovary and gastrointestinal cancers, such as colorectal, pharynx and stomach, have been observed in populations exposed to various types of asbestos (IARC, 2012; NRC, 2006). Some studies have also noted excess deaths from, or reported cases of, cancers at other sites, such as the kidney and esophagus; however, the evidence is not consistent.

Non-malignant diseases are also caused by asbestos, including asbestosis and asbestos-related pleural thickening.

Environmental Health Strategy Center, Healthy Building Network, Comments to the U.S. Environmental Protection Agency (EPA) on the Scope of its Risk Evaluation for the TSCA Work Plan Chemical: CARBON TETRACHLORIDE (CTC) CAS Reg. No. 56-23-5 (March 15, 2017). This information is not reflected in the problem formulation for CTC.

[55] Problem Formulation of the Risk Evaluation for 1,4-Dioxane (May 2018) at 18.

[56] Problem Formulation of the Risk Evaluation for Asbestos at 34.

[57] Scope of the Risk Evaluation for Asbestos (May 2017) at 34-35.

The comprehensive approach to risk evaluations in TSCA requires EPA to address all known hazards of a chemical, particularly one whose dangers to human health are so serious and well documented. The law provides no basis for failing to evaluate documented adverse health effects, let alone effects of this severity and magnitude.

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

Six of the 10 chemicals -- asbestos, TCE, MC, CTC, PERC and 1,4-dioxane -- have been assessed under the EPA Integrated Risk Information System (IRIS). The IRIS process is the Agency's authoritative mechanism for reviewing available studies, characterizing the health effects of chemicals and identifying concentrations below which these chemicals are not likely to cause adverse effects. IRIS assessments typically reflect 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.[58]

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. 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. Like other Agency actions, IRIS assessments often give rise to differences of opinion and some stakeholders may be disappointed by the outcome. But this does not mean that EPA should reinvent the wheel and provide another bite at the apple on scientific determinations that have been made after thorough deliberation. 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.

The only rationale for revisiting IRIS findings is where significant new data have become available since the final IRIS assessment that could inform the weight of the evidence on particular end-points. If that is the case, then the IRIS program should be tasked with updating its previous assessment, using a systematic review protocol that is consistent with the state of the science such as the National Toxicology Program (NTP) method.[59] In its response to comments on the scoping documents, EPA seems to adopt this limited approach to reopening IRIS conclusions, stating that:

[58] 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.

[59] 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

> OPPT has used IRIS documents as a starting point for identifying key and supporting toxicity studies and initial hazard identification. However, EPA also expects to consider other available hazard and exposure data to ensure that all reasonably available information is taken into consideration. Specifically, EPA will screen information developed after the completion of any IRIS assessment and evaluate the relevant information using OPPT's structured process . . . [60]

In the problem formulations themselves, however, EPA outlines a much broader approach. It indicates that *all* studies on IRIS-assessed chemicals will be reviewed using the "study quality" scoring system in EPA's TSCA systematic review document and other as-yet unidentified protocols for reviewing study relevance and weight.[61] This process would necessarily involve revisiting the interpretation of studies already evaluated in IRIS, potentially making different judgments about their quality and relevance and modifying overall IRIS determinations of the "best available science" and "weight of the evidence." Moreover, these judgments would be driven by a deeply flawed and unscientific method for reviewing studies that would result in less defensible conclusions than peer reviewed IRIS assessments.[62]

While TSCA section 26(h) establishes "scientific standards" for science-based decisions under section 6 and other provisions, these standards are general and flexible and do not materially change long-standing criteria used by agencies and the scientific community to assess the reliability, relevance and completeness of scientific evidence. The TSCA standards are consistent with the data review

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[60] EPA's Responses to Public Comments Received on the Scope Documents for the First Ten Chemicals for Risk Evaluation under TSCA, at 10.

[61] Typical is this description of EPA's approach in the problem formulation for asbestos, the subject of a comprehensive IRIS assessment:

> EPA expects to consider and analyze human health hazards as follows:
>
> 1) Included human health studies will be reviewed using the evaluation strategies laid out in the Application of Systematic Review in TSCA Risk Evaluations (U.S. EPA, 2018).
> - Studies will be evaluated using specific data evaluation criteria.
> - Study results will be extracted and presented in evidence tables by cancer endpoint.
>
> 2) Evaluate the weight of the scientific evidence of human health hazard data.
> - EPA will rely on the weight of the scientific evidence when evaluating and integrating human health hazard data. The data integration strategy will be designed to be fit-for-purpose in which EPA will use systematic review methods to assemble the relevant data, evaluate the data for quality and relevance, including strengths and limitations, followed by synthesis and integration of the evidence.
> - Assess dose-response information to refine quantitative unit risk for lung cancer and mesothelioma. Review the appropriate human data identified to update, or reaffirm, the 1988 quantitative estimate of the unit risk of asbestos-related lung cancer and mesothelioma by the inhalation route.
>
> 3) In evaluating reasonably available data, EPA will determine whether particular human receptor groups may have greater susceptibility to the chemical's hazard(s) than the general population.

Problem Formulation of the Risk Evaluation for Asbestos, at 51-52.

[62] See comments on the TSCA Systematic Review guidance from SCHF, NRDC, and UCSF-PRHE to Docket EPA-HQ-OPPT-2018-0210

methodologies used by IRIS, other EPA programs and expert organizations like NTP and provide no justification for questioning science judgments and study interpretations made in the IRIS process.

The drawbacks of reopening IRIS assessments are particularly troubling in the case of asbestos. The problem formulation indicates that EPA will review the asbestos database "with the goal of updating, or reaffirming, the unit risk." [63] It describes this review as follows:

> Asbestos has an existing EPA IRIS Assessment and an ATSDR Toxicological Profile; hence, many of the hazards of asbestos have been previously compiled and reviewed. EPA relied heavily on these comprehensive reviews in preparing the scope and problem formulation documents. EPA expects to use these documents as a starting point for identifying key and supporting studies to inform the human health hazard assessment, including dose-response analysis. EPA also expects to consider other studies that have been published since these reviews, as identified in the literature search conducted by the Agency for asbestos (Asbestos (CASRN 1332-21-4) Bibliography: Supplemental File for the TSCA Scope Document, EPA-HQ-OPPT-2016-0736). . . . The relevant studies will be evaluated using the data quality criteria in the Application of Systemic Review in TSCA Risk Evaluations document (U.S. EPA, 2018).[64]

There is no benefit – and considerable downside – in reconsidering the unit risk estimates provided by the IRIS program for asbestos of all fiber types (IRIS 1988) and Libby amphibole asbestos (IRIS 2014).[65] The highly flawed TSCA systematic review method for determining study "quality" would make it difficult for EPA to include important human health and toxicology studies in its chemical hazard assessments if there is any information that is missing or not publicly available. [66] Rejecting or downgrading epidemiological studies on asbestos on this ground could lead EPA to develop a new risk estimate that adopts the asbestos-industry position that chrysotile is safe – a position that was proposed by EPA under the George W. Bush Administration,[67] but rejected by the Scientific Advisory Board, which specifically warned that failure to consider epidemiology and toxicology data for asbestos is problematic.[68] These errors and scientific omissions could be repeated if application of the TSCA systematic review criteria results in discarding much of the asbestos epidemiology evidence.[69] This

[63] Problem Formulation of the Risk Evaluation for Asbestos at 9.
[64] Id., at 34-35.
[65] IRIS 2014. Libby amphibole asbestos assessment. https://cfpub.epa.gov/ncea/iris2/chemicalLanding.cfm?substance_nmbr=1026
[66] See details documented in comments on the TSCA Systematic Review from SCHF, by NRDC, and by UCSF-PRHE to Docket EPA-HQ-OPPT-2018-0210
[67] EPA 2008. Proposed Approach for Estimation of Bin-Specific Cancer Potency Factors for Inhalation Exposure to Asbestos. https://www.epa.gov/sites/production/files/2015-11/documents/2008_prop_asbestos_approach.pdf
[68] SAB consultation on EPA's Proposed Approach for Estimation of Bin-Specific Cancer Potency Factors for Inhalation Exposure to Asbestos. Nov, 2008. EPA-SAB-09-004. https://yosemite.epa.gov/sab/sabproduct.nsf/77CFF6439C00ABF3852575010077801F/$File/EPA-SAB-09-004-unsigned.pdf
[69] See for example Table H-8 of the draft systematic review guidance which lists several pages of "serious flaws that would make epidemiological studies unacceptable for use," including failure to report various sorts of information, which is not considered a measure of study quality by any other peer reviewed systematic review framework.

would be a huge step back from the settled scientific consensus on the severe dangers of asbestos to public health.

Even without IRIS assessments, the risks of many substances have been thoroughly reviewed and determined by the Agency and other authoritative bodies but these earlier findings will now be subject to revision as EPA reinterprets studies using its TSCA systematic review document. For example, 1-Bromopropane is classified by the National Toxicology Program as "reasonably anticipated" to cause cancer in humans. In 2016 the EPA Draft Risk Assessment recognized the relevance and reliability of this health endpoint when it derived an inhalation unit risk estimate based on lung tumors. So, it is particularly disturbing that the problem formulation for this chemical states that the "the weight-of-evidence analysis for the cancer endpoint is inconclusive" and it will be evaluated using the flawed TSCA systematic review (EPA 2018 Problem Formulation, p. 45). The concern raised by SCHF, NRDC, and others regarding the industry bias of the TSCA systematic review document makes it likely that a re-analysis will result in a false negative – that is, discounting evidence of cancer (see comments on TSCA systematic review by SCHF, NRDC, Docket EPA-HQ-OPPT-2018-0210 incorporated by reference).

In sum, we strongly oppose any reopening of IRIS or other findings that have been finalized and represent authoritative determinations by the Agency. As it proceeds with the risk evaluations, EPA should rely on previous IRIS assessments except where significant new data are available. In this case, the IRIS program should evaluate whether the new data warrants modification of its previous determinations of the weight of the evidence for specific endpoints.

XI. EPA Risk Evaluations Should Not Reassess Uses of TCE, MC And NMP That Were Fully Assessed In Its Proposed Section 6(a) Rules for These Chemicals

EPA has proposed to ban certain uses of TCE, MC and NMP under section 6(a) of amended TSCA.[70] As the basis for these proposed rules, EPA conducted comprehensive exposure and risk assessments on the targeted uses of the three chemicals and concluded that these uses presented unreasonable risks of injury under TSCA. The EPA assessments were subject to public comment and peer review both during their development and again as part of the rulemaking process.

Although the EPA Administrator recently agreed to finalize the proposed MC ban, the problem formulations indicate that EPA will not rely on the completed assessments but will "reassess" the targeted uses for TCE and NMP.[71] We strongly disagree with this approach.

E.g., 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

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

[71] See, e.g., Problem Formulation of the Risk Evaluation for Trichloroethylene, at 24-25.

In its peer reviewed IRIS assessment for TCE, EPA concluded that "[i]ncreased incidence of fetal cardiac malformations was identified as the most sensitive health endpoint within the developmental toxicity domain."[72] This finding was reaffirmed in EPA 2014 TCE Work Plan Chemical Assessment. In 2016, EPA scientists published a systematic review of the data confirming the basis for linking TCE exposure to congenital heart malformations.[73] Congenital heart effects can be disabling or even deadly. The significant and unreasonable risks posed by TCE in consumer and industrial products,[74] particularly from exposures during pregnancy, led EPA to propose to ban its use in aerosol and vapor degreasing operations.

Despite EPA's repeated findings of heart malformations linked to TCE, the problem formulation states that: "The relevant studies will be evaluated using the data quality criteria in the *Application of Systematic Review in TSCA Risk Evaluations document*."[75] This evaluation could result in EPA rejecting the peer-reviewed findings of earlier assessments. Significantly, at the same time as TSCA issued its systematic review guidance for public comment, an industry-sponsored consulting firm published its analysis of why the studies linking TCE with heart defects were "not sufficiently reliable for the development of toxicity reference values."[76] Since the industry-sponsored publication uses reasoning similar to that in the flawed TSCA systematic review guidance, it seems likely that the TSCA risk evaluation may similarly dismiss the evidence of congenital heart defects. Disregarding this important scientific evidence of harm would put the public at great risk.

It would be both scientifically indefensible and counterproductive for the Agency to reopen these assessments for yet another round of public input and to redo the extensive analyses they contain simply so industry commenters can have another bite at the apple on findings they dislike. The next step in the rulemakings should be to issue final rules as quickly as possible. These rules, once issued, should close the book on the targeted uses and enable EPA to focus its risk evaluations on uses that have not yet been assessed.

XII. EPA Should Not Presume That Occupational Exposure Standards Are Fully Protective of Workers, Can be Equated with the Absence of Unreasonable Risk and are Representative of Actual Worker Exposure

[72] EPA 2018 TCE Problem Formulation, Section 2.4.2, page 45

[73] Makris SL, Scott CS, Fox J, Knudsen TB, Hotchkiss AK, Arzuaga X, Euling SY, Powers CM, Jinot J, Hogan KA, Abbott BD, Hunter ES 3rd, Narotsky MG. A systematic evaluation of the potential effects of trichloroethylene exposure on cardiac development. Reprod Toxicol. 2016 Oct;65:321-358.

[74] EPA 2017. Regulation of Certain Uses under Toxic Substances Control Act: Trichloroethylene. https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0163-0001
EPA 2017. Regulation of Certain Uses under Toxic Substances Control Act: Trichloroethylene; Vapor Degreasing. https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0387-0001

[75] EPA 2018 TCE Problem Formulation, Section 2.4.2, page 44

[76] Wikoff D, Urban JD, Harvey S, Haws LC. Role of Risk of Bias in Systematic Review for Chemical Risk Assessment: A Case Study in Understanding the Relationship Between Congenital Heart Defects and Exposures to Trichloroethylene. Int J Toxicol. 2018 Mar/Apr;37(2):125-143.

Occupational exposure is significant for nearly all of the 10 chemicals and should be a major focus of EPA's risk evaluations. The problem formulations indicate that when evaluating occupational risks, the Agency will heavily weigh mandatory and voluntary workplace standards and "will consider the influence of the recommended exposure limits on occupational exposures."[77] We agree that existing workplace standards are relevant in determining risks to workers. However, for several reasons, it would be unjustified for EPA to presume that these standards are fully protective of workers or that their existence can be equated with the absence of unreasonable risk.

First, TSCA and the Occupational Safety and Health Act (OSH Act) apply differing standards of protection and the level of risk reduction afforded by OSHA limits may well be inadequate to satisfy the more stringent requirements of TSCA. OSHA is only authorized to adopt workplace standards for chemicals presenting "significant risks of harm," a term interpreted by the Supreme Court's *Benzene* decision as requiring OSHA to demonstrate by substantial evidence that "it is at least more likely than not that long-term exposure to [a chemical] presents a significant risk of material health impairment."[78] By contrast, the term "unreasonable risk" under TSCA does not impose this high threshold for regulation. Further, OSHA may impose only economically and technologically feasible limits on exposure.[79] However, economic and technological considerations have no bearing on EPA's determinations of unreasonable risk, which cannot take into account cost and other non-risk factors under section 6(b)(4)(A).[80] Finally, while OSHA is only authorized to place limits on exposure, TSCA provides a broad array of remedies, including bans of production and use, which may provide a level of protection that OSHA lacks authority to impose.

Second, a number of the OSHA standards that apply to chemicals subject to the first 10 risk evaluations were developed many years ago and do not reflect current data and scientific understanding of the health effects of the regulated chemicals.[81] Thus, the levels of exposure allowed by these standards may be unsafe when evaluated using the best available science.

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[77] See, e.g., Problem Formulation of the Risk Evaluation for 1-Bromopropane (May 2018), at 64.

[78] *Industrial Union Department, AFL-CIO v. American Petroleum Institute,* 448 U.S. 607 (1980)

[79] *American Textile Manufacturers Institute, Inc. v. Donovan*, 452 U.S. 490, 508-11 (1981).

[80] Based on these considerations, EPA decided against referring to OSHA workplace risks from exposure to trichloroethylene (TCE) under section 9(a) of TSCA, even though OSHA had earlier promulgated a workplace standard for TCE. In deciding to address risks to workers through a section 6(a) rulemaking instead, EPA compared its authority under TSCA to eliminate these risks to that of OSHA, concluding that "there is no other federal law that provides authority to prevent or sufficiently reduce these . . . exposures." It further concluded that risks that EPA found to be "unreasonable" under TSCA might not be deemed "significant" by OSHA. 82 Federal Register 7432, 7454 (January 19, 2017).

[81] OSHA has two types of standards. Under section 6(a) of the OSH Act, OSHA adopted hundreds of PELs in 1971 that were, at that time, considered national consensus standards. They have not been updated since and are based on science from the 1960s or earlier. Since 1971, OSHA has regulated only about 40 chemicals under section 6(b). These more comprehensive standards are based on thorough evaluation of health effects and a determination that risks are significant. OSHA has 6(b) standards regulating only asbestos and MC. It has PELs (adopted under 6(a)) for PERC and TCE but not for the other 10 chemicals. In the case of both asbestos and MC, OSHA's published Federal Register preambles found that even at the revised PEL, employees continued to be exposed to significant risks i.e., risks above 1/1000 – OSHA's definition of significant risk.

Third, OSHA does not cover all workers. It only covers private sector employees of employers. It does not cover employees of federal, state or local governments. These workers might include building maintenance people exposed to asbestos, hospital workers exposed to PERC when laundering linens or other supplies, etc. OSHA also does not cover independent contractors. In the construction sector, many people performing remodeling work, such as stripping paint and otherwise using MC, or removing asbestos insulation are independent. These workers have no OSHA protection. So even if OSHA standards were adequately protective of the workers they covered, there would still be a need for EPA to act under TSCA to make sure all workers had an equivalent level of protection.

Fourth, there is no basis for EPA to assume across-the-board compliance with OSHA standards. As the Agency pointed out in its proposed section 6(a) rule for MC paint removal products, exposures above the OSHA limit have been well documented.[82] To determine actual workplace exposures, we encourage EPA to obtain and review all the data gathered by law under OSHA's Access standard, 29 CFR 1910.1020 which "provide[s] employees and their designated representatives a right of access to relevant exposure and medical records; and to provide representatives of the Assistant Secretary a right of access to these records in order to fulfill responsibilities under the Occupational Safety and Health Act."[83] (1910.1020(a)). This would provide a basis for comparing actual exposures to OSHA standards and, for specific chemicals, determine whether and to what extent OSHA standards reliably limit exposure. While these data will provide a valuable snapshot of exposures, it should be kept in mind that OSHA exposure monitoring data is not systematic or comprehensive, and therefore may not be representative of workplace chronic or peak exposures that are likely to be missed with snapshot monitoring.

Finally, as EPA has recognized, some of the industrial hygiene strategies embodied in OSHA standards – such as labels and respirators – are known to be of limited effectiveness in protecting workers and have been required by OSHA to compensate for the lack of effective engineering controls or constraints on its authority, not because they are uniformly protective. For example, in its proposed section 6(a) rules for TCE, MC and NMP, EPA analyzed a universe of 48 studies[84] and concluded that:

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[82] Studies referenced by EPA found widespread non-compliance with the OSHA MC workplace standard during paint and coating removal, resulting in MC exposures above the OSHA standard, despite the mandatory nature of the OSHA requirements. 82 FR 7405 (Ref. 70)

[83] These data include:

- "Environmental (workplace) monitoring or measuring of a toxic substance or harmful physical agent, including personal, area, grab, wipe, or other form of sampling, as well as related collection and analytical methodologies, calculations, and other background data relevant to interpretation of the results obtained" (1910.1020(c)(5)(i)); and,
- "Biological monitoring results which directly assess the absorption of a toxic substance or harmful physical agent by body systems (e.g., the level of a chemical in the blood, urine, breath, hair, fingernails, etc.)" (excluding drug and alcohol testing) 1910.1020(c)(5)(ii).

For example, the OSHA standard for methylene chloride can be found at 29 CFR 1910.1052, which describes details of mandatory exposure monitoring, employee notification requirements, and long-term retention of the monitoring results. Under OSHA's Access standard, 29 CFR 1910.1020 (D)(7)(ii), employers must retain these records for 30 years.

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

> [C]onsumers and professionals do not consistently pay attention to labels; consumers and professional users often do not understand label information; consumers and professional users often base a decision to follow label information on previous experience and perceptions of risk; even if consumers and professional users have noticed, read, understood, and believed the information on a hazardous chemical product label, they may not be motivated to follow the label information, instructions, or warnings; and consumers and professional users have varying behavioral responses to warning labels, as shown by mixed results in studies.[85]

Similarly, EPA cautioned that "there are many documented limitations to successful implementation of respirators," explaining that:

> "Not all workers can wear respirators. Individuals with impaired lung function, due to asthma, emphysema, or chronic obstructive pulmonary disease for example, may be physically unable to wear a respirator. Determination of adequate fit and annual fit testing is required for a tight fitting full-face piece respirator to provide the required protection. Also, difficulties associated with selection, fit, and use often render them ineffective in actual application, preventing the assurance of consistent and reliable protection, regardless of the assigned capabilities of the respirator. Individuals who cannot get a good face piece fit, including those individuals whose beards or sideburns interfere with the face piece seal, would be unable to wear tight fitting respirators. In addition, respirators may also present communication problems, vision problems, worker fatigue and reduced work efficiency (63 FR 1156, January 8, 1998). According to OSHA, 'improperly selected respirators may afford no protection at all (for example, use of a dust mask against airborne vapors), may be so uncomfortable as to be intolerable to the wearer, or may hinder vision, communication, hearing, or movement and thus pose a risk to the wearer's safety or health. (63 FR 1189-1190).'" [86]

Because of these considerations, EPA cannot assume that, simply because they are required by OSHA standards, labeling or respirators will in fact provide adequate worker protection and successfully prevent unsafe exposure. Rather, as it did in its proposed rules for MC, TCE and NMP, EPA should explicitly recognize the limitations of these industrial hygiene controls and determine whether risks to workers are unreasonable given that labeling and respirators are often unprotective and unreliable in the real world.

Conclusion

The EPA problem formulations are replete with questionable exclusions and loopholes, failures to require necessary testing, deviations from accepted scientific methods and refusal to accept previous peer reviewed determinations of risk. As a result, the Agency is on a path to produce evaluations that ignore important exposure pathways and at-risk populations, disregard evidence of adverse effects and reach misleading, incomplete and understated conclusions about risk that weaken public health protection. EPA should put the 10 evaluations on hold, rethink how they are being conducted, and reinitiate them in accordance with the law and principles of sound science.

[85] 81 FR at 91601.
[86] 82 FR 7445

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