EDF Oral Comment Presented at EPA Trichloroethylene SACC Meeting

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EDF oral comments from Jennifer McPartland, Richard Denison, and Lindsay McCormick.

Jennifer McPartland, PhD

Good afternoon. I am Dr. Jennifer McPartland, senior health scientist at Environmental Defense Fund.

I must open my remarks by expressing utter dismay at the agency's decision to hold this meeting in light of the COVID19 pandemic, and the very real burden it is placing on individuals and communities across the country, including SACC members, who as a result are unable to fully and meaningfully participate today.

My comments focus on our concerns with the human health hazard assessment of the draft risk evaluation. The most significant and consequential flaw is EPA's decision to make determinations of acute and chronic risks based on immune-related endpoints. EPA relied on a 2010 study by Selgrade and Gilmour to derive the point of departure for acute non-cancer risks; and a 2009 study by Keil et al. for chronic non-cancer risks. It worth emphasizing that mortality is the endpoint used from the Selgrade and Gilmour study.

EPA's use of immune-related endpoints is at odds with previous agency TCE assessments including the 2011 IRIS review and 2014 OPPT work plan risk assessment that based TCE's risks on fetal cardiac malformations, the most sensitive endpoint.

TCE-induced fetal cardiac malformations are supported by several scientific studies across multiple lines of evidence including epidemiological, animal, and mechanistic. Indeed, EPA's draft indicates that this endpoint is supported by the weight of the scientific evidence. EPA also correctly maintains that Johnson et al. 2003 remains appropriate for characterizing risk of fetal cardiac malformations. However, when reaching its determinations of risk EPA switched endpoints. As documented in an in-depth investigation by Elizabeth Shogren of Reveal News, extensive revisions made to EPA's draft after White House intervention resulted in determinations of risk based on immune effects rather than fetal cardiac malformations.

EPA and other scientific authorities have repeatedly examined and reaffirmed the fetal cardiac effects. This slide provides a snapshot of these reviews.

The ACC and HSIA-funded study by Charles River Laboratories, subsequently published by DeSesso et al., not only does not negate findings from Johnson et al.; it has serious shortcomings, including using an

insensitive heart dissection methodology, downplaying observed ventricular septal defects, and ignoring extensive literature showing fetal cardiac effects below 1,000 ppm.

EPA's reliance on the TSCA systematic review method remains fundamentally flawed. Its use of numerical study scoring defies consistent recommendations in the field of systematic review including those made in the 2014 Academies review of the IRIS program. Such scoring plays a particularly nefarious role in this draft, whereby EPA claims the evidence for fetal cardiac defects are of "medium" quality while that for immune effects is "high" quality –leading EPA to rely on risk estimates orders of magnitude less than should be the case.

Richard Denison, PhD

I'm Dr. Richard Denison, lead senior scientist at EDF.

TSCA explicitly requires that the SACC include "representatives that have *specific* scientific expertise in the relationship of chemical exposures to women [and] children" as well as other potentially exposed or susceptible subpopulations." Such expertise is particularly relevant to TCE. This panel has only two medical doctors. If they or others with this expertise cannot attend all parts of this virtual meeting because, for example, they are on the front lines of the COVID-19 crisis, then holding this meeting may violate both TSCA and FACA's balance requirement. EPA's insistence on proceeding with this meeting is deeply disrespectful of those panelists and for that matter the entire panel, and it will lead to a compromised peer review of a critical EPA risk evaluation.

I will address three decisions EPA has made that deviate from scientific best practices, defy requirements under the law, ignore longstanding agency policy, and are not sufficiently protective, including of pregnant women, infants, children, and workers. Each decision is directly relevant to the SACC's charge, as each results in serious underestimations of TCE's risks.

First, EPA failed to base its risk assessment on the most sensitive endpoint and most sensitive subpopulation. EPA instead relies on a 500-fold less sensitive endpoint – lethality in mice from immunosuppression – that is also not the most relevant to the most sensitive subpopulations.

This unprecedented decision contradicts multiple previous agency assessments of TCE, existing agency guidance, and expert advice of the NAS to use the most sensitive endpoint and protect the most sensitive group. Our written comments identify these strong precedents that EPA is now casting away without any basis of support.

EPA's decision also flouts TSCA's requirement to protect vulnerable subpopulations, which explicitly include pregnant women and children. EPA relies on a far less sensitive endpoint that does not adequately identify or protect against risks to those subpopulations.

If EPA protects against the most sensitive endpoint, it will also generally protect against other effects. In contrast, EPA asserts without a shred of evidence that it *expects* that addressing risks for immune effects would address other identified risks. EPA should be ashamed of itself.

Second, EPA has once again assumed that workers throughout the value chain and lifecycle will use universally effective PPE in almost all cases. EPA not only fails to presents any supporting evidence, it ignores significant evidence to the contrary. Worker exposure to TCE in the absence of PPE must be considered reasonably foreseen, at a minimum.

While EPA does still find unreasonable risk for most conditions of use – due to the extremely high toxicity of TCE – EPA has dramatically underestimated the risk by assuming PPE use.

This underestimation means that EPA may well not regulate the risks at all or sufficiently, forgoing EPA's only opportunity to ensure that PPE is actually used.

EPA assumption flouts the long-established Industrial Hygiene Hierarchy of Controls, which puts PPE as the last resort. It also flouts TSCA's requirements that EPA rely on the best available science and provide special protection for workers as a vulnerable subpopulation.

An analysis we provided to the SACC shows that EPA's PPE assumption underestimates acute risks from TCE by an average of 16-fold and acute *inhalation* risks by 50-fold –even using EPA's 500-fold more lax immunosuppression endpoint. Chronic and cancer risks are underestimated by an average of 34-fold and 23-fold, respectively.

Third, EPA again applied a cancer risk benchmark up to two orders of magnitude less protective than warranted. EPA's benchmark of 1 in 10,000mean it provides far less protection to workers than the general population, let alone other vulnerable subpopulations, again directly contravening TSCA. The only support EPA cites is policy and practice under other laws or by other agencies, ignoring the fact that their standards differ fundamentally from TSCA's, as detailed in our written comments.

EPA failed to identify risk estimates for at least 11 occupational exposure scenarios as presenting unreasonable risk that even a 1-in-100,000 cancer risk benchmark would have flagged. And where EPA did identify such risk using its lax benchmark, it again understated the magnitude of cancer risk and the needed reduction in exposure by at least 10-fold.

Lindsay McCormick, MPH

Good afternoon, I'm Lindsay McCormick with Environmental Defense Fund. I must start by also expressing my deep concern that EPA has insisited on holding this peer review meeting during a time of national emergency from COVID-19. Some SACC members were not able to be here today, and still others likely unable to prepare sufficiently given competing personal and professional priorities.

With that said, I will discuss four significant areas of concern with EPA's draft.

First, EPA has inappropriately excluded all general population exposures to TCE, asserting without support that they have been assessed and effectively managed under other laws.

Aside from the absent legal basis, these exclusions present significant health concerns, and mean that EPA has failed to comprehensively evaluate exposures to TCE.

For example, while TCE is regulated as a hazardous air pollutant under the Clean Air Act, those standards are set for individual source categories, and even by EPA's own account, do not eliminate risk to exposed populations. Exposures from multiple sources in combination are never considered.

The releases and exposures EPA ignores are far from trivial. Despite the existing regulations under other laws EPA relies on, facilities still release 2-3 million pounds annually of TCE into air, water and land. EPA's approach effectively pretends this quantity is zero.

This is particularly troubling for TCE, which is one of the most pervasive and toxic chemical pollutants in our environment.

EPA and ATSDR[1] have documented the following key exposure pathways:

- *Outdoor Air*
- *Indoor Air and Vapor Intrusion*
- *Groundwater and Drinking Water Wells*
- *Food, and*
- *Breast Milk and Formula*

(Of note, TCE is one of the most frequently detected chemical contaminants in groundwater. Shallow private drinking and irrigation wells are particularly vulnerable and are neither monitored nor regulated by the Safe Drinking Water Act.)

Second, EPA fails to consider those that face greater exposure due to their proximity to conditions of use.

[1] The information presented in this subsection is drawn from EPA's (2011) Toxicological Review of Trichloroethylene, available at https://www.epa.gov/iris/supporting-documents-trichloroethylene.

On page 177, EPA acknowledges that it has underestimated exposure to *consumers* by failing to consider or aggregate background exposures in the assessment – specifically mentioning populations living near facilities emitting TCE.

Despite this acknowledgment, EPA erroneously limits its analysis of 'potentially exposed or susceptible subpopulations' to those that might face greater *susceptibility*. With the exception of workers and consumers, EPA does not consider whether the general population or specific subpopulations face a greater risk due to *greater exposure*.

Of particular concern, EPA does not consider people who live or work near manufacturing, processing, use, or disposal sites, or provide any analysis of the extent to which they are at greater risk. This includes people living near the 731 active superfund sites containing TCE in the U.S.

Third, EPA failed to assess how exposures combine to increase risk.

First, even from a single condition of use, EPA failed to assess how inhalation exposure and dermal exposure combine. EPA quickly dismisses this approach by invoking "uncertainties present in the current exposure estimation procedures." EPA's decision not to apply an additivity approach because of "uncertainties" will necessarily result in an underestimate of exposure, and thus, risk.

Second, EPA also failed to combine any exposures from multiple conditions of use. Instead, EPA looked at each condition of use separately, and never considered the possibility that the same person may be exposed to TCE through multiple conditions of use.

Fourth, EPA also erroneously invokes "uncertainty" to dismiss unreasonable risks to the environment.

Among the numerous flaws in EPA's environmental assessment, EPA's own analysis found excessive risks to aquatic organisms from 521 facilities (in one case exceeding the concentration of concern by 1,000-fold). But EPA dismisses the actual unreasonable risks it found merely by invoking uncertainty.

Even had EPA not actually found risk, uncertainties in EPA's analysis should counsel in favor of finding unreasonable risk. Uncertainty increases the chances of an unreasonable risk; it does not diminish them.