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Testimony for the Public Meeting of the Science Advisory Committee on Chemicals Comments by Gary E. Timm on behalf of the Environmental Protection Network Regarding Perchloroethylene (PERC)

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Good morning. My name is Gary Timm. Today I am representing the Environmental Protection Network, an organization comprised of over 500 U.S. Environmental Protection Agency (EPA) alumni volunteering their time to protect the integrity of the EPA, human health and the environment.

First, I want to express empathy for the EPA staff who are shouldering a heavy workload and working under tight deadlines to conduct the risk evaluations under the amended Toxic Substances Control Act (TSCA). We have all been there. However, EPA needs to ensure that its risk evaluations address all important components leading to risks and to provide adequate time for public input before peer review.

The court decision in Safer Chemicals Healthy Families v. EPA, et al. in the 9th Circuit now obligates the agency to consider legacy uses and disposal when conducting risk evaluations. To that end, the agency must include a discussion of this topic in the final PERC risk evaluation, providing either documentation of the absence of any legacy uses, or identifying and then assessing these uses to the fullest degree for both environmental and human health consequences.

In the real world, people may be exposed to chemical(s) of concern in a work setting and/or as a user/consumer/bystander of a product, as well as through the ambient environment. The agency states in the Risk Evaluation Rule (82 FR 33726 (July 20, 2017)) that they must describe whether or not they have considered aggregate exposures in their assessments. EPA has not, however, conducted such an assessment or made findings of (no) unreasonable risk based upon combined (aggregate) exposures. The agency has neither accounted for multiple routes of exposure known to occur simultaneously during a specific condition of use, in this case inhalation and dermal, nor with consideration of exposures from non-TSCA-related scenarios.

There is another dimension to the human health and environmental assessments that should be acknowledged and incorporated in the PERC risk evaluation, that is, cumulative risk assessment. We identified several criteria that should be applied when determining when a cumulative assessment would be appropriate: 1) concomitant exposure attendant to a category or subcategory of conditions of use; 2) close structural similarities, that is, members of the same chemical class; 3) shared metabolic pathways and byproducts of metabolism; 4) similar toxicity profiles; and 5) similar modes/mechanisms of action of shared toxicity endpoints. The sextet of chlorinated VOCs listed in

Table 3-4 meet most, perhaps all, of these criteria. The lack of aggregate and cumulative assessment clearly leads to an underestimation of exposure and risk and, potentially, an incorrect declaration of "no unreasonable risk" when one actually exists.

PERC has been detected in rain from industrial cities in the UK and USA, and in snow in Australia, Italy, and Antarctica. It is found in human blood, urine, and breast milk. Its widespread presence in outdoor and indoor air is well-documented, with higher levels found near dry-cleaners and commercial operations that use PERC. Clearly, this evidence points to an ongoing body burden of PERC across the general population, with higher levels in subgroups with greater exposure because of use of consumer products, consumption of contaminated drinking water, or proximity to emissions sources like dry cleaners or open degreasing facilities. Yet EPA does not address risks to the general population and actually concludes that chronic health effects are not relevant to consumers despite the evidence of ongoing, chronic exposure. The risk evaluation should be integrating these findings and examining their implications not only under TSCA but under other laws like the CAA, where there is reason to believe that emissions are not being adequately controlled and risks are excessive.

With regard to environmental risks, confidence in acute and chronic concentrations of concern (COCs) for fish and invertebrates is high. However, confidence in the algal COC is medium given that the COC for algae is based on a single study, and the data were only available for three algal species that may not represent the most sensitive species at a given site. Therefore, one recommendation that would help improve the hazard component of EPA's aquatic risk evaluation would be to conduct further algal testing using additional species.

With respect to risks to human health, the hazard database available on PERC reveals a substantial number of studies in both humans and animals that would appear adequate to address the needs for robust assessment without having to account for any key data deficiencies. However, there are two important exceptions. There are indications in both human and animal studies that PERC has the potential to produce adverse effects on the immune system and various hematological components; however, the data on these endpoints were not adequate to determine dose-response. As a result, as EPA notes, "There is uncertainty whether the PODs for other endpoints carried forward are sufficiently protective of any potential immune or hematological effects that were not accounted for in this risk evaluation." The consequence of this "insufficiency" is that a conclusion of "no unreasonable risk" could be made with regard to a condition of use when one actually exists. Therefore, we recommend the following:

- Incorporate an additional uncertainty factor of at least 3 for data deficiencies (UF_D) into each chronic Benchmark MOE relevant for all of the non-cancer endpoints used in risk estimation and determination;
- Revise chronic inhalation and dermal risk estimations and determinations for all conditions of use (COUs);

- Use enhanced testing authority to require additional observations in human cohorts and/or non-human studies to answer the outstanding questions, using standardized or tailored study designs, and incorporate these results in the final risk evaluation; and
- If the results of the new studies show the PODs for other endpoints are sufficiently protective of any potential immune or hematological effects, reduce the Benchmark MOEs accordingly.

Thank you for this opportunity to present a summary of EPN's comments. We invite your attention to our full written comments.