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EPN COMMENTS FOR THE PUBLIC MEETING OF
THE SCIENCE ADVISORY COMMITTEE ON CHEMICALS
REGARDING THE DRAFT METHYLENE CHLORIDE RISK EVALUATION UNDER TSCA
December 3, 2019

Good afternoon. My name is Penelope Fenner-Crisp. Once again, I have the privilege of presenting comments on behalf of the Environmental Protection Network (EPN). EPN is an organization comprised of over 450 U.S. Environmental Protection Agency (EPA) alumni volunteering their time to protect the integrity of EPA, human health and the environment. We harness the expertise of former EPA career staff and confirmation-level appointees to provide insights into regulations and policies proposed by the current administration that have a serious impact on public health and environmental protections.

While these comments are tailored to address the methylene chloride (MC) draft Risk Evaluation, they also highlight and reprise the inadequate and inappropriate application of best management and science assessment and policy practices seen in the five draft risk evaluations previously peer reviewed by this committee.

Let's begin with Scheduling. This is now the third time that the agency has scheduled a public meeting of its key peer review committee too soon after opening a public comment period on draft risk evaluations. As EPN has noted previously, this practice deprives the Science Advisory Committee on Chemicals (SACC) of scientific and policy input that would be valuable in informing its review of the MC (and for N-methylpyrrolidone, NMP) draft evaluations and, thus, greatly reduces the value of the public comment process. This repeated action reinforces the view articulated previously by EPN and shared by other commenters that the current agency approach seems to value meeting a deadline for a decision over the integrity of the information going into the decision, and that they just don't care what anyone else has to say.

Systematic Review: The program continues to use its non-peer-reviewed, flawed draft guidance. The agency claimed during the 1,4-dioxane/HBCD peer review meeting that it was planning to consult with the National Academies, but no evidence of such activity has surfaced in the public domain to date. In the meantime, given that the draft guidance remains inconsistent with best practices in systematic review, it should not be used for any purpose until peer reviewed and revised in accordance with the feedback received.

Benchmark Margins of Exposure: The database supporting the development of the toxicity profile for human health risk assessment is substantial. Nonetheless, the absence of some key information renders both the Acute and Chronic Benchmark margins of exposure (MOE) inadequate. Each should be increased. With regard to the Acute MOE, the single dose Bornschein et al. neurodevelopmental study revealed effects, but did not identify a lowest-observed-adverse-effect level (LOAEL) or higher) nor a no-observed-adverse-effect-level (NOAEL). This calls into question whether the Hazard Values (PODs) for Acute Exposure Occupational and Consumer Scenarios are adequately protective for the fetus (in the case

of exposures to pregnant women) as well as infants and children. With regard to the Chronic non-cancer Occupational Scenarios, we are not comfortable with the UF_H of 3, given that the agency has not provided adequate evidence to show that variability in sensitivity of the specific subpopulations described will be accommodated within that range.

Aggregate Risk Assessment: As EPA notes in the draft risk evaluation, it is required to describe whether aggregate or sentinel exposures under the conditions of use were considered and the basis for their consideration. It further acknowledges that "For workplace exposures, inhalation and dermal exposures are assumed to occur simultaneously i.e., both occur at the start of the task and continue through the end of the task, shift, or work day. For household exposures, inhalation and dermal exposures occur at the start of the task and continue through the end of the task." But then, they provide a feeble excuse for not proceeding with an aggregate assessment by stating that the physiologically based pharmacokinetic (PBPK) models they used lacked a dermal compartment so they could not aggregate the inhalation and dermal exposures. They also chose not to employ simple additivity of exposure pathways within a condition of use "because of the uncertainties present in the current exposure estimation procedures."

This is simply a cop-out. Aggregation can be done under these conditions and the uncertainties can be accommodated for. The lack of aggregation leads to an underestimate of exposure and risk and, potentially, the incorrect declaration of "no unreasonable risk" when one actually exists. This situation is further compounded by EPA's refusal to consider concomitant exposures in media/scenarios covered by regulatory measures under other statutes. Just because an exposure would not be regulated under the Toxic Substances Control Act (TSCA) does not mean it should not be considered when assessing risks that would be regulated under TSCA.

Worker Exposure and Risk: EPN continues to be concerned about the agency's approach for determining unreasonable risk to workers. It underestimates that risk by assuming workers will use personal protective equipment (PPE) for the entire duration of the work activity throughout their careers, even when such equipment is not required, provided or used. EPA appears to discount the risks to workers by assuming constant use of PPE. We would argue that while EPA may assess and characterize worker risk with and without the use of PPE, it should make its unreasonable risk determinations based upon the "no PPE" scenarios. Lacking the guarantee of consistent use of PPE, EPA should focus its regulatory options on mitigating risk to the unprotected individual.

Thank you for your attention.