

SUMMARY

EPN Comments on Supplemental Analysis of the Draft Risk Evaluation for Toxic Chemical 1,4-Dioxane

December 10, 2020

On December 10, 2020, EPN submitted [comments](#) in response to EPA's [request](#) for public input on a supplemental analysis of the draft risk evaluation conducted under the reformed Toxic Substances Control Act (TSCA) for the toxic chemical 1,4-dioxane, a potentially carcinogenic solvent used mainly in the production of other chemicals. Increases in tumors of the liver, kidneys and other tissues have been observed in multiple long-term animal toxicity studies of the chemical. This supplemental analysis covers eight consumer uses, such as surface cleaners, laundry/dishwashing detergents, and paint/floor lacquer, in which 1,4-dioxane is created from the breakdown of other chemicals. It also assesses exposure to surface water.

EPN commented on the June 2019 draft 1,4-dioxane risk evaluation on [July 19](#) and [August 30](#), 2019, urging EPA to add an uncertainty factor of 10 to the benchmark margin of exposure (MOE) for inhalation and dermal exposures in order to account for the lack of critical data. EPN believes EPA should have made the MOE adjustment before evaluating the consumer risks of 1,4-dioxane in this supplemental analysis. EPN also pointed out the need for EPA to evaluate the risks of the chemical to the general population from contaminated drinking water supplies. EPN found the evaluation of risks to the general population to be inadequate because the supplemental analysis focuses solely on swimming risks.

EPN's review of the 1,4-dioxane supplemental analysis found that:

- **The approach that EPA employs to estimate consumer exposures to a substance under evaluation in the TSCA Existing Chemicals review program consistently underestimates exposure for several reasons:**
 - It summarily ignores sources not specifically associated with the condition of use (COU) under scrutiny (e.g., ambient indoor or outdoor air, drinking water, etc.), arguing that these exposures are outside of its regulatory jurisdiction. This does not excuse the agency from acknowledging real-world situations and aggregating those exposures in the exposure assessment.
 - The agency has not aggregated dermal and inhalation exposure to single products, when that is clearly the situation for consumers.
 - EPA has evaluated inhalation and dermal exposures only on a product-specific basis, considering use of only one product type within a day. However, a subset of consumers and bystanders is likely to use more than one product in an overlapping time frame, and these exposures should be aggregated.
 - Some of the receptors targeted in the acute exposure COU scenarios for adults and children and chronic exposure COU scenarios for adults are the same as exposures assessed following environmental releases in ambient water/surface water in a variety of occupational exposure scenarios. These exposures should also be aggregated.
- **EPA should have modified the Benchmark MOEs used in this supplemental analysis to account for data deficiencies.** EPA ignored EPN's comments on the 2019 worker risk evaluation and retained the Benchmark MOE for inhalation and dermal risks without adding an additional uncertainty factor for data deficiencies. As a result, EPN finds that EPA has not adequately evaluated whether these consumer conditions of use present an unreasonable risk of cancer or noncancer effects.
- **EPA's evaluation of general population risk in this supplemental analysis focuses solely on risks from swimming.** EPA's evaluation is particularly flawed because it does not evaluate the chronic drinking water risks due to the contamination of surface water at the intake point of drinking water treatment plants. It is imperative that the parties responsible for 1,4-dioxane releases to the environment posing unacceptable risks to public health be

responsible for eliminating those risks, and it is imperative that the TSCA risk evaluation ensures this happens.

Background

TSCA was passed in 1976 to keep dangerous chemicals off the market and protect people from exposure to existing chemicals. It was [amended and strengthened](#) in 2016, requiring EPA to set priorities for which chemicals to assess, evaluate their risks, and impose restrictions to protect people's health and the environment.