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EPN Comments on Supplemental Analysis to the Revised Draft TSCA Risk Evaluation for 1,4-Dioxane

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The Environmental Protection Network (EPN) is an organization comprised of almost 550 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.

EPN commented on the June 2019 draft 1,4-dioxane risk evaluation on July 19 and August 30, 2019, urging EPA, among other things, to add an uncertainty factor of 10 to the Benchmark margin of exposure (MOE) for inhalation and dermal exposures to account for the lack of critical data. We feel that EPA should have made that Benchmark 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 general population risks from contaminated drinking water supplies. We found the general population risk evaluation in this supplemental analysis to be inadequate because it focuses solely on swimming risks.

Consumer Risk Evaluation

EPA selected eight consumer conditions of use (COUs) to evaluate: surface cleaner, dish soap, dishwasher detergent, laundry detergent, antifreeze, paint and floor lacquer, textile dye, and spray polyurethane foam (SPF). Acute inhalation exposures to both consumers and bystanders are described for all COUs, while chronic inhalation exposures to both consumers and bystanders are described only for COUs reasonably expected to involve daily use intervals (i.e., surface cleaner, dish soap, dishwasher detergent, and laundry detergent). Acute dermal exposures to consumers, but not bystanders, are described for all COUs, while chronic dermal exposures to consumers, but not bystanders, are described only for COUs reasonably expected to involve daily use intervals.

Exposure assessment

All consumer COU exposures were modelled. There is some confusion in the text in Section 2.1.3.3 Consumer Exposure Modeling Approach as to what model was used for each scenario. It states "Exposures via inhalation and dermal contact to consumer products were estimated using EPA's Consumer Exposure Model (CEM) Version 2.1 (U.S. EPA, 2019a), along with consumer behavioral pattern data (i.e., use patterns) and product-specific inputs. An older version of the CEM, available within E-FAST 2014, was used to estimate chronic inhalation exposures and obtain lifetime average daily concentration outputs (U.S. EPA, 2014c)." Reading this leads the reader to conclude that estimation of inhalation exposure was conducted using both CEM version 2.1 and the older CEM version from E-FAST (2014). This could be clarified by revising the first sentence to read "Acute exposures via inhalation and acute and chronic dermal contact to consumer products were estimated using EPA's Consumer Exposure Model (CEM) Version 2.1…" "An older version of CEM, available within E-FAST 2014, was used to estimate chronic inhalation exposures…" This distinction becomes clearer when examining the contents of Table 2-9.

The approach that EPA employs to estimate exposures to a substance under evaluation in the Toxic Substances Control Act (TSCA) Existing Chemicals review program consistently underestimates exposure, for several reasons. It summarily ignores sources not specifically associated with the COU under scrutiny (e.g., ambient indoor or outdoor air, drinking water, etc.), arguing that these exposures are outside of its regulatory jurisdiction. While that may be true, it does not excuse the agency from acknowledging real-world situations and aggregating those exposures in the exposure assessment. There also are three other serious flaws in this supplemental analysis.

1. The agency has not aggregated dermal and inhalation exposure to single products, when that is clearly the situation for consumers.
2. EPA has evaluated inhalation and dermal exposures only on a product-specific basis, considering use of only one product type within a day. However, since a subset of consumers and bystanders is likely to be involved in more than one consumer COU in an overlapping time frame, their exposures from those COUs should be aggregated.
3. Some of the receptors targeted in the acute exposure COU scenarios (adult ≥21 years and children 11-15 years) and chronic exposure COU scenarios (adult ≥21 years) are the same as those whose exposures in ambient water/surface water are assessed following environmental releases to water. These exposures also should be aggregated with the COUs.

Benchmark Margin of Exposure

In the draft supplemental analysis for 1,4-dioxane, EPA evaluates eight conditions of use involving consumer products in which the chemical is present as a byproduct. Unfortunately, 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. This inadequate risk evaluation has serious consequences, as Section 18 of TSCA preempts states from taking action where EPA has acted pursuant to the statute. If finalized, EPA's finding of no unreasonable risk in this draft supplemental analysis will undermine actions currently being taken by both New York and California to restrict 1,4-dioxane in consumer products (the use of which, as a matter of interest, is banned in Canada)..

EPA should have modified the Benchmark MOEs used in this supplemental analysis to account for data deficiencies. EPA seems to believe it is exempt from having to consider deficiencies in the hazard/toxicity database when deriving Benchmark MOEs as a prelude to making determinations of reasonable/unreasonable risk based upon non-cancer effects. It is not. Agency-wide guidance, as articulated in USEPA 2002 and USEPA 2005, presents the criteria that an MOE (and guidance values such as the Reference Dose or Reference Concentration) must meet to be able to employ a database deficiency uncertainty factor (UFD) equal to 1X. The hazard database for 1,4-dioxane falls short, because there are no studies that assess the potential for reproductive effects or for developmental neurotoxicity (in light of its known neurotoxic effects in adults), both of which are critical endpoints of concern. Therefore, in this analysis of consumer uses, the short-term inhalation and dermal Benchmark MOEs should be established at 3,000, rather than 300, and the long-term inhalation and dermal Benchmark MOEs at 300, not 30.

General Population Risk Evaluation:

EPA's evaluation of general population risk in this supplemental analysis focuses solely on risks from swimming. Because 1,4-dioxane is highly soluble in water and does not readily biodegrade, EPA appropriately uses the predicted surface water concentration at the point of release to evaluate the acute risks of incidental ingestion and dermal exposure while swimming. EPA should aggregate the incidental ingestion and dermal exposure risks from swimming instead of evaluating them separately. EPA should also evaluate the risks of consuming contaminated fish because the supplemental analysis documents a bioconcentration factor (BCF) of 0.9, resulting in tissue levels nearly equivalent to the water concentration. Even though 1,4-dioxane is not bioaccumulative up the food chain, fish tissue concentrations may still pose a risk to consumers.

EPA's evaluation of general population risks is particularly flawed because it does not evaluate the chronic drinking water risks of the surface water concentrations predicted at the point of release. EPA claims in the supplemental analysis that the agency is not evaluating the drinking water risks of surface water contaminated with 1,4-dioxane because the agency is relying on the Safe Drinking Water Act to regulate drinking water. That claim cannot be justified because EPA has no drinking water standard for 1,4-dioxane now and has no plans to develop such a standard in the future. EPA also claims that the agency is evaluating the risks of surface water contaminated with 1,4-dioxane on swimmers because EPA lacks human health water quality criteria for this chemical and, thus, cannot rely on regulation under the Clean Water Act to control 1,4-dioxane discharges. EPA inaccurately describes the human health criteria as being designed to protect swimmers and fish consumers. In fact, EPA's human health criteria are designed to protect drinking water consumers and fish consumers, not swimmers. EPA publishes separate recreational water quality criteria to protect swimmers. The human health water quality criteria methodology is based on the source water protection principle that the polluter should pay for pollution control rather than the downstream drinking water customer. EPA should have evaluated the impact of 1,4-dioxane wastewater discharges on the quality of source water for public water supply systems and been prepared to find an unreasonable risk if predicted concentrations exceeded EPA's recommended lifetime drinking water health advisory of 0.35 ug/L at the 10-6 cancer risk level. EPA's evaluation of the impact of these discharges on swimming and fish consumption are appropriate analyses but do not substitute for analysis of the much higher risk pathway of drinking water.

It is well known that 1,4-dioxane is an impurity in a broad range of personal care and cleaning products used by millions of consumers. These "down the drain" products contribute 1,4-dioxane to wastewater and surface water and, together with other sources of this chemical, account for the widespread presence of 1,4-dioxane in drinking water throughout the country. During EPA's third unregulated contaminant monitoring program in 2013-2015, the agency found that 6.9 percent of public water supply systems had drinking water concentrations of 1,4-dioxane in excess of 0.35 ug/L. In 2017, the Environmental Working Group did its own analysis of water utility monitoring data and found that the water supplies for more than 7 million people in 27 states have concentrations of 1,4-dioxane that exceed 0.35 ug/L. Given that 1,4-dioxane is a likely human carcinogen, is highly soluble in water, and does not readily biodegrade in the environment, it is critical that the TSCA risk evaluation of this chemical focus on the impact of wastewater discharges on drinking water in the U.S. Regulation of pollutant discharges under the Clean Water Act is based on the need to protect source water for drinking water utilities so that the costs of pollution are borne by the polluter, not by the utility. It is very difficult to remove 1,4-dioxane from source water, and few utilities in the country employ the expensive, energy-intensive advanced oxidation or other

processes needed to remove or otherwise treat this chemical. 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.