

**EPN Comments for the Public Meeting of the Science Advisory  
Committee on Chemicals Regarding Draft HBCD & 1,4-Dioxane  
Risk Evaluations Under the TSCA**

July 19, 2019

The [Environmental Protection Network](http://environmentalprotectionnetwork.org) (EPN) is an organization comprised of over 450 U.S. Environmental Protection Agency (EPA) alumni volunteering their time to protect the integrity of the agency, human health and the environment. We harness the expertise of former EPA career staff and confirmation-level appointees to provide an informed and rigorous defense against current administration efforts to undermine public health and environmental protections.

EPN is submitting these general comments to the Science Advisory Committee on Chemicals (SACC) to aid in their review of the Cyclic Aliphatic Bromide Cluster (HBCD) and 1,4 Dioxane [draft risk evaluations](#) during their scheduled meeting on July 29 – August 2, 2019. HBCD is mainly used as a flame retardant, and studies show it may affect human reproduction and development. 1,4-Dioxane is a solvent that is used mainly in the manufacture of other chemicals. Short-term exposure can cause eye, nose and throat irritation; exposure to large amounts may cause kidney and liver damage.

EPN expects to prepare more detailed comments on these two draft risk evaluations by the August 30 deadline but was concerned that the SACC will have concluded their review before the public comment period closes. As a matter of policy, EPN finds it extremely disingenuous to have the SACC meeting prior to the deadline for the comments, a reversal of the way EPA normally does things. This approach indicates that a) the arbitrary deadline for a decision is more important than the information going into the decision making or b) this is a mechanism to discourage the comments of the citizenry that desire to see a standardized risk evaluation process followed, or both.

EPN is focusing these initial comments on the most critical policy issues that affect not only these two chemicals but all future chemical risk evaluations under the Toxic Substances Control Act (TSCA).

EPN has the following policy concerns regarding the draft risk evaluations for HBCD and 1,4 Dioxane:

- 1) continued use of the flawed TSCA systematic review process to identify the key studies and synthesize the weight of evidence for each type of data and the body of information overall;
- 2) exclusion of pathways of exposure which could be regulated by other environmental statutes;
- 3) focus on worker risks primarily under central tendency conditions;
- 4) assumption that Personal Protective Equipment (PPE) will eliminate all worker risks even when there are no requirements for such protection;
- 5) failure to evaluate the risks of consumer products containing 1,4-Dioxane; and
- 6) analysis and inclusion of threshold cancer risk model for 1,4-Dioxane previously found unsupportable.

EPN and many other organizations submitted [persuasive reasons](#) why the problem formulations should not exclude pathways of exposure which could be regulated under environmental statutes such as the Clean Air Act (CAA), Safe Drinking Water Act, Clean Water Act (CWA) and Resource Conservation and Recovery

Act. Standards and non-regulatory guidance established under these other programs may be years out of date, may be technology-based rather than risk-based, and may not be complied with at all times or in all locations. In addition, these pathways add to the cumulative risk of highly exposed people such as workers or residents near the fence line of point sources and should be added to their exposures. In the draft risk evaluation, EPA ignored those comments and refused to evaluate risks to the general public, including children and pregnant women, because these other statutes “adequately assess and effectively manage risks from 1,4-dioxane.” EPA cannot justify the failure to consider drinking water contamination when there is no drinking water standard currently established for this chemical, which occurs in ground water and surface water. In addition, ambient air levels of this contaminant must be taken into consideration, even though there is an established standard in order to evaluate the cumulative exposure from all pathways. A comprehensive analysis of all pathways of exposure under TSCA may lead to recommendations that a drinking water standard or an air standard should be promulgated or updated rather than a restriction placed on a chemical’s use via an action under TSCA. Recommendations for action under another statute should be seen as an appropriate end result of a TSCA evaluation and is consistent with Section 9 of TSCA, which directs the Administrator “to coordinate actions taken under TSCA with actions taken under other federal laws administered by EPA, such as the CAA and CWA. If risk is already managed *effectively* (emphasis added) under a different statute, regulation under TSCA is not necessary.” This section indicated that TSCA evaluations should include an assessment of these exposure scenarios so that a decision can be made on the need for action under these other statutes.

EPN is deeply concerned that workers will not be protected under TSCA because of two policy decisions EPA has made. The first policy decision of concern is EPA’s statement in the draft 1,4-Dioxane risk evaluation that the agency is “more likely to determine unreasonable risk exists for workers where risks greater than the acceptable benchmarks are identified for both central tendency and high end exposures under the conditions of use.” Where risks greater than acceptable benchmarks are identified only for workers with high-end exposures, EPA will not make the determination that unreasonable risk occurs unless there are special circumstances. This policy is problematic because the agency is not factoring in worker exposure to contaminants in drinking water or other “regulated pathways” under central tendency or high-end conditions, so worker exposures are being underestimated under both scenarios. The second problematic policy is that when the agency finds unreasonable risk to workers, it dismisses that risk by assuming workers will use PPE the entire duration of the work activity throughout their careers, even when such equipment is not required, provided or used. This last point was demonstrated in the case of HBCD, which has no Occupational Safety and Health Administration or National Institution of Occupational Safety and Health standard, but EPA still overrode the risks to workers by assuming constant use of respirators and gloves.

In the 1,4-Dioxane draft risk evaluation, EPA stated that no consumer product exposures will be considered because its regulatory tools under TSCA Section 6(a) are better suited to addressing any unreasonable risks that might arise from these products through regulation of the activities that generate 1,4-Dioxane as an impurity or cause it to be present as a contaminant in the products. It is fine that EPA plans to prevent 1,4-Dioxane impurities in consumer products one day, but that does not eliminate the need to account for this pathway of exposure now as part of the cumulative exposure to the general population and workers.

EPN was also surprised to find that EPA spent considerable effort evaluating a threshold cancer risk model for 1,4-Dioxane when EPA’s Office of Research and Development determined in 2013 that there was not sufficient evidence to support a mode of action (MOA) of cytotoxicity and regenerative cell proliferation. Given EPA’s time constraints to deliver the first 10 chemical risk evaluations this year, it seems unwise to

have spent time and resources to carry out an evaluation of this alternative cancer risk model, unless significant new information had been generated after 2013. EPN will be examining this issue in greater detail before submitting its second set of more detailed comments in August.