

# American Chemistry Council

The American Chemistry Council's comments on the draft VI guidance are attached.



December 20, 2021

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Toxics Cleanup Program  
Washington State Department of Ecology  
P.O. Box 47600  
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Re: Draft Guidance for Evaluating Vapor Intrusion in Washington State –  
Investigation and Remedial Action, Publication No. 09-09-047, Draft for  
Public Comment (November 2021)

Mr. Gordon:

The American Chemistry Council's Trichloroethylene Panel provides the following comments on the Draft Guidance for Evaluating Vapor Intrusion in Washington State. Specifically, our comments are focused on the approach for addressing short-term exposures to trichloroethylene (TCE) resulting from vapor intrusion (VI). ACC's TCE Panel represents companies with a strong interest in the application of the best and most up-to-date scientific information in the development of policies related to TCE. We are deeply concerned that the draft VI guidance does not consider the significant amount of information on non-cancer health effects of TCE that has become available since the Department's 2019 memorandum<sup>1</sup> that is the basis for the draft guidance on the chemical. Based on recent information, we urge the Department to remove the short term action levels proposed for TCE in the draft VI guidance and focus on action levels based on potential cancer and chronic non-cancer effects.

The 2019 policy references memos from US Environmental Protection Agency (USEPA) Regions 9 and 10 which in turn reference USEPA's 2011 Integrated Risk Information System (IRIS) assessment of TCE. The IRIS assessment derived a non-cancer reference concentration (RfC) from studies reporting fetal cardiac defects in rats from a single laboratory using a non-standard dissection technique and statistical methods.<sup>2</sup> These results have generated

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<sup>1</sup> WDOE. Vapor Intrusion (VI) Investigations and Short-Term Trichloroethylene (TCE) Toxicity. Memorandum from Jeff Johnston, Information & Policy Section. Implementation Memorandum No. 22 (October 1, 2019)

<sup>2</sup> The results of these studies are summarized in Johnson PD *et al.* Threshold of trichloroethylene contamination in maternal drinking waters affecting fetal heart development in the rat. *Environ Health Perspect* 111: 289-292 (2003). <http://dx.doi.org/10.1289/ehp.5125>



considerable controversy and have been rejected by the National Research Council<sup>3</sup> and California's Office of Environmental Health Hazard Assessment (OEHHA)<sup>4</sup>. Further, the findings have not been replicated in studies conducted at three other laboratories, including in a 2019 study designed to mimic the conditions of the single positive study to the greatest extent possible.<sup>5</sup>

After considering all of the available information, USEPA decided not to use the cardiac endpoint as the basis for evaluating non-cancer health effects in its 2020 risk evaluation of TCE conducted under Section 6 of the Toxic Substances Control Act (TSCA), as amended.<sup>6</sup> In reviewing this risk evaluation, the Agency's Science Advisory Committee on Chemicals (SACC) supported the decision not to use the results of Johnson *et al.*, concluding that the study did not meet USEPA's quality criteria and was inadequate for use in quantitative risk assessment.<sup>7</sup> This conclusion is supported by systematic reviews of the human, animal, and mechanistic data available for this endpoint.<sup>8,9</sup>

The events that have occurred since the Department's 2019 assessment provide overwhelming evidence that regulatory decisions involving TCE should not be based on health reference values derived from Johnson *et al.* identifying fetal cardiac defects. Accordingly, we respectfully request that DOE remove the short term action levels proposed for TCE and all sampling requirements related to short term effects from exposure to TCE in groundwater, soil

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<sup>3</sup> National Research Council. Assessing the Human Health Risks of Trichloroethylene: Key Scientific Issues. Washington, DC: The National Academies Press (2006). <https://doi.org/10.17226/11707>

<sup>4</sup> OEHHA. Public Health Goal for Trichloroethylene in Drinking Water (July 9, 2009). <https://oehha.ca.gov/water/public-health-goal/public-health-goal-trichloroethylene-drinking-water>

<sup>5</sup> DeSesso JM *et al.* Trichloroethylene in drinking water throughout gestation did not produce congenital heart defects in Sprague Dawley rats. 2019. *Birth Defects Res* 111(16):1217-1233. <https://doi.org/10.1002/bdr2.1531>

<sup>6</sup> USEPA. Risk Evaluation for Trichloroethylene CASRN: 79-01-6. EPA #740R18008. Office of Chemical Safety and Pollution Prevention. Washington, DC (November 2020). <https://www.regulations.gov/document/EPA-HQ-OPPT-2019-0500-0113> In the final Risk Evaluation for TCE, USEPA selected immunosuppression as the appropriate short-term endpoint for TCE and derived an acute RfC of 325 µg/m<sup>3</sup>.

<sup>7</sup> USEPA. TSCA Science Advisory Committee on Chemicals peer review for EPA draft risk evaluation for trichloroethylene. Final Report No. 2020-4 (June 2020). <https://www.regulations.gov/document/EPA-HQ-OPPT-2019-0500-0111>

<sup>8</sup> Wikoff D *et al.* Role of risk of bias in systematic review for chemical risk assessment: a case study in understanding the relationship between congenital heart defects and exposures to trichloroethylene. *Intl J Toxicol* 37(2):125-143 (2018) <https://doi.org/10.1177/1091581818754330>

<sup>9</sup> Urban JD *et al.* Systematic evaluation of mechanistic data in assessing *in utero* exposures to trichloroethylene and development of congenital heart defects. *Toxicol* 436:152427 (2020). <https://doi.org/10.1016/j.tox.2020.152427>



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gas, or indoor air. This includes specific approaches for immediate sampling of indoor air including most of the information provided in Appendix A. DOE should rely instead on action levels keyed to chronic health effects from TCE exposure.

Sincerely,

***Steve Risotto***

Stephen P. Risotto  
Senior Director

