

April 28, 2023

Dr. Alaa Kamel  
Mission Support Division (7602M),  
Office of Program Support  
Office of Chemical Safety and Pollution Prevention  
Environmental Protection Agency  
1200 Pennsylvania Ave, NW; MC-7602M  
Washington, DC 20460

Re: Comments of the Styrene Information and Research Center  
Draft Proposed Principles of Cumulative Risk Assessment under TSCA  
88 Fed. Reg. 12,354 (Feb. 27, 2023)  
Dkt. No. EPA-HQ-OPPT-2022-0918

Dear Dr. Kamel:

The Styrene Information and Research Center appreciates the opportunity comment on the *Draft Proposed Principles of Cumulative Risk Assessment under the Toxic Substances Control Act* (Feb. 2023).<sup>1</sup> These comments supplement comments separately submitted by the American Alliance for Innovation, which SIRC endorsed.

The draft document properly acknowledges that TSCA § 26(h) requires EPA to use the “Best Available Science” when making decisions in connection with TSCA § 6 risk evaluations. Best Available Science is defined in the regulations in critical part as,

science that is reliable and unbiased. Use of best available science involves the use of supporting studies conducted in accordance with sound and objective science practices, including ... supporting studies and data collected by accepted methods ... (if the reliability of the method and the nature of the decision justifies use of the data). Additionally, EPA will consider as applicable: ...the extent to which the variability and uncertainty in the information, or in the procedures, measures, methods, protocols, methodologies, or models, are evaluated and characterized; and ... [t]he extent of independent verification ... of the procedures, measures, methods, protocols, methodologies or models.<sup>2</sup>

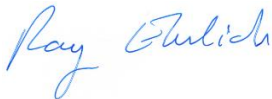
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<sup>1</sup> Cumulative Risk Assessment; Science Advisory Committee on Chemicals (SACC) Virtual Public Meeting; Notice of Availability and Request for Comment, 88 Fed. Reg. 12,354 (Feb. 27, 2023) (Doc. No. EPA-HQ-OPPT-2022-0918-0008).

<sup>2</sup> 40 C.F.R. § 702.33.

EPA has not demonstrated that the framework it has proposed will reliably predict cumulative risk and is unbiased as is required to be considered “Best Available Science.” EPA recently stated that the scientific foundation for cumulative risk and impacts needs to be strengthened and EPA is funding research in this area.<sup>3</sup> If there is a general scientific theorem or law of cumulative risk (*i.e.*, a scientific “principle”), EPA needs to identify it, and must be able to demonstrate its applicability to measuring cumulative risk in the TSCA context by developing testable hypotheses that can be validated over time consistent with its approach to validating New Approach Methods (NAMs) with substantial evidence.<sup>4</sup> Since CRA is still an active area of research with need for methodology and tool development, the use of this framework is premature, running ahead of the science. Given the current uncertainty of this work, it would be perhaps more accurate to characterize this document as a draft framework or pilot project for developing an approach for including cumulative risk TSCA evaluations.

Respectfully,



Ray Ehrlich  
Executive Director

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<sup>3</sup> “To support federal, state, tribal, and community decision-making, ORD must strengthen the scientific foundation for assessing cumulative exposures, impacts, and risks through existing and new methods, tools, data, and monitoring.” [U.S. EPA. Cumulative Impacts Research: Recommendations for EPA’s Office of Research and Development.](#) U.S. Environmental Protection Agency, Washington, D.C., EPA/600/R-22/014a, 2022. Page vii.

<sup>4</sup> Cf., 15 U.S.C. § 2618(c)(1)(B)(i)(I) (“... the court shall hold unlawful and set aside [a TSCA §6(a)] rule if the court finds that the rule is not supported by substantial evidence in the rulemaking record”).