



April 28, 2023

Dr. Alaa Kamel
Mission Support Division (7602M)
Office of Program Support, OCSPP
Environmental Protection Agency
1200 Pennsylvania Ave NW
Washington DC 20460-0001

Submitted via www.regulations.gov

Re: Comments on EPA's Draft Proposed Principles of Cumulative Risk Assessment under the Toxic Substances Control Act, EPA-HQ-OPPT-2022-0918

Dear Dr. Kamel,

The Society of Chemical Manufacturers & Affiliates ("SOCMA")¹ appreciates the opportunity to provide comments to EPA and the Science Advisory Committee on Chemicals ("SACC") on EPA's *Draft Proposed Principles of Cumulative Risk Assessment under the Toxic Substances Control Act* ("Draft Principles").²

SOCMA is the national trade association dedicated to the specialty and fine chemical industry. Founded in 1921, SOCMA represents a diverse membership of chemical companies who batch manufacture new and innovative chemistries used in a wide range of commercial, industrial, and consumer products. SOCMA maintains a strong record of member service through programs that maximize commercial opportunities, enhance regulatory and legal compliance, and promote industry stewardship. SOCMA's members also implement ChemStewards®, an EHS&S performance improvement program that is a mandatory component of membership.

The open development of guidance including contributions and consultation with industry is the best path to developing a successful cumulative risk assessment ("CRA") under the Toxic Substances Control Act ("TSCA"). It will serve to inform stakeholders as to how this approach will be used by EPA to evaluate groups of chemicals for potential unreasonable risks to human health and the environment. As EPA

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² 88 Fed. Reg. 12354 (Feb. 27, 2023), draft document available at <https://www.regulations.gov/document/EPA-HQ-OPPT-2022-0918-0008>.



develops its procedures for CRA, SOCMA offers the following recommendations to improve the transparency, predictability and robustness of CRAs:

1. EPA Must Provide More Specific Guidance to Stakeholders Rather than General “Principles”

EPA’s Draft Principles are too high-level to be implemented and do not provide clarity or certainty for stakeholders regarding EPA’s implementation of CRAs in TSCA risk evaluations and risk management decision in the future. EPA has stated in the Draft Principles that these are not “guidance” or a “framework” on the process for conducting CRAs. SOCMA recommends EPA develop more specific guidance to provide stakeholders greater transparency and certainty, along with consistency in conducting CRAs. For example, while the Draft Principles refer to evaluating “toxicologically similar” chemical substances, this critical term is not defined. When grouping chemicals, SOCMA encourages EPA to consider chemicals that have similar chemical makeups with similarly reasonably foreseeable exposures. EPA should also take into consideration whether these chemicals cause a common toxic effect through a common mechanism or mode of action.

2. EPA Must Use Refined Approaches Rather than Screening-Level Approaches to Evaluating Groups of Chemicals to Ensure CRAs Use the Best Available Science (“BAS”)

EPA should not use screening-level CRA approaches to inform important regulatory decisions that will have significant economic impacts on regulated entities. Instead, EPA should use more refined approaches. SOCMA supports an approach to CRA that is fit-for-purpose (the extent or complexity of the evaluation of the scientific evidence should be commensurate with the importance of the decision), consistent with the best available science. This approach should also be based on actual product uses, as opposed to theoretical or off-label uses. EPA should do robust literature reviews of chemical groupings it evaluates to ensure that its approach is informed by the best available science.

This recommendation is consistent with the recent EPA Science Advisory Board (SAB) report which considered approaches to evaluating mixtures of PFAS. When commenting on an evaluation approach (in this case, a Hazard Index approach for mixtures) that combined chemicals with points of departure that were based on differing health effects and target organs, SAB stated that the approach is only appropriate for “initial screening.” Instead, focusing on target organs that are affected by a common mode of action provides for a more robust and more scientifically reliable CRA. This more robust approach has been used by EPA’s Office of Pesticide Programs and should be considered for CRAs that will inform TSCA risk management decisions.

EPA must also ensure that when highly conservative assumptions lead to a finding of unreasonable risk in a CRA, it further evaluates the substance, incorporating more refined information to ensure that the CRA is reflective of the best available science. Conservative, default assumptions are not sufficiently robust to inform risk management decisions that may have significant economic implications.



SOCMA appreciates this opportunity to provide these comments on improving EPA's Draft Principles for cumulative risk assessments. If you have any questions about these comments, please do not hesitate to contact me at 571-348-5107 or rhelminiak@socma.org.

Regards,

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