

November 29, 2024

Alie Muneer
Designated Federal Official
Office of Program Support
Office of Chemical Safety and Pollution Prevention
U.S. Environmental Protection Agency
Email: muneer.alie@epa.gov

Re: 1,3-Butadiene; Draft Risk Evaluation Peer Review by the SACC; Request for Comments on Experts Being Considered as *Ad Hoc* Peer Reviewers; Docket ID EPA-HQ-OPPT-2024-0425

Dear Ms. Muneer,

The American Chemistry Council (ACC) 1,3-Butadiene TSCA Risk Evaluation Consortium (Consortium) appreciates the opportunity to provide comments on the *ad hoc* reviewers under consideration for selection to review the 2024 Draft Risk Evaluation for 1,3-Butadiene (Draft Risk Evaluation). We understand that EPA is seeking to add approximately 8-10 reviewers to the EPA Science Advisory Committee on Chemicals (SACC) to conduct the peer review of the Draft Risk Evaluation.

Additionally, we are extremely concerned that EPA has announced a Feb 25-28, 2025, date for the SACC peer review.¹ Working back from this date, as is typical for other SACC reviews, we expect EPA will likely request public comments by February 18, 2025, and EPA is likely to request comments for the preparatory meeting by February 7, 2025. This extremely short timeline for a draft risk evaluation, that has yet to be made publicly available, is inappropriate. The short time frame encompasses multiple religious and secular holidays in December and the start of the new year, further shortening the actual time stakeholders, Consortium members, and SACC experts, will have to review these important and highly technical draft documents. Based on previous risk evaluations, we expect the draft risk evaluation to contain dozens of supplemental documents, extensive detailed, technical excel worksheets, and likely new analyses on the hazard endpoints. Expecting public stakeholders and SACC experts, some of which have not even been appointed, to review all these documents in such a short time is unrealistic and is not consistent with best practices for peer review and stakeholder input. We request that EPA reschedule the SACC peer review such that sufficient time is provided for public stakeholders and SACC reviewers to review and develop comments on the draft risk evaluation.

The Consortium fully supports the selection of *ad hoc* reviewers who will contribute to a scientifically robust peer review of the Draft Risk Evaluation for 1,3-Butadiene by expanding the breadth of scientific expertise and perspectives of peer reviewers. As we noted in our letter of October 18, 2024,² it is

¹ EPA Memo Opening Docket for Comments, Nov. 14, 2024, available at: <https://www.regulations.gov/document/EPA-HQ-OPPT-2024-0425-0003>.

² <https://www.regulations.gov/document/EPA-HQ-OPPT-2024-0425-0002>.

imperative that the SACC review not be unduly narrow and the Consortium recommends adding expertise beyond the areas noted in the September 18, 2024, Federal Register notice.³ Critical expertise is needed in biological modeling, including mechanisms of carcinogenicity, industrial hygiene, occupational epidemiology, ambient air monitoring, and conducting fenceline reviews. The Consortium recommends that EPA not arbitrarily limit the number of *ad hoc* reviewers to 8-10. EPA must ensure sufficient expertise is present on the panel and that the SACC membership is appropriately balanced.

The Consortium Fully Supports the Selection of *Ad Hoc* Reviewers Who Will Contribute to a Scientifically Robust Peer Review of the Draft Risk Evaluation for 1,3-Butadiene

As discussed in the Consortium's October 18 letter, the role of the SACC in TSCA implementation is significant. The SACC is required to provide independent advice and expert consultation to EPA staff on scientific and technical aspects of issues related to TSCA implementation. The SACC deliberates on cross-cutting scientific and technical issues that can have broad impact, as well as the review of individual TSCA Section 6 risk evaluations for chemical substances.

EPA's Sept. 18, 2024 Federal Register notice requests nominations of peer reviewers with expertise in areas including: risk assessment; ecological risk assessment, specifically with expertise in physical chemistry, environmental fate, synthetic polymers; human health assessment, specifically with expertise in modes of action, mutagenicity, developmental and reproductive toxicity, dose response, cancer epidemiology; and exposure assessment, specifically with expertise in occupational inhalation monitoring and air exposure modeling.

As the Consortium notes its October 18 letter, the SACC should conduct a review of the totality of scientific inputs, methods and their application in the entire risk evaluation, instead of focusing solely on methods and analyses that are novel and have not been reviewed in other venues. Other important areas where critical expertise is needed include biological modeling, including mechanisms of carcinogenicity, industrial hygiene, occupational epidemiology, ambient air monitoring, and conducting fenceline reviews. Furthermore, the SACC should have a balanced representation of subject matter experts in the private sector and governmental agencies both at the state and federal levels

The Consortium fully supports EPA's call for comments on the candidates for the peer-review of the Draft Risk Evaluation for 1,3-Butadiene.⁴ The Consortium requests that the Agency conduct a robust peer review of the Draft Risk Evaluation in an open and transparent manner. The Consortium recommends that the Agency include the following scientists as *ad hoc* reviewers since they possess expertise in areas critical to this review: Drs. Rowlands, Maier, Kaden, Fenner-Crisp, Green, Lu, Wikoff, York, and Johnson (human health risk assessment), Drs. Boffetta and Eastmond (cancer epidemiology), Drs. Fairbrother and Johnson (ecological risk assessment), Drs. Havics, Kaden, and Maier (industrial hygiene and exposure assessment), Dr. Lu (DNA adducts), Drs. Roby and York (reproductive and

³ 89 Fed. Reg. 76467 (Sept. 18, 2024).

⁴ [EPA Calls for Comments on Candidates for Peer Review of 1,3-Butadiene | US EPA](#)

developmental), Drs. Kaden and Rish, and Mr. Smith and Mr. Owen (fenceline assessment).

Once again, the Consortium requests that EPA reschedule the SACC peer review such that sufficient time is provided for public stakeholders and SACC reviewers to review and develop comments on the draft risk evaluation.

On behalf of the Consortium, I appreciate your consideration of these comments. Please feel free to contact me directly at the email address below should you have any questions.

Sincerely,
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