



April 9, 2024

VIA ELECTRONIC SUBMISSION

Michal Freedhoff, Ph.D.
Assistant Administrator
Office of Chemical Safety Pollution and Prevention
U.S. Environmental Protection Agency
1200 Pennsylvania Ave. NW
Washington, DC 20460

Re: Formaldehyde; Draft Risk Evaluation Peer Review by the Science Advisory Committee on Chemicals (SACC); Notice of Availability, Public Meetings, and Request for Comment. Docket No. EPA-HQ-OPPT-2023-0613.

Dear Assistant Administrator Freedhoff:

On March 15, 2024, the U.S. Environmental Protection Agency (EPA) published a notice of availability for the draft risk assessment and peer review by the Science Advisory Committee on Chemicals (SACC) for formaldehyde.¹ The Office of Advocacy (Advocacy) is concerned that the current comment period, ending on May 3, 2024, does not give small entities enough time to analyze both the draft risk assessment and associated materials that have been placed in the docket. Advocacy recommends EPA extend the comment period for an additional 60 days.

I. Background

A. The Office of Advocacy

Congress established the Office of Advocacy under Pub. L. 94-305 to represent the views of small entities before federal agencies and Congress. Advocacy is an independent office within the U.S. Small Business Administration (SBA) that seeks to ensure small business concerns are heard in the federal regulatory process. Advocacy also works to ensure that regulations do not unduly inhibit the ability of small entities to compete, innovate, or comply with federal laws. The views expressed by Advocacy do not necessarily reflect the views of the SBA or the Administration.

¹ 89 Fed. Reg. 18933 (Mar. 15, 2024).

The Regulatory Flexibility Act (RFA),² as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA),³ gives small entities a voice in the rulemaking process. For all rules that are expected to have a significant economic impact on a substantial number of small entities, the RFA requires federal agencies to assess the impact of the proposed rule on small entities and to consider less burdensome alternatives.⁴ Additionally, section 609 of the RFA requires the Consumer Financial Protection Bureau, the Occupational Safety and Health Administration, and the Environmental Protection Agency to conduct special outreach efforts through a review panel.⁵ The panel must carefully consider the views of the impacted small entities, assess the impact of the proposed rule on small entities, and consider less burdensome alternatives for small entities.⁶ If a rule will not have a significant economic impact on a substantial number of small entities, agencies may certify the rule.⁷ The agency must provide a statement of factual basis that adequately supports its certification.⁸

The Small Business Jobs Act of 2010 requires agencies to give every appropriate consideration to comments provided by Advocacy.⁹ The agency must include a response to these written comments in any explanation or discussion accompanying the final rule's publication in the Federal Register unless the agency certifies that the public interest is not served by doing so.¹⁰

Advocacy's comments are consistent with Congressional intent underlying the RFA, that "[w]hen adopting regulations to protect the health, safety, and economic welfare of the nation, federal agencies should seek to achieve statutory goals as effectively and efficiently as possible without imposing unnecessary burdens on the public."¹¹

B. The Draft Risk Assessment

On March 15, 2024, the EPA published a notice seeking comment on the draft risk assessment for formaldehyde under the Toxic Substances Control Act (TSCA).¹² The EPA further announced a SACC meeting to consider the draft risk assessment on May 20-23, 2024, and a preparatory meeting on May 7, 2024, to consider draft charge questions for peer review.¹³

TSCA requires the EPA to conduct risk evaluations on high-priority chemical substances to determine whether a chemical substance presents an unreasonable risk to human health or the environment under the chemical's conditions of use. The EPA must also determine whether a chemical substance presents an unreasonable risk to potentially exposed or susceptible subpopulations deemed relevant by the Administrator.¹⁴ Recommendations from the

² Pub. L. No. 96-354, 94 Stat. 1164 (1980) (codified at 5 U.S.C. §§ 601-612).

³ Pub. L. No. 104-121, tit. II, 110 Stat. 857 (1996) (codified in scattered sections of 5 U.S.C. §§601-612).

⁴ 5 U.S.C. § 603.

⁵ *Id.* § 609.

⁶ *Id.*

⁷ *Id.* § 605(b).

⁸ *Id.*

⁹ Small Business Jobs Act of 2010, Pub. L. No. 111-240, §1601, 214 Stat. 2551 (codified at 5 U.S.C. § 604).

¹⁰ *Id.*

¹¹ Regulatory Flexibility Act, Pub. L. No. 96-354, 94 Stat. 1164 (1980) (codified at 5 U.S.C. §§ 601-612).

¹² 89 Fed. Reg. 18933 (Mar. 15, 2024).

¹³ *Id.* at 18,934.

¹⁴ *Id.* at 18,935.

formaldehyde SACC review and public comments will be considered in the development of the final TSCA risk evaluation for formaldehyde and may inform other EPA efforts related to the assessment and regulation of formaldehyde.¹⁵

Formaldehyde is found in a variety of products, including:

- Resins used in the manufacture of composite wood products (i.e., hardwood plywood, particleboard, and medium-density fiberboard);
- Building materials and insulation;
- Household products such as glues, permanent press fabrics, paints and coatings, lacquers and finishes, and paper products;
- Preservatives used in some medicines, cosmetics, and other consumer products such as dishwashing liquids and fabric softeners; and
- Fertilizers and pesticides.¹⁶

Small entities that manufacture and use these products will be directly impacted by the EPA's forthcoming regulations on the use of formaldehyde. It is vital to obtain small entity input early in the regulatory process, at the draft risk assessment stage, rather than wait for an eventual proposed rule. This will allow the EPA to consider the input of small entities as it considers what further regulation is appropriate as opposed to not hearing from small entities until after a draft rule is proposed.

II. Advocacy Recommends Extending the Public Comment Period by 60 Days.

Currently, the various elements of the draft risk assessment total nearly 1,000 pages and there are more than 50 supporting documents in the docket.¹⁷ Small entities often do not have expert regulatory or scientific staff who are trained in analyzing and commenting on draft risk assessments and their underlying materials. Additionally, when small entities do have the time to examine these materials, it is often done in addition to the full-time job of running their business, governmental entity, or organization.

Advocacy has been contacted by multiple small entity representatives who feel the current comment period is not long enough. Also, the current deadline of May 14 is roughly one week prior to the SACC meeting. Extending the current deadline would allow small entities the chance to attend and participate in the SACC meeting and could use the information from the meeting to inform their comments. Additionally, extending the comment period will allow small entity representatives adequate time to explain the draft risk assessment to their members and gather input which will be beneficial to the EPA as they consider future regulatory action on formaldehyde.

¹⁵ *Id.*

¹⁶ See U.S. ENV'T PROT. AGENCY, *Facts About Formaldehyde*, <https://www.epa.gov/formaldehyde/facts-about-formaldehyde> (last updated Mar. 6, 2024).

¹⁷ U.S. ENV'T PROT. AGENCY, *Browse Documents, Science Advisory Committee on Chemicals (SACC) Peer Review of 2024 Draft Formaldehyde Risk Evaluation*, <https://www.regulations.gov/docket/EPA-HQ-OPPT-2023-0613/document> (last visited Apr. 3, 2024).

Advocacy recommends the EPA extend the comment period for the draft risk assessment by an additional 60 days.

III. Conclusion

The draft risk assessment for formaldehyde will be used to inform future EPA rulemaking. As such, it is important to receive the input of small entities that manufacture and use products containing formaldehyde as early as possible. Advocacy urges the EPA to extend the current comment period by 60 days to give small entities the time they need to both fully evaluate the draft risk assessment and associated materials. This will allow them to offer information that will aid the EPA in ensuring future regulatory actions do not unnecessarily or disproportionately impact their activities.

If you have any questions or require additional information, please contact me or Assistant Chief Counsel Nick Goldstein at (202) 772-6948 or by email at nick.goldstein@sba.gov.

Sincerely,

/s/

Major L. Clark, III
Deputy Chief Counsel
Office of Advocacy
U.S. Small Business Administration

/s/

Nick Goldstein
Assistant Chief Counsel
Office of Advocacy
U.S. Small Business Administration

Copy to: The Honorable Richard L. Revesz, Administrator
Office of Information and Regulatory Affairs
Office of Management and Budget