SIDLEY

AHFA Regulatory Summit: From Risk Assessment to Risk Management

Sam Boxerman

August 20, 2025

CONFIDENTIAL

TALENT. TEAMWORK. **RESULTS.**

Confidentiality

This briefing is confidential.

Agenda

I. TSCA Background

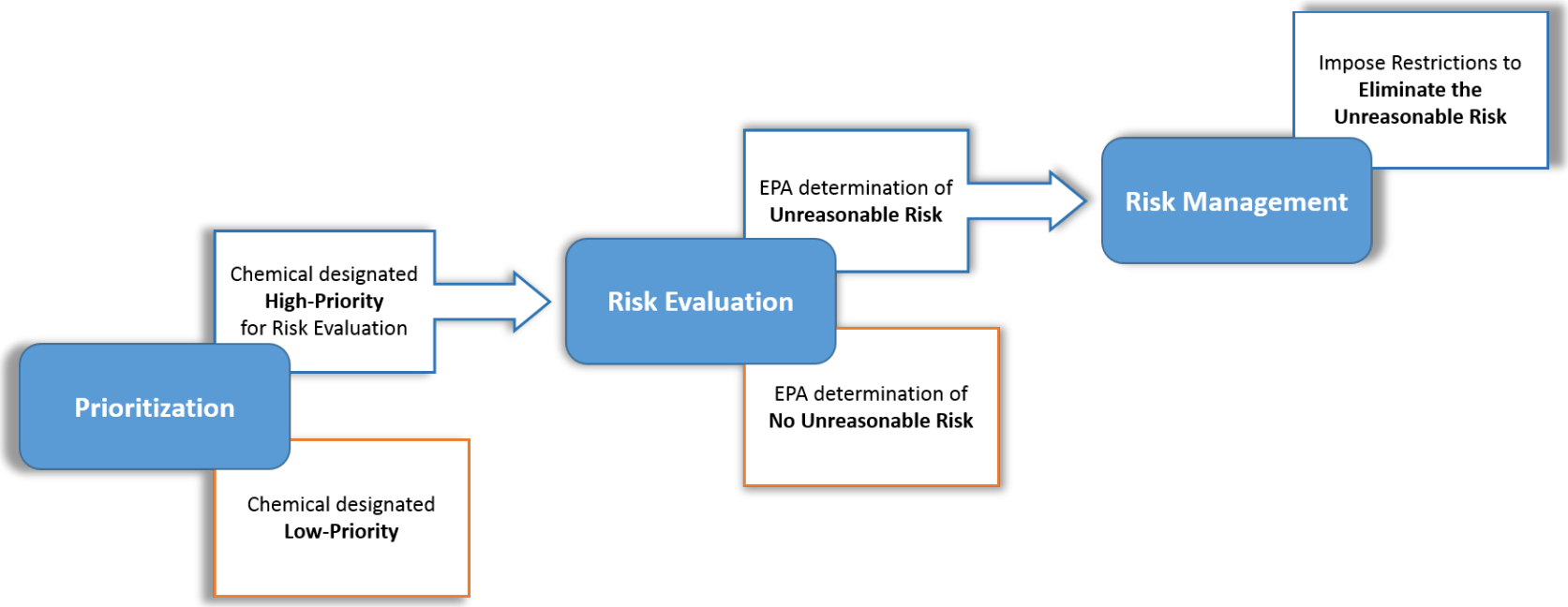
II. Formaldehyde Draft Risk Evaluation → Final Risk Evaluation → Possible Next Steps

III. Discussion

BACKGROUND: TSCA PRIORITIZATION, RISK EVALUATION, AND RISK MANAGEMENT PROCESSES

TSCA Background: 2016 Amendments

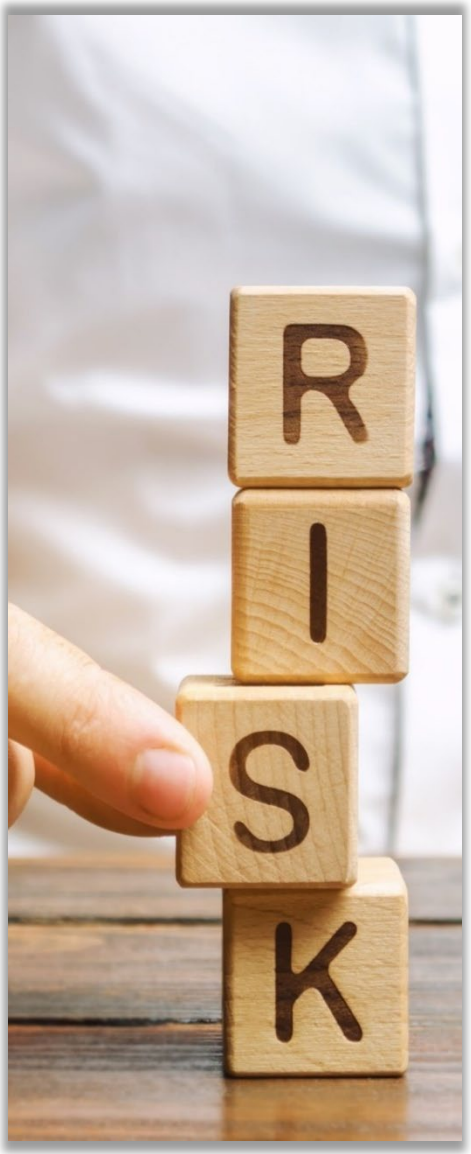
- Original TSCA – question if it did/could effectively regulate "existing chemicals"
- 2016 TSCA amendments revised the process
- Congress established 3-step framework—each with statutory deadlines and many opportunities for public comment—for EPA to develop regulations to eliminate "unreasonable risk" from chemical substances



TSCA Background: Prioritization & Risk Evaluation

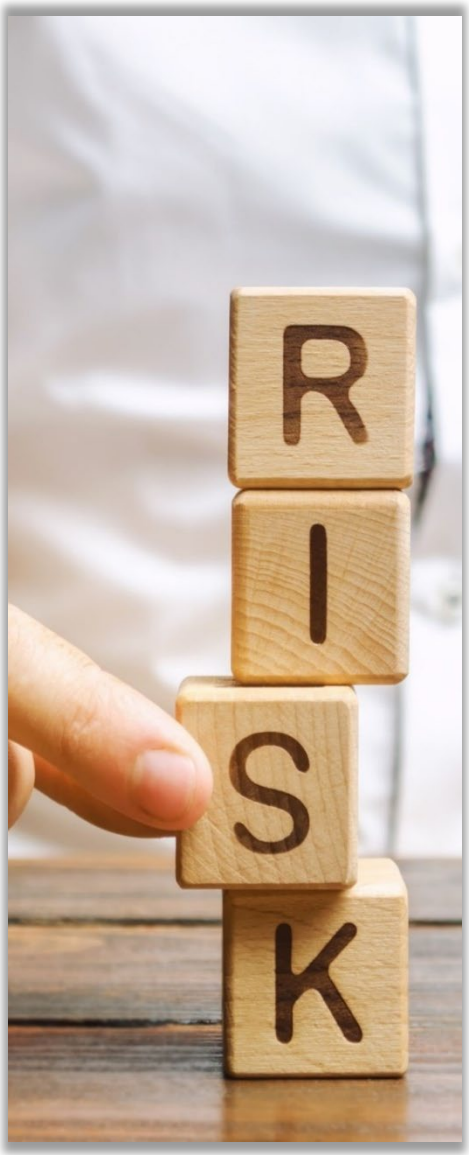
- TSCA requires EPA to designate chemical substances as **high priority** for further evaluation and to identify additional high priority chemical substances as each evaluation is completed.
- High priority chemicals go through the **risk evaluation** process to determine whether they present an unreasonable risk to health or the environment under its **conditions of use**.
- EPA issued general regulations governing the risk evaluation process referred to as the EPA **framework rules**
- TSCA directs EPA to rely on the **best available science** and consider the weight of the scientific evidence when conducting risk evaluations.

TSCA Background: Risk Management



- If a chemical is determined to present an unreasonable risk, EPA will develop **a risk management rule** to address the risk, considering appropriate factors.
- A risk management rule could include:
  - Ban/restrict entirely
  - Ban/restrict for particular use(s) or use(s) > concentration
  - Limit the amount for particular use(s) or use(s) > concentration
  - Marked w/minimum warnings and instructions
  - Recordkeeping, monitoring, testing
  - Otherwise regulate any manner/method of commercial use
  - Notice of EPA finding to: distributors, persons in possession, and public – and replace/repurchase as person may elect

TSCA Background: Risk Management cont.



According to TSCA, **factors to consider** include:

- Effects on health / magnitude of human exposure
- Effects on / magnitude of exposure to the environment
- Benefits for various uses
- Reasonably ascertainable economic consequences of a rule
  - Likely effect on US economy, small business, technological innovation, environment, and public health
  - Costs and benefits of the action and of primary alternative(s) considered by EPA

Timelines in the statute:

- Prioritization: 9-12 months from initiation
- Risk Evaluation: Within 3 years of initiation
- Risk Management: Within 2 years of finding unreasonable risk in final Risk Evaluation

Judicial challenges

- Generally – *after* a risk management rule issued

TSCA Background: Biden EPA to Trump 2.0 EPA

- **Biden EPA** completed a number of risk evaluations and completed / initiated the risk management process for various chemicals that EPA has determined to present an unreasonable risk, including:
  - Final Risk Management Rules: Asbestos, Carbon Tetrachloride, Methylene Chloride, Perchloroethylene, Trichloroethylene
  - Proposed Risk Management Rules: 1-Bromopropane, C.I. Pigment Violet 29, N-methylpyrrolidone
  - Final Risk Evaluations: Formaldehyde, 1,1-Dichloroethane, among others

- **Trump 2.0 EPA** now reconsidering some of these Biden EPA actions
  - Reconsidering framework rule (relevant to risk evaluations moving forward)
  - Reconsidering final risk management rules
  - Issuing supplemental rules/notices for further public comment on risk evaluations or proposed risk management rules issued under Biden
  - Revisiting prioritizations

FORMALDEHYDE DRAFT RISK EVALUATION

Formaldehyde Risk Evaluation: Timeline

December 2019

- EPA designated formaldehyde as a “High-Priority Substance” under TSCA.

August 2020

- EPA publicly released its Final Scope of the Risk Evaluation for Formaldehyde. Excluded composite wood products (hardwood plywood, particleboard, and medium density fiberboard [including thin-medium density fiberboard]), and laminated products regulated under Title VI.

Formaldehyde Risk Evaluation: Timeline cont.

April 2022

- EPA publicly released its *Draft IRIS Toxicological Review of Formaldehyde (Inhalation).*
  - —EPA then contracted the National Academies of Sciences, Engineering, and Medicine (NASEM) to manage an independent external scientific peer review and provide recommendations to improve the draft IRIS assessment.

July 20, 2023

- The American Chemistry Council (ACC) filed suit against the EPA and NASEM.
  - —ACC asserted that both organizations failed to follow "basic standards for scientific integrity, independent peer review, and governmental transparency."

Formaldehyde Risk Evaluation: Timeline cont.

August 9, 2023

- NASEM published its *Review of EPA's 2022 Draft Formaldehyde Assessment*
  - The report finds that EPA's draft IRIS assessment follows the advice of prior National Academies reports and that EPA's findings on hazard and quantitative risk are supported by the evidence identified in the document

March 14, 2024

- EPA released the draft Risk Evaluation for Formaldehyde.
  - EPA included composite wood products in the risk evaluation and determined the use of formaldehyde in wood articles, including furniture, mattresses, furnishings, and other interior wood finishes presents an unreasonable risk – but with some ambiguity.

Formaldehyde Risk Evaluation: Timeline cont.

May 7, 2024

- Public Meeting on the Scope and Clarity of the Draft Charge for the Science Advisory Committee on Chemicals (SACC) Review of the Draft Risk Evaluation for Formaldehyde.
  - The SACC and the public had the opportunity to ask questions about EPA's charge questions for each part of the draft *Risk Evaluation*.

May 20-23, 2024

- Meeting of the SACC
  - EPA presented on each part of the draft *Risk Evaluation* and SACC had the opportunity to ask questions and listen to public comments. SACC members critiqued the evaluation and its reliance on the IRIS assessment.

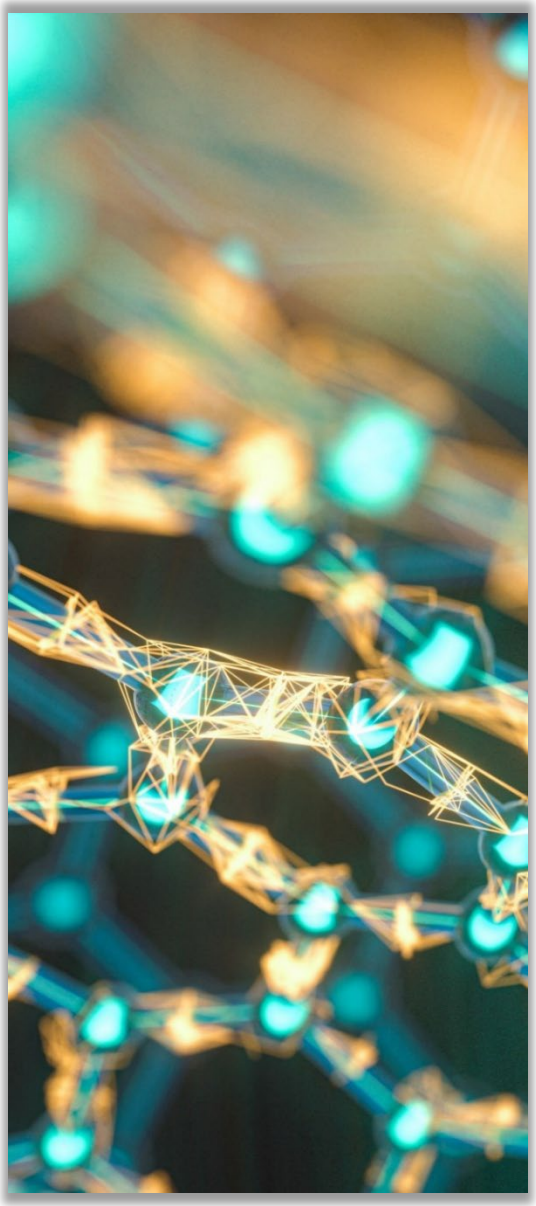
Formaldehyde Risk Evaluation: Findings of the *Draft* Risk Evaluation

- EPA **preliminarily found that formaldehyde presents an unreasonable risk** of injury to human health, but recognized that risks relate to specific activities and products.
- EPA evaluated conditions of use (COU) in manufacturing, processing, industrial use, commercial use, and consumer use.
- **EPA included wood articles**, including furniture, mattresses, furnishings, and other interior wood finishes – but **in the same COU as cleaning products.**

Formaldehyde Risk Evaluation: AHFA Comments on *Draft* Risk Evaluation

EPA should:

- Consider wood articles in residences in a **separate COU from cleaning products**.
- **Find that exposure to formaldehyde from wood articles in residences** does not present an unreasonable risk of injury to human health.
- Rely on best available science, including current data for wood articles that meet **EPA's strict Title VI emission (chamber studies) and show no unreasonable risk**



Formaldehyde Risk Evaluation: AHFA Engagement With EPA on *Draft* Risk Evaluation

Drano is not Furniture

≠

FORMALDEHYDE FINAL RISK EVALUATION

Formaldehyde Risk Evaluation: Findings of the *Final* Risk Evaluation

- Published December 2024.
- EPA **found formaldehyde presents an unreasonable risk**.
- **The Good News:** EPA found that composite wood panels regulated by TSCA VI **do not** pose an unreasonable risk.
- **The Unexpected Bad News:** EPA's found an unreasonable risk from foam seating and bedding for commercial/consumer use.

Summary: A public commenter (0270) stated that EPA should find that foam, fabric, and other covers in home furnishings do not contribute to an unreasonable risk determination, which is supported further by the fact that many furniture and mattress foams are manufactured without formaldehyde through the CertiPUR-US program. The commenter added that EPA should retain its finding that there is no unreasonable risk associated with furniture seat covers. Both of these conclusions are supported by the submitted data from chamber tests conducted to identify the potential "worst case" formaldehyde emissions from common foam, textiles, and raw materials used in constructing furniture products in the U.S.

EPA Response: While not intentionally added to the polyurethane foam, because formaldehydye is formed due to the degradation of a foam product, formaldehyde is therefore reasonably foreseen to be present. As such, the use of polyurethane foam becomes a condition of use (COU) under which EPA must evaluate. There are a number of general categories of circumstances that are considered conditions of use that generally must be included within the scope of TSCA risk evaluations, including and the presence of a chemical as an impurity or within an article.

Polyurethane foam is considered a COU and falls under these two categories:

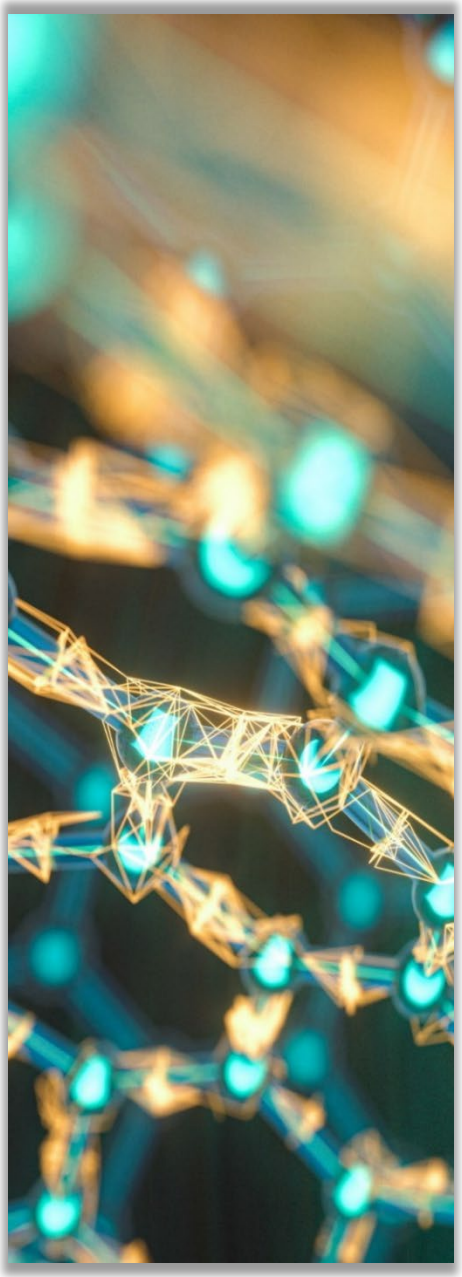
- *Commercial use - Floor coverings; Foam seating and bedding products; Furniture & furnishings including stone, plaster, cement, glass and ceramic articles; metal articles; or rubber articles; Cleaning and furniture care products; Leather conditioner; Leather tanning, dye, finishing impregnation and care products; Textile (fabric) dyes; Textile finishing and impregnating/ surface treatment products.*
- *Consumer use - Floor coverings; Foam seating and bedding products; Cleaning and furniture care products; Furniture & furnishings including stone, plaster, cement, glass and ceramic articles; metal articles; or rubber articles.*

147

Formaldehyde Risk Evaluation: AHFA Engagement with EPA on *Final* Risk Evaluation

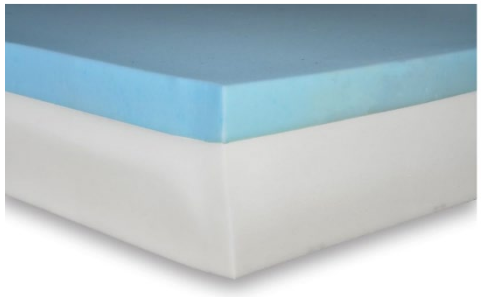
Met with and explained to EPA – both pre/post transition to Trump EPA:

- ***EPA should revise and correct the COU*** – foam seating and bedding *do not* use foam insulation – the article category ***foam insulation seating*** is incorrect.
- **Provide the data used/relied on** – EPA incorrectly relied on an SDS for ***'slab foam wall insulation'*** and 25-yr old trailer data that are not characteristic of current use.
- **Decomposing polyols are not a concern** – For 50 years additives have eliminated that issue.
- **Review and consider the *relevant d*ata submitted** – AHFA and CertiPur® data show that foam seating, furniture covers, etc. do not contribute to an unreasonable risk of injury to human health.



Formaldehyde Risk Evaluation: AHFA Engagement with EPA on *Final* Risk Evaluation

COU - Foam Seating/Bedding is not Slab Insulation

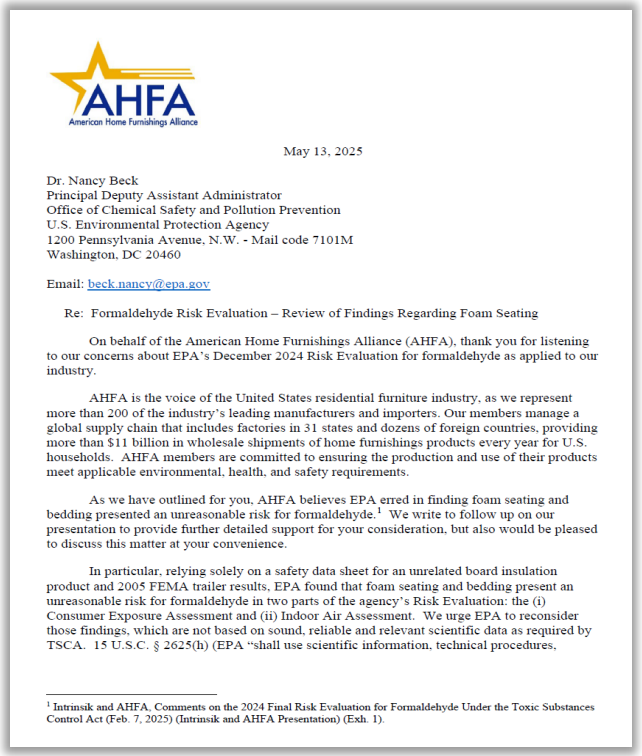


Flexible Polyurethane Foam

≠

Foam Slab Insulation

Formaldehyde Risk Evaluation: AHFA Engagement with EPA on *Final* Risk Evaluation



AHFA
American Home Furnishings Alliance

May 13, 2025

Dr. Nancy Beck
Principal Deputy Assistant Administrator
Office of Chemical Safety and Pollution Prevention
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W. - Mail code 7101M
Washington, DC 20460

Email: beck.nancy@epa.gov

Re: Formaldehyde Risk Evaluation – Review of Findings Regarding Foam Seating

On behalf of the American Home Furnishings Alliance (AHFA), thank you for listening to our concerns about EPA's December 2024 Risk Evaluation for formaldehyde as applied to our industry.

AHFA is the voice of the United States residential furniture industry, as we represent more than 200 of the industry's leading manufacturers and importers. Our members manage a global supply chain that includes factories in 31 states and dozens of foreign countries, providing more than $11 billion in wholesale shipments of home furnishings products every year for U.S. households. AHFA members are committed to ensuring the production and use of their products meet applicable environmental, health, and safety requirements.

As we have outlined for you, AHFA believes EPA erred in finding foam seating and bedding presented an unreasonable risk for formaldehyde.[1] We write to follow up on our presentation to provide further detailed support for your consideration, but also would be pleased to discuss this matter at your convenience.

In particular, relying solely on a safety data sheet for an unrelated board insulation product and 2005 FEMA trailer results, EPA found that foam seating and bedding present an unreasonable risk for formaldehyde in two parts of the agency's Risk Evaluation: the (i) Consumer Exposure Assessment and (ii) Indoor Air Assessment. We urge EPA to reconsider those findings, which are not based on sound, reliable and relevant scientific data as required by TSCA. 15 U.S.C. § 2625(h) (EPA "shall use scientific information, technical procedures,

[1] Intrinsik and AHFA, Comments on the 2024 Final Risk Evaluation for Formaldehyde Under the Toxic Substances Control Act (Feb. 7, 2025) (Intrinsik and AHFA Presentation) (Exh. 1).

EPA suggested we could have raised the issue earlier / was the best data they had available / the issue can be addressed in Risk Management.

- Documented that **EPA had not provided notice** of its intent to rely on foam insulation.
- Documented further EPA's **error in reliance on Owens Corning SDS for foam insulation**.
- Explained again that **25-yr old trailer data are not characteristic** of current use.
- Reaffirmed **AHFA and CertiPur® data** show that foam seating, furniture covers, etc. do not contribute to an unreasonable risk of injury to human health.

Have not heard further from EPA to date.

Possible Next Steps…

- EPA is reconsidering TSCA Framework Rules
- But - EPA is proceeding with Risk Management already in progress, including formaldehyde
- Engage further with EPA/Administration before Risk Management proposed
- Participate in Risk Management rulemaking

DISCUSSION

Environmental and Mass Torts Practices

Sidley has leading environmental and mass torts practices in the U.S.

Our environmental practice has extensive experience representing trade associations and coalitions and with the EPA rule-making process, including having drafted comments on the initial formaldehyde risk evaluation scoping document.

Our mass torts practice has decades of experience handling claims associated with products, the facilities that manufacture them, and the companies that sell them. We defend clients in state and federal courts and are typically lead counsel in multidistrict litigations and state coordinated proceedings. We are comfortable working with co-counsel and witnesses in non-U.S. venues and courts.

These practices work collaboratively to gain a better understanding of the scientific, medical, and global regulatory issues that are essential to building a successful defense.

Biographies

Samuel B. Boxerman
Partner

sboxerman@sidley.com
Washington, DC
+1 202 736 8547

SAM BOXERMAN, a partner in the firm's Environmental practice, has 38 years of experience in environmental law, handling complex litigation and providing strategic counseling. Sam defends government investigations and enforcement actions under TSCA, the Clean Air Act (Title I and II), Clean Water Act, CERCLA and RCRA, and advises clients on regulatory matters, assisting with comments on agency proposals and challenges to agency actions.

Sam has been named to *Best Lawyers* and *Super Lawyers*, where he is described as "an outstanding attorney" who brings "years of in-depth experience" providing "sound advice," and has been recognized as a *BTI Client Service All-Star*. He is listed among the 2024 *Best Lawyers* "Lawyer of the Year" honorees in Environmental Law and the 2025 *Lawdragon* "Green 500: Leaders in Environmental Law."

Sam joined Sidley in 1991 from the U.S. Department of Justice, where he handled environmental enforcement litigation. Sam also served as a Special Assistant U.S. Attorney prosecuting criminal matters.

SIDLEY

Beijing	Hong Kong	Palo Alto
Boston	Houston	San Francisco
Brussels	London	Shanghai
Century City	Los Angeles	Singapore
Chicago	Miami	Sydney
Dallas	Munich	Tokyo
Geneva	New York	Washington, D.C.

sidley.com

TALENT. TEAMWORK. **RESULTS.**