



**SIDLEY**

**AHFA Regulatory Summit**

**EPA Draft Risk Evaluation  
for Formaldehyde**

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# Agenda

- Background
- Formaldehyde Risk Evaluation
- Possible Next Steps
- Intrinsic Review
- Discussion

## Background: TSCA Process

- 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.
- TSCA directs EPA to rely on the best available science and consider the weight of the scientific evidence when conducting risk evaluations.
- If a chemical is determined to present an unreasonable risk, EPA will develop risk management rules to address the risk, considering appropriate factors.



## Background: TSCA Risk Evaluation

There are multiple risk evaluations in progress and EPA is rolling out risk management rules for chemicals EPA has determined to present an unreasonable risk, including:

- Formaldehyde – draft risk evaluation released in March 2024
- Asbestos – draft risk evaluation released in April 2024
- Methylene Chloride (MC) – final risk management rule issued in April 2024
- Trichloroethylene (TCE) – proposed risk management rule issued in October 2023
- N-methylpyrrolidone (NMP) – proposed risk management rule issued in June 2024

More are coming: In April 2024, EPA announced a court settlement setting an enforceable timeline to finalize five risk evaluations and issue drafts for an additional seven by the end of 2024 and to complete high priority evaluations by December 31, 2026.







## Background: Risk Management Rules

EPA has shown a willingness to ban products it determines present an unreasonable risk and to require workplace chemical protection programs.

In Oct. 2023, EPA proposed to ban the manufacture (including import), processing, and distribution in commerce of TCE for all uses, with longer compliance timeframes and workplace controls for some processing and industrial commercial uses until the prohibitions come into effect.

In the April 2024 MC rules, EPA prohibited MC in consumer uses after May 5, 2025, and most commercial uses after April 28, 2026.

- For very specific furniture refinishing, MC can be used until May 8, 2029.

EPA proposed to ban NMP in fertilizers, lubricants and a handful of other products and set strict requirements for use in other sectors, including both workplace exposure limits and product restrictions.



# FORMALDEHYDE RISK EVALUATION

# Timeline of the Risk Evaluation

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](#).



# Exclusions from the Final Scope of the Risk Evaluation

- Final Scope of the Risk Evaluation for Formaldehyde, OCSPP, EPA-740-R-20-014 at 54-55 (August 2020):
  - “composite wood products (hardwood plywood, particleboard, and medium density fiberboard [including thin-medium density fiberboard]), and laminated products currently regulated under the Formaldehyde Emission Standards for Composite Wood Products final rule (i.e., 40 CFR 770) will not be included in the scope of this evaluation ... in their panel form, or as these panels are fabricated into component parts or finished goods.”
- Summary of Public Comments Received on the Draft Scopes of the Risk Evaluations for Twenty Chemical Substances Under the Toxic Substances Control Act (TSCA), OCSPP (Aug. 2020) at 111:
  - EPA “excluded the three composite wood products (i.e., hardwood plywood, medium-density fiberboard (including thin-MDF), and particleboard) from the scope of the risk evaluation ... the risk evaluation also excludes formaldehyde (50-00-0) emissions from those panels as they are further fabricated into component parts and finished goods.”

# Timeline of the Risk Evaluation

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.”

# Timeline of the Risk Evaluation

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.

# Timeline of the Risk Evaluation

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.



# 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.



# AHFA, IWPA, and NRF Comments

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



## AHFA, IWPA and NRF Comments (cont'd)

As a result of the emission standards in TSCA Title VI and CARB regulations, current data show that consumer exposure to formaldehyde emissions from wood articles in residences does not present an unreasonable risk to human health.

- We submitted data from AHFA chamber studies that represents the best available science. The data:
  - Considers furniture that meets current regulatory emission standards.
  - Assesses emissions from assembled furniture, which is how consumers and the general population are exposed to furniture.
  - Reflects the emissions reductions due to laminates and other surface coatings that impede formaldehyde from escaping over time.
  - Considers the emission decay rates between manufacturing and when the product reaches the consumer.
- Data demonstrate that formaldehyde emissions from wood articles in residences are below EPA's proposed benchmark risk levels.

## Possible Next Steps





## A word about *Loper Bright* ...

- In *Loper Bright* the US Supreme Court officially reversed *Chevron*
- Change in test applied by courts when considering an agency's interpretation of its authority under a federal statute
- Implications generally
- What about EPA's Risk Management authority?
  - Interpretation of TSCA terms – e.g., “best available science” and “unreasonable risk of injury to health or the environment”
  - Application of EPA's technical expertise



# 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



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SAMUEL BOXERMAN, a partner in the firm’s Environmental practice, has 33 years of experience in environmental law, handling complex litigation and providing strategic counseling. Sam defends government investigations and enforcement actions under 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 also represents private and sovereign clients in investment treaty and commercial arbitrations. 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 2023 *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.



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HANNAH POSEN is a senior managing associate in the Environmental group of the firm’s Chicago office. Her practice includes defending and advising clients on a wide range of environmental matters, including civil and criminal enforcement actions, regulatory compliance, civil litigation, and environmental aspects of transactions. Hannah is particularly focused on matters arising under the Clean Air Act and Clean Water Act and she has represented and advised various clients in state and federal enforcement proceedings involving alleged violations relating to air emissions and effluent discharges. Hannah has extensive experience conducting internal investigations for manufacturing companies relating to Clean Air Act and Clean Water Act compliance issues. Hannah has also defended multiple automotive sector clients against Clean Air Act enforcement actions. Hannah’s litigation experience includes defending a company in a citizen suit and criminal investigation under the Clean Water Act for alleged effluent discharge violations and defending companies against environmental state-law claims. In addition, Hannah maintains an active pro bono practice representing clients in civil rights litigation in federal court. In 2019, she received the Award for Excellence in Pro Bono Service from the United States District Court for the Northern District of Illinois and the Chicago Chapter of the Federal Bar Association. Prior to joining Sidley, Hannah served as a Law Clerk to the Honorable Michael J. Melloy of the United States Court of Appeals for the Eighth Circuit.



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