KEY TAKEAWAYS
REVISED DRAFT FORMALDEHYDE RISK EVALUATION
DECEMBER 2025

What Did Not Change

- Whole Chemical Unreasonable Risk Determination
  - No change in determination that formaldehyde presents an unreasonable risk to human health under the conditions of use.
  - No change in determination that formaldehyde does not present an unreasonable risk to the environment.
  - No change in determination that unreasonable risk is driven by inhalation and dermal exposure routes in workers, including occupational non-users, and consumers, including bystanders.
  - No change in determination that general population exposures do not significantly contribute to the unreasonable risk.

- Continued Overly Conservative Assumptions for Dermal Route
  - While there are changes to the inhalation estimates, dermal risk findings remain unchanged and continue to contribute to the unreasonable risk for the COUs.

- Exposure Data Used to Assess Inhalation Exposures
  - EPA updated risk calculations but continued to rely on the same exposure data.

- EPA Not Seeking Peer Review on Proposed Revisions
  - EPA is relying on existing peer reviews by SACC, HSRB, NASEM as well as reviews by international bodies including the EU SCOEL, WHO, and Health Canada.

Proposed Changes

- Revised Approach Based on Best Available Science
  - No longer relying on IRIS chronic values
  - Applying a mode of action threshold approach
  - Sensory irritation is the critical effect
  - Based on controlled human chamber studies
  - No application of uncertainty factors (UF =1)
  - No application of duration adjustments

- Revised Acute POD = 0.3 ppm
  - Protective for all hazards (non-cancer and cancer)
  - Applied across all exposure durations (acute and chronic)
  - Applied to all populations (including workers)
  - If exposure > 0.3 ppm for a sustained, long-term duration, there is potential for cancer to develop.

- Revised Acute OEV = 0.3 ppm
    - Occupational Exposure Value (OEV) applies to all durations of exposure and serves as the short-term exposure value. Use of this OEV is health-protective against other effects, including cancer.
    - This calculated value may be used to support risk management efforts for formaldehyde.

- Five COUs "No Longer Indicate Unreasonable Risk for Workers Due to Inhalation" (dermal is now driver of unreasonable risk for these COUs):
    - Lawn and garden products
    - Oxidizing/reducing agent
    - Adhesives and sealant chemicals in wood product manufacturing; plastic material (including structural and fireworthy aerospace interiors); construction (including roofing materials); paper manufacturing
    - Recycling
    - Laboratory chemicals

- If finalized, OEL may not apply to these 5 COUs, but they may still be subject to any dermal exposure requirements.

EPA Memorandum and Supporting Documents – Public Comments Due Feb 2, 2026

Federal Register Notice (Dec 3, 2025)

- Formaldehyde Updated Draft Risk Calculation Memorandum Notice of Availability and Request for Comment

Memorandum and Supplemental Documents

1. Updated Draft Risk Calculation Memorandum
2. Occupational Risk Calculator for Formaldehyde
3. Acute and Chronic Inhalation Risk Calculator for Consumer and Indoor Air
4. IIOAC Assessment Results and Risk Calcs for Formaldehyde Supplement A
5. IIOAC Assessment Results and Risk Calcs for Formaldehyde Supplement B
6. IIOAC Assessment Results and Risk Calcs for Formaldehyde Supplement C
7. Revised Draft Human Health Risk Assessment for Formaldehyde
8. Revised Draft Human Health Hazard Assessment for Formaldehyde
9. Revised Draft Unreasonable Risk Determination for Formaldehyde
10. Revised Draft Executive Summary of the Risk Evaluation for Formaldehyde

EPA Formaldehyde TSCA Website
https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-evaluation-formaldehyde

EPA Formaldehyde TSCA Docket
https://www.regulations.gov/docket/EPA-HQ-OPPT-2018-0438