AMERICAN COLLEGE OF
OCCUPATIONAL AND
ENVIRONMENTAL MEDICINE

January 19, 2026

Re: Docket No. EPA-HQ-OPPT-2018-0438 [FRL-11608-05-OCSPP]
Formaldehyde; Updated Draft Risk Calculation Memorandum; Notice of Availability and Request for Comment

Dear Deputy Assistant Administrator Beck:

On behalf of the American College of Occupational and Environmental Medicine (ACOEM), thank you for the opportunity to comment on EPA's Updated Draft Risk Calculation Memorandum ("Draft Memorandum") for a Revised Draft Risk Evaluation for Formaldehyde under the Toxic Substances Control Act (TSCA).

About ACOEM
Founded in 1916, ACOEM is the nation's largest medical society dedicated to promoting the health of workers through preventive medicine, clinical care, research, and education. ACOEM is a physician-led professional society representing more than 3,000 physicians and other health care professionals specializing in occupational and environmental medicine (OEM).

ACOEM provides leadership to promote optimal health and safety of workers, workplaces, and environments, and serves as the pre-eminent organization championing the health of workers, the safety of workplaces, and the quality of environments. Its members practice in diverse settings—including hospitals, clinics, academic medical centers, industry, and government—and are engaged in developing positions and policies on critical issues in preventive, occupational, and environmental medicine. ACOEM actively participates in federal and state rulemakings, including past comments to OSHA and EPA, to advocate for evidence-based standards that incorporate margins of safety and protect susceptible worker populations.

Position statement
ACOEM is concerned that the Draft Memorandum for Formaldehyde appears to functionally relax health-protective benchmarks for a known human carcinogen without adequate scientific justification and therefore risks failing TSCA's requirement to protect susceptible subpopulations, including workers and members of the public resident in manufactured housing. Established authorities, including the National Toxicology Program and IARC, classify formaldehyde as a human carcinogen and recognize its associations with cancers such as nasopharyngeal cancer and myeloid leukemia.

EPA has stated its commitment to "best available science" and "weight of the scientific evidence," but in this proposed rulemaking moves away from quantitative cancer risk estimates toward a threshold-style construct anchored in acute portal-of-entry irritation. This is not merely a technical refinement; it is a substantive policy shift that predictably increases allowable exposures and, in turn, the expected number of preventable cancer cases at the population level. ACOEM urges EPA to retain a conservative cancer-risk framework that is proportionate to the current scientific evidence and aligned with the science of carcinogenesis and the positions of other authoritative bodies.

Linear cancer risk vs threshold approaches

ACOEM is especially concerned that EPA appears to abandon linear cancer-risk characterization in favor of categorical thresholds without demonstrating the existence of a genuine biological threshold for all relevant carcinogenic modes of action. A true threshold for a genotoxic carcinogen requires robust evidence that key precursor events do not occur below a specific exposure level in any susceptible subgroup, which EPA has not shown for formaldehyde-associated leukemia.

Relying on an acute sensory irritation point of departure (POD) of 0.3 ppm as effectively protective "for all durations" embeds several untested assumptions: that irritation is the most sensitive and health-relevant endpoint, that preventing overt irritation prevents leukemogenic processes, and that inter-individual variability in cancer susceptibility is no greater than variability in irritation thresholds. These are contestable assumptions that should be explicitly justified and evaluated in sensitivity analyses, not treated as neutral defaults. The well-known carcinogens benzene and vinyl chloride monomer can cause irritation at high levels, but their chronic cancer risks occur at levels well below levels that would trigger a sensory warning. Asbestos fibers are odorless and tasteless. Asbestos causes no irritation at airborne levels associated with significant risks of cancer. ACOEM therefore requests that EPA quantify the excess cancer cases implied under prior linear models at concentrations effectively tolerated by the new framework and explain why those excess cases are considered acceptable under TSCA.

Cancer evidence and portal-of-entry emphasis

The Draft Memorandum's emphasis on portal-of-entry irritation and a single acute POD as the primary basis for margins of exposure risks substituting a convenience endpoint for a comprehensive cancer-risk characterization. Sensory irritation reflects upper airway and mucosal responses, whereas leukemogenesis involves bone marrow and hematopoietic stem and progenitor cells; the presence of lower-dose irritation does not establish that leukemogenic mechanisms share the same threshold.

Epidemiologic studies in occupational settings, including embalmers, industrial workers, and laboratory personnel, have reported leukemia excesses at cumulative and peak exposures that do not map neatly onto a single short-term irritation threshold. ACOEM urges EPA to demonstrate how a 0.3 ppm acute POD with reduced uncertainty factors

would have performed had it been applied in those historical cohorts. If the answer is that such a standard would not have prevented observed excess leukemia, then the POD should not be used as a protective benchmark. Uncertainty about mechanisms may persist, but positive human evidence exists, best-available-science and weight of evidence principles argue for maintaining, not weakening, linear cancer-risk characterization.

Worker safeguards, PPE, and uncertainty factors

The Draft Memorandum requests comment on worker safeguards, including PPE, engineering controls, administrative controls, and monitoring practices. ACOEM strongly supports anchoring risk management in a prevention-first hierarchy of controls but cautions against treating PPE as the primary basis for deeming risks acceptable. In real workplaces, PPE performance is highly variable and task-dependent, and is degraded by fit challenges, heat burden, communication needs, and practical limitations that are especially prevalent in small and under-resourced employment settings.

TSCA is fundamentally a chemical safety statute, and risk determinations that are only acceptable under assumptions of ideal PPE use are, in practice, risk determinations that are not protective for many real-world workers. ACOEM therefore recommends that EPA:

- Prioritize substitution where feasible, closed systems, and effective local exhaust ventilation, with PPE as a supplemental, not primary, control.
- Explicitly disclose the PPE protection factors assumed in its scenarios, present analyses using more conservative, field-realistic protection factors, and avoid using PPE assumptions to justify higher airborne concentrations.
- Treat worker-reliant PPE scenarios as evidence of residual risk needing stronger engineering and administrative controls, not as proof that risk has been acceptably mitigated.

From a worker-protection standpoint, the proposed reduction of the intra-human uncertainty factor (UFH) to 1× for an irritation endpoint is particularly concerning. Even if sensory irritation is a point-of-contact effect, clinically meaningful variability arises from baseline respiratory disease, rhinitis, prior sensitization, concurrent irritants, and repeated exposures. ACOEM urges EPA to maintain a UFH of at least 3–10× for such endpoints and to address variability through explicit, conservative risk-management requirements (engineering controls, exposure monitoring, training, and medical surveillance) in real workplaces, not by assuming that studies in laboratory conditions fully bound worker-reliant workplace susceptibility.

Workplace monitoring, peaks, and verification

ACOEM strongly supports requirements for robust workplace exposure monitoring and verification. Short-term peak exposures, task-based excursions, and intermittent high concentrations can drive both acute symptoms and chronic inflammatory stress in settings such as manufacturing, recycling, and construction. Monitoring programs should include

repeated measurements, documentation, worker access to results, and clear, enforceable triggers for corrective action when concentrations approach or exceed health-protective benchmarks.

These safeguards are especially important if EPA intends to rely heavily on acute metrics as protective "for all durations," because task-based peaks can produce biologically important doses even when longer-term averages appear acceptable. ACOEM recommends that EPA explicitly require task-based and short-term monitoring in scenarios with potential excursions and ensure that monitoring requirements are harmonized with, and at least as protective as, existing OSHA formaldehyde standards.

Indoor and residential exposures

Beyond workplaces, ACOEM is concerned that shifting away from linear risk characterization may unintentionally under-protect residents exposed via consumer products and building materials. EPA's own information on indoor air quality acknowledges that pressed-wood products, furnishings, and building materials are significant sources of indoor formaldehyde, particularly in energy-efficient and manufactured housing where ventilation may be limited. These indoor exposures will disproportionately affect families, children, and low-income communities, and add to workplace exposures.

Deemphasizing quantitative cancer assessment and treating a threshold-based approach as fully protective may permit higher emission levels from furniture and building materials, increasing indoor concentrations in some microenvironments to levels exceeding those historically associated with elevated risk. Even modest risk increases, when applied across large exposed populations, can translate into meaningful numbers of preventable cancers. ACOEM therefore urges EPA to:

- Conduct transparent quantitative analyses of leukemia and other cancer impacts under alternative risk frameworks, including scenarios for manufactured housing and other high-emission indoor environments.
- Model multiple indoor concentration scenarios (e.g., newer tight buildings, small apartments, child-occupied spaces), apply conservative linear unit-risk estimates, and report the implied excess cancer cases and risk per 100,000 persons under each scenario.
- Explain explicitly how any increased tolerated risk for this ubiquitous indoor carcinogen is justified under TSCA, and how vulnerable and overburdened populations will be protected.

Conclusions and Recommendations

ACOEM urges EPA to ensure that TSCA risk management actions for formaldehyde strengthen, not relax, worker safeguards and public health protections. EPA should:

1. Maintain conservative, evidence-based approaches for cancer-risk characterization where uncertainty persists, retaining linear cancer models and appropriate uncertainty factors rather than treating threshold constructs as synonymous with "safe."

2. Avoid risk determinations that depend on idealized PPE usage; instead, implement enforceable engineering and administrative controls and robust exposure monitoring as the primary means of risk reduction.

3. Explicitly address real-world human variability and susceptible subpopulations in setting points of departure and uncertainty factors, especially for irritation endpoints used as proxies for broader health protection.

4. Analyze and manage indoor exposure scenarios from building materials and consumer products, including manufactured housing and other high-emission or tight-building environments, as integral components of a comprehensive prevention strategy.

ACOEM is committed to working collaboratively with EPA to develop standards that effectively protect workers while allowing businesses to operate productively and sustainably. The College would welcome participation in any public hearings or stakeholder meetings on this docket and stands ready to serve as a resource in developing practical, effective strategies to reduce formaldehyde exposures in workplaces and communities.

Sincerely,

Laura G. Gillis, MD, MPH, FACOEM
President, American College of Occupational and Environmental Medicine (ACOEM)