Draft Formaldehyde IRIS Assessment:

What scientists are saying

Formaldehyde is a critical facet of everyday life and a core building block of the U.S. chemical industry. A formaldehyde Integrated Risk Information System (IRIS) assessment that does not consider the weight of scientific evidence could lead to unwarranted regulations that would ripple through the supply chain. Researchers and scientists across the country are raising concerns about the U.S. Environmental Protection Agency (EPA) draft formaldehyde IRIS assessment, including omission of legitimate studies, misinterpretation of evidence, methodological bias, and limited stakeholder input.

The assessment did not consider the full body of available science

"...Overall, **the 2022 Draft does not fully consider or integrate the findings of the fuller analyses that call into question Zhang et al. (2010)'s findings...**The fact remains that **there are no studies supporting a MOA for formaldehyde causing leukemias (including AML) and there are several key findings that detract from this hypothesis."** – Kenneth A. Mundt, PhD, FACE, former Chairman of the EPA Science Advisory Board's Chemical Assessment Advisory Committee

"We are concerned that the [EPA's] evaluation of noncancer endpoints...**largely ignores several important studies** that the formaldehyde working group considered key..." – Debra A. Kaden, PhD, ATS and Peder Wolkoff, DSc(Med), PhD, co-authors of the formaldehyde section of the World Health Organization Indoor Air Quality Guidelines for Select Pollutants (2010)

"While [a study by McGregor et al. (2006)] was included [in EPA's draft formaldehyde IRIS assessment], a similar publication...**was not included**... [This study] demonstrated the **significant amount of research supporting the null hypothesis that there is no causal association between formaldehyde inhalation exposure and leukemia."** – P. Robinan Gentry, PhD, DABT, Toxicologist

"We...**were dismayed to find that two of our recent papers were not considered in your assessment...**The first paper... is a comprehensive review of genotoxicity studies of formaldehyde...**In this review, we conclude that...There is no implication of causation in these association studies."** – Richard Albertini, MD, PhD, Research Professor, Pathology, University of Vermont and Debra A. Kaden, PhD, ATS, Toxicologist

The assessment draws incorrect conclusions from limited evidence

"It is difficult to understand how the EPA can continue to propose safe levels for chemicals such as formaldehyde that **approach, or in some cases are lower than, levels that occur naturally or are produced in human metabolic pathways...The EPA's choice of dosimeter for cumulative exposure for its cancer modeling is wrong."** – Michael Dourson, PhD, DABT, FATS, FSRA, on behalf of the American Council on Science & Health

"...[I]n several instances, EPA has **mis-interpreted and mis-cited my publications** in a manner that **substantively affects the interpretation of these individual studies** and the overall weight of the evidence regarding formaldehyde carcinogenicity." – Gary Marsh, PhD, FACE, Professor Emeritus, Biostatistics, University of Pittsburgh School of Public Health

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American Chemistry Council

"EPA's choice of dosimeter for its cancer modeling, that is cumulative exposure, is **wrong**...EPA needs to develop a low dose response extrapolation on the basis of peak exposure...Otherwise, **EPA's projected lifetime cancer risks are not credible."** – Michael Dourson, PhD, DABT, FATS, FSRA (President) and Bernard Gadagbui, MS, PhD, DABT, UK(RT) (Senior Toxicologist), Toxicology Excellence for Risk Assessment

"...I believe there is an issue with the interpretation of a manuscript that I was the senior author...**There is no evidence to support a temporal nature of a mutagenic carcinogen as outlined by EPA..."**
– Leslie Recio, PhD, DABT, Toxicologist

The assessment was produced through a potentially biased process

"I have **scientific and procedural concerns** with this report...I searched the entire IRIS document and **could not find EPA's definition of what 'the appropriate exposure circumstances'** are for formaldehyde to cause cancer...[O]ne wonders whether there wasn't a **predetermined bias toward showing that formaldehyde caused cancer."**
– Susan Goldhaber, MPH, Environmental Toxicologist, American Council on Science & Health

EPA did not allow for adequate stakeholder input

"Our comments on the Formaldehyde Toxicological Review address the following main issues: EPA has **not allowed for adequate stakeholder engagement** during the comment period; the extent to which EPA has addressed the 2011 NAS recommendations is **unclear**; EPA **did not clearly develop a pre-published protocol**; [and] EPA **did not model all cancer endpoints."** – Swati Rayasam, MSc, Juleen Lam, PhD, MHS, MS, Courtney Cooper, MPH, Chanese Forté, PhD-PhD, MPH, Nicholas Chartres, PhD, Tracey Woodruff, PhD, MPH, University of California, San Francisco Program on Reproductive Health and the Environment

Draft Formaldehyde IRIS Assessment:

What lawmakers are saying

Formaldehyde is a critical facet of everyday life and a core building block of the U.S. chemical industry. A formaldehyde Integrated Risk Information System(IRIS) assessment that does not consider the weight of scientific evidence could lead to unwarranted regulations that would ripple through the supply chain—already in crisis due to pandemic-related disruptions. Lawmakers on both sides of the aisle have called on the U.S. Environmental Protection Agency (EPA) to produce a rigorous scientific document worthy of public confidence—and to allow appropriate time for thorough stakeholder input.

The assessment had insufficient interagency input

"It is vital that the assessment **fully documents how it has incorporated comments** from the previous peer review as well as feedback from other federal agencies with an interest in this chemistry and any associated risks…Unfortunately, my understanding is that **the EPA-led interagency coordination only provided a few weeks** for [U.S. Department of Agriculture, the Food and Drug Administration, the Small Business Administration, the Department of the Interior, and the Department of Defense] to comment on this several-thousand-page-assessment…**I ask that you provide these key federal agencies at least 60 days to review the draft assessment and provide comments."**
– Rep. Sanford Bishop (D-GA)

"I write in support of…**a robust interagency review and coordination process** for the Environmental Protection Agency's (EPA) forthcoming draft assessment of formaldehyde…I ask that you provide [U.S. Department of Agriculture and the Food and Drug Administration] **at least 60 days to review the draft assessment and provide comments."**
– Rep. Joyce Beatty (D-OH)

The assessment fails to consider the best available science

"Since 2011, **more than 40 peer reviewed studies** have demonstrated **safe thresholds for formaldehyde** and found that **associations with leukemia are inconsistent** with biological mechanisms. It is, therefore, imperative that the U.S. EPA and the IRIS program…assess the **voluminous new scientific evidence supporting the safe use of formaldehyde."**
– Reps. Mike Carey (R-OH), Bill Johnson (R-OH), Troy Balderson (R-OH), Robert Latta (R-OH), David Joyce (R-OH), Bruce Westerman (R-AR), Glenn Grotham (R-WI), Hal Rogers (R-KY), and David McKinley (R-WV)

Bias and impartiality concerns cast doubts on the integrity of impending peer review

"…I was **concerned to learn that [a National Academies of Sciences, Engineering and Medicine (NASEM) staff officer] had extensive involvement with the revisions to the IRIS formaldehyde assessment** during [their] career as a senior official in U.S. EPA' s Office of Research and Development (which houses IRIS)…[this includes] **coordinating closely with, as well as with supervisory responsibilities for and coauthor relationships with, EPA employees who are actively involved in the 2010 and 2021 IRIS assessments for formaldehyde,** including the assessment managers and individuals whose work products are under review; being a member of the Agency's 'Formaldehyde Team,' **exchanging frequent emails** on the 2011 NASEM review and U.S. EPA's response; **frequent coordination on formaldehyde and IRIS matters** with participants in the 2011 NASEM review and current BEST members; and **serving as a reviewer** for U.S. EPA's 2020 ORD Staff Handbook for Developing IRIS Assessments." – Sen. John Kennedy (R-LA)

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What lawmakers are saying

"... NASEM has long been considered the 'gold standard' with regulators and lawmakers often relying upon the NASEM to do work of the highest scientific standards, buttressed by unimpeachable integrity in both independence and peer review. We are concerned that **the flawed panel review process through which NASEM is conducting the formaldehyde review risks losing public and Congressional confidence in the panel, and NASEM as a whole.** For instance, evidence suggests that key officials appear to have **violated basic standard of independence and bias during the peer review process."** – Reps. Babin (R-TX), John Carter (R-TX), Troy Balderson (R-OH), Mike Carey (R-OH), Richard Hudson (R-NC), David Rouzer (R-NC), Tim Scott (R-SC), John Moolenaar (R-MI), Glenn Grothman (R-WI), Kelly Armstrong (R-ND), Morgan Griffith (R-VA), and Markwayne Mullin (R-OK)

Ill-informed regulations could have significant economic consequences

"Because formaldehyde is a **building block chemica**l used in a **wide variety of agricultural settings,** including for specimen preservation in laboratories, as a **disinfectant in veterinary clinics,** and as a **food additive for animal feeds,** conclusions in EPA's draft assessment around the health effects of formaldehyde could result in regulatory actions with **enormous economic impacts for this critical economic sector."** – Rep. Sanford Bishop (D-GA)

Draft Formaldehyde IRIS Assessment:

What business leaders are saying

American Chemistry Council

Formaldehyde is a critical facet of everyday life and a core building block of the U.S. chemical industry. A formaldehyde Integrated Risk Information System(IRIS) assessment that does not consider the weight of scientific evidence could lead to unwarranted regulations that would ripple through the supply chain—already in crisis due to pandemic-related disruptions. Representatives from sectors across the economy have highlighted formaldehyde's critical importance in a variety of applications, underscoring the need for any formaldehyde regulation to be informed by the best available science and thorough stakeholder input.

The assessment draws incorrect conclusions from limited evidence

"The current Review demonstrates **misunderstandings of this complex data set** and **truncated descriptions of the scientific studies** on asthma and sensory irritation. The Review appears to be **searching for the lowest possible concentrations by whatever means possible** instead of providing a weight of the evidence approach using the Best Available Science. The document **must be rewritten objectively** and thoroughly to provide any program office including TSCA the best information to conduct an appropriate Risk Evaluation." – Stewart Holm, Chief Scientist, American Forest & Paper Association (AF&PA) and the American Wood Council (AWC)

The assessment could cause more harm than good

"...[T]he Chamber believes this approach **sets a troubling precedent for other chemical risk assessments,** and we **strongly encourage EPA to revise the 2022 draft IRIS assessment** and incorporate the **best available science** and practices for systematic review." – Martin J. Durbin, Senior Vice President, Policy, U.S. Chamber of Commerce and President, Global Energy Institute

"Formaldehyde-donor biocides...are **important compounds that have been used safely and effectively** by ILMA member companies for years. The Agency's proposed changes will likely make their continued use infeasible, **negatively affecting the safety of ILMA member companies' employees and operations,** and ultimately **the safety of hundreds of thousands of machinists and end-user customers' workers."** – Holly Alfano, CEO, Independent Lubricant Manufacturers Association (ILMA)

EPA did not provide time for adequate stakeholder input

"Given the critical role of formaldehyde in animal agriculture for animal health and food safety, as well as the significant economic consequences associated with EPA's IRIS assessment, **we are disappointed that the agency did not extend the comment period** as we requested to allow the industry a more **meaningful and thorough scientific review** of the document. From our initial review of EPA's formaldehyde assessment, we note that there is **no descriptive reference or acknowledgement of the presence, use, benefit or possible hazards associated with formaldehyde applications in the animal agriculture sector."** – American Feed Industry Association, National Chicken Council, National Pork Producers Council, National Turkey Federation, U.S. Poultry & Egg Association

"We note several federal agencies have commented on the Draft IRIS Toxicological Review of Formaldehyde (Inhalation), but we **did not see comment from FDA or USDA**, both of which have f**amiliarity with the animal heath, public health, and food safety uses of formaldehyde."** – Janet D. Donlin, DVM, CAE, Executive Vice President and CEO, American Veterinary Medical Association (AVMA)

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What business leaders are saying

Formaldehyde has critical applications acoss the economy

"Formaldehyde has **multiple uses across the animal industries.** It is **widely used, of course, in histopathologic laboratories for specimen preservation,** and is sometimes used as a **disinfectant and sterilant** in veterinary clinics and other animal facilities. Formaldehyde is also **used as a food additive** in the manufacture of animal feeds to improve handling characteristics and to **maintain complete animal feeds or feed ingredients negative for Salmonella…"** – Janet D. Donlin, DVM, CAE, Executive Vice President and CEO, American Veterinary Medical Association (AVMA)

"Composite wood panels are produced using wood fiber that would **otherwise be discarded or decay in the environment…**Various resin systems are employed in the panel making process. **Many contain formaldehyde as a key ingredient."** – Andrew T. O'Hare, President, Composite Panel Association (CPA)

"Formaldehyde-based products are the **leading products used for embalming** in the United States…Formaldehyde is **preferred by funeral service professionals…"** – Lesley Witter, MPA, CAE, Senior Vice President, Advocacy, National Funeral Directors Association (NFDA)