

**Congress of the United States**  
**Washington, DC 20515**

April 1, 2022

Administrator Michael Regan  
U.S. Environmental Protection Agency (U.S. EPA)  
William Jefferson Clinton Building  
1200 Pennsylvania, N.W.  
Washington, D.C. 20460

Dear Administrator Regan:

We write to you with concerns about the U.S. EPA's forthcoming dissemination of a draft assessment of formaldehyde under the Integrated Risk Information System (IRIS). The U.S. EPA has recently circulated the draft assessment to federal agencies for informal review and has contracted with the National Academy of Sciences, Engineering, and Medicine (NASEM) to conduct an independent peer review over the next 18 months.

We are concerned that releasing a rushed assessment, without the benefit of the best available science or an independent peer review process, could have devastating economic impacts on our states. Therefore, we ask that you address the concerns laid out in more detail below before releasing the draft IRIS assessment for formaldehyde.

Formaldehyde and associated products represent an essential and irreplaceable industry. It is a critical chemical building block used in the production of hundreds of items from wood products to prescription drugs to automobiles. An ill-advised hazard determination under IRIS could threaten hundreds of thousands of American jobs, over half a trillion dollars in annual economic contribution, and critical supply chains for dozens of American industries.<sup>1</sup>

As you are likely aware, this is not the first time NASEM has reviewed a draft U.S. EPA IRIS assessment for formaldehyde. In 2011, NASEM highlighted the U.S. EPA's failure to use the best available science and modern scientific methods to assess human health risks in the assessment. Noting that "problems with clarity and transparency of the methods appear to be a repeating theme over the years" with the IRIS program. The well-respected group of experts "found that EPA's draft assessment was not prepared in a logically consistent fashion, lacks clear links to an underlying conceptual framework, and does not sufficiently document methods and criteria used to identify evidence for selecting and evaluating studies."<sup>2</sup>

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.<sup>3</sup> It is, therefore, imperative that the U.S. EPA and the IRIS program address these major issues and assess the voluminous new scientific evidence supporting the safe use of formaldehyde.

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<sup>1</sup> American Chemistry Council, "[Formaldehyde Producers Boost U.S. Economy](#)," 2021; John D. Graham and Cory R. Liu, "[Regulatory and Quasi-Regulatory Activity Without OMB and Cost-Benefit Review](#)," *Harvard Journal of Law & Public Policy*, Vol. 37 (2014): 439-442.

<sup>2</sup> [http://books.nap.edu/catalog.php?record\\_id=13142#toc](http://books.nap.edu/catalog.php?record_id=13142#toc).

<sup>3</sup> <https://www.americanchemistry.com/chemistry-in-america/news-trends/press-release/2021/studies-confirm-no-causal-association-between-formaldehyde-and-leukemia>.

We believe the U.S. EPA should require that the IRIS program utilize the best available science and a transparent, impartial, and independent process for peer review in its evaluation of formaldehyde. In this context, that means:

1. That the U.S. EPA has adequately addressed and fully documented, prior to public release, all of the critical recommendations in the NASEM 2011 Review of the 2010 IRIS assessment.<sup>4</sup> This will ensure that the U.S. EPA uses the best available science, incorporating the most recent scientific studies as well as a scientifically sound weight of the evidence and mode of action approach. The U.S. EPA should guarantee that the NASEM peer review panel will have an opportunity to broadly examine the updated draft assessment and specifically determine whether U.S. EPA has addressed all criticisms raised a decade ago.
2. The NASEM peer review process should be transparent, independent, impartial, and nonpartisan. All steps should follow U.S. EPA and NASEM requirements for peer review, committee composition, and scientific integrity. For example, U.S. EPA's *Peer Review Handbook* calls for complete separation of employee "responsibilities for developing work products from conducting the peer review" and avoiding repeatedly turning to the same reviewers in the interest of ensuring "greater independence and transparency."<sup>5</sup>
3. Follow the law under the updated, bipartisan 2016 amendments to the Toxic Substances Control Act as well as U.S. EPA procedural requirements under long-standing executive orders and other statutes. IRIS has never been authorized by Congress, and U.S. EPA should not be rushing ahead with these activities given the clear direction by Congress for the Agency to use the best available science in its chemical assessments.
4. Seek public comment on the peer review committee's "task" and associated "charge" questions prior to the selection of peer reviewers or release of the draft assessment. U.S. EPA's *Peer Review Handbook* explains that "the success and usefulness of any peer review depends on the quality of the draft work product" and "the care given to the statement of the issues or 'charge,'" and directing the agency to transparently develop the charge prior to selection of panelists.<sup>6</sup>
5. Conduct a robust interagency review of the draft assessment prior to its public dissemination, including opportunities for meaningful feedback by interested federal agencies like the Small Business Administration, Food and Drug Administration, and U.S. Department of Agriculture as well as providing these interagency comments and associated changes to the assessment to the public as well as the peer reviewers.

This is not about politics. It is about American jobs, public confidence, and sound science. A rushed assessment and problematic process could irresponsibly threaten good-paying manufacturing jobs in our states and across the country.

In the interest of ensuring that the draft assessment and peer review process are sound, we ask that you brief our offices prior to the dissemination of the draft assessment or selection of NASEM committee members.

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<sup>4</sup> <https://www.nationalacademies.org/our-work/review-of-epas-draft-iris-assessment-of-formaldehyde>; <https://www.nap.edu/read/18764/chapter/3#5>; <https://www.nationalacademies.org/our-work/review-of-epas-iris-assessment-handbook>.

<sup>5</sup> U.S. EPA, *Peer Review Handbook*, 4th Edition (2015): 32; B-16.

<sup>6</sup> U.S. EPA, *Peer Review Handbook*, 4th Edition (2015): 12; 82-83; B-14-B-16.

Sincerely,



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Rep. Mike Carey  
Member of Congress



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Rep. Troy Balderson  
Member of Congress



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Rep. David P. Joyce  
Member of Congress



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Rep. Glenn Grothman  
Member of Congress



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Rep. David McKinley  
Member of Congress



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Rep. Bill Johnson  
Member of Congress



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Rep. Robert E. Latta  
Member of Congress



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Rep. Bruce Westerman  
Member of Congress



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Rep. Hal Rogers  
Member of Congress