April 8, 2022

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

Submitted via email and mail

RE: Preventing Inappropriate Use of U.S. EPA's Draft Formaldehyde Assessment

Dear Administrator Regan:

The U.S. Environmental Protection Agency ("U.S. EPA" or "the Agency") intends to release for public comment and subsequent peer review a draft assessment of formaldehyde under the Integrated Risk Information System (IRIS) in the coming months.[1] The American Chemistry Council ("ACC")[2] Formaldehyde Panel ("the Panel") writes to request that the Agency take proactive steps, consistent with U.S. EPA's commitment to transparency, responsible risk communication, and peer review, to ensure that federal and non-federal users of IRIS do not rely on a draft, non-peer reviewed assessment. There is substantial evidence that the States and U.S. EPA regulatory programs may rely on the draft assessment, with major economic, legal, and scientific consequences. These concerns are compounded by the numerous concerns previously raised by the National Academy of Sciences, Engineering, and Medicine ("NASEM") in 2011 on U.S. EPA's prior draft formaldehyde assessment.[3] It is critical that the NASEM review of the draft formaldehyde IRIS assessment evaluates that the NASEM's recommendations from 2011 have been fully and adequately addressed.

U.S. EPA should use all the tools at its disposal to discourage the use of this draft assessment, by:

- Committing to not using draft, non-peer reviewed material from this assessment in any Agency activities (including risk evaluation activities under the amended *Toxic Substances Control Act* (TSCA)). Agency reliance on the assessment should occur only after U.S. EPA has incorporated revisions based on both public comment and peer review and subsequently issued a final assessment.

[1] https://www.epa.gov/system/files/documents/2022-02/iris-program-outlook_feb-2022.pdf.
[2] The American Chemistry Council (ACC) represents the leading companies engaged in the business of chemistry.
[3] https://www.americanchemistry.com/industry-groups/formaldehyde/resources/formaldehyde-panel-follow-up-letter-to-epa.

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- Including the required disclaimer[4] on every page of the draft assessment, including appendices and other accompanying information. This action is critical as the Agency has recognized that this assessment is "highly relevant to specific policy or regulatory deliberations."[5]
- "[D]iscourag[ing] state, local, international, and private organizations from using information in draft reports that are undergoing peer review," consistent with U.S. EPA's *Peer Review Handbook*[6] and the White House Office of Management and Budget's (OMB*) Final Information Quality Bulletin for Peer Review*.[7] This should include proactive outreach to state risk assessors and regulators, professional societies, and international bodies.

U.S. EPA's Use of Draft Assessment Violates Statutory Requirements for "Best Available Science"

Perhaps most concerning, U.S. EPA has signaled that, in its forthcoming draft and final formaldehyde risk evaluation under TSCA, it "plans to include information developed from the draft IRIS hazard and dose response assessment."[8] The push to use draft IRIS information in a regulatory setting prior to finalizing the assessment, by incorporating both public and peer review comments, runs contrary to EPA policies and would render superfluous both public comment and a rigorous peer review process.

Under TSCA, when undertaking rulemaking and risk evaluations of substances, the Administrator is required to "use scientific information, technical procedures, measures, methods, protocols, methodologies, or models, employed in a manner consistent with the best available science." The Administrator must consider, among other factors, "the extent to which the variability and uncertainty… are evaluated and characterized" and "the extent of independent verification or peer review of the information or of the procedures, measures, methods, protocols, methodologies, or models."[9] As ACC explained in it's comments on the Draft Formaldehyde Risk Evaluation Scoping Document, the IRIS program fails to apply a weight the evidence approach to integrate and evaluate data, and relies on epidemiological data to draw conclusions, while generally ignoring or discounting relevant toxicological or mode of action information[10]. This approach is inconsistent with TSCA scientific standards. As the EPA Administrator, you are required by the statue to ensure that TSCA risk evaluation activities are based on the best available science, which means verified, peer reviewed, final information produced inside or outside U.S. EPA. A 2013 survey by the U.S. EPA Office of Inspector General found that EPA program and regional office use of IRIS cancer risk values are driven predominately by internal agency requirements as opposed to scientific accuracy, recency, accessibility, fit-for-purpose, or validity of the underlying assessment.[11]

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[4] "This information is distributed solely for the purpose of pre-dissemination peer review under applicable information quality guidelines. It has not been formally disseminated by [the agency]. It does not represent and should not be construed to represent any agency determination or policy."

[5] For example, U.S. EPA has designated the draft assessment as "highly influential." (https://cfpub.epa.gov/si/si_public_pra_view.cfm?dirEntryID=352623&Lab=CPHEA).

[6] https://www.epa.gov/sites/default/files/2016-03/documents/epa_peer_review_handbook_4th_edition.pdf (pg. B-9 to B-10).

[7] 70 Fed. Reg. 2667 (Jan. 14, 2005).

[8] EPA, *Final Scope of the Risk Evaluation for Formaldehyde*, August 2020, 74, https://www.epa.gov/sites/default/files/2020-09/documents/casrn_50-00-0-formaldehyde_finalscope_cor.pdf.

[9] 15 U.S.C. § 2625(h).

[10] Regulations.gov https://www.regulations.gov/comment/EPA-HQ-OPPT-2018-0438-0041

[11] https://www.epa.gov/sites/default/files/2015-09/documents/20130131-13-p-0127.pdf (pg. 4).

U.S. EPA's Failure to Add Required Disclaimers Risks Inappropriate Use by Other Regulatory Bodies

Statements from regulatory offices inside and outside the Agency underscore significant risk of regulatory use of the draft IRIS assessment for formaldehyde prior to the completion of public comment and peer review. Dr. John Graham, former Administrator of OMB's Office of Information and Regulatory Affairs, noted in *Risk Analysis*: that some states have an explicit requirement to use draft IRIS values "even if they are not yet fully peer reviewed and corrected by EPA,….The users are not always careful in distinguishing a draft IRIS toxicity value from a final, 'official' position of the EPA…. The growing recognition of the policy impact of IRIS updates has caused more scrutiny of the entire process, including concerns about premature release of draft and final IRIS updates."[12]

Similarly, the Environmental Council of the States-Department of Defense Sustainability Work Group noted a long-standing U.S. EPA Office of Land and Emergency Management directive that "[i]n general, draft toxicity assessments are not appropriate for use until they have been through peer review" and "the peer review comments have been addressed…,"[13] but nonetheless found that "there are some agencies applying and requiring that the draft toxicity assessments be used in health risk assessments."[14] Examples from environmental agencies in Colorado,[15] Ohio,[16] and New Hampshire[17] demonstrate these regulators' willingness to rely on IRIS even when values have not been finalized.

EPA's Failure to Proactively Discourage Use of Draft Assessment Violates Agency Policies

Failure to proactively prevent use of the draft IRIS assessment by those inside and outside the Agency would contradict long-standing EPA policies on peer review, information quality, and intergovernmental collaboration. EPA's *Peer Review Handbook* makes clear that draft work products, prior to peer review or subsequent revisions, are inappropriate for regulatory decisions. It notes: "A well-planned peer review applied to a quality draft work product and followed by responsible employment of peer review suggestions in the final product ensures a credible and

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[12] John Graham, "Why IRIS is Outdated: An Additional Perspective," *Risk Analysis* 26, No. 6 (2006): 1411.

[13] U.S. EPA, Office of Superfund Remediation and Technology Innovation, OSWER Directive 9285.7-53, *Human Health Toxicity Values in Superfund Risk Assessments*, Michael B. Cook, December 5, 2003, pg. 3.

[14] ECOS-DoD Sustainability Work Group, *IDENTIFICATION AND SELECTION OF TOXICITY VALUES/CRITERIA FOR CERCLA AND HAZARDOUS WASTE SITE RISK ASSESSMENTS IN THE ABSENCE OF IRIS VALUES*, April 2007, https://www.ecos.org/wp-content/uploads/2016/05/FINAL-ECOS-PV-Paper-4-23-07.pdf.

[15] Colorado Department of Public Health and Environment, *Policy on Use of Human Health Toxicity Values in Environmental Risk Assessment and Remediation Management*, https://cdphe.colorado.gov/environmental-cleanup-guidance-and-policy ("Where there is an on-going toxicity evaluation by EPA of a value that is posted in IRIS, the Department generally will rely on that IRIS value for environmental management decisions until the evaluation is concluded.") https://oitco.hylandcloud.com/CDPHERMPop/docpop/docpop.aspx?clienttype=html&docid=3223226

[16] Ohio Environmental Protection Agency, Assessing Compounds without Formal Toxicity Values Available for Use in Human Health Risk Assessment, April 2010, https://epa.ohio.gov/static/Portals/30/rules/Assessing+compounds+without+formal+tox+values.pdf.

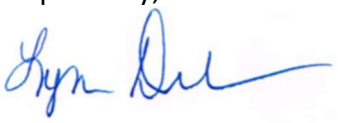
[17] https://www.des.nh.gov/sites/g/files/ehbemt341/files/documents/env-a1400-comments-fp.pdf (IRIS "is the primary source of toxicity information used by the NHDES…. It should be noted that EPA has developed a draft IRIS formaldehyde assessment and this assessment addresses both non-cancer and cancer human health effects that may result from chronic inhalation exposure to this chemical.") https://www.des.nh.gov/sites/g/files/ehbemt341/files/documents/20201210-formaldehyde-aals.pdf

defensible product for use in Agency decision making. Sometimes the draft work product may not be finalized after the peer review."[18] The *Handbook* also requires that EPA "shall discourage state, local, international and private organizations from using information in draft reports that are undergoing peer review" and include a standard disclaimer on every page of a draft assessment that is "highly relevant to specific policy or regulatory deliberations."[19]

Additionally, U.S. EPA's *Risk Characterization Handbook* makes clear that all major scientific work products "for use in Agency decision making will be peer reviewed," further noting that "[p]eer review is critical to ensure the scientific soundness of a risk assessment."[20] Finally, U.S. EPA's failure to properly provide context and disclaimers on the use of the draft assessment could limit administrative mechanisms for correction of information under the Agency's *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency*. The Agency notes there that it will almost always "address information quality issues in conjunction with the **final** Agency action or information product."[21] Premature use of **draft** IRIS assessments, however would eliminate stakeholders opportunities to correct flawed scientific information from the draft assessment.

ACC and the Panel appreciate U.S. EPA's commitment to transparency and use of the best available science. Taking the steps outlined above will help ensure the integrity and utility of both public comment and the peer review process to inform a credible final assessment.

Respectfully,



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[18] https://www.epa.gov/sites/default/files/2016-03/documents/epa_peer_review_handbook_4th_edition.pdf (pg. 88-89).
[19] Ibid., pg. B-9 to B-10.
[20] https://www.epa.gov/sites/default/files/2015-10/documents/osp_risk_characterization_handbook_2000.pdf (pg. 14).
[21] https://www.epa.gov/sites/default/files/2020-02/documents/epa-info-quality-guidelines_pdf_version.pdf (pg. 32).