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Dear Dr. Orme-Zavaleta:

Thank you for meeting with members of the American Chemistry Council's Formaldehyde Panel (the Panel) on January 24, 2018. The meeting provided the Panel with an opportunity to stress the importance of producing a revised formaldehyde IRIS assessment that fully implements and resolves scientifically the recommendations of the 2011 National Academy of Sciences (NAS) report.[1] The Panel left the meeting very alarmed and troubled that the revised draft formaldehyde IRIS assessment will not utilize a mode of action framework as the organizing principle to assess hazard and dose response. Further, during the meeting Dr. Bahadori indicated that the revised draft IRIS assessment has not revisited the science but instead will be a restructuring of the draft. Notably the previous draft relied on studies that have been shown in recent years to have significant scientific and methodological issues[2,3]. The Panel is unsure what is meant by "restructuring" but what was previously missing from the draft formaldehyde IRIS assessment was the consideration of mode of action in drawing conclusions. Given the significant amount of science generated for this chemical and the resources committed by the American taxpayers, a revised draft IRIS assessment must revisit all previous conclusions, demonstrate effective and science-based integration of all the lines of evidence and meet the standards of scientific integrity and transparency requested by the NAS and the public.

Additionally, during our meeting the Panel inquired about the regulatory drivers for an updated final formaldehyde IRIS assessment. EPA's Office of Air and Radiation (OAR) staff indicated that they had some activities for completion in 2018 that could be informed if a final revised IRIS assessment was available. EPA staff indicated that the revised draft formaldehyde IRIS assessment is unlikely to be finalized in 2018 due to the necessary and critical internal and external review required. Thus, a final IRIS assessment would not be available to inform the upcoming OAR activities. Given this information, the Panel was surprised to learn that OAR staff will consider the 1989 final IRIS assessment as best available science even though the

[1] National Academy of Sciences (NAS). National Research Council (NRC). 2011. Review of the Environmental Protection Agency's Draft IRIS Assessment of Formaldehyde. Committee to Review EPA's Draft IRIS Assessment of Formaldehyde. Board of Environmental Studies and Toxicology. Division of Earth and Life Sciences.
[2] Mundt, K., Gallagher, A., Dell, L., Natelson, E., Boffetta, P., and Gentry, R. Does occupational exposure to formaldehyde cause hematotoxicity and leukemia-specific chromosome changes in cultured myeloid progenitor cells? (2017) Critical Reviews in Toxicology. Aug;47(7):592-602.
[3] Gentry, R., Rodricks, J., Turnbull, D., Bachand, A., Van Landingham, C., Shipp, A., Albertini, R., and Irons, R. (2013). Formaldehyde exposure and leukemia: Critical review and reevaluation of the results from a study that is the focus for evidence of biological plausibility. Critical Reviews in Toxicology 43, no. 8: 661-670.

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science of formaldehyde has vastly evolved over the last 29 years. The Clean Air Act requires reliance on the best available science and we strongly encourage OAR to use a more recently updated regulatory standard or develop its own formaldehyde risk value, for use in pending activities instead of relying on an outdated 1989 value. Notably, EPA has independently developed values for use in risk assessment related air activities in the past[4].

The Panel has proactively supported cutting-edge research with leading scientists that directly addresses and informs the 2011 NAS recommendations, resulting in several dozen peer reviewed publications. The state of the science has evolved to the point where it is clear that using mode of action as the organizing framework is scientifically justified and necessary in drawing conclusions. The current assumption that any level of formaldehyde exposure results in some level of potential cancer risk, is inconsistent with the available recognized mode of action for this chemical. A "restructuring" of the 2010 draft assessment will not meet the EPA's scientific responsibility to make sound public policy decisions. As discussed during our meeting these new scientific studies demonstrate:

1. The biological implausibility of any relationship between formaldehyde inhalation and leukemia.

2. A threshold mode of action for any potential adverse health effects at the portal of entry.

3. The importance and utility of mode of action science for understanding potential impacts from inhalation exposure to formaldehyde.

4. The need for transparent integration of all streams of scientific evidence (epidemiology, toxicology and mode of action information) to draw scientifically defensible conclusions regarding human health risk.

The integration of mode of action evidence is a key element in an overall weight of the evidence assessment. Failure to account for this scientific evidence in revising a draft formaldehyde IRIS assessment would erroneously suggest that none of these available data inform understanding of cancer risks in the low concentration region, which is most important to understanding potential daily human exposures.

As stated in our meeting, a premature release of a draft assessment that has not followed the full IRIS review process or benefited from the sound scientific advice received during that process will cause irreparable harm to the companies represented by the Panel and to the many companies and jobs that depend on the broad use of the chemical; ACC estimates that approximately 963,000 jobs depend on the use of formaldehyde. The Panel urges you to ensure that the revised draft formaldehyde IRIS assessment can be held to the highest scientific standards. This involves fully implementing and resolving all the NAS recommendations; transparently identifying, evaluating, and integrating the available data using mode of action as the organizing framework; and recognizing that a threshold approach for portal of entry effects is supported by overwhelming evidence. I again reiterate, that the Panel is extremely concerned that a revised draft

[4] April 29, 2004 EPA Office of Air Quality Planning & Standards tabulated dose-response values used in the risk assessment of hazardous air pollutants. In 2004, the Air Office indicated that it did not plan to use the 1987 dose-response value reported in IRIS as it no longer represented the best available science in the peer-reviewed literature. See April 2008 GAO Report titled "EPA's New Assessment Process Will Increase Challenges EPA Faces in Evaluating and Regulating Chemicals" for full details. Webpage: https://www.gao.gov/new.items/d08743t.pdf

formaldehyde IRIS assessment that does not meet these benchmarks will also not meet NAS's original intentions in making its 2011 recommendations and fail to build public confidence in the scientific rigor and value of assessments produced by the IRIS program.

Sincerely,

Kimberly Wise White, Ph.D.
American Chemistry Council (ACC)
Senior Director, Chemical Products and Technology Division
On Behalf of the ACC Formaldehyde Panel

cc
The Honorable Scott Pruitt, Administrator
Mr. Ryan Jackson, Chief of Staff
The Honorable William Wehrum, Assistant Administrator, Office of Air and Radiation

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