UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
National Center for Environmental Assessment
Washington, DC 20460

OFFICE OF
RESEARCH AND DEVELOPMENT

October 06, 2017

Kimberly Wise White, Ph.D.
Senior Director
American Chemistry Council
Chemical Products and Technology Division
On Behalf of the ACC Formaldehyde Panel
700 Second St., NE
Washington, DC 20002

Dear Dr. Wise White,

Thank you for your letter of September 13, 2017 reiterating the American Chemistry Council (ACC) Formaldehyde Panel's interest in the EPA's formaldehyde IRIS assessment. I forwarded a copy of your letter and the accompanying National Toxicology Program (NTP) report to the assessment team. The assessment team is aware of this report and will be including consideration of its findings in the public comment draft of the formaldehyde assessment.

I would like to reassure you and the Panel again that we are very aware of the importance of this assessment and are mindful of your concerns. This is why we hope to complete the draft of this assessment as expeditiously as possible and make it available for public comment and peer review by the National Academy of Sciences (NAS). We are also aware that the Panel has been committed to conducting research to address the recommendations of the NAS and engaging scientists on approaches to integrate the scientific evidence for formaldehyde. As you indicated, EPA scientists will participate in the ACC-sponsored October workshop.

In your letter, you also raised a number of questions about the draft assessment which we addressed separately below. But truthfully, the only way to demonstrate our commitment to a scientifically robust and transparent formaldehyde assessment is to present the document for public comment and rigorous peer review by the NAS.

Again, thank you for your letter. Should you have further questions, you may contact me by phone (703-347-8600), or email (bahadori.tina@epa.gov).

Sincerely,

Tina Bahadori, Sc.D.
Director, National Center for Environmental Assessment
National Program Director, Human Health Risk Assessment
U.S. EPA, Office of Research and Development

CC:
Robert Kavlock
Richard Yamada
Kris Thayer
Dan Morgan

Responses to ACC Questions on the IRIS Toxicological Review of Formaldehyde (October 2017)

1. How is EPA considering new scientific information, like the NTP study, for incorporation into the weight of evidence for the formaldehyde IRIS assessment?

EPA is carefully reviewing and considering new, peer-reviewed science as it becomes available, for inclusion in the revised draft formaldehyde assessment. We are fully incorporating the NTP study into the current draft assessment.

2. When did EPA last conduct a search of the formaldehyde literature for science to incorporate into the IRIS assessment and how frequently does EPA monitor the formaldehyde literature to identify potential studies that should be incorporated into the assessment?

The last formal literature search was completed in October, 2016, and the next formal literature search is currently underway. In addition, the assessment managers and team of scientists working on the assessment continually monitor the scientific literature for awareness and consideration of the latest available research. Our partners and stakeholders who have great interest in this assessment have remained vigilant in ensuring that all pertinent studies are brought to our attention and confirming that our formal and informal searches are complete. The NTP study is just one example of that very situation, where a document released after the last formal literature search has already been incorporated into the draft assessment, as appropriate.

3. What guidance documents or procedures will EPA utilize to evaluate study quality for studies relied upon to reach conclusions in the formaldehyde IRIS assessment? Please provide specific references if available.

EPA will be using Agency risk assessment guidelines as a framework for evaluating study quality and to reach conclusions in the draft formaldehyde assessment. Public guidance documents can easily be accessed at https://www.epa.gov/iris/basic-information-about-integrated-risk-information-system#guidance. In addition, as you know, EPA has been incorporating principles of systematic review into the assessment development process, in response to the recommendations from the 2011 and 2014 NAS reports. The draft assessment which we hope to share with the public soon will transparently explain the procedures utilized in development of the assessment.

4. When will EPA release a weight of evidence framework illustrating how various data streams (i.e. mechanistic, toxicology and epidemiology studies) are evaluated for quality and then integrated to reach conclusions about formaldehyde?

EPA is using existing Agency guidance to weigh, synthesize, and integrate evidence to evaluate formaldehyde toxicity. The criteria used for identifying studies, evaluating quality, and integrating evidence streams, will be clearly and transparently described in the formaldehyde assessment, as was recommended by the NAS.

5. How has EPA addressed all the 2011 NAS recommendations for formaldehyde?

EPA has addressed all the 2011 NAS recommendations for formaldehyde in the revised draft assessment. A section in the appendix will clearly describe how the Agency addressed the recommendations.

6. How will EPA seek public input and peer review on the formaldehyde IRIS assessment and what types of public meetings or workshops will be held to receive input?

The revised draft formaldehyde assessment EPA will follow the established IRIS process. Following agency and interagency review, the draft assessment will be released for public comment, and an accompanying public science meeting. Following the public comment draft, EPA will make any necessary revisions, and a peer review draft will be released for independent peer review by the NAS. The NAS peer review will also include an opportunity for public comment.