



March 4, 2015

Public statement by Kimberly Wise, Ph.D, on behalf of the Center for Advancing Risk Assessment Science and Policy (ARASP), submitted to the Science Advisory Board's (SAB) Chemical Assessment Advisory Committee (CAAC) for the review of the Draft IRIS Benzo[a]pyrene (BaP) Assessment.

Statement submitted via email to Diana Wong, EPA Designated Federal Officer.

Good afternoon members of the SAB CAAC,

Thank you for the opportunity to provide oral comments, on behalf of the American Chemistry Council (ACC)¹ Center for Advancing Risk Assessment Science and Policy (ARASP)² at this meeting of the SAB CAAC for the draft IRIS BaP assessment. Early and effective engagement to address key scientific issues associated with the BaP assessment and a rigorous scientific peer review process are essential elements to ensure that up-to-date science and the most relevant methodologies and data inform the assessment.

However, the current BaP assessment does not appear to address all comments received by the public and the current conference call agenda does not clearly implement the EPA's Fiscal Year 2012 Initiatives to Enhance Public Involvement in Advisory Activities (SAB Initiatives).³

In November 2013, ARASP submitted comments on the BaP assessment which recommended that the assessment benefit from the National Research Council's 2011 recommendations for the IRIS program⁴ to improve data acquisition, evaluation and integration. I have submitted a copy of those 2013 comments⁵ to the CAAC for its consideration. We specifically noted issues with:

¹ The American Chemistry Council (ACC) represents the leading companies engaged in the business of chemistry. ACC members apply the science of chemistry to make innovative products and services that make people's lives better, healthier and safer.

² ARASP is a coalition of 22 organizations focused on promoting the development and application of up-to-date, scientifically sound methods for conducting chemical assessments. ARASP supports science based chemical assessments that utilize objective, transparent data acquisition and evaluation criteria.

³ EPA FY 2012 Initiatives to Enhance Public Involvement in Advisory Activities; website:

<http://yosemite.epa.gov/sab/sabproduct.nsf/WebSABSO/PublicInvolvement?OpenDocument>

⁴ National Research Council, Review of the Environmental Protection Agency's Draft IRIS Assessment of Formaldehyde (2011), Chapter 7. Available at: https://download.nap.edu/catalog.php?record_id=13142

⁵ ARASP November 2013 Comments on the IRIS Toxicological Review of Benzo[a]pyrene (Public Comment External Review Draft), Docket ID No. EPA- HQ-ORD-2011-0391; website: <http://www.regulations.gov/#!documentDetail:D=EPA-HQ-ORD-2011-0391-0024>

- the presentation and evaluation of study quality;
- identification and discussion of problem formulation;
- the peer review of new methodology for extrapolating dermal toxicity from animals to humans; and
- additional charge questions to discuss concordance and the inclusion of forestomach tumors in the cancer risk values.

However, it doesn't appear that these items were addressed in the current BaP assessment. For example, no charge question was added related to the forestomach tumors and while charge question #3e asked SAB CAAC members to consider the proposed dermal slope factor it does not explicitly elaborate on evaluation and peer review of this newly used methodology or require more than a yes/no response from CAAC members regarding its validity. We ask that the SAB CAAC members review charge question #5 to ensure that public comments have been reviewed and adequately addressed. This review should also include whether the Agency has adequately implemented and addressed the NRC's 2011 and 2014⁶ recommendations for the IRIS program.

In addition to the chemical specific comments I have mentioned, the SAB peer review process should afford an opportunity for open discourse on the assessment with public stakeholders. This includes fully implementing the FY 2012 SAB Initiatives. Consistent with the intent and spirit of the FY 2012 recommendations we hope the CAAC will allow for clarifying remarks from the public at the end of the meeting.

We encourage the SAB CAAC to consider these comments and ensure that the specific scientific issues in our 2013 comments are adequately considered and addressed in its review of the BaP assessment. As well, all SAB CAAC meetings should clearly comply with the recommendations from "FY 2012 Initiatives to Enhance Public Involvement in Advisory Activities."

⁶ National Research Council (NRC). Review of EPA's Integrated Risk Information System (IRIS) Process. Washington, DC: The National Academies Press, 2014.