



Oral Comments
SAB Chemical Assessment Advisory Committee (CAAC)
Augmented for the Review of EPA's draft Benzo(a)Pyrene (B(a)P)
Integrated Risk Information System (IRIS) Assessment

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I am Dr. Anne LeHuray, Executive Director of the Pavement Coatings Technology Council. Thank you for this opportunity to say a few words as the benzo(a)pyrene Committee begins its peer review. In written comments, I've suggested a few improvements and additions to EPA's Charge to the Committee. Today, I would like to highlight several aspects of the Committee's charge.

The benzo(a)pyrene assessment includes a few of the late-stage presentation and summary improvements that EPA is developing to enhance the IRIS process. These are welcome and EPA is to be commended for them. But the benzo(a)pyrene assessment is one of the last that has not had the benefit of early-stage enhancements, such as increased public involvement, improved literature search methods, systematic literature review, and other initiatives now in the implementation process. The benzo(a)pyrene draft assessment demonstrates why the enhanced IRIS process is critical..

For benzo(a)pyrene, the strategy has been to develop a hazard assessment using case reports and selected studies of exposures to different PAH-containing materials. Then, the dose-response assessment relies primarily on studies of isolated benzo(a)pyrene in animal models *in vitro* and *in vivo*.

The public review comments illustrated repeated instances in which the literature cited in support of identifying hazards associated with exposure to PAH-containing materials were mischaracterized. The review also found that a data-rich exposure pathway – pharmaceutical uses - was given short-shrift. It also appears that the literature search revealed primarily reports of adverse effects, while failing to identify literature on exposures not associated with adverse effects. We believe that a literature search conducted to find *all* documentation of exposures to PAH-containing materials would have produced a substantially different hazard assessment.

My suggested additions to the charge questions are meant to focus on specific issues raised by the benzo(a)pyrene assessment. Suggested additions include questions about technical aspects of the assessment such as:

- Appropriateness of study selection,
- Appropriateness of animal models for human risk assessment, and
- Adequacy of responses to public comments on introductory materials, and the hazard and dose-response assessments.

Today, I suggest another additional charge question:

- The draft assessment does not attempt “real world” validation testing, but exposure data and EPA risk assessment guidance are sometimes available to make it possible to conduct validation exercises for certain endpoints. So the question is, when adequate information is available, should IRIS assessments include validation testing scenarios? If yes, for which endpoints should benzo(a)pyrene validation testing be considered?

Finally, I suggest an additional process-oriented question about whether the Committee would recommend a modular approach to finalization of IRIS assessments as a method of increasing throughput.

Thank you for your attention.

