

Comments to SAB Chemical Assessment Advisory Committee Augmented for the Review of Benzo(a)pyrene IRIS Assessment

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Good morning. I am Anne LeHuray of the Pavement Coatings Technology Council. Thank you for this opportunity to address the Committee, and thank you to the members of the Benzo(a)Pyrene panel for taking on the enormous task of evaluating the hazard and dose-response assessment of Benzo(a)Pyrene, EPA's index compound for the PAHs. My comments are directed to three issues.

The first concerns the human exposure and effect information relied on in the BaP hazard assessment. Because real world exposure occurs only to BaP-containing mixtures, BaP hazard assessments rely on more than a century's worth of information about exposures to mixtures. Assessments rely on reports of varying quality, from anecdotal to case reports to well conducted occupational exposure studies. EPA's hazard assessment relies heavily on reviews of such information conducted previously by other organizations for different reasons. In most instances, EPA has not reviewed the primary literature, and not all hazard reviews have been included in the IRIS hazard assessment. The quality of the primary literature reports remain unassessed. The risk of bias is high because only reviews that focus on reports of adverse effects seem to be considered. Many of these reviews were conducted before the value of systematic review procedures was recognized. Further, entire classes of literature concerning exposure to BaP-containing mixtures – particularly, coal tar pharmaceuticals – receives the barest minimum of attention. For these reasons, I ask the Committee to urge EPA to improve the BaP assessment by reviewing the primary literature concerning potential hazards posed by human exposure to BaP. EPA's review should use a modern approach to systemic review as well as to evaluation of exposure and epidemiological data.

The second issue is a procedural question: is a compound-specific IRIS assessment the appropriate vehicle for introducing new, previously unreviewed assessment techniques, such as the evaluation of dermal dose-response presented in the BaP assessment? Should EPA develop a dermal dose-response assessment guidance document before applying novel methodologies to individual assessments? I note that, in his preliminary comments, Dr. Burchiel asks a similar question about developing an immunotoxicity guidance document to foster standardization of risk assessment. Well thought out standardized approaches are to be preferred to *ad hoc* application of procedures developed for individual cases. For this reason, I ask the Committee to urge EPA to develop guidance for use in evaluating different end points considered in IRIS hazard and dose-response assessments before application to individual cases. Until such guidance is available, the dermal dose-response assessment of BaP should not be finalized.

The third point is related to the first in that it concerns the quality of studies and the role of study quality in EPA's IRIS assessment. Several Committee members have questioned aspects of certain studies identified as key to the evaluation of a given end point. Such concerns raise the

question of whether a low quality study should be relied on for an IRIS assessment because it is the only available information concerning an end point. For example, the Thyssen et al. (1981) study was selected as the best available study for dose-response analysis for inhalation unit risk as it represents the only lifetime inhalation cancer bioassay available for describing exposure-response relationships for cancer from inhaled BaP. That study, however, was not deemed of sufficient quality to support an EPA inhalation assessment in 1990 (1), and was not used by EPA to develop a Provisional Peer Reviewed Toxicity Value in 2009 (2). These precedents raise the question whether this specific study is of sufficient quality to be relied on in an IRIS assessment. Simply because only one study exists does not mean it is the study should be used. More generally, I ask the Committee to urge EPA to determine the appropriate use of low quality studies in the BaP and other IRIS assessments.

Thank you again for the time you are devoting to the important work of the BaP review Committee.

Citations

1. Summaries in a (never finalized) draft inhalation assessment (EPA 1990) available at <https://ntrl.ntis.gov/NTRL/dashboard/searchResults.xhtml?searchQuery=PB93161016> and Clement Associates 1990 (citation at http://hero.epa.gov/index.cfm/reference/details/reference_id/2252038)
2. Provisional Peer-Reviewed Toxicity Values for Complex Mixtures of Aliphatic and Aromatic Hydrocarbons (CASRN Various) http://www.epa.gov/reg3hwmd/risk/human/rb-concentration_table/documents/TPH.pdf