

**NASA COMMENTS, SUBMISSION TO EPA DURING INTERAGENCY COMMENT PERIOD,
JULY 7, 2011 ON BENZO(a)PYRENE (BaP)**

NASA thanks EPA for the opportunity to review and comment on the draft IRIS risk assessment of BaP. NASA reviewed the current draft and identified the following global issues and a short summary of specific concerns. Due to EPA's current short schedule for review and significant number of draft IRIS documents undergoing simultaneous interagency review, NASA will emphasize the significant global scientific and technical issues in the provided comments. This emphasis highlights the need for EPA to undertake a systemic and complete editing and clarification of this draft, as written.

Global Issues:

- The BaP draft exhibits the technical weaknesses and verbosity found in many EPA draft IRIS documents, issues that NASA has repeatedly identified and supported by recommendations provided by the NAS to EPA in the recent review of the draft IRIS Formaldehyde assessment. The BaP draft provides little discussion of methodologies or methods EPA used to evaluate and chose critical studies. The bulk of the draft is a summary of numerous studies which are not necessarily comparable but often yield contradictory data and results, with no explanation from EPA on the choice, validity or overall state of information applied in this assessment of BaP. The reader is left confused how EPA has applied its own methodologies and guidance in the evaluation of the oral, inhalation and dermal exposure risks. Overall, the document lack scientific rigor and transparency, issues receiving significant public interest now with no clear path for EPA to address in this and other current drafts undergoing review.
- BaP, as a constituent of cigarette smoke and selected industrial applications, has been heavily researched but EPA fails to clearly identify its methodology to synthesize the most relevant and critical literature from the vast pool of potential research. EPA does not provide the reader with clear discussion of the range of animal studies, human epidemiological studies and occupational data are chosen and applied for this specific assessment.
- EPA, throughout the draft, uses the terms BaP and the group of Poly Aromatic Hydrocarbons or PAHs interchangeably throughout the document. Aside from the simple confusion this creates, the BaP draft lacks any discussion that definitively states and explains the apparent assumption that BaP serves as the appropriate surrogate or index chemical for an entire group of diverse chemicals (PAHs). Within this draft. EPA acknowledges that data on individual chemicals defined as PAHs produce highly variable impacts on animals and humans in comparison to other PAHs. EPA's use of BaP and PAHs (and the numerous studies that provide result on BaP, BaP and other PAHs, PAHs as a group or individual PAHs) as interchangeable terms is not supported clearly by research or direct explanation by EPA. EPA appears to simply assume the interchangeability of BaP and PAHs, a controversial and unsubstantiated opinion.
- This one issue showcases the need for EPA to revisit and expand the current draft to clarify this most critical assumption that has significant implications on the risk inherent in a diverse group of substances and EPA's methodologies to evaluate human health risk. NASA supports transparent discussion of scientific matters and this lack of transparency on this fundamental issue raises major concern and a major flaw in this draft assessment.

- As noted in the previous comments, EPA's apparent use of BaP as an index chemical for the larger diverse group of PAHs lacks substantiation and definition. EPA needs to delete supporting studies which target PAHs doses or BaP in concert with PAHs from this draft and focus its assessment on BaP studies. In keeping with its guidance, EPA has targeted individual chemicals and their metabolites in many currently existing IRIS documents. EPA noted that the toxicity and other relevant factors vary across the array of identified PAH chemicals and use of these studies add additional confusion and lack of scientific rigor to this specific assessment of BaP alone.
- The draft Peer Review charge questions need to directly target these significant global issues directly and the draft language should be edited to include:
 - Whether EPA reviewed and considered the relevant studies available and the critical study chosen reflects the best science;
 - Is EPA's assumption valid and supported to use BaP as an index chemical to represent the larger group of PAHs;
 - Does EPA's assessment of BaP conform with established EPA guidance on Carcinogenicity (2005) and Weight of Evidence;
 - Does EPA adequately characterize and substantiate its determinations on dermal exposure and related assessment, in keeping with current literature and state of the science;
 - What studies evaluating BaP and other PAHs and PAHs generically should be considered in this BaP assessment, and;
 - Does EPA's evaluation of BaP mesh with the current state of the science on BaP and its volume of research on human health impacts (primarily from cigarette smoking and occupational exposures)?

Short Summary of Specific Issues:

- NASA noted numerous examples of typos, inconsistencies in presentation throughout the document and inaccuracies or confusing language in the review of the draft. No specific comments are provided but EPA is encouraged to review this draft to improve the consistency, accuracy and readability of the draft and underscores one of the many issues noted in the global comments.
- EPA's application of UFs of 3000 for the RfD and 1000 for the RfC for such a heavily researched chemical as BaP underscores NASA's concern that EPA did not make a defensible choice of critical studies and lacks a methodology to ensure targeting appropriate studies to serve as the basis of the RfD and RfC.
- The first one hundred plus pages provides short summaries of numerous BaP, BaP and other PAHs and generic PAHs which present a confusing array of differing methods, target populations (differing animal species, human epidemiology studies or occupations exposures), inconsistencies

or technical weaknesses. EPA does not establish basic parameters of why these studies were chosen, how they were evaluated and what, if any support, they provide to the EPA assessment. As noted in the global comments, the lack of clarity and transparency continues to be a significant barrier to the reader using the IRIS assessment or the decision maker utilizing its results in sound decision making. NASA requests EPA edit this draft and provide clear explanation of what studies are considered and how studies are chosen as critical and applied in the development of the RfD and RfC. Examples of outstanding questions are why did EPA not use the IARC 2004 study and why were studies targeting smokers exposure to BaP and other early work not be considered.

- EPA's discussion and assessment of dermal exposure is poorly documented and supported. NASA suggests EPA revisit and clarify its assessment of dermal exposure and request the Peer Review team consider this expanded, clarified discussion during its review.

Again, NASA thanks EPA for the opportunity to comment on the draft IRIS assessment of Benzo(a)Pyrene. Please contact NASA, if you have any questions or require clarification or more information.