

PAH mixtures NASA comments 10_28_09

NASA comments on draft PAHs risk assessment
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to:

IRISInterAgency

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Peter:

NASA thanks EPA for the option to review and comment on EPA's draft PAH Mixture risk assessment under the IRIS process. We reviewed the text and identified broad areas of concern and the appearance of potential inconsistencies with established policies and practices. We suggest expanding the current draft Peer Review questions to address the following issues:

Does EPA provide adequate justification for the decision to limit use of data to only a narrowly defined subset of data? If not, what further information and input is needed to support EPA's draft risk assessment and its findings or should EPA reconsider its approach?

Issue: The current draft actively narrows data use to only those experiments performed at the same lab and does not consider the range of available data, especially for a diverse group of chemicals, such as PAH mixtures. Of particular concern is the EPA approach to limit the use to only "positive results", a concern that NASA previously identified in its review of the draft TCE risk assessment under IRIS. Overall, this limitation of data raises the potential for skewed results, the appearance of "cherry picking" data for a desired results and would exclude much of the literature or data sources used consistently in other EPA risk assessments.

Does EPA provide adequate documentation and justification for its determination of the primary mode of carcinogenic action? If not, what additional information and justification is needed from EPA to support a defensible determination or should EPA reevaluate this determination. In addition, does EPA adequately support its subsequent determination on low dose estimation?

Issue: Review of the current draft found extensive discussion of mode of action but little to no substantiation for EPA's actual determination of the primary mode of carcinogenic action. Without clarification of this critical factor, the subsequent decision on linear vs. nonlinear extrapolation at low doses is not defensible.

Does EPA provide adequate justification for its specific approach to quantify risk factors across a diverse group of chemicals, such as PAHs? Also, does the draft PAHs risk assessment meet requirements for estimation of relative potency factors (RPF) for mixtures?

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Issue: EPA's specific approach for PAHs raises areas of concern and potential inconsistencies in the application to PAH mixtures. As this approach has many differences from current risk assessment practices and EPA policies (e.g., EPA Guidelines for Carcinogen Risk Assessment (2005), EPA's 2005 Supplemental Guidance for Assessing Susceptibility from Early-Life Exposure to Carcinogens, Guidelines for Carcinogenic Risk Assessment (1986)) for single chemical that EPA needs to substantiate its specific approach on PAH mixtures.

NASA requests that EPA strengthen and clarify its draft Peer Review questions to ensure consideration and peer review direction on these significant outstanding issues.

Again, NASA thanks EPA for the opportunity to review and comment on this draft risk assessment in the IRIS process.

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