

NASA COMMENTS ON THE FINAL DRAFT TCE IRIS RISK ASSESSMENT

JULY 2011

NASA thanks EPA for the opportunity to review and comment on the final draft TCE IRIS risk assessment, reviewing EPA's response to interagency, public and external peer review comments. We appreciate that EPA provided general supporting documentation of three specific areas identified by the external peer review and EPA's subsequent response. NASA's global and more specific comments are provided below.

Global Issues:

- NASA does appreciate that EPA did add specific language additional or more current studies to clarify and support its assessment in three areas identified by the external peer review. However, NASA is not aware of nor has been provided with a formal response to comments documentation from EPA on its response to significant interagency issues with scientific and technical aspects of the draft assessment. Lack of a response to comments document and the extremely verbose nature of the draft inhibit interagency participants' review of EPA's response to previous version of this draft. In addition, the provided redline document exhibited errors in the organization and numbering, making a review of the changes difficult and confusing.
- NASA's notes that the TCE draft reflects the systemic issues with the lack of clarity, transparency, support of scientific decision making and adherence to established EPA guidance and methods that the NAS detailed in its review of EPA's formaldehyde draft IRIS risk assessment. The TCE draft continues to exhibit all these fundamental weaknesses that the NAS identified as consistent issues with numerous IRIS assessments. EPA did add specific statements in direct response to the external peer review for specific clarification on several issues but the resulting document is in excess of 3000 pages and offers the reader a most daunting task to review and understand EPA's assessment and establishment of the proposed TCE RfD and RfC. EPA indicates it plans to address these significant, systemic weaknesses in future draft IRIS assessments. However, the current TCE draft lacks clarity, transparency and consistency with EPA policies and guidance. NASA questions whether the current draft is of sufficient quality and clarity to be ready to finalize, especially on such a significant concern as TCE.
- EPA cites studies for chemicals that are not the target chemical or its documented metabolites. This concern has been identified during interagency review on other draft IRIS reviews. Inclusion of non-targeted chemicals in such a complex IRIS review confuses the reader, offers little insight into EPA's evaluation process and raises technical questions about EPA's internal review process. EPA is encouraged to address this issue prior to finalizing the draft TCE IRIS draft.

- Significant issues identified by the peer review were not adequately addressed in this draft. Examples of outstanding issues and recommendations by the peer review that require additional EPA action include:
 - MOA and the assessment of kidney and liver data
 - Discussion and definition of mutation
 - Explanation of liver data
 - Consistency with established EPA guidance, such as the 1991 Guidelines and the 2002 RFD and RFC guidance and EPA's modeling criteria for RfDs and RfCs
 - Appearance of preference for studies with detrimental results, especially at low level doses while not appearing to consider studies which show no impacts
 - Previous interagency comments mirrored many of the same technical and scientific issues, as well as weaknesses in clarity and transparency, as stated by the peer reviewers.

NASA thanks EPA for the opportunity to review and comment on the final draft of the TCE IRIS risk assessment.