

## **Council on Environmental Quality (CEQ) Comments on the Interagency Science Discussion Draft IRIS assessment of Biphenyl (dated April 2013)**

Date: May 22, 2013

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The Council on Environmental Quality (CEQ) appreciates the opportunity to review the post-peer review draft (Step 6b in the IRIS Process) of the Toxicological Review for Biphenyl. CEQ reviewed the peer review panel comments, the public comments and the changes made in the assessment to address all of the comments. CEQ also reviewed the revised assessment with consideration of EPA's guidance documents and overarching advice focusing on IRIS assessment development received from the National Research Council (Chapter 7 of the 2009 Formaldehyde Review).

We find that EPA's revisions to the draft assessment demonstrate a strong and successful effort to incorporate the input received from the peer reviewers and the public commenters. All of the major comments from the panel have been addressed and the assessment remains concordant with EPA guidance documents. An example of a change to make the assessment consistent with peer reviewer comments is the revised assessment's use of Umeda et al., 2002 as the critical study for the development of the reference dose. This was a recommendation of several reviewers and a plausible option expressed by others. Another example is the improved discussion related to the cancer descriptor and routes of exposure: two of the reviewers had noted that there is "scanty" evidence supporting the "suggestive" cancer descriptor for routes other than oral. The edits made in section 4.7 better clarify the existence of absorption data and studies demonstrating systemic effects from biphenyl exposure. The new text in section 4.7 was added following a summary of the 2005 Cancer Guidelines language describing how cancer descriptors should be applied across differing routes of exposure when chemicals are absorbed and have systemic effects. The revised section 4.7 provides a clear and scientifically justified resolution to this issue. In addition, the revised document also appropriately incorporates many of the comments and suggestions received from the public, including the inclusion of submitted relevant information.

The revised draft has improved clarity and transparency consistent with the advice provided by the National Research Council in 2009. In the current version of the assessment, several sections have been re-written to be more to the point. The description of literature search methods and the use of tables to summarize information are also consistent with the 2009 National Research Council recommendations.

Following our review, CEQ sees no reason not to finalize and post the draft assessment to the IRIS database in the very near future.