

**Office of Management and Budget (OMB) and Office of Science and Technology Policy (OSTP)
Comments on the Interagency Science Discussion Draft IRIS assessment of Libby Amphibole
Asbestos (dated August 2014)**

Date: September 3, 2014

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Interagency Review (6B) of EPA IRIS Toxicological Review of Libby Asbestos

Dear EPA IRIS:

Thank you for the opportunity to review the draft Toxicological Review of Libby Asbestos. Please find below the major comments for your consideration.

- 1) For the inhalation RfC, the uncertainty factor for adjustment of exposure period was revised from 1 to 10, based on a mathematical extrapolation of the dose-response model function. As noted in EPA's explanation, the average duration of exposure in the key study was >7 years, which has heretofore been considered a chronic exposure scenario. Table 5.3 indicates that the exposure duration in the Libby workers cohort at the OM Scott plant in Marysville is mean 18.93 yrs and median 20.75 yrs, with a follow-up time since first exposure of mean 24.42 yrs and median 25.96 yrs. Time from first exposure ranged from 23.14 up to 47.34 years. While the SAB recommended that EPA reconsider the uncertainty factor of 1 in the previous draft, the need for an uncertainty factor of 10 is questionable. Rarely will epidemiology studies have the long study durations as in the asbestos literature, and the use of a factor of 10 will set the precedent that this will become the de facto uncertainty factor or procedure for epidemiology studies. Also, the extrapolation of a selected dose-response mathematical function appears novel and precedent setting in the context of basing an RfC on an epidemiological study, especially modeling out to 70 years "time since first exposure," raising further science-policy considerations of implied childhood exposure extrapolation. The definition of what is considered a chronic exposure scenario argues for the original uncertainty factor of 1.
- 2) While EPA responded to public comments that contend that ambient asbestos levels exceed the RfC (p. A-50), there remains interest on having a broader scientific discussion on how to address reference values that are at or near background and/or endogenous levels. Reference values are often mistakenly used as "bright line" values inferring a causal relationship with an adverse health effect if the exposure is greater than the reference value. Understanding that the risk management considerations are beyond the scope of the context of reference value derivation, there is still a need to explore and understand quantitative risk for noncancer endpoints and its impact on real world issues. We recommend that EPA organize a scientific meeting to discuss the impact of reference values that are derived at, near, or below background/ambient/endogenous levels.
- 3) An Information Quality Request for Correction was filed by Beveridge & Diamond PC in regards to the August 2011 External Review Draft, "Toxicological Review of Libby Amphibole Asbestos in Support of Summary Information on the Integrated Risk Information System," (<http://www.epa.gov/quality/informationguidelines/iqg-list.html>). In the current interagency

review draft, Appendix A (responses to SAB peer review and public comments) will have to be revised to specifically indicate EPA's responses to comments and issues raised in the Information Quality Request for Correction. This will have to be reviewed by OMB prior to release.