

**Department of Defense (DoD) Comments on the Interagency Science Discussion Draft IRIS Assessment of Benzo[a]pyrene November 2016
(Date Received: December 14, 2016)**

**Department of Defense Comments on
IRIS Toxicological Review of Benzo(a)pyrene, Step 6b Review**

(Comments are based on the redline strikeout version)

Comments submitted by: OASD(EI&E), ESOH
Directorate, CMMR Program

Organization: Department of Defense

Date Submitted: 12/14/2016

*Comment categories: Science or methods (S); Editorial, grammar/spelling, clarifications needed (E); or Other (O). Also please indicate if Major i.e. affects the outcome, conclusions or implementation of the assessment.

Comment No.	Section	Pages	Comment	Suggested Action, Revision and References (if necessary)	*Category
1	Preamble, Section 3	xxv	PECO statements (Populations, Exposures, Comparisons, Outcomes) are said to govern literature searches text added to the Preamble. However, in the benzo(a)pyrene (BaP) document we do not see the PECO statements used for the BaP literature search.	Suggest adding a disclaimer or footnotes noting which of the procedures described in the Preamble were not utilized in the BaP Toxicological Review.	E/M
2	Preface	xvii, line 23	http://www.epa.gov/pbt/pubs/benzo.htm hyperlink is not a valid website. Clicking on the hyperlink takes the reader to a "Page Not Found" EPA page.	Provide active link.	O
3	ES and General	xv and numerous locations	Hyperlinks to the EPA HERO website required pre-registration.	Ensure that links in the version released to the public are to the appropriate website.	O
4	2.2.3	2-32	The text states that the Wu et al. (2003a) had a 19% decrease in fetal survival, whereas Table 2.4 states 10% and earlier text on page F-16 and Appendix F states 9%.	Please correct to be accurate reflection of results as published.	E

5	Appendix F	F-16, lines 25 - 36	<p>In Appendix D the summary of Wu et al (2003a) notes that "The number of resorptions at 75 and 100 µg/m³, but not at 25 µg/m³, was statistically significantly increased compared with controls." But in response to the SAB comments in Appendix F "...an apparent decrease in fetal survival of approximately 9% (relative to the pooled carbon black control groups) at 25 µg/m³." is described. It appears that another group, perhaps EPA, performed this analysis. If EPA were able to obtain the data to perform this analysis (we noted Wu et al. was an NIH funded study, so perhaps the data were available) and perform the pooled control analysis perhaps BMD modeling would be possible. We acknowledge that further analysis of Wu et al. was recommended by the SAB.</p>	<p>Please describe why the conclusions as presented by Wu et al. were not presented and used in Tables 2-4 and 2-5 as a NOAEL. Please increase the clarity and transparency surrounding the further analysis of the data from Wu et al. Please cite the further analysis and if EPA performed it, include the analysis in an appendix. If EPA obtained the data please further justify why dose response modeling was not performed using it.</p>	S/M
6	Table E-18	E-54	<p>The table states: "Polynomial 2° had the lowest AIC. However, the BMDL at 1% was excessively low. No model was selected." It is our understanding that, if the other criteria are met, IRIS always selects the lowest AIC</p>	<p>How does EPA determine when the lowest AIC should be rejected, i.e., how is a value determined to be "excessively low"? If our understanding is correct and there was a deviation from the standard practice, it should be described and justified in the main body of the text in addition to being noted in the Appendix table. Also, we note that the BMDL was excessively low but we understand that the BMDL selected can be such that it is in the observable range.</p>	S