

Comments of Industry Group¹ on 2013 Draft Benzo(a)Pyrene IRIS Assessment Not Addressed in 2014 Draft Appendix G

PDF page	Comment
8	It is noted that much of the information in the main document does not match the information provided in the Supplemental Information document.
10-42	By relying on secondary literature reviews, EPA mischaracterized hazard <ul style="list-style-type: none"> - Comments include detailed review of primary literature <ul style="list-style-type: none"> o Skin Cancer in Humans (p. 11-20) o Lung Cancer in Humans (p. 11-42)
43-50	Oral Reference Dose, detailed analysis of Chen et al. <ul style="list-style-type: none"> - Although EPA responds, several points (such as the errors in reporting data in Chen et al.) were not addressed
50-52	Reproductive Endpoint <ul style="list-style-type: none"> -The comment focused on the study chosen for the reproductive endpoint, and included a detailed evaluation of Xu et al. (2010), Zheng et al. (2010), Mohamed et al. (2010), and Gao et al. (2011)
52-55	Immunotoxicity Endpoint <ul style="list-style-type: none"> - The comment addresses and evaluates studies considered for immunotoxicity endpoint
55-56 63	Uncertainty Factors <ul style="list-style-type: none"> - Comment disagreed with use of “database uncertainty factor” of 3 for a compound that arguably has the largest number of toxicological studies available for any substance
56-60	Choice of studies for RfD development <ul style="list-style-type: none"> - “The commenters disagree with the manner in which studies with multiple toxicological comparisons were mined to find test/control comparisons that gave the lowest BMDL₁₀ or NOAEL. At every step, USEPA (2013) chose the worst case rather than consider the overall weight of evidence from within or among available studies.”
62-63	NOAEL/LOAEL approach for POD <ul style="list-style-type: none"> - “Benchmark dose modeling was attempted, but it was confirmed that the data as presented (means +/- SEM) were not amenable to benchmark dose modeling.”
65-66	Oral Cancer Slope Factor <ul style="list-style-type: none"> - “The commenters disagree, however, that forestomach tumors are relevant to the assessment of human health because humans do not have forestomachs.”
66-68	Oral Slope Factor

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 American Fuels and Petrochemical Manufacturers
 American Petroleum Institute
 Asphalt Institute
 Association of American Railroads
 Beazer East, Inc.
 Pavement Coatings Technology Council

	<ul style="list-style-type: none"> - "USEPA (2013) should fully implement the 2005 risk assessment guidelines and not default to a linear low dose extrapolation for every OSF calculation. Benchmark dose modeling of the Beland and Culp (1998) data using the Multistage Cancer model gives plots that show evidence of a threshold for carcinogenic risk." - Results of modeling of data shown & discussed
68-75	<p>Inhalation Unit Risk</p> <ul style="list-style-type: none"> - Detailed discussion of Thyssen et al. and other studies relevant to development of a IUR - Results of BMDL modeling conducted by commenters shown & discussed
75-101	<p>Dermal Slope Factor</p> <ul style="list-style-type: none"> - Although EPA responded to selected points within the comments, the comments are detailed concerning selected studies and studies completely omitted - Errors noted in EPA BMD modeling were not addressed
101-120	<p>Interspecies scaling for DSF</p> <ul style="list-style-type: none"> - Although EPA addresses some scaling issues, the interspecies differences and real world validation studies noted in comments are not addressed
120-140	Reference list