

Comments of the Utility Solid Waste Activities Group (USWAG)¹
 on 2013 Draft Benzo(a)Pyrene IRIS Risk Assessment
 Not Addressed in 2014 Draft BaP Assessment / Appendix G²

Page	Comment
6-7	Application of DSF to Exposure from Environmental Media EPA should provide direct guidance <ul style="list-style-type: none"> • Comments cite to studies showing that interactions between chemicals and soil constituents impede dose of chemicals to skin when the chemical dose is applied in soil; EPA has failed to acknowledge or account for these data • Highlighted the need for guidance regarding how to incorporate adjustments to appropriately calculate BaP doses from soil, accounting for the binding of soil • Table 2-15 highlights the confusion regarding use of DSF
12-13	Bias in Potency Analysis <ul style="list-style-type: none"> • The selection criteria for studies used to derive DSF “are biased toward studies with little power to identify upward-curving low-dose dose-response patterns, thereby biasing the DSF toward an overestimate of risk that is not consistent with what would be supported by the available body of literature” – compounded by application of EPA’s Benchmark Dose software to estimate DSF • Draft ignores data from studies that EPA identified as “critical” to development of the DSF and from other studies that indicate a non-linear dose-response relationship at low doses of dermally applied BaP

¹ Note that the page references herein refer to the page number of the Exponent Report attached to and incorporated by reference in USWAG’s November 21, 2013 comments to docket EPA-HQ-ORD-2011-0391. This list includes comments by USWAG that were wholly ignored in Appendix G to the September 2014 draft BaP assessment as well as USWAG comments that may have been referenced by or partially addressed in Appendix G but that were either mischaracterized in Appendix G and/or only partially addressed. Note that the omission of any comment from this chart in no way represents an endorsement of the adequacy of EPA’s consideration of and/or response to the omitted comment.

² This summary chart has been provided for reference purposes only, to facilitate the Science Advisory Board (SAB) Chemical Assessment Advisory Committee (CAAC) Panel reviewing EPA’s BaP assessment during the Panel’s April 17th meeting in Washington, D.C. This list may not represent an exhaustive list of major comments made by USWAG and/or Exponent in 2013 which EPA has failed to adequately address in the 2014 BaP draft.

SUBMITTED TO THE SAB CAAC PANEL FOR BENZO[A]PYRENE
FOR REFERENCE IN CONNECTION WITH APRIL 15-17, 2015 PUBLIC MEETING

13-14	<p>Inconsistency with Human Epidemiology</p> <ul style="list-style-type: none">• Comment focuses on failure to consider available data on cancer incidence among a large human population with topical BaP exposures: data on cancer rates among smokers provide the opportunity to “ground truth” the DSF for use in estimating human cancer risk• “Smoking has been associated with only a modest elevation in certain forms of skin cancer (Leonardi-Bee 2012). In contrast, the DSF implies that the surfaces of the mouth and nasopharyngeal regions of cigarette smokers should be subject to pronounced elevations in corresponding epithelial tumors due to direct contact with BaP from inhaled cigarette smoke.”
14-15	<p>Uncertainties in RfD Value</p> <ul style="list-style-type: none">• Comment focuses on consequences of using large uncertainty factor (300), pointing out that the large uncertainty factor reflects the general lack of precise information for understanding actual toxicity• Large uncertainty factor represents attempt to account for extrapolation from animals to humans, for interindividual differences in human susceptibility, and for deficiencies in the toxicity database; no direct evidence that BaP will cause developmental effects in humans
15	<p>Perspective on RfD Value</p> <ul style="list-style-type: none">• The 2013 draft “does not provide perspective regarding the occurrence of developmental effects that would allow users to understand risks associated with exposure to a specific chemical.”• If proceeding with a highly uncertain RfD, EPA should consider inclusion of perspective regarding the nature and prevalence of developmental effects.