

August 26, 2015

VIA EMAIL

Dr. Diana Wong, Designated Federal Officer (“DFO”)
Science Advisory Board SAB Staff Office
wong.diana-M@epa.gov

Re: Comments to the SAB Chemical Assessment Advisory Committee
 (“CAAC”) Augmented for the Review of the Draft Benzo[a]pyrene
 IRIS Assessment (CAACBenzo[a]pyrene Panel);
 Comments in advance of September 2, 2015 teleconference

Dear Dr. Wong:

The Utility Solid Waste Activities Group (“USWAG”)¹ submits these comments to the Environmental Protection Agency (“EPA” or the “Agency”) Science Advisory Board (“SAB”) Chemical Assessment Advisory Committee (“CAAC”) Augmented for the Review of the Draft Benzo[a]pyrene (“BaP”) Integrated Risk Information System (“IRIS”) Assessment (“CAAC Panel”).² USWAG appreciates the opportunity to provide comments to the CAAC Panel as it continues its review of EPA’s September 2014 draft toxicological review of BaP (“2014 Draft BaP Assessment”). These comments respond to issues raised in the “SAB Draft (7/24/2015) Review of EPA Draft Assessment entitled Toxicological Review of Benzo[a]pyrene (September 2014)” (hereinafter the “Draft Report”).³

¹ USWAG, formed in 1978, is an organization of over one hundred electric utilities, power producers, utility operating companies, and utility service companies located throughout the country, including the Edison Electric Institute (“EEI”), the American Gas Association (“AGA”), the American Public Power Association (“APPA”), and the National Rural Electric Cooperative Association (“NRECA”). Throughout these comments, we refer to our industry as the “utility” or “electric utility” industry. This term is intended to include those portions of the industry and those USWAG members that generate electricity but do not directly provide electricity to the public and are technically not “utilities.” Together, USWAG members represent more than 73% of the total electric generating capacity of the United States, and service more than 95% of the nation’s consumers of electricity and 92% of the nation’s consumers of natural gas.

² See 80 Fed. Reg. 2415 (Jan. 16, 2015).

³ See the “SAB Draft (7/24/2015) Review of EPA Draft Assessment entitled Toxicological Review of Benzo[a]pyrene (September 2014)” (“Draft Report”), available online at

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USWAG appreciates the effort that the CAAC Panel has undertaken to review and comment on the 2014 Draft BaP Assessment. We are hopeful that the Agency will give the CAAC Panel's final recommendations the weight they are due in order to produce a final risk assessment that is scientifically supportable and may be properly applied in the regulatory context.

In comments submitted to CAAC Panel on April 8, 2015 (including the technical report prepared by Geosyntec Consultants entitled "Comments on EPA's Draft IRIS Toxicological Review of Benzo[a]pyrene (External Review Draft – September 2014)"), USWAG raised concerns with several aspects of the 2014 Draft BaP Assessment, and reiterated USWAG's comments first raised in response to the August 21, 2013 draft BaP risk assessment ("2013 Draft BaP Assessment").⁴ USWAG's comments on the 2013 and 2014 drafts raised concerns regarding the Agency's lack of scientific support for its novel dermal slope factor ("DSF"), as well as the Agency's failure to adequately account for differences in mouse and human epidermal structure and metabolism. With regard to the latter concern, USWAG pointed out that, while the 2014 Draft BaP Assessment is based largely on mouse data, the risk assessment fails to acknowledge or account for the significant differences in thickness and permeability between human and mouse skin. Similar comments were made by other commenters – representing a vast swath of the regulated community – in response to the 2013 Draft BaP Assessment⁵ and the 2014 Draft BaP Assessment.

Now concerns regarding the development of the DSF, dose response analysis, and the draft risk assessment's reliance on mouse data have been raised once again, this time by members of the CAAC Panel. Following discussion of these troubling issues during the CAAC Panel's April 2015 public meeting in Washington, D.C., the panel has included in its Draft Report recommendations intended to address these shortcomings.

Specifically, the CAAC Panel observes in Section 3.3.5 of the Draft Report that "[n]either the proposed dermal slope factor nor the proposed method for cross-species scaling is sufficiently scientifically supported," and makes several recommendations to EPA (see Draft Report at 36-37) to improve the quality of the risk assessment. USWAG agrees that a robust evaluation of the issues raised in the Draft Report will be critical to the development of a scientifically defensible risk assessment. USWAG urges the CAAC Panel to increase the firmness with which

http://yosemite.epa.gov/sab/sabproduct.nsf/fedrgstr_activites/IRIS%20BaP!OpenDocument&TableRow=2.2#2 (current as of the date of these comments).

⁴ See 78 Fed. Reg. 51719 (Aug. 21, 2013).

⁵ See Docket No. EPA-HQ-ORD-2011-0391, available online at www.regulations.gov.

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it advises EPA to revisit its risk assessment. The Agency should do more than simply “consider” making these changes; the legitimacy of the ultimate BaP risk assessment – and, ultimately, the risk assessment for polycyclic aromatic hydrocarbon (“PAH”) mixtures, which will be based on the final BaP risk assessment – depends on the Agency taking these steps to move towards a scientifically supportable risk assessment.

Similarly, USWAG supports all of the recommendations made in the Draft Report regarding dose-response analysis and cross-species scaling (see *id.* at 37-39), and additional recommendations for describing cancer risk calculated with the DSF (see *id.* at 39). It is because the shortcomings the CAAC Panel has identified in these sections so severely undermine the risk assessment that USWAG encourages the CAAC Panel to reframe these recommendations with greater urgency.

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USWAG appreciates the opportunity to comment on the CAAC Panel’s Draft Report concerning this important risk assessment. Please contact USWAG counsel Allison Foley at Venable LLP (202-344-4416) with questions regarding these comments.

Respectfully submitted,



James R. Roewer
Executive Director