

## **Comments to SAB Chemical Assessment Advisory Committee Augmented for the Review of Benzo(a)pyrene IRIS Assessment**

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Good morning, and thank you for the opportunity to provide comments today. I will briefly touch upon two issues that are described in much more detail in EPRI's written comments, which I hope the Panel has had an opportunity to review.

First, EPRI believes that there is a lack of real-world validation of cancer risks presented in the IRIS document. We have calculated skin cancer risk associated with dermal contact with soil and coal tar pharmaceuticals; these calculations were provided in EPRI's comments on the public review draft as well as in an addendum transmitted to IRIS staff in January 2014. They have been updated to reflect the increased proposed DSF of  $0.006 \text{ (}\mu\text{g/day)}^{-1}$ , the PAH mixture extended analyses performed by Embso-Mattingly et al. (2014), and the dermal risk assessment equations presented by EPA in Appendix G of the IRIS document.

Our calculations show that dermal contact with soil, using data on BaP toxic equivalents for the United States, would account for 26% of all skin cancers on the head, hands, lower legs, and forearms for the entire US population. If stratified by race, EPA's DSF predicts that BaP-TE in background urban soil explains 1,733% of skin cancer in these areas in black Americans. Further, if stratified by body part, EPA's DSF predicts that BaP-TE is responsible for a major portion and often >100% of the actual observed skin cancer in certain areas. Specifically, EPA's DSF predicts that BaP-TE is responsible for 68% of skin cancer on hands in the white population, 4,600% on hands in the black population, 2,500% on feet in the white population, and 168,000% on feet in the black population.

Dermal contact with coal tar pharmaceuticals presents a similar situation, with the estimated excess lifetime risk of skin cancer from these products at 0.86. Epidemiological studies of these products have repeatedly shown no increase in skin cancer rates compared to background skin cancer rates in the reference populations. In contrast, EPA's proposed DSF would predict that almost all coal tar pharmaceutical users should have developed skin cancer.

The second issue I will touch upon today was also highlighted in my oral comments during the March 4 teleconference. During the teleconference, I mentioned the addendum to EPRI's written comments submitted to IRIS staff outlining the differing mutational signatures in human skin tumors versus experimental mouse skin PAH-induced skin

tumors. In our written comments to this Panel submitted on April 8<sup>th</sup>, this addendum was updated to include additional references. Overall, the literature search strongly suggests that human skin tumors have a unique mutational signature attributed to UV exposure, which agrees with the signature of mouse skin tumors induced by UV light, and that mouse skin tumors induced by PAHs contain a distinct and separate mutational signature, which is not seen in human skin tumors. Furthermore, while EPA states in Appendix G of the external review draft that “studies which examine mutational spectra in human skin tumors thought to be related to PAH exposure are not available in the literature”, this is because there are no such tumors to examine. Workers exposed occupationally to PAHs do not develop tumors, nor do coal tar pharmaceutical users. Thus, there are no tumors to analyze.

In closing, I will also add that we have transmitted to EPA staff three published EPRI reports documenting PAH concentrations in US soils that we encourage the Agency to use in validation calculations. The three reports are titled *Polycyclic Aromatic Hydrocarbons (PAHs) in Surface Soils in Western New York*, *Polycyclic Aromatic Hydrocarbons (PAHs) In Surface Soil in Illinois*, and *Examination of the Sources of PAHs in Urban Background Soil*.

Thank you for your time and for the opportunity to provide input into the IRIS process.