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ENVIRONMENT

**Subject:**

SAB Chemical Assessment Advisory Committee (CAAC) Augmented for the Review of EPA's draft Benzo(a)Pyrene (B(a)P) Integrated Risk Information System (IRIS) Assessment

Date:  
March 2, 2015

Dear Chairman Faustman and Members of the SAB CAAC Augmented for the B(a)P Review:

Contact:  
Brian Magee, Ph.D.

Thank you for participating on this important Panel. I look forward to assisting you in your review by highlighting some important issues. On behalf of the American Petroleum Institute, the Asphalt Institute, and the Pavement Coatings Technology Council, I am submitting some brief comments for your review in advance of the March 4 public teleconference. For background, I was the primary author on a 140-page comment document submitted to the docket in November 2013 on behalf of the American Coke and Coal Chemicals Institute, the American Fuels and Petrochemical Manufacturers, the American Petroleum Institute, the Asphalt Institute, the Association of American Railroads, Beazer East, Inc., and the Pavement Coatings Technology Council. A subset of these comments was presented verbally at the December 2013 Quarterly IRIS meeting.

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Our ref:

**Comments of Brian Magee, Ph.D. on EPA's *Appendix G. Summary of External Peer Review and Public Comments and EPA's Disposition***

**Comment:** *Inclusion of studies of patients therapeutically treated with coal tar.*

The final draft of the IRIS *Toxicological Review of Benzo[a]pyrene and Appendix G Summary of External Peer Review and Public Comments and EPA's Disposition* fail to consider 15 papers on coal tar pharmaceutical epidemiology that were brought to the Agency's attention in written and verbal comments. The documents also fail to consider an externally peer reviewed risk assessment report (ICF Consulting, 2000) of coal tar pharmaceuticals that derived dose data from the Pittelkow et al. (1981) epidemiology study. This report was submitted to the EPA docket in written comments.

Imagine the result

EPA's IRIS assessment fails to acknowledge the most important comment made in comments submitted by the American Coke and Coal Chemicals Institute, American Fuels and Petrochemical Manufacturers, American Petroleum Institute, Asphalt Institute, Association of American Railroads, Beazer East, Inc., Pavement Coatings Technology Council and verbal comments made by Dr. Brian Magee of ARCADIS in December 2013 about the coal tar pharmaceutical using population. This key comment is that the lifetime skin cancer risk from typical coal tar users is conservatively calculated to be  $8.1E-01$  using the 2013 proposed Dermal Slope Factor (DSF) and, now,  $8.6E-01$  using the 2014 proposed DSF. Despite any methodological issues that may exist in any specific epidemiological study, the fact remains that EPA's proposed DSF estimates that most coal tar users discussed in any case study, health survey or formal epidemiological study should have developed skin cancer if the DSF were an accurate predictor of human risk. For instance, surely among 8,062 patients that received coal tar treatments in Roelofzen et al. (2010), there should have been at least a hint of an increase in skin cancers if their lifetime risk was  $8.6E-01$  or even substantially less than  $8.6E-01$ .

**Comment:** *"Real world" validation of dermal slope factor.*

In my written and verbal comments, I stated that preliminary, conservative risk assessment calculations done in accordance with EPA guidance using the proposed DSF gives a lifetime risk of skin cancer in the general population that explains 30% of all human skin cancers. *Appendix G Summary of External Peer Review and Public Comments and EPA's Disposition* states that: "The commenters did not provide the exposure equation, benzo[a]pyrene soil concentration, or assumptions used in their calculation of a 30% risk estimate."

It is true that there is a typographical error in the document on page 8, which states 30%. The correct estimate was 10%. However, EPA's response implies that no back-up information was provided that would allow one to check the calculation. This is not the case. Every assumption and every parameter is listed on pages 115, 116, and 117 of the comments submitted by the American Coke and Coal Chemicals Institute, American Fuels and Petrochemical Manufacturers, American Petroleum Institute, Asphalt Institute, Association of American Railroads, Beazer East, Inc., and Pavement Coatings Technology Council.

I am presenting today updated risk assessment calculations that demonstrate that the proposed DSF does not pass a real world validation, because it predicts that a majority of all human nonmelanoma skin cancer must be caused by PAHs despite what is known about the role of UV radiation in causing human skin cancer. More importantly, *more than 100%* of skin cancer is predicted at certain anatomical locations in certain populations. Such a result is impossible.

In the following comment, I address the issue of DSF-predicted skin cancer versus actual skin cancer in the population. I am also in the process of performing similar calculations for dermal exposures to BaP-TE from other media, such as air deposition onto skin, contact with indoor house dust, and charbroiled meat. When

other exposure pathways by which typical Americans dermally contact PAHs are included in a validation exercise, the degree to which the DSF over predicts actual human skin cancer risk increases with each additional exposure pathway. The result is overwhelmingly clear: the proposed DSF results in nonsensical results and cannot be codified in the IRIS database. These calculations and their basis and documentation will be provided to the Panel before the April public meetings for your consideration.

*Appendix G Summary of External Peer Review and Public Comments and EPA's Disposition* has presented a calculation based on the mean concentration of benzo(a)pyrene in soil from 27 locations, only one of which was in the United States. The estimated risk posed by dermal contact to this concentration of 0.1 mg/kg of benzo(a)pyrene to a person was exposed for a total of 18 years was reported to be 7.52E-06.

The calculations in Appendix G are fundamentally flawed in several ways when performing a real world validation.

1. EPA's default soil adherence rates for soil are 200 ug/cm<sup>2</sup> for children and 70 ug/cm<sup>2</sup> for adults, not 40 ug/cm<sup>2</sup> for children and 10 ug/cm<sup>2</sup> for adults.

EPA (2014) recently updated its standard exposure factors that are used in all risk assessments. The adherence factors for soil did not change. They have been 200 ug/cm<sup>2</sup> for children and 70 ug/cm<sup>2</sup> for adults for many years and must be used for soil risk assessments.

2. BaP-Toxic Equivalents (BaP-TE) must be assessed, not just BaP.

BaP is the indicator PAH that is used to estimate risks for all PAHs that are considered to be potentially carcinogenic by EPA. The BaP-TE value is calculated by the use of EPA's Relative Potency Factors.

3. BaP-TE must include the full proposed list of 25 PAHs, not the 1993 list of 7.

The IRIS assessment on BaP is not being prepared and evaluated in isolation. Instead, it needs to be considered along with other EPA guidance documents for the evaluation of PAH mixtures. The EPA (2010) Development of a Relative Potency Factor (RPF) Approach for Polycyclic Aromatic Hydrocarbon (PAH) Mixtures document lists 25 PAHs that EPA considers potentially carcinogenic. Embso-Mattingly, et al. (2014) have shown with extended PAH analyses that the BaP-TE for many common PAH containing mixtures will increase from 10 to >100-fold compared to the 1993 list of 7 PAHs. The calculation presented here conservatively assumes only a 10-fold increase to take into account the addition 18 potentially carcinogenic PAHs.

4. Urban background BaP-TE concentrations from the United States must be assessed, not data from other countries.

Appendix G presented BaP data only and from the United Kingdom, Norway, Australia, Poland, Estonia, Spain, Poland, and other countries. To compare estimated skin cancer risks in the United States to actual skin cancer rates in the United States, data from the United States must be used. The comment document submitted to the EPA docket in 2013 identified 5 relevant studies that Appendix G has neither used nor commented on. These documents demonstrate that the average urban background level of BaP-TE for the 1993 list of 7 potentially carcinogenic PAHs is about 3 mg/kg.

- Bradley, L.J.N., B.H. Magee, and S.L. Allen. 1994. Background Levels of Polycyclic Aromatic Hydrocarbons
- (PAH) and Selected Metals in New England Urban Soils. *Journal of Soil Contamination*.3:1-13.
- Electric Power Research Institute (EPRI). 2003. Polycyclic Aromatic Hydrocarbons (PAHs) in Surface Soils in Western New York. 1005296. October.
- Electric Power Research Institute (EPRI). 2004. Polycyclic Aromatic Hydrocarbons (PAHs) In Surface Soil in Illinois. Background PAHs. 1011376. December.
- Electric Power Research Institute (EPRI). 2008. Examination of the Sources of Polycyclic Aromatic Hydrocarbon (PAH) in Urban Soil. Electric Power Research Institute. 1015558. December
- USGS. 2003. Concentrations of Polynuclear Aromatic Hydrocarbons and Inorganic Constituents in Ambient Surface Soils, Chicago, Illinois: 2001-02. Water-Resources Investigations Report 03-4105. In cooperation with the Chicago Department of Environment.

5. A total exposure time of 70 years must be used, not 18 years

Appendix G estimates the lifetime cancer risk from dermal contact with 0.1 mg/kg of BaP for receptors only exposed for 18 years in total. To compare the estimated skin cancer risks to actual skin cancer rates, one must assume a lifetime exposure, which is considered to be 70 years according to EPA guidance.

When the Appendix G calculation is modified as noted above by using EPA's default soil adherence factors, using BaP-TE urban soil data from the United States, assuming a lifetime exposure, and conservatively pro-rating the BaP-TE upwards by a factor of 10 to account for the additional 18 potentially carcinogenic PAHs, the lifetime skin cancer risk from exposure to background levels of PAHs in urban soils is **2.6E-2**, which is similar to the value reported in the written comments from 2013. This value exceeds the high end of EPA's Superfund risk range by a factor of 260, and because 80% of Americans live in urban areas, this lifetime skin cancer risk level applies to the majority of the United States' population.

The fact that dermal exposure to urban background levels of potentially carcinogenic PAHs, *if the proposed DSF were a true predictor of human skin cancer risk*, yields a lifetime risk estimate 260 times the Superfund risk range indicates that the proposed DSF cannot be valid. Otherwise, the implication would be that all urban soils should be considered to be Superfund sites and remediated immediately.

More importantly, the proposed DSF predicts that dermal exposure to urban soils containing PAHs is the main cause of skin cancer in the entire population. The DSF also predicts more than 100% of the skin cancer burden in some populations and at some anatomical sites. Accordingly, the next step in a validation exercise is to compare the lifetime skin cancer risk estimated for exposures to PAHs in urban soils to the lifetime nonmelanoma skin cancer risk for the general population (0.2) and the black population (0.003).

Appendix G assumes soil exposure to the head, hands, lower legs, forearms, and feet. The total nonmelanoma skin cancer lifetime risk is  $2E-1$ , but the lifetime risk for head/scalp, cheeks, neck, forearms, lower legs, hands, and feet is 50% of this, at  $1E-01$  (Scotto, et al., 2003, NIH Publication 83-2433). In addition, Strom et al. (1997) and others have reported that nonmelanoma skin cancer rates for blacks are 68 times lower than those for whites. As noted below, the proposed DSF predicts that dermal contact with urban background soils explains 26% of skin cancers on the head, hands, lower legs, and forearms of white Americans, which is unlikely given the myriad other dermal exposures people have to PAHs and the known role of UV radiation in causing nonmelanoma skin cancer. More importantly, the DSF predicts that PAHs in soil explain more than 100% of skin cancers in black Americans, which, of course is not possible.

Finally, one can perform the same calculation for specific body parts, such as hands or feet. As noted below, the proposed DSF predicts that dermal exposures to urban soils explain much more than 100% of skin cancer in feet, which is a rare site for skin cancer in the population (0.1% of skin cancers) but not a rare site for exposure to urban soils. Even if we assume that children and adults contact urban soils with their feet with a much lower frequency than assumed by EPA's default exposure assumptions, this validation exercise demonstrates that the proposed DSF is fundamentally flawed and would lead to nonsensical estimates of risk whenever it is used for risk assessment of any environmental medium or commercial product containing BaP or any of the other 24 PAHs that EPA has determined is potentially carcinogenic.

**Table 1, Comparison of Estimated Skin Cancer Risks Versus Actual Risk**

<b>Body Parts Assessed</b>	<b>Estimated Lifetime Risk Assuming DSF</b>	<b>Actual Lifetime Risk</b>	<b>Amount Predicted by Proposed DSF</b>
Head, hands, lower legs, and forearms, white population	2.6 E-02	1.0E-01	26%
Head, hands, lower legs, and forearms, black population	2.6 E-02	1.5E-03	1,733%
Hands, white population	3.8E-03	5.6E-03	68%
Hands, black population	3.8E-03	8.2E-05	4,600%
Feet, white population	5.0E-03	2.0E-04	2,500%
Feet, black population	5.0E-03	2.9E-06	168,000%

I would be pleased to follow up with the Panel and provide a detailed spreadsheet that provides these calculations and copies of all cited references if so requested. Thank you again for your consideration.

Sincerely,

Brian Magee, Ph.D.  
 Vice President, Principal Scientist