PAVEMENT COATINGS TECHNOLOGY COUNCIL

PCTC

WWW.PAVEMENTCOUNCIL.ORG

December 6, 2012

Ms. Lori White

Designated Federal Officer for the National Toxicology Program (NTP) Board of Scientific Councilors (BSC)

Office of Liaison, Policy and Review

Division of NTP, National Institute of Environmental Health Sciences (NIEHS)

P.O. Box 12233

K2-03

Research Triangle Park, NC 27709

Phone: 919–541–9834 Fax: 919–541–0295

Email: whiteld@niehs.nih.gov

SUBJECT: COMMENTS OF THE PAVEMENT COATINGS TECHNOLOGY COUNCIL (PCTC) ON THE DOCUMENT TITLED NTP RESEARCH CONCEPT: POLYCYCLIC AROMATIC HYDROCARBONS (PAHS) SLATED FOR DISCUSSION AT THE DECEMBER 11, 2012 MEETING OF NTP'S BSC

The Pavement Coatings Technology Council ("Council") submits these comments on the document titled NTP Research Concept: Polycyclic Aromatic Hydrocarbons (PAHs) (hereinafter referred to as the PAH Research Concept) for consideration of NTP's BSC before and during its meeting on December 11, 2012. Council members manufacture or supply materials needed to manufacture pavement sealers and other pavement products. Some materials used in the manufacturing process are refined fractions of fossil fuels, and contain variable mixtures of PAHs. Because of efforts to communicate about its members' products, the Council is well aware that, despite the voluminous scientific literature on PAHs, understanding of environmental and health impacts possibly associated with mixtures of PAHs continues to be underdeveloped, highly uncertain and of variable quality. Recognizing both the need for improved understanding of PAH mixtures, and the complexities involved in designing a research program that achieves the goal of improving understanding, the Council commends NTP for considering a research program on PAH mixtures. As a user of information gathered in studies of PAH mixtures, the Council submits this letter to urge BSC members and NTP researchers to think about research design considerations that address NTP's mission of providing information

relevant to understanding potential environmental and health effects of PAH mixtures in the real world.

As its title implies, the *PAH Research Concept* presents a research design concept. The contemplated research concept is described as an iterative approach comprising a three phase (called "rounds") project:

Round 1: Focus on collecting data on 6 individual polycyclic aromatic compounds (PACs) and a simulated complex mixture;

Round 2: Focus on predicting and comparing results for additional individual PACs (to be identified), simulated mixtures and at least one real-world complex mixtures, and Round 3: To be determined based on results from previous rounds

COMMENTS

1. The primary goal of the *PAH Research Concept* should be to study real world PAH mixtures.

The *PAH Research Concept* is primarily focused on individual PAHs ("component-based" approach) and refinement and/or validation of the Environmental Protection Agency's (EPA's) Relative Potency Factor (RPF) method of estimating potential cancer risks of PAH-containing mixtures. A secondary goal of the proposed research is to refine or validate the RPF approach through comparison of results obtained from individual components and studies of simulated mixtures and at least one identified real-world PAH mixture ("whole mixture" approach). The Council urges NTP and the BSC to consider that, whereas research on individual PAHs and PACs may be of academic interest, research in support of NTP's mission of understanding real-world exposures should focus more on mixtures representative of those found in the environment, with validation of the RPF approach as a possible secondary goal. In its March 17, 2011 report to the Administrator, the EPA's Science Advisory Board (SAB) included the following recommendation:

The SAB recommends that the Agency seek support from the National Toxicology Program (NTP) and/or other entities to conduct testing of an appropriate portfolio of different complex PAH mixtures. These complex PAH mixtures should represent a diverse array of mixtures, but also represent the most important PAH mixture classes of concern to EPA. (EPA SAB 2011)



The <u>full EPA SAB Report is available at this link</u>. The Council concurs with the SAB's recommendation to focus testing on representative real-world mixtures, and urges NTP's BSC to consider real-world mixture-based studies as the principle goal of PAH research to be undertaken by the NTP.

Details of the Council's concerns with regard to the RPF approach are also explained in comments submitted by the Council jointly with other industry associations on EPA's 2010 draft revised RPF guidance document (which has yet to be finalized). The comments to EPA are of continued relevance to evaluating the state of PAH hazard and risk science, and are included as an attachment to this letter. Comments by the US Department of Defense, the National Aeronautics and Space Agency along with comments of other Federal agencies and members of the public are also available on EPA docket no. EPA–HQ–ORD–2010–0047.

2. The BSC should defer consideration of the *PAH Research Concept* pending public availability of the studies conducted by Health Canada (HC) that seem to form the basis for the "whole mixtures" research design of proposed PAH studies.

The *PAH Research Concept* document states that the "whole mixtures" aspect of the proposed research program is, in some significant part, based on studies conducted on "coal tar" mixtures by Health Canada (HC). The HC studies do not appear to be available as yet to the public or, perhaps, even to the BSC. The *PAH Research Concept* document contains neither citations nor other information about the HC studies. These studies should be available to both the BSC and the public to allow thoughtful and thorough review of the *PAH Research Concept* document.

To illustrate just one basic and essential question that remains unanswerable without better understanding of the HC studies, the *PAH Research Concept* contains the information that the HC studies include one or more "coal tar" mixtures. The *PAH Research Concept* document does not include details such as which of the several types of material commonly referred to as "coal tar" is being tested by HC that eventually would also be studied by NTP.

The term "coal tar" is commonly used to refer:

o to the by-product of low-temperature gasification of coal that is often found at legacy Manufactured Gas Plant (MGP) sites,



- o to the by-product of high-temperature carbonization of coal produced in metallurgical coking ovens, and
- o colloquially, to many different individual materials or products that are manufactured using some quantity of a refined fraction of high-temperature coal tar.

Low-temperature and high-temperature coal tars have some physicochemical similarities, but potential exposure, chemical and toxicological profiles are different. Scientific studies available concerning different types of coal tars are varied. The comparative bioassays of benzo(a)pyrene and two MGP-type coal tar mixtures (Beland and Culp, 1998; Culp et al. 1998; Gaylor et al. 2000) conducted by the National Center for Toxicological Research (NCTR) are relevant to NTP's proposed PAH research program, especially if NTP's studies are to focus on PAH mixtures typical of MGP-type coal tars.

Unlike MGP-type coal tars, high temperature coal tars are refined into different fractions that are used beneficially in the manufacture of many products. Opportunities for exposure to unrefined carbonization coal tars are extremely limited. Opportunities for exposure to products manufactured using different refined coal tar fractions depend on the nature and intended use of the manufactured product. End-use products are manufactured using refined coal tar fractions as ingredients, which means the products are themselves a mixture containing ingredients other than refined coal tar. Some manufacturers may use different ingredients in otherwise functionally similar products. As with any toxicological studies, test material identification and characterization are paramount considerations. And the amount of existing information about products manufactured using refined coal tar fractions as ingredients varies depending on the intended use of the product. For example, significant research exists concerning human dermal exposure to products that contain refined coal tars as an essential ingredient in coal tar soaps, shampoos, skin creams and other skin medications commonly prescribed for psoriasis, eczema or dandruff.

The basic questions researchers must consider in designing studies of each of these PAH-containing substances illustrates that, without information about the HC studies, the "whole mixtures" aspect of the proposed *PAH Research Concept* cannot be evaluated by the BSC or the public. For this reason, the Council urges the BSC to defer further discussion of the proposed *PAH Research Concept* until the HC studies are available for evaluation by NTP researchers, the BSC and the public.

In summary, the Council requests that consideration of NTP's *PAH Research Concept* be deferred until such time as the HC studies that form the basis of the "whole mixtures" research design are available for public review. The Council also urges the BSC to



take the recommendations of EPA's SAB under advisement, and recommend that NTP prioritize testing of representative complex PAH mixtures, with validation of the RPF approach as a secondary consideration.

Thank you for your time and consideration. Please contact me by phone (703-299-8470) or e-mail (<u>alehuray@pavementcouncil.org</u>) with questions or requests for additional information.

Yours truly,

Anne P. LeHuray

Attachment

Comments of the *ad hoc* PAH Consortium to EPA's SAB PAH Mixtures Review Panel (April 27, 2010).

References

- Beland, F. and S. Culp. 1998. Chronic bioassay of two composite samples from selected manufactured gas plant waste sites. Division of Biochemical Toxicology, National Center for Toxicological Research, Jefferson, Arkansas. Technical Report 6722.02. Unpublished report.
- Culp, S.J., D.W. Gaylor, W.G. Sheldon et al. 1998. A comparison of the tumors induced by coal tar and benzo[a]pyrene in a 2-year bioassay. Carcinogenesis 19:117-124.
- EPA SAB (2011). Letter to Lisa P. Jackson from EPA SAB PAH Mixtures Review Panel dated March 17, 2011. <u>EPA-SAB-11-004</u>.
- Gaylor, D.W., S.J. Culp, L.S. Goldstein and F.A. Beland. 2000. Cancer risk estimation for mixtures of coal tars and benzo(a)pyrene. Risk Analysis 20(1):82-85.
- Interagency Comments for Docket ID No. EPA–HQ–ORD–2010–0047, Development of a Relative Potency Factor (RPF) Approach for Polycyclic Aromatic Hydrocarbon (PAH) Mixtures. http://www.regulations.gov/#!documentDetail;D=EPA-HQ-ORD-2010-0047-0002
- Public Comments for Docket ID No. EPA–HQ–ORD–2010–0047, Development of a Relative Potency Factor (RPF) Approach for Polycyclic Aromatic Hydrocarbon (PAH) Mixtures. http://www.regulations.gov/#!docketBrowser;dct=PS;rpp=25;po=0;D=EPA-HQ-ORD-2010-0047

