



March 4, 2015

Comments submitted to the SAB CAAC via email to Diana Wong

Public statement from Nancy Beck, PhD, DABT, on behalf of the American Chemistry Council, to the Scientific Advisory Board Chemical Assessment Advisory Committee (CAAC) for the review of the Draft IRIS Benzo[a]pyrene Assessment.

Good Afternoon.

I am providing remarks today on behalf of the American Chemistry Council (ACC). We greatly appreciate the willingness of each of you to volunteer your time to serve on this committee. Not only is it important to get the benzo[a]pyrene (BaP) science correct, but as this is one of the first semi-revised IRIS assessments you are reviewing, your comments on the structure, approach and methodologies used in this assessment will have precedent setting implications for many other IRIS assessments.

ACC commented in 2013 on an earlier version of the assessment you are currently reviewing. In Appendix G, EPA responds to public comments and in many cases has made appropriate changes and provided clear rationales. However, as will be noted by my colleague, EPA did not respond to any of the comments we provided.

My comments now will focus on the general charge questions and I would like to bring five points to your attention.

- 1) ACC is very concerned that many of the charge questions have been written such that a “yes” or “no” response would be sufficient. In the past, SAB has not approved questions like this due to a concern that answers would not be robust and sufficiently informative. It is unclear to us why this charge is unique in asking for some “yes” or “no” responses. While we have been told that EPA does not expect such terse answers, we suggest adding the following language to the introduction of the charge to ensure answers that are sufficiently helpful to resolve scientific differences:

“While some questions may allow for “yes” or “no” answers, such responses would not be considered sufficiently helpful to EPA and stakeholders. Please ensure that all answers

to charge questions below include a thorough justification and rationale explaining each response.”

- 2) Charge Question 5, regarding the handling of public comments, should be more robust. Unfortunately, in a recent review the CAAC is simply commenting on whether or not EPA provided a response and not on whether or not they agree with the substance of the response. This type of response is not sufficient for an SAB review. While responses are the Agency’s responsibility, the goal of external peer review is to provide constructive commentary on the Agency’s science, which in this case includes evaluating the reasoning presented in Appendix G. We suggest the question be revised as follows¹:

In August 2013, EPA asked for public comments on an earlier draft of this assessment. Appendix G summarizes the public comments and this assessment’s responses to them. ~~Please comment on EPA’s response to the scientific issues raised in the public comments.~~ Please consider in your review whether there are scientific issues that were raised by the public as described in Appendix G that may not have been adequately addressed by EPA.”

- 3) As I noted above, this assessment is among the first five where the IRIS program has attempted to revise the structure and approach to the assessment in accordance with the NRC’s recommendations. Unfortunately, you have not been asked any questions about this revised structure and approach. We would encourage you to comment on these elements including, but not limited to: the accuracy of the preamble in reflecting approaches taken in the BaP assessment, and how well EPA implemented 2011 NRC recommendations noting that that all critical studies need to be thoroughly evaluated with standardized approaches that are clearly formulated and that “strengthened, more integrative, and more transparent discussions of weight of evidence are needed.” An example of specific charge questions can be found by looking at the recent CAAC charge for review of the IRIS ammonia assessment.²

¹ Note that this edit makes the question consistent with the charge questions used by the CAAC panel reviewing the IRIS Ammonia Assessment.

² The Ammonia charge can be found here: [http://yosemite.epa.gov/sab/sabproduct.nsf/0/2FE334E0BEC7A3CF85257B65005C500B/\\$File/Charge%20for%20Ammonia%20updated%20July%202014.pdf](http://yosemite.epa.gov/sab/sabproduct.nsf/0/2FE334E0BEC7A3CF85257B65005C500B/$File/Charge%20for%20Ammonia%20updated%20July%202014.pdf). The general questions of relevance include: “1. NRC (2011) indicated that the introductory section of IRIS assessments needed to be expanded to describe more fully the methods of the assessment. NRC stated that they were “not recommending the addition of long descriptions of EPA guidelines to the introduction, but rather clear, concise statements of criteria used to exclude, include, and advance studies for derivation of [toxicity values].” Please comment on whether the new Preamble provides a clear, concise, useful and objective description of the guidance and methods that EPA uses in developing IRIS assessments. 2. NRC (2011) provided comments on ways to improve the presentation of steps used to generate IRIS assessments and indicated key outcomes at each step, including systematic review of evidence, hazard identification, and dose-response assessment. Please comment on the new IRIS document structure and whether it will increase the ability for the assessments to be more clear, concise, and easy to follow. 3. NRC (2011) states that “all critical studies need to be thoroughly evaluated with standardized approaches that are clearly formulated” and that “strengthened, more integrative, and more transparent discussions of weight of evidence are needed.” NRC also indicated that the changes suggested would involve a multiyear process. Please comment on EPA’s success thus far in implementing

We also encourage you to add a charge question regarding the clarity and utility of the executive summary.

- 4) In 2011, the NRC recommendations to EPA focused on the need to have clear criteria for study selection and evaluation. This is a critical step in any IRIS assessment. We suggest that charge question 1 be broadened as follows:³

Literature Search/study selection and evaluation. ~~Is the literature search strategy well documented? Please identify additional peer-reviewed studies that might have been missed.~~ Please comment on whether the literature search approach, screening, evaluation, and selection of studies for inclusion in the assessment are clearly described and supported. Please comment on whether EPA has clearly identified the criteria (e.g., study quality, risk of bias) used for the selection of studies to review and for the selection of key studies include in the assessment. Please identify any additional peer-reviewed studies from the primary literature that should be considered in the assessment of noncancer and cancer health effects of BaP.

- 5) Finally, as you have likely been made aware, in FY12 the SAB adopted initiatives to enhance public involvement in advisory activities.⁴ In addition to ensuring that charges are not unduly narrow and that there is sufficient opportunity for public comment, the initiatives also note that “Advisory committee reports will acknowledge scientific information from the public that was helpful in forming the committee’s conclusions and recommendations.” While we know the task ahead of you is great in regards to reviewing the science, your input on how the public can be more helpful would also be appreciated.

Thank you again for the time and energy you will put into this important review. I would be happy to answer any questions.

these recommendations. 4. EPA solicited public comments on the draft IRIS assessment of ammonia and has revised the assessment to respond to the scientific issues raised in the comments. A summary of the public comments and EPA’s responses are provided in Appendix G of the Supplemental Information to the Toxicological Review of Ammonia. Please consider in your review whether there are scientific issues that were raised by the public as described in Appendix G that may not have been adequately addressed by EPA.”

³ Note this suggested language is consistent with the language used by the CAAC panel evaluating the IRIS Ammonia Assessment.

⁴ The SAB FY12 Initiatives can be found here:

<http://yosemite.epa.gov/sab/sabproduct.nsf/WebSABSO/PublicInvolvement?OpenDocument>