



May 22, 2014

Comments submitted to the SAB CAAC via email to Thomas Carpenter

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 Trimethylbenzene (TMB) 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 trimethylbenzene 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 on an earlier version of the assessment you are reviewing in 2012. However, since no redline is provided by the Agency and the current Appendix F (resolution of public comments) is a bit vague, it is difficult to determine exactly what changes the Agency has made regarding the general approach, which relates to general charge questions 1-3 as well as some of the chemical specific charge questions. It appears that sufficiently responsive changes have not yet been made since 2012. Thus, our previous comments are still relevant and we would like you to consider them as you conduct your review. We have sent them to the SAB and they have been made available to you on the SAB's meeting webpage.

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

- 1) In response to general charge question 1, while EPA states that they have implemented the 2011 NAS recommendations, we do not agree that this implementation is responsive or sufficiently helpful. In the new preamble, EPA offers an abbreviated view of EPA policies, guidance and planned standard practices but fails to include the detail necessary to provide useful information on how the Agency reviewed or weighed scientific information in the

current TMB assessment. This abbreviated view omits critical information and simply is not useful for informing stakeholders about the process that was used in this particular assessment. Our detailed comments are available on this concern in the 2012 Comments from the Hydrocarbon Solvents Panel and even further details are available in the ACC/ARASP Comments on the draft IRIS handbook that have been made available to you as well. In addition, the 2014 NAS review on the IRIS process continues to express concerns with the preamble and notes that “it does not substitute for an overview that indicates how the general principles in the preamble have been applied in any given assessment” (Page 5). This is a major gap in the TMB assessment. Additionally, the NAS has recommended that the preamble be peer reviewed. We agree with this recommendation as the current version inappropriately communicates new criteria, guidance and approaches that have not been transparently peer reviewed. We encourage you to recommend further revisions, an opportunity for stakeholder input, and peer review regarding the preamble.

- 2) Charge question 3 focuses on EPA’s implementation of a standardized and transparent approach to identifying, presenting, and integrating evidence. We encourage you to look closely at EPA’s approach. For instance, the “systematic review” of the evidence identifies, in Figure LS-1, 24 animal studies addressing neurotoxicity and 5 animal developmental studies. However, in Section 1 it is not clear where all these studies are discussed and only some of the studies are presented in each of the relevant summary tables (e.g., there is only 1 study presented in Table 1-4, where there should be 5 studies). EPA has provided no criteria or guidelines by which they evaluated the quality and relevancy of studies that became the critical studies. Transparency and the use of *a priori* criteria by which to evaluate and choose studies is critical for this assessment as well as future IRIS assessments. This is consistent with recommendations made by the NAS in 2011 and was further reiterated earlier this month in the NAS 2014 review. We do not believe the TMB review is sufficiently transparent or responsive in this regard.
- 3) Finally, in response to charge question 4, we are concerned that EPA’s Appendix F, the response to comments appendix, is not sufficiently responsive. For instance, in EPA’s first response on page F-1 it is impossible to determine what changes EPA has made and when they were made. We cannot judge if EPA is referring to the approach used in the 2012 draft or if EPA is referring to new changes made in response to comments received in 2012. Thus we cannot tell if EPA agrees with the comment and has made new changes or if EPA disagrees with the comment and has not made further changes. In addition if you read the responses closely, you will see that in certain situations, EPA is not responding directly to the comment that was raised and in at least one case responds to concrete scientific evidence with broad generalized statements made in older EPA guidance documents. We encourage EPA to rely on the scientific evidence and hope that your review will be supportive of this

approach. In addition, consistent with previous recommendations from the SAB/BOSC¹, we encourage this panel to similarly recommend that EPA put in place strategies to ensure that recommendations from the public and peer reviewers are appropriately addressed. Adequate response to public comments is an important component to the assessment development process as this helps to ensure that the draft assessment that the CAAC receives addresses scientific issues already raised. Similarly, it will be important to ensure that the final draft is responsive to your recommendations. Currently, EPA staff responsible for writing and producing the assessments are the sole judge and jury of the adequacy of responses.

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

¹ See SAB/BOSC 2012 report available at:
[http://yosemite.epa.gov/sab/sabproduct.nsf/3822EB089FCCB18D85257A8700800679/\\$File/EPA-SAB-12-012-unsigned.pdf](http://yosemite.epa.gov/sab/sabproduct.nsf/3822EB089FCCB18D85257A8700800679/$File/EPA-SAB-12-012-unsigned.pdf).