June 2, 2014

Comments submitted to the SAB CAAC via email to Suhair Shallal

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 Ammonia 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 ammonia 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 2012 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, in a few cases, it is not clear to us that EPA has been sufficiently responsive. We are pleased to see that a general charge question has been included which asks the CAAC to comment on these responses.

My comments now will focus on the general charge questions and I would like to bring five 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 sufficiently useful information on how the Agency reviewed, evaluated or integrated the scientific information in the current ammonia 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 ARASP on the draft Ammonia assessment and even further details are available in the ACC/ARASP Comments on the draft IRIS handbook. We have made both these documents available to you.

Similarly, the 2014 NAS review on the IRIS[1] 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 ammonia 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.

We hope your review will go beyond the charge question regarding whether the preamble is "clear and concise", and will also address the utility of the preamble as it relates to the conduct of the draft ammonia assessment.

2) Charge question 2 focuses on the new document structure. As you have likely noticed the supplemental information/appendices is as large as the main document and when you review the response to comments, you will see that much critical information regarding the studies has been relegated to the supplemental information. Your comments and feedback on this approach will be very helpful for this assessment as well as future assessments.

3) Charge question 3 focuses on EPA's implementation of a standardized and transparent approach to identifying, presenting, and integrating evidence. We hope you will closely examine EPA's approach. To help inform your review, we encourage you to look at the recent NAS IRIS Review, released in May 2014. In this review the NAS evaluates the draft ammonia assessment, the same exact draft you are evaluating, to see how it compares to some of the elements of a robust systematic review process. As you will find in the NAS review, the draft ammonia assessment falls short in certain areas. Your constructive comments here will help to improve not only this assessment, but also future IRIS assessments.

4) In response to charge question 4, consistent with previous recommendations from the SAB/BOSC[2], we encourage this panel to 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 of the assessment

[1] See http://www.nap.edu/catalog.php?record_id=18764
[2] See SAB/BOSC 2012 report available at: http://yosemite.epa.gov/sab/sabproduct.nsf/3822EB089FCCB18D85257A8700800679/$File/EPA-SAB-12-012-unsigned.pdf.

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.

5) Finally, we were pleased to see that EPA has added a chemical-specific question related to the endogenous production of ammonia and your insights on EPA's approach will be greatly appreciated. While EPA states that the amount of ammonia in breath exhaled from the nose and trachea is lower than the draft RfC, the draft RfC is in the range of breath exhaled from the mouth and oral cavity. Our assumption would be that the body therefore experiences ammonia exposures that are similar to those found in the mouth and oral cavity. However, EPA states that the breath exhaled from the nose and trachea is thought to be a better representation of the ammonia levels in the lung or trachea-bronchial region and thus more relevant for understanding systemic ammonia levels. Unfortunately, EPA provides no citations for this statement, thus your input into this very important question will be very important.

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