December 17, 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). ACC appreciates all the time and effort you have put into your review of the draft IRIS Ammonia Assessment; the draft report is extremely thorough. Since my time is limited today, I will not be able to comment on all the recommendations we agree with and support (particularly those that are consistent with NRC 2014 and IOM 2011 recommendations for systematic review), but will only point out a few areas where we think the report could be strengthened.

1) It is clear that a lot of time and attention has been given to the charge question that asks about the preamble. We believe this level of review is appropriate. In discussing the clarity of the preamble the draft report recognizes that the preamble describes the general approach and methods that will eventually be used by the IRIS program for all assessments. The draft report also recognizes that the extent to which the preamble methods and approaches were applied in the Ammonia Assessment is not clear. The relevance of the preamble to a particular assessment may not be clear to readers of a final assessment and should be explicitly stated in the final IRIS assessment. We are already seeing other program offices refer to completed IRIS assessments as having followed a systematic review process consistent with National Research Council recommendations. While those that follow IRIS closely recognize that it will be a few more years before any IRIS assessment will be fully consistent with the recommendations, many other users, including those that are interested in just one chemical, may not be aware of this. Thus, it is important that the preamble include a clear statement noting that it is not specific to the Ammonia Assessment and does not represent the methods and approaches that were followed as EPA developed the assessment.

Alternatively, the CAAC could recommend that the preamble be amended to reflect the relevant processes and procedures that were in fact applied in the Ammonia Assessment.

2) ACC is supportive of your recommendation to EPA to try to obtain individual level data from the Holness publication. As the *Science* editor-in-chief, Marcia McNutt, recently noted: "Reproducibility, rigor, transparency, and independent verification are cornerstones of the scientific method".[1] Obtaining these data, and making them available to all stakeholders, is preferred. However if the data are not made available, and if EPA subsequently finds that there is not sufficient information available to estimate the mean concentration for the high exposure group, it may be helpful for your report to provide EPA with an alternative path forward. Upon reading the report, it was not clear what the CAAC would recommend in such a situation. Having a recommendation in the final report would be quite helpful and would likely allow EPA to finalize the assessment most expeditiously. For example, the CAAC may want to recommend that EPA not rely on the Holness publication if the individual level data is not made publicly available.

3) Regarding the review process for this assessment, we were confused by the sentence on page 9 (at line 27) that notes that the Ammonia Assessment has been reviewed by the NRC. While the NRC evaluated how well EPA had followed a systematic review approach, they did not review how well EPA had responded to public comments on all aspects of the draft assessment. Thus the NRC review should not be seen as a substitute for your review of how substantively EPA has responded to public comments. Providing responses to public comments and ensuring that the responses are scientifically sound and appropriately incorporated into the final assessment is an important part of the IRIS process and thus is part of the charge EPA provided to you.

Finally, the report contains many excellent observations and recommendations that will help bring the IRIS program closer to implementing the NRC recommendations from both 2011 and 2014. As ACC has noted before, not only is it important to get the ammonia science correct, but as this assessment reflects implementation of some of the enhancements to IRIS assessment process[2], your comments on the structure, approach and methodologies used in this assessment will have precedent setting implications for many other IRIS assessments.

Thank you again for the all the time, energy, effort, and good thoughts you will continue to put into this important review. I would be happy to answer any questions.

---

[1] See: http://blog.americanchemistry.com/2014/11/returning-to-fundamental-principles-can-help-science-live-up-to-the-public-trust/

[2] 2013 Enhancements to EPA's Integrated Risk Information System Program; http://www.epa.gov/iris/pdfs/irisprocessfactsheet2013.pdf