



November 17, 2016

Public statement by Nancy Beck, Ph.D., DABT on behalf of American Chemistry Council (ACC), submitted to the Science Advisory Board's (SAB) Chemical Assessment Advisory Committee (CAAC) for the review of the Draft IRIS Hexahydro-1,3,5-trinitro-1,3,5-triazine (RDX) Assessment.

Statement submitted via email to Diana Wong, EPA Designated Federal Officer.

Good afternoon members of the SAB CAAC;

Thank you for the opportunity to provide oral comments on behalf of the American Chemistry Council (ACC)¹ at the meeting of the SAB CAAC for the draft IRIS RDX assessment. A rigorous scientific peer review process is essential to ensuring that up-to-date science and the most relevant methodologies and data inform the RDX final assessment.

One of the main purposes of this teleconference is to discuss the charge questions that this group will address. This is a very important step. Consistent with SAB Fiscal Year 2012 Initiatives to Enhance Public Involvement in Advisory Activities,² public comments are welcome on the charge document and this committee will ensure that the charge is appropriate and not unduly narrow.

We have three recommendations for the charge that I hope you will discuss and incorporate today. Other CAAC panels have modified their charge questions based on public input (see for instance the record for the benzo[a]pyrene IRIS assessment) so you will be implementing a process that is important to enhance public engagement to ensure that the peer review is robust and helpful to stakeholders.

- 1) In response to comments from previous CAAC panels and public input, the draft RDX assessment contains a significantly revised Preamble. The revised Preamble is in some cases very responsive to suggestions received and in other cases, the suggestions have not been

¹ The American Chemistry Council (ACC) represents the leading companies engaged in the business of chemistry. ACC members apply the science of chemistry to make innovative products and services that make people's lives better, healthier and safer.

² EPA FY 2012 Initiatives to Enhance Public Involvement in Advisory Activities; website: <http://yosemite.epa.gov/sab/sabproduct.nsf/WebSABSO/PublicInvolvement?OpenDocument>

incorporated. IRIS staff had informed previous CAAC panels that this Preamble would be subject to its own review; however, this review does not appear to be planned.

The RDX draft assessment is the first assessment undergoing CAAC review where there is an opportunity for the CAAC to comment on this new Preamble. No similar opportunity for comment has been provided to the public. It would be very helpful if this panel added a charge question that allowed for the panel to provide comments on the utility of this revised Preamble.

Suggested charge language, for new charge question #6: “Preamble. Please comment on the utility and clarity of the Preamble.”

- 2) Charge question 3e(ii), asks whether the draft assessment adequately explains the rationale for the quantitative analysis of the cancer endpoint. This is important as EPA characterizes the cancer endpoint as providing “suggestive evidence of carcinogenic potential.” Consistent with the EPA Cancer Guidelines, EPA notes that when there is suggestive evidence, the agency would typically not conduct dose-response modeling as the nature of the data generally would not support it. In this case, EPA finds that the study supports dose-response modeling and is appropriately asking for your input on it.

The Cancer Guidelines also note that when evidence is “suggestive” it may be useful for some purposes (e.g., providing a sense of the magnitude and uncertainty of potential risks, ranking hazards or setting research priorities). Unfortunately, EPA has not described which particular purposes they think the quantified value should be used for; thus we are assuming that EPA is implicitly suggesting that the value should be used for all purposes. Considering the “suggestive” cancer classification, we recommend that this CAAC panel provide comments to EPA on the appropriate uses of this value. This information will be very important to risk managers and other IRIS users regarding the types of decisions that should be informed by the quantitative analysis.

Suggested charge language, added to 3e(ii), could include: “Considering the strength of the cancer evidence, please describe the types of uses that would be appropriately supported by the quantified cancer slope factor.”

- 3) The EPA IRIS staff are now interpreting their process to exclude responding to public comments when the IRIS assessments are made final. While the draft RDX assessment contains an Appendix D which responds to public comments, the final assessment (based on in the recent final assessments for ammonia and trimethylbenzenes) is not likely to include

any responses to public comments. The 2012 handbook for SAB members³ notes that you are expected to “thoroughly review” and “consider” public comments. To improve transparency, ACC recommends that this panel provide written responses to the public comments that it receives. Having a written record of how the panel considered the comments is particularly important now that EPA will not be providing any responses to stakeholder comments in the final RDX assessment. We recommend that the CAAC panel provide these responses in an appendix of the report that will be provided to EPA.

Suggested charge language could state: “Public Comments. In an appendix to your report, please provide responses to the substantive scientific comments that are provided to the committee by stakeholders.”

ACC appreciates the opportunity to provide these suggestions to you today. I would be happy to answer any questions you may have.

³ See EPA 2012 SAB Handbook for Members and Consultants available at: [https://yosemite.epa.gov/sab/sabproduct.nsf/WebBOARD/Serving%20on%20the%20EPA%20Science%20Advisory%20Board:%20A%20Handbook%20for%20Members%20and%20Consultants/\\$File/Serving%20on%20the%20EPA%20Science%20Advisory%20Board%20SABSO-12-001.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/WebBOARD/Serving%20on%20the%20EPA%20Science%20Advisory%20Board:%20A%20Handbook%20for%20Members%20and%20Consultants/$File/Serving%20on%20the%20EPA%20Science%20Advisory%20Board%20SABSO-12-001.pdf)