



August 20, 2013

Dr. Suhair Shallal
Designated Federal Officer
Chemical Assessment Advisory Committee
EPA Science Advisory Board
Ariel Rios Building
1200 Pennsylvania Avenue, N.W.
Mail Code: 1400R
Washington, D.C. 20460

Submitted via email to: shallal.suhair@epa.gov

Re: CAAC Engagement on the IRIS Assessment Process and the IRIS Instructional Materials

Dear Dr. Shallal:

We have reviewed the recently released meeting minutes from the April 2-3, 2013, Chemical Assessment Advisory Committee (CAAC) meeting and were pleased to see that “CAAC members did agree that some early involvement before an IRIS assessment has been developed is needed.”¹ Early engagement from the CAAC will be critical in helping to develop a strong, scientifically rigorous Integrated Risk Information System (IRIS) Program and ensuring robust peer review of IRIS related materials.

On January 30, 2013 the Environmental Protection Agency (EPA) IRIS Program submitted materials² (EPA Submission) to the National Research Council (NRC) committee reviewing the changes being implemented by the IRIS Program and identifying further opportunities to improve the scientific and technical performance of the IRIS Program. The EPA Submission includes detailed information regarding the changes EPA has made to the IRIS Program, and is proposing to make, to address the recommendations from the 2011 NRC *Review of the*

¹ See meeting minutes, page 7, available at:

[http://yosemite.epa.gov/sab/sabproduct.nsf/a84bfee16cc358ad85256ccd006b0b4b/1363EB27571284ED85257B0F0062F32B/\\$File/Summary+Minutes+CAAC--FINAL.pdf](http://yosemite.epa.gov/sab/sabproduct.nsf/a84bfee16cc358ad85256ccd006b0b4b/1363EB27571284ED85257B0F0062F32B/$File/Summary+Minutes+CAAC--FINAL.pdf).

² EPA Jan 30, 2013, Part 1: Status of Implementation of Recommendations

http://www.epa.gov/IRIS/pdfs/IRIS%20Program%20Materials%20to%20NRC_Part%201.pdf and EPA Jan 30, 2013; Part 2: Chemical -Specific Examples.

http://www.epa.gov/IRIS/pdfs/IRIS%20Program%20Materials%20to%20NRC_Part%202.pdf.



*Environmental Protection Agency's Draft IRIS Assessment of Formaldehyde*³ to improve the scientific methodologies used throughout the IRIS Program. It is important for the CAAC to be kept informed of IRIS Program's evolving approaches to the scientific analysis of potential hazards and risk of chemical exposures. Early constructive engagement and independent peer review of the IRIS handbook by the CAAC as EPA develops a standardized assessment process and IRIS Handbook would be consistent with the discussion at the April meeting and will assuredly help the IRIS Program. Without peer review of the IRIS Handbook by the CAAC, the CAAC may find itself repeatedly addressing the same or similar scientific shortcomings in any number of future IRIS assessments.

The American Chemistry Council (ACC)⁴ together with ACC's Center for Advancing Risk Assessment Science and Policy (ARASP)⁵ have been actively engaged in reviewing and providing scientific information to the IRIS Program. We strongly support the need for improvements in IRIS to ensure that the Program produces high quality and scientifically sound chemical assessments. To this end, we have reviewed the EPA Submission to the NRC IRIS Committee and welcome the opportunity to provide comments and share our perspectives on these documents with the CAAC. The enclosed Attachment (ACC and ARASP Comments on the EPA IRIS Program's January 2013 Submission to the NRC IRIS Committee) includes an Executive Summary, General Comments and Specific Comments on the EPA Submission. We have also submitted these comments directly to the IRIS Program as well as to the NRC Committee. ACC and ARASP commend EPA's efforts to improve its IRIS Program's documentation and to enhance consistency and transparency in developing hazard assessments. However, as noted in our attached comments, there are still opportunities for EPA to improve and refine its processes.

As you will see from the EPA Submission and from our comments, there are many important scientific issues that the IRIS Program will need to address in the near future as they work to improve the IRIS assessment process and develop a complete IRIS Handbook. We believe this provides an excellent opportunity for early engagement by the CAAC, as advisors, to help EPA

³ National Research Council, Review of the Environmental Protection Agency's Draft IRIS Assessment of Formaldehyde (2011). Available at https://download.nap.edu/catalog.php?record_id=13142

⁴ 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. ACC is committed to improved environmental, health and safety performance through Responsible Care®, common sense advocacy designed to address major public policy issues, and health and environmental research and product testing.

⁵ ARASP is a coalition of 19 organizations focused on promoting the development and application of up-to-date, scientifically sound methods for conducting chemical assessments. ARASP supports science based chemical assessments that utilize objective, transparent data acquisition and evaluation criteria. ARASP also advocates for the use of mode of action data in risk assessment. ARASP members include: Acrylonitrile Group, ACC's Chlorine Chemistry Division, Ethylene Oxide Panel, Formaldehyde Panel, Hexavalent Chromium Panel, High Phthalates Panel, Hydrocarbon Solvents Panel, Olefins Panel, Oxo Process Panel, Propylene Oxide/Propylene Glycol Panel, Public Health and Science Policy Team, Silicones Environmental, Health and Safety Center of North America and Vinyl Chloride Health Committee, American Cleaning Institute, American Petroleum Institute, CropLife America, Halogenated Solvents Industry Alliance, Nickel Producers Environmental Research Association, and Styrene Information and Research Center.



Dr. Suhair Shallal

August 20, 2013

Page 3

work through many of these complex issues (including, but not limited to: evaluating study quality, integration of toxicological, epidemiological and mechanistic information, dose-response analysis, and the role of endogenous exposures in hazard characterization).

In addition, on July 31, 2013, EPA released enhancements to the IRIS assessment process.⁶ This new process provides multiple opportunities for early engagement with all stakeholders and we encourage the CAAC to participate in the reviews and public meetings that will be forthcoming. One such opportunity for CAAC participation is the EPA's August 26th scheduled workshop that will focus on "Applying Systematic Review to Assessments of Health Effects of Chemical Exposures".⁷ In addition, EPA recently issued the enclosed Federal Register notice of several forthcoming meetings.

As the Designated Federal Officer for the CAAC, we are requesting that you share this letter and our comments with CAAC members. We understand that you will also likely post this correspondence on the April 2, 2013, CAAC meeting webpage as it pertains directly to the issue of early involvement in IRIS which was discussed at the April meeting and recorded in the April meeting minutes.

We appreciate the consideration that the CAAC will give to these comments and would be pleased to meet with you to answer any questions you may have. Please feel free to contact either one of us by phone (202-249-7000) or by email (Nancy_Beck@americanchemistry.com or Kimberly_Wise@americanchemistry.com) with any questions.

Sincerely,

Nancy Beck, Ph.D., DABT
Senior Director
Regulatory & Technical Affairs

Kimberly Wise, Ph.D.
Senior Director
Chemical Products & Technology, ARASP

Attachments:

- 1) ACC and ARASP Comments on the IRIS Program's January 2013 Submission to the NRC IRIS Committee
- 2) EPA Federal Register Notice of a Series of Public Meetings and the Availability of Preliminary Materials, August 9, 2013.

⁶ See EPA release documents available at: <http://www.epa.gov/iris/process.htm>.

⁷ See EPA Systematic Review Workshop Website: <http://www.epa.gov/iris/irisworkshops/systematicreview/>



Dr. Suhair Shallal
August 20, 2013
Page 4

cc:
Christopher Zarba, EPA
Dr. Ken Olden, EPA

