



September 24, 2012

Dr. Angela Nugent
Designated Federal Officer
SAB Staff Office
Mail Code: 1400R
U.S.EPA Headquarters
Ariel Rios Building
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460

RE: EPA's SAB Libby Amphibole Asbestos Review Panel's August 30, 2012, Draft Report of the LAA IRIS assessment.

Dear Dr. Nugent:

The American Chemistry Council (ACC) appreciates the opportunity to comment on EPA's SAB Libby Amphibole Asbestos (LAA) Review Panel's (SAB Panel or Panel) August 30, 2012, Draft Report of the LAA Integrated Risk Information System (IRIS) assessment. ACC¹ and its members make substantial, ongoing investments in research to support product development, health, safety and environmental protection, and to abide by product stewardship and regulatory policies. We have a significant interest in an IRIS process that is not only efficient and effective, but that objectively considers all relevant scientific data in each of its assessments. This letter addresses two very specific concerns that we hope the chartered SAB will consider.

The SAB Should Recommend that EPA Subject a Revised LAA IRIS Assessment to Further Public Comment and SAB Review Prior to Finalization

We appreciate the comprehensive comments of the SAB Panel. To address many charge questions, the Panel undertook a detailed review of the draft IRIS assessment and provided numerous constructive recommendations and suggestions. The Panel's report accurately states

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. 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. The business of chemistry is a \$720 billion enterprise and a key element of the nation's economy. It is one of the nation's largest exporters, accounting for ten cents out of every dollar in U.S. exports. Chemistry companies are among the largest investors in research and development. Safety and security have always been primary concerns of ACC members, and they have intensified their efforts, working closely with government agencies to improve security and to defend against threats to the nation's critical infrastructure.



that “there are many areas that need more consideration.”² For example, in regards to the reference concentration (RfC), the Panel recommends consideration of other exposure metrics, consideration of other models, including a more thoughtful approach to model selection, as well as a sensitivity analysis of additional exposure metrics. Similarly, for the cancer endpoint, the Panel suggests further justification and more support for the use of the statistical exposure-response analysis, including further evaluation of time dependence and model uncertainty, as well as more consideration of the literature on other amphiboles as EPA makes its model selection for dose-response assessment.³

To address the Panel’s recommendations, EPA’s IRIS office should explore and include a discussion of alternative modeling approaches that could have a significant impact on the final RfC and Inhalation Unit Risk value (IUR). In fact, until the analyses are conducted, and available for review, it is impossible to know what impact they will have. While it is unfortunate EPA has not extensively included consideration of such alternatives and robust analysis in the current draft LAA IRIS assessment, such analyses will greatly improve the scientific support for and utility of a final LAA IRIS assessment.

Therefore, after conducting these new analyses, EPA should solicit public comment and subject the revised draft LAA IRIS assessment to further peer review. This is analogous to a scientific manuscript that has been accepted, subject to revision, where the peer reviewers’ decision for acceptance is predicated upon expanded or additional data analyses necessary to inform the final conclusions. Following the author’s revisions, the revised manuscript is sent back to the original peer reviewers for their evaluation to ensure that the requested expanded or additional analyses have been made and the required major revisions have been fully and adequately incorporated.

Dr. Kenneth Olden, the newly appointed Director of EPA’s National Center of Environmental Assessment (NCEA), recently addressed the National Academy of Sciences (NAS) committee tasked with reviewing the IRIS program, and emphasized that openness and transparency will be a hallmark of his tenure at NCEA.⁴ Simply put, there is far too much additional analysis that must be incorporated and considered before EPA can finalize the LAA assessment. The public should have the opportunity to review and comment on these new analyses, and their implications, before the assessment is made final.

It is critically important that in its report to the EPA Administrator, the SAB Panel recommend that EPA move expeditiously to revise the draft LAA IRIS assessment, seek public comment, and then re-submit the revised draft to the SAB Panel for further review. In addition, the public

² See the SAB Aug 30, 2012 draft report at page 1 which states: “However, there are many areas that need more consideration, and we provide recommendations to further enhance the clarity and strengthen the scientific basis of the analyses.”

³ See the SAB Aug 30, 2012 draft report for specific and more detailed recommendations.

⁴ On September 17, 2012, Dr. Ken Olden addressed the NAS panel reviewing the IRIS process. He spoke of a “new day” at NCEA and the hallmark would be “openness and transparency.”

should be given an opportunity to provide input on additional charge questions the expert reviewers should address.

All Panelist Opinions Must Be Presented

The draft SAB report cursorily mentions that one panel member, Dr. Ferson, did not concur with the draft SAB report. However, nothing further is presented regarding his opinions or why he did not concur. A formal statement of Dr. Ferson's concerns and scientific judgments should be presented as part of the final SAB report. Additionally, as EPA works to revise the assessment, the opinions of all panelists, including those that did not concur, should be considered and addressed.

Thank you for considering our comments. Please do not hesitate to contact me if you have any questions regarding this submission. I can be reached by phone at (202) 249-6717 or by e-mail at David_Fischer@americanchemistry.com.

Sincerely,

David Fischer

David B. Fischer, M.P.H., J.D
Senior Director