



April 24, 2012

Dr. Diana Wong
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

Dear Dr. Wong,

The American Chemistry Council (ACC) appreciates the opportunity to comment on the draft Libby Amphibole Asbestos (LAA) 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 fairly and reasonably considers all relevant scientific data. We have long sought to improve the quality of government science generally and risk assessment in particular.

As you are aware, in April 2011, a National Academy of Sciences (NAS) committee issued its independent scientific review of EPA's draft IRIS assessment of formaldehyde, which has broad implications regarding the assessment of other chemicals. As the NAS committee report documents, the IRIS program continues to fall well short of meeting the benchmarks of

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.



objectivity, scientific accuracy and transparency necessary to ensuring high quality, reliable assessments. Indeed, the expert committee felt so strongly about, “[t]he persistence of limitations of the IRIS assessment methods and reports...” that the committee included a separate chapter on a roadmap for revising the IRIS evaluation processes that applies to all ongoing and future IRIS assessments.

EPA has explicitly embraced the NAS recommendations and has publicly committed² to address all of them. Nonetheless, EPA has opted to gradually phase in the recommendations over a multi-year time frame. Consequently, numerous draft and final IRIS assessments will not benefit from all the NAS recommendations. These assessments, including the draft LAA IRIS assessment, therefore, continue to suffer from many of the very same critical scientific shortcomings that plagued the draft formaldehyde assessment.

In the draft LAA IRIS assessment, the most visible areas that fall short in meeting the data evaluation procedures specified by the NAS include:

1. Absence of transparent, scientifically objective data evaluation protocols for each major type of study – animal toxicity studies, mechanistic and in vitro studies, and human epidemiology studies. The draft LAA toxicological review does not provide a clear description of the criteria used by the Agency to determine which model was most appropriate for use in the exposure-response modeling.
2. Absence of an objective, transparent and systematic weight of evidence framework for integrating results from the full body of reliable scientific studies to determine whether a threshold or non-threshold mode of action would apply to the dose response for toxicity in humans and to establish cause and effect at relevant exposure levels.
 - a. The draft LAA toxicological review does not provide sufficient justification for the new and unpublished data sets used in the Agency’s assessment of cancer and non-cancer risks.
 - b. The Agency does not provide adequate justification for the composite uncertainty factor of 100 that was applied to the point of departure in order to calculate the reference concentration.
3. Absence of a “validity” or “plausibility” check, comparing the derived resulting health guidance values with the actual health outcome statistics in relevant populations.

²Written Testimony of Paul Anastas, PhD, Assistant Administrator for Research and Development, U.S. Environmental Protection Agency (EPA) Hearing on EPA’s Integrated Risk Information System Before the U.S. House of Representatives Committee on Science, Space and Technology, Subcommittee on Oversight, July 14, 2011 http://science.house.gov/sites/repUBLICans.science.house.gov/files/documents/hearings/071411_Anastas.pdf



To properly serve the needs of the public all stakeholders expect that the science relied on by IRIS will be firmly based on up-to-date scientific knowledge, meet the highest of standards of scientific inquiry and be evaluated in accordance with acceptable scientific approaches. Unfortunately, the current policies and practices and resulting assessments of the IRIS program do not consistently meet these standards.

The draft LAA IRIS assessment is another in the long line of IRIS assessments which have demonstrated data evaluation shortcomings leading to lack of confidence in the scientific conclusions drawn. Therefore, we believe it is important for the SAB to specifically recommend in its peer review report that EPA address and implement the critical and necessary improvements in the data evaluation and weight of evidence procedures in the draft LAA assessment before finalizing it, particularly because the Agency has not yet implemented its program-wide IRIS reforms. These improvements in data evaluation procedures speak specifically to scientific methodology, which is squarely in the purview of the SAB and is exactly the kind of science advice it has been tasked to provide to EPA.

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

