October 4, 2011

The Honorable John Shimkus
Chairman
House Subcommittee on Environment
and Economy
2125 Rayburn House Office Building
Washington, D.C.  20515

The Honorable Gene Green
Ranking Member
House Subcommittee on Environment
and Economy
2322A Rayburn House Office Building
Washington, D.C.  20515

Dear Chairman Shimkus and Ranking Member Green:

The American Chemistry Council (ACC) welcomes your Subcommittee’s hearing on the Environmental Protection Agency’s (EPA) Integrated Risk Information System (IRIS). ACC and its members have a significant interest in the IRIS program, and we are pleased to provide these comments in advance of your hearing.

In April, 2011, the National Academy of Sciences (NAS) released its review of the draft IRIS assessment for formaldehyde. The report included a number of recommendations to improve the IRIS process, including fundamental changes to the manner in which the IRIS program obtains scientific data, analyzes studies, integrates data using a weight of the evidence approach, conducts causal determinations, and assesses uncertainty. Some of the scientific inadequacies pointed out by the NAS report have persisted for more than a decade. I have attached a summary of the NAS committee’s recommendations to IRIS for the Subcommittee’s information.

On July 14, 2011, Dr. Paul Anastas, the Assistant Administrator for Research and Development at EPA testified before the Oversight Subcommittee of the Science, Space and Technology Committee. Dr. Anastas acknowledged the NAS review of the IRIS formaldehyde assessment, and indicated that the NAS recommendations would be addressed in a phased-in approach. While ACC welcomed the news that EPA will “fully implement” the NAS recommendations for new assessments, we remain concerned that IRIS assessments currently underway will not benefit from the suite of changes recommended for the program.

IRIS currently lists 49 substances for which it expects to complete assessments between now and the second quarter of 2012, and an additional 14 assessments for which completion dates are yet to be determined.1 Based on our understanding of Dr. Anastas’ July, 2011 statement, however, most if not all of these assessments will not be improved to address the NAS recommendations. For example:

- EPA has indicated that assessments already released for peer review or that have been peer reviewed would be revised to address the peer review comments. Over one-third of the pending and near-term IRIS assessments appear to fall into this category (24 of 63). However, we are not aware that any of

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1 The list of substances is available on EPA’s IRIS Track website, at http://cfpub.epa.gov/ncea/iristrac/.
the charge questions posed to the peer reviewers specifically addressed whether the draft IRIS assessments fully comported with the NAS recommendations to improve IRIS.

- EPA also indicated that for assessments under development but not yet released for peer review, the rationale for study selection and evidence evaluation would be examined to ensure they are “clear.” Assuming that pending and near-term assessments fall into this category, it appears that EPA is likely to fall woefully short of implementing the complete set of NAS recommendations.

- The NAS review also recommended, among other things, the development of clear guidelines for study selection and a standardized approach to weight-of-the-evidence guidelines. However, the EPA has only committed to providing clarity on what studies and evaluation approaches were used, not to ensure the application of a uniform approach. Equally as important, EPA apparently will not apply the NAS recommendations concerning the calculation of reference doses and unit risks to these assessments, suggesting that the conclusions reached in the assessments will not be complete.

In short, ACC is concerned that an entire generation of IRIS assessments due to be completed in the next 9 to 12 months will suffer from the very same shortcomings that plagued the draft formaldehyde assessment. Flawed assessments create public confusion, unwarranted alarm, unnecessary product de-selection and litigation, all of which can put jobs at risk without sound scientific basis. Moreover, these shortcomings may have significant unwarranted economic impacts, because risk management decisions throughout the federal government, as well as state governments, routinely draw upon the risk numbers contained in IRIS assessments.

ACC believes it is incumbent on the IRIS program to fully implement the NAS recommendations on all pending and near-term assessments. Adopting these changes will improve the reliability of IRIS assessments and their credibility as a basis for future regulation. These changes will also ensure that the IRIS program completes assessments more efficiently and provides answers to the public, public health professionals and industry in a far more timely way.

We commend your Subcommittee’s attention to the quality of government assessment programs and the scientific review process. If we can provide any additional information on ACC’s view of the IRIS program, please let me know.

Sincerely,

Cal Dooley
President and CEO

Attachment