Moving Forward With IRIS Reform:
Implementing National Academies’ Roadmap for Revisions

April 18, 2012

In its 2011 review of the US Environmental Protection Agency’s (EPA) draft Integrated Risk Information System (IRIS) assessment for formaldehyde, a National Research Council (NRC) committee identified “recurring methodologic problems” with IRIS assessments generally, and offered a “roadmap for revisions.” The committee recognized that implementation of its recommended changes would “involve an extensive effort by EPA staff and others.” To aid in this effort, the George Washington University Regulatory Studies Center and Center for Risk Science and Public Health teamed up with the National Capital Area Chapter of the Society for Risk Analysis to host a panel discussion on “Moving Forward With IRIS Reform: Implementing the National Academies’ Roadmap for Revisions.”

The event was held at the George Washington University on April 18, 2012, and attracted more than 70 participants from government, academia, the private sector, and non-governmental organizations.

GW Professor George Gray, Director of the Center for Risk Science and Public Health, moderated the discussion.

Professor Lynn Goldman, Dean of the GW School of Public Health and Health Services and former Assistant Administrator for the EPA's Office of Prevention, Pesticides and Toxic Substances, provided background on the evolution of IRIS, considering it one of the most important resources on chronic and cancer toxicity in the world. She encouraged Congress and others to give EPA time to respond to the NRC recommendations but suggested it may be time to rethink paradigms to ensure that IRIS addresses information critical to decision makers and enables the use of risk analysis tools by more parties to promote product de-selection.

Professor Yiliang Zhu, professor of epidemiology, biostatistics, and internal medicine at the University of South Florida served as a member of the NRC Committee that reviewed EPA's draft IRIS assessment of formaldehyde, as well as the committees that reviewed IRIS assessments of dioxin and tetrachloroethylene. He summarized the NRC formaldehyde report and focused on the Committee’s recommendations for progress on the IRIS program overall. Specific areas included
study evaluation approaches, use of consistent weight-of-evidence evaluations and characterization of uncertainty in risk estimates.

**Chuck Elkins**, President, Chuck Elkins & Associates and former Director for the EPA Toxic Substances Program, encouraged EPA to engage stakeholders more effectively throughout the assessment process. He recommended more oversight of the peer review process, envisioning a role similar to that of a journal editor.

**Rebecca Clark**, Acting Director for the EPA National Center for Environmental Assessment, explored myths and concerns surrounding the IRIS process. Among the myths – that IRIS involves risk assessment (rather than hazard assessment which does not consider exposure), and that EPA does not engage in peer review. She said EPA embraces the recommendations in chapter 7 of the NRC report and suggested that the recent TCE assessment reflects many of the recommendations.

**Heidi R. King**, Chief Economist, House Energy and Commerce Committee, said that Congress attempts to balance competing concerns to serve their constituents, and that Members are interested in IRIS because it is influential in policy decisions. She encouraged participants to recognize the tradeoffs involved in setting IRIS levels, including the possible negative health consequences of chemical substitutions. She observed that single point estimates are not informative for identifying and managing the most important risks.

During the discussion, panelists discussed creative ways to make IRIS more timely and effective, including changing its focus to provide an array of information to facilitate risk analysis by different users, supporting emerging approaches to data gathering and processing (e.g., crowd sourcing), and matching the level of effort in the assessment to the needs of users.