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of the Committee on Science, Space, and Technology

"EPA's IRIS Program: Evaluating the Science and Process Behind Chemical Risk Assessment"

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Good morning Mr. Chairman and Members of the Committee. I am Cal Dooley, president and CEO of the American Chemistry Council. I appreciate the opportunity to be here today to speak to the pressing need to fix the Environmental Protection Agency's (EPA) Integrated Risk Information System, or IRIS.

Shortly after taking office, President Obama committed that science and the scientific process would guide decisions of his Administration. We at the American Chemistry Council (ACC) welcomed this pledge, because we agree that credible, accurate, modern science must form the foundation of regulatory decisions.

Three years later, though, our confidence in the Administration's commitment to scientific integrity in the regulatory process has eroded. This is in large part due to troubling inconsistencies, inefficiencies and lack of transparency in the federal system for assessing the safety of chemicals.

IRIS is one of the most important programs EPA uses to assess chemical safety. It serves as a leading source of health risk information for other federal, state, and international regulatory bodies. But over the years, the program has been repeatedly criticized for failing to consistently meet high standards of scientific inquiry, transparency and quality.

It is time to fix the IRIS program to protect health, safety and the environment and preserve the ability of American industry to innovate, compete and create jobs.

Several examples illustrate the shortcomings of the IRIS program:

Formaldehyde

Perhaps the most telling example can be found in the recent case of formaldehyde. Formaldehyde has been the subject of scientific study for years. Numerous organizations including the World Health Organization have concluded that a large body of evidence shows that the levels of formaldehyde most people encounter do not cause adverse health effects. Despite this, EPA completed its IRIS review of formaldehyde in 2010, asserting that a link exists between exposure to formaldehyde and certain types of leukemia. EPA's conclusions quickly came under scrutiny. To provide clarity, EPA asked the National Academies of Science (NAS) to convene an expert Committee to review its findings.

The NAS Committee issued its report earlier this spring and in it, they questioned the evidence EPA used to support its conclusion. In the report NAS stated:

> **"Conclusions appear to be based on a subjective view of the overall data, and the absence of a causal framework for these cancers is particularly problematic given the inconsistencies in the epidemiologic data, the weak animal data and the lack of mechanistic data."**

In the report, the NAS Committee also offered a harsh critique of the IRIS program in general. In fact, the expert committee felt so strongly that they included an *entire chapter* devoted to the program improvements that they saw as "critical for the development of a scientifically sound IRIS assessment." The NAS report stated:

> **"The committee is concerned about the persistence of problems encountered with IRIS assessments over the years, especially given the multiple groups that have highlighted them. If the methodologic issues are not addressed, future assessments may still have the same general and avoidable problems that are highlighted here."**

Hexavalent Chromium

In 2009, industry undertook a multi-million dollar mode-of-action research program to develop new data that EPA could use to assess the risk that Cr6 poses from low-level, environmentally-relevant exposure through drinking water. The research was directly responsive to the data needs of the Agency, and EPA staff was consulted during the process of developing the research plan.

Despite the pending research, due later this year, the agency significantly accelerated its timetable for the hexavalent chromium IRIS assessment, publishing a draft in late 2010. EPA's independent peer review group expressed significant concerns about the scientific quality of the draft assessment, citing knowledge gaps, including those that could be filled by the industry research. EPA still intends to finalize the IRIS assessment by the end of September, about the same time that the new research should be completed.

With this intensive schedule, we are concerned that EPA will not fully incorporate the extensive comments from EPA's peer review group. Failure to address the peer review comments and include the new research findings will result in a risk assessment that will be out-dated and inaccurate as soon as it is released.

Dioxin

The IRIS program first published its draft assessment of dioxin in the mid nineteen-eighties, but it remains a point of contention today. Specifically, both EPA's own Science Advisory Board (SAB) and the NAS criticized the model that EPA used in the IRIS assessment to evaluate cancer risk.

In 1995, the Scientific Advisory Board told the IRIS program that it was inappropriate to extrapolate using a linear low dose method to estimate cancer risk to humans. EPA revised the assessment, but failed to follow the SAB directive.

In 2006, after reviewing EPA's 2003 reassessment of dioxin, the NAS concluded – unanimously – that a non-linear method (as opposed to a linear dose-response model) should be used to extrapolate for estimating cancer risk to humans.

Despite the National Academy's 2006 recommendation, EPA's reanalysis of key issues in the dioxin assessment again used a linear dose-response model.

Sixteen years after EPA was given a clear recommendation by the SAB peer review to use a model that reflects knowledge of mode of action in the dioxin IRIS assessment, IRIS continues to push an out-dated risk assessment model for dioxin. Based on the expert review in 1995 and 2006, IRIS has no scientific justification for doing so.

Inorganic Arsenic

In a case similar to dioxin, EPA defaulted to a linear no-threshold model in its draft IRIS assessment of inorganic arsenic, disregarding the 2005 EPA peer review panel recommendation to consider a threshold model. This is critical because applying the proposed model would result in naturally occurring levels in many soil and water supplies around the country being considered "unacceptable" by EPA guidelines.

If this draft IRIS assessment stands, it could lead to confusion, undue concern and unnecessary costly modifications to water treatment systems, the abandonment of water sources, and the forced identification of alternative water supplies. And it could create the impression that typical arsenic levels in foodstuffs such as rice, fish, grapes, and other common foods could be cancer-causing.

These examples clearly demonstrate that IRIS has failed to evolve with the significant progress that has been made in the science and technology of chemical risk assessment.

Over the years, researchers and health professionals have gained a greater scientific understanding of the human body; the ways chemicals can interact with the body at different levels of exposures; and how that knowledge applies to determine the safety of chemical uses. However, IRIS risk assessments lag behind these advances and rely too heavily on outdated assumptions formulated in the 1970s.

For example, IRIS assessments of carcinogenic responses in high-dose animal studies typically take the most conservative default approach, rather than applying relevant mode of action and real world exposure information to more accurately show the risk to humans.

In effect, IRIS has clung to risk assessment approaches that assume that there is no safe dose or threshold – even when experts tell the program otherwise – as was the case with dioxin and inorganic arsenic. IRIS's failure to integrate this information into program decisions undermines the development of new science-based risk assessment practices, wastes investments in research and undercuts effective public health science policy.

Not only has IRIS failed to keep pace with modern science, the program lacks the scientific accountability needed to be considered objective and credible.

There is little independence in the IRIS program's standard peer review process: the IRIS office controls the development of the assessment, the design of the peer review charge questions, and the evaluation of the peer review findings. Ultimately, the IRIS program itself decides which recommendations from peer review groups to act upon and which to ignore. As we have seen in the case of dioxin, the IRIS office has exhibited steadfast reluctance to upgrade the assessments in response to the demands of independent peer reviewers.

To restore credibility to the program, there must be an honest broker to ensure that EPA adequately considers and incorporates changes from peer reviews and public comments. That is why ACC has called for the NAS to review all pending IRIS assessments. Unfortunately, EPA dismissed this suggestion saying, "IRIS is a model for openness, transparency, scientific integrity and scientific quality."

Anyone who looks at the evidence, whether you are a state regulator, a public health official or a furniture maker, can see that the IRIS program is broken and fails to effectively support EPA's mission to protect public health and the environment.

EPA's refusal to fully acknowledge and rectify the many problems with the IRIS program calls for Congress to step in.

EPA must be required to take immediate steps that will ensure pending IRIS assessments meet the highest standards of accuracy and scientific integrity:

- IRIS assessments in progress should incorporate the recommendations described in Chapter 7 of the NAS panel formaldehyde scientific peer review report where they are applicable;

- IRIS assessments that are currently in draft form (or that will be issued as draft for public comment and peer review in 2011 and 2012) should be submitted to the NAS for independent scientific peer review; and,
- Revised IRIS assessments developed by the Agency must be evaluated (preferably by the same NAS panel that conducted the initial peer review) to ensure that the peer review panel's findings and recommendations have been adequately and transparently addressed.

While NAS review of pending assessments will help improve the program in the interim, EPA must also initiate a comprehensive overhaul of the program to make IRIS effective and efficient in the future:

- Assessments must rely on proven scientific data instead of outdated assumptions;
- EPA must establish consistent data evaluation methods;
- EPA must adopt a consistent weight of evidence framework, based on transparent, rigorous evaluation methods, so that all available data can be taken into account, with the best and most relevant science given the greatest weight;
- Assessments should be based on 21st century knowledge of how chemicals interact with the human body;
- EPA must adopt proven approaches for evaluating cause, effect and uncertainty as part of IRIS assessments; and,
- EPA must enhance public comment and independent scientific peer review processes.

The IRIS program is a critical part of our chemical regulatory system, and it must be improved. The current deficiencies and lack of confidence in the program are resulting in delays and unnecessary costs as the frequent shortcomings in draft assessments are addressed. Flawed assessments have significant consequences in and of themselves. They create public confusion, unwarranted alarm, unnecessary product de-selection and litigation, all of which ultimately can put jobs at risk without sound scientific basis.

To be clear, ACC is not suggesting that IRIS assessments be suspended or delayed. We are proposing concrete ways to make pending and future reviews more accurate and more credible. Making the necessary changes will ensure that the program completes assessments more efficiently and provides answers to the public, public health professionals and industry in a far more timely way.

Thank you very much for the opportunity to testify. I look forward to taking your questions.