

**U.S. House of Representatives
Committee on Science, Space, and Technology
Subcommittee on Oversight
Subcommittee on Environment**

HEARING CHARTER

Status of Reforms to EPA's Integrated Risk Information System

Wednesday, July 16, 2014
2:00 p.m. – 4:00 p.m.
2318 Rayburn House Office Building

Purpose

On Wednesday, July 16, 2014, the Subcommittees on Oversight and Environment will hold a joint hearing entitled *Status of Reforms to EPA's Integrated Risk Information System*.

In May, the National Research Council (NRC) released a report, *Review of EPA's Integrated Risk Information System (IRIS) Process*.¹ This report is a follow-up assessment of how EPA is implementing recommendations from an NRC review published in April 2011 on EPA's formaldehyde assessment.² In the 2011 report, the NRC "strongly faulted EPA's methodology in crafting its draft assessment, warning of a pattern of problems in how the agency crafts assessments for its Integrated Risk Information System (IRIS) database that could continue to hamper future risk studies."³ Chapter 7 of the 2011 NRC report detailed the deficiencies in EPA's formaldehyde assessment as well as shortcomings with the agency's overall IRIS assessment methods.

This hearing will examine EPA's actions in response to both NRC reports in order to evaluate the status of the agency's reforms to the IRIS program. The Science, Space, and Technology Committee has held several hearings on this program, with the most recent one in 2011.⁴ Initially, these hearings focused on the IRIS interagency review process, and delved into the role of the White House and other agencies to determine the extent of their involvement in IRIS' chemical risk assessments. The focus of the most recent hearings, including this hearing, has shifted to reviewing the efficacy of EPA's overall IRIS process.

¹ NRC Report, "Review of EPA's Integrated Risk Information System (IRIS) Process," May 6, 2014, available at: http://www.nap.edu/catalog.php?record_id=18764; hereinafter NRC 2014 IRIS Report.

² NRC Report, "Review of the Environmental Protection Agency's Draft IRIS Assessment of Formaldehyde," April 8, 2011, available at: http://www.nap.edu/catalog.php?record_id=13142; hereinafter NRC 2011 Formaldehyde Report.

³ Maria Hegstad, "NAS Sets Back EPA Proposal For Strict Formaldehyde Risk Assessment," Environmental NewsStand, April 8, 2011, available at: <http://insideepa.com/Superfund-Report/Superfund-Report-04/18/2011/nas-sets-back-epa-proposal-for-strict-formaldehyde-risk-assessment/menu-id-1094.html>.

⁴ Subcommittee on Investigations & Oversight Hearing, "EPA's IRIS Program: Evaluating the Science and Process Behind Chemical Risk Assessment," July 14, 2011, available at: <http://science.house.gov/hearing/investigations-and-oversight-hearing-epas-iris-program>.

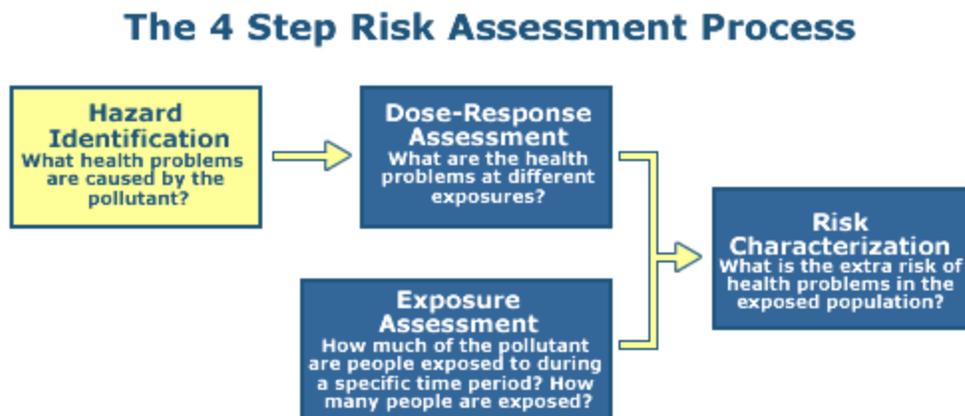
Witnesses

- **Dr. David Dorman**, Member, Committee to Review EPA’s IRIS Process, National Research Council
- **Dr. Kenneth Olden**, Director, National Center for Environmental Assessment, U.S. Environmental Protection Agency
- **Ms. Rena Steinzor**, Professor of Law, University of Maryland; President, Center for Progressive Reform
- **Mr. Michael P. Walls**, Vice President of Regulatory and Technical Affairs, American Chemistry Council

Background

IRIS was established in the 1980s as an internal EPA database to provide a single source of information on the risks associated with exposure to chemicals. The IRIS database provides hazard identifications and dose-response assessments of chemicals that cover cancer and non-cancer outcomes. Examples of potential non-cancer health effects addressed in IRIS assessments include effects on the immune system, the reproductive system, the nervous system and the endocrine system. Hazard identifications and dose-response assessments are two of the four components that allow regulatory agencies to produce risk assessments, with the other two components being exposure assessment and risk characterization. The National Academy of Sciences defines risk assessments as “the characterization of the potential adverse health effects of human exposure to environmental hazards.”⁵ Figure 1 further elaborates on the four-step risk assessment process.

Figure 1



Source: EPA website, available [here](#).

⁵ NRC Report, “Risk Assessment in the Federal Government: Managing the Progress,” 1983, available at: http://www.nap.edu/catalog.php?record_id=366.

Historically, entries to the IRIS database were the result of extensive in-house development by the science staff at EPA, peer review processes with experts from outside the agency, and opportunities for public input and comment. However, as IRIS grew and gained more influence, EPA restructured the IRIS process which led to the end of other, previously successful collaborative platforms. EPA's restructuring ultimately led to several reorganizations of the IRIS process, but the quality of IRIS assessments continue to be an issue of concern.

In addition to the NRC report in 2011, the U.S. Government Accountability Office (GAO) also reviewed the IRIS program in March 2008. GAO reported that "the IRIS database was at serious risk of becoming obsolete because EPA had not been able to routinely complete timely, credible assessments. After subsequent reports, in January 2009 [GAO] added EPA's processes for assessing and controlling toxic chemicals to [its] list of areas at high risk for waste, fraud, abuse, and mismanagement or in need of broad-based transformation."⁶ EPA's IRIS program remains on GAO's High-Risk list.⁷

The IRIS program was originally created to ensure consistency solely within the EPA. However, "other federal agencies, various state and international agencies, and other organizations have come to rely on IRIS assessments for setting regulatory standards, establishing exposure guidelines, and estimating risks to exposed populations."⁸ The most recent GAO report on this matter also mentions the increasing importance of the program at EPA program offices and regions, local environmental programs, and international regulatory bodies. In addition, GAO highlights that "[a]lthough the information in the IRIS database is a critical primary component of EPA's capacity to support scientifically sound decisions, policies, and regulations, we have reported previously on EPA's difficulty producing timely, credible IRIS toxicity assessments."⁹

2011 NRC Report

In April 2011, the NRC published a study on EPA's draft formaldehyde IRIS assessment issued in 2010. In addition to providing recommendations specific to the formaldehyde assessment, the NRC also dedicated a chapter titled "A Roadmap for Revision" that offered suggestions regarding EPA's IRIS assessment process.¹⁰

In the summary of the report, the panel commented on the similarities in some of the problems with the IRIS assessment on formaldehyde, and those identified in other reports published by previous NRC committees:

⁶ David Trimble, GAO Director, Natural Resources and Environment, "Testimony before the Subcommittee on Investigations & Oversight, Committee on Science, Space, and Technology," July 14, 2011, available at: http://science.house.gov/sites/republicans.science.house.gov/files/documents/hearings/071411_Trimble.pdf

⁷ GAO Report to Congressional Committees, "High-Risk Series: An Update," February 2013, available at: <http://www.gao.gov/assets/660/652133.pdf>.

⁸ NRC 2014 IRIS Report, *supra*, note 1.

⁹ GAO Report to Senate Committee on Environment and Public Works, "Chemical Assessment: An Agencywide Strategy May Help EPA Address Unmet Needs for Integrated Risk Information System Assessment," May 2013, available at: <http://www.gao.gov/assets/660/654489.pdf>.

¹⁰ NRC 2011 Formaldehyde Report, *supra*, note 2.

“Overall, the committee noted some recurring methodologic problems in the draft IRIS assessment of formaldehyde. Many of the problems are similar to those which have been reported over the last decade by other NRC committees tasked with reviewing EPA’s IRIS assessments for other chemicals. Problems with clarity and transparency of the methods appear to be a repeating theme over the years, even though the documents appear to have grown considerably in length. In the roughly 1,000-page draft reviewed by the present committee, little beyond a brief introductory chapter could be found on the methods for conducting the assessment. Numerous EPA guidelines are cited, but their role in the preparation of the assessment is not clear. In general, the committee found that the draft was not prepared in a consistent fashion; it lacks clear links to an underlying conceptual framework; and it does not contain sufficient documentation on methods and criteria for identifying evidence from epidemiologic and experimental studies, for critically evaluating individual studies, for assessing the weight of evidence, and for selecting studies for derivation of the RfCs and unit risk estimates.”¹¹

2014 NRC Report

House Report 112-151¹² that accompanied the Consolidated Appropriations Act of 2012 (P.L. 112-74) directed EPA to adopt the recommendations from Chapter 7 of the NRC’s 2011 report into the IRIS program and contract with the NRC for a new report to review the agency’s implementation of those recommendations – leading to the review completed in May 2014.

While the 2014 NRC report describes EPA’s proposed changes as “substantial improvements,”¹³ it does offer “further guidance and recommendations to improve the overall scientific and technical performance of the program.”¹⁴ For example, according to the NRC press release accompanying the 2014 report:

“In response to the recommendations in the formaldehyde report, EPA developed a new document structure, added a standard preamble to all assessments that describes the IRIS process, drafted a handbook that provides a more detailed description of this process and its underlying principles, formed chemical assessment support teams to oversee the process and ensure consistency, and increased opportunities for stakeholder input.”¹⁵

¹¹ Ibid.

¹² House Report 112-151, Department of the Interior, Environment, and Related Agencies Appropriations Bill, 2012, available at: <http://www.gpo.gov/fdsys/pkg/CRPT-112hrpt151/pdf/CRPT-112hrpt151.pdf>.

¹³ NRC 2014 IRIS Report, *supra*, note 1.

¹⁴ NRC Press Release, “Substantial Improvements Made in EPA’s IRIS Program, Report Says,” May 6, 2014, available at: <http://www8.nationalacademies.org/onpinews/newsitem.aspx?RecordID=18764>; hereinafter NRC 2014 IRIS Report Press Release.

¹⁵ Ibid.

The NRC press release also states that while the review committee considered the preamble useful, “it doesn’t fulfill the need for a description in each assessment that indicates how the general principles are applied. The report recommends that the handbook be peer-reviewed, that IRIS assessments clearly identify the members of all teams involved, and that outside experts be engaged when needed. It adds that EPA should provide technical assistance to stakeholders who might not have the resources to provide input into the IRIS process.”¹⁶

Under the leadership of Dr. Kenneth Olden with the EPA, who will testify at this hearing, there appears to be an effort by the agency to implement reforms to IRIS in response to the NRC recommendations and suggestions from the 2011 and 2014 reports. Dr. Olden previously served as the Director of the National Institute of Environmental Health Sciences from 1991 to 2005¹⁷ and was also a member of the Bipartisan Policy Center’s 2009 Science for Policy Project, which called for “greater transparency in analyzing the science behind policy making.”¹⁸ Dr. Olden’s background and position at EPA is encouraging news for transparency advocates for the IRIS program as well as at the agency in general.

EPA is still early in its reform of the IRIS process as there have been no IRIS assessments issued yet that reflect the NRC recommendations. According to the NRC’s 2014 report, questions still remain regarding the specifics and timing of EPA’s actions, examples of which include:¹⁹

- A major challenge for EPA in problem formulation is determining which adverse health outcomes should be evaluated in a specific IRIS assessment;
- EPA has implemented a standardized approach to evaluating evidence, and while it correctly identifies attributes that can be used to judge study quality, it does not describe how it plans to assess the risk of bias in the identified studies. NRC did not recommend any specific approach to assessing bias, but said that the approach chosen by EPA and its results should be fully described and reported in the IRIS assessment;
- After systematic review is completed, an IRIS assessment must combine all the individual lines of evidence to come to a judgment about whether a chemical is hazardous to human health, a process the committee referred to as “evidence integration.” EPA currently relies on a guided expert judgment process for evidence integration. EPA should either make this process more transparent if it chooses to continue using this approach or adopt a structured process for evidence integration;

¹⁶ Ibid.

¹⁷ Eddy Ball, “Olden Named to Head EPA Programs,” *Environmental Factor*, July 2012, available at: <http://www.niehs.nih.gov/news/newsletter/2012/7/spotlight-oldenepa>.

¹⁸ Bipartisan Policy Center’s Science for Policy Project, “Improving the Use of Science in Regulatory Policy,” August 5, 2009, available at: <http://bipartisanpolicy.org/sites/default/files/BPC%20Science%20Report%20fnl.pdf>.

¹⁹ NRC 2014 IRIS Report Press Release, *supra*, note 14.

- EPA should develop templates for narrative justifications of the evidence integration process and its conclusions, and work to ensure that its guidelines for integration are uniform for cancer and noncancer outcomes;
- In addition to hazard identification, IRIS assessments derive toxicity values for given substances when data allow. NRC was encouraged by the improvements that EPA has made in this area, particularly the shift away from choosing one study as the “best” study for deriving a toxicity value and toward deriving and graphically presenting multiple candidate values. EPA, however, should develop formal methods for combining results of multiple studies and selecting the final IRIS values with an emphasis on achieving a transparent and replicable process;
- To ensure that the IRIS program provides the best assessments possible, the committee recommended that EPA develop a plan for strategically updating its methodology, systematically addressing any identified inefficiencies, and continually evaluating whether the IRIS teams have the appropriate expertise and training.