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Strengthening the IRIS Process - 2011

What is IRIS?

IRIS, or EPA's Integrated Risk Information System, provides information on potential human health risks from long term exposure to over 540 chemicals present in air, water, or on land. IRIS assessments are critical to the agency's programs and regulations, as they provide a scientific foundation for many of EPA's decisions. IRIS assessments are also utilized by many local, state, and international governments to assess health risks posed by exposure to various environmental contaminants.

Background

In May 2009, EPA implemented a new IRIS process to make it more responsive to the needs of the Agency and its government partners. In part, the changes were in response to a 2008 report by the Government Accountability Office (GAO) that found that the IRIS database was at serious risk of becoming obsolete because EPA had not been able to routinely complete timely, credible assessments or decrease its backlog of ongoing assessments—a total of 4 were completed in fiscal years 2006 and 2007. The aim of the new process was to ensure the highest level of scientific quality, integrity, transparency, and timeliness.

Changes to IRIS Process under Administrator Lisa P. Jackson

The May 2009 revised process included the following key features:

- EPA manages the IRIS program and has final responsibility for the content of all IRIS assessments
- The assessment development time was shortened to 23 months—a reduction of more than half the estimated time for an assessment to be developed under the previous process
- The number of steps in the assessment development process was reduced from 14 to 7
- Other federal agencies and White House offices have the opportunity to provide scientific input at two points in the assessment development process, and their comments are made publicly available
- The assessment development process includes the opportunity for public comment and relies on an open, rigorous and independent external peer review
- A public listening session is offered for each chemical assessment
- Changes in EPA's scientific judgments during the process are clearly documented and explained

Further Changes to IRIS since May 2009:

- EPA's program and regional offices now have an extended role in nominating and prioritizing chemicals for assessment—ensuring the IRIS program is focused on the highest Agency needs.
- IRIS program managers regularly meet with EPA programs and regions to discuss individual IRIS assessments and the IRIS process.
- EPA has created an IRIS logistics team to help streamline the assessment development process
- EPA has developed the Health and Environmental Research Online Database – or HERO – which makes the scientific studies selected and used by the Agency to develop assessments available to the public.
- EPA has developed Memoranda of Understanding with the California Environmental Protection Agency's Office of Environmental Health Hazard Assessment and the Agency for Toxic Substances and Disease Registry, to cooperate in the development of health assessments to encourage data sharing and avoids duplication of effort.

Results of Improved IRIS since 2009

Since the new process was instituted in 2009, EPA has completed 16 assessments, more than the number of assessments that were completed in the previous four years. The IRIS backlog has been significantly reduced and the Agency has 70 assessments in the IRIS process at various stages.

In FY 2010, EPA completed 10 IRIS assessments and released nine for public comment and external peer review, seven of which were major assessments. In FY 2011, EPA anticipates releasing 13 completed assessments, including a number of major assessments such as trichloroethylene, tetrachloroethylene, arsenic and ethylene oxide. In addition, EPA has a number of assessments that will be released for external peer review, including PCBs and Libby amphibole asbestos.

2011 National Academy of Sciences (NAS) Report on EPA's IRIS Formaldehyde Assessment

In April, 2011, the NAS released its "Review of the Environmental Protection Agency's Draft IRIS Assessment of Formaldehyde." In addition to offering comments about EPA's draft formaldehyde assessment, the NAS included comments and recommendations to improve IRIS documents. The NAS focused their comments on the development of draft IRIS assessments and did not recommend changes to the overall IRIS process. EPA welcomes these recommendations and is taking the following actions to implement them:

1. *NAS recommended that EPA edit documents to reduce the text volume and address redundancies and inconsistencies.*
   In response, EPA is editing our assessment documents to substantially reduce the volume of text and eliminate redundancies and inconsistencies; building on existing IRIS guidelines and process to enhance the clarity and transparency of data evaluation and the presentation of findings and conclusions; consolidating related discussions to eliminate redundancies; increasing the use of tables and figures to improve communication of information; and providing reference information on the IRIS website for all studies considered.

2. *NAS recommended that EPA include a fuller discussion of methods and develop concise statements of the criteria used to exclude, include and advance studies for hazard evaluation and derivation of toxicity values.*
   In response, EPA is providing a fuller discussion of the methods used in its assessments, along with concise statements of the criteria used to exclude, include, and focus on the highest quality studies for hazard assessment and for derivation of toxicity values; working towards replacing text descriptions of the studies with standardized evidence tables that provide the methods and results of each study for all health outcomes; and including text that will accompany evidence tables to present the criteria used to include or exclude studies.

3. *NAS recommended that EPA provide a clearer articulation of the rationale and criteria for screening studies.*
   In response, EPA is enhancing the sequential approach for progressively focusing on the most pertinent information, including: searching the literature, identifying the pertinent studies, and evaluating study characteristics; evaluating the overall weight of evidence for each health outcome; identifying plausible approaches for developing toxicity values; selecting the most pertinent data and developing toxicity values for each health hazard; and, portraying toxicity information graphically.

4. *NAS recommended that EPA use uniform approaches to thoroughly evaluate the strengths and weaknesses of critical studies, summarize findings in tables, and clearly articulate the rationale for the studies used to calculate toxicity values.*
   In response, EPA is streamlining IRIS assessment documents and more fully documenting the approach for assembling and evaluating the range of scientific data. As the NAS report indicated, EPA has already made similar changes to how the scientific evidence is presented on the criteria air pollutants in its Integrated Science Assessments. EPA is also implementing a more uniform approach to the evaluation of the strengths and weaknesses of critical studies to increase the clarity of the rationale for selecting the studies used to calculate toxicity values. Lastly, EPA is increasing the use of evidence tables that summarize the factual details of pertinent studies for each health hazard and developing standardized language to describe study strengths and limitations.

5. *NAS recommended that EPA provide descriptions to indicate various determinants of weight of evidence to promote understanding of what elements were emphasized in synthesizing the evidence.*
   In response, EPA is augmenting our current analysis of data to indicate which criteria were most influential in evaluating the weight of evidence.

   In addition, EPA is working closely with the Agency's Science Advisory Board to develop a dedicated advisory committee that will exclusively focus on the quality, transparency and scientific rigor of IRIS assessments and guide EPA's response to the NAS recommendations. A hallmark of the new IRIS process is strengthened independent peer review of the IRIS program.

   EPA will also create a new peer consultation step early in the development of major IRIS assessments to enhance the input of the scientific community as assessments are designed.

In making these changes, EPA's goal is to continually improve its IRIS assessments without taking any assessment backwards to earlier steps of the process. Therefore, these recommendations will be implemented in a tiered approach, making the most extensive changes to documents that are in the earlier stages of the assessment development process.