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EPA's Path Forward for the Integrated Risk Information System Program

What is IRIS?

IRIS, or EPA's Integrated Risk Information System, provides information on potential human health effects from long term exposure to over 550 chemicals present in air, water, or 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 used by 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 the Program more responsive to the needs of the Agency and government partners while ensuring the highest level of scientific quality, integrity, transparency, and timeliness. In April 2011, the National Research Council (NRC) provided recommendations for improving the development of draft IRIS assessments. The NRC was clear that their intent was not to delay assessments, and that fully addressing their recommendations would require a multi-year process. Consistent with this advice, EPA is implementing the NRC recommendations using a phased approach.

Overview of Improvements from May 2009 – April 2011

Since the new IRIS process was instituted, and as of March 2012, EPA has completed 24 final IRIS assessments, including the long-awaited assessments for trichloroethylene, tetrachloroethylene, and the non-cancer assessment for dioxin. Additionally, from May 2009 to April 2011, EPA:

- Expanded the role of EPA's programs and regions in nominating and prioritizing chemicals for assessment development to ensure that the IRIS Program is responsive to the most critical Agency needs;
- Hosted regular meetings between the IRIS Program and EPA's programs and regions to discuss individual IRIS assessments and the IRIS process; and
- Developed the web-based Health and Environmental Research Online database (www.epa.gov/hero), which promotes transparency by capturing and making available to the public the references and abstracts to scientific studies used in Agency assessments.

Overview of EPA's "Roadmap to Revisions"

Since receiving the NRC report in April 2011, EPA has been implementing the recommendations as quickly as possible, using a phased approach and making the most extensive changes to documents that are in the earlier stages of the assessment development process. EPA initially focused on implementing a subset of the NRC's short-term recommendations, such as editing and streamlining documents, increasing transparency and clarity, and using more tables and figures to present information and data in assessments. EPA is now responding to all of the short-term NRC recommendations and recently released a draft assessment that represents a major advancement in implementing the NRC recommendations. Highlights of EPA's initiatives related to addressing the NRC recommendations are below.

Revision Initiatives

New document structure

EPA is improving the IRIS assessment template to substantially reduce the volume of text and address redundancies and inconsistencies in assessments. This includes:

- Adding an *Executive Summary* to the beginning of each assessment to provide a concise summary of the major conclusions of the assessment related to hazard characterization and dose response analyses.
- Organizing the body of the assessment into two sections, *Hazard Identification* and *Dose-Response Analysis*, to help further reduce the volume of text and redundancies.

Preamble

EPA is replacing Chapter 1 of IRIS assessments with a *Preamble* that will describe the application of existing EPA guidance and the methods and criteria used to develop the assessments. The term "*Preamble*" is used to emphasize that these methods and criteria are being applied consistently across IRIS assessments. The new *Preamble* includes discussions about:

- Identifying and selecting pertinent studies
- Evaluating the quality of individual studies

- Weighing the overall evidence of each effect
- Selecting studies for derivation of toxicity values
- Deriving toxicity values

Literature Search Strategy

EPA's new document structure includes a detailed description of the literature search strategy and study evaluation process used to develop IRIS assessments. This description will be included in new IRIS assessments as they are developed. In discussing the literature search strategy, EPA will describe how the scientific literature was gathered and emphasize how studies were selected to be included in the document, and, if applicable, explain the rationale for excluding certain studies from the assessment. This section will be specific to each chemical assessment. It is designed to provide enough information that an independent literature search would be able to replicate the results of the search used by EPA in developing the assessment. EPA will provide a link to an external database (www.epa.gov/hero) that contains the references that were cited in the document, along with those that were considered for inclusion in the assessment, but not cited.

Weight of Evidence

EPA is developing a formal framework to establish conclusions about the weight of evidence for health effects other than cancer. In the meantime, the Agency is using existing guidelines that address these issues to inform its assessments. In addition, EPA is taking a more systematic approach to analyze the available human and animal toxicity data in IRIS assessments. In conducting this analysis and developing the synthesis, EPA evaluates the data for the:

- strength of the relationship between the exposure and response and the presence of a dose-response relationship;
- specificity of the response to chemical exposure and whether the exposure precedes the effect;
- consistency of the association between the chemical exposure and response; and
- biological plausibility of the response or effect and its relevance to humans.

EPA currently uses this weight of evidence approach to identify the potential hazards associated with chemical exposure but recognizes the benefit of adopting a formal weight of evidence framework that includes standardized classification of causality. Thus, a workshop on adapting weight of evidence procedures for effects other than cancer will be convened. EPA will consider the comments and discussions from the workshop to either adopt or adapt existing approaches to weight of evidence classification for use in subsequent IRIS assessments.

Early Peer Consultation

In addition to the public listening session and public comment period that are already part of the IRIS assessment development process, EPA will increase the use of public peer consultation workshops to enhance the input of the scientific community early in the process as certain assessments are designed. These workshops will be open to the public with opportunity for oral and written comments. The goal of these workshops will vary. For example, the workshops may focus on the state-of-the-science for a particular chemical or provide a forum for discussion with experts about certain cross-cutting scientific issue that may impact the development of scientifically complex assessments.

Chemical Assessment Advisory Committee

EPA has established a dedicated Chemical Assessment Advisory Committee, under the auspices of EPA's Science Advisory Board (SAB), to provide advice to EPA on draft IRIS Toxicological Reviews and the IRIS Program. EPA will send a draft assessment to the new committee for a consultation as soon as it is established, followed by a face-to-face meeting in summer 2012. Two additional meetings with the panel are anticipated for later in the year. EPA will consult the panel for peer review of a range of IRIS assessments and seek advice on how the IRIS Program implements the NRC recommendations. A schedule for meetings and draft assessments to be reviewed is under development and will be publicized in a Federal Register Notice and on the IRIS website.

Looking Ahead

EPA understands that a strong, scientifically rigorous IRIS Program is of critical importance. Over the past three years, EPA has strengthened and streamlined the IRIS Program, improving transparency and increasing the number of final assessments added to the IRIS database while remaining firmly committed to public engagement and rigorous expert peer review. Continually improving the IRIS Program is a priority for the Agency. EPA will continue to pursue excellence in the IRIS Program, using the most up-to-date science in support of EPA's mission to protect the health of the American public.