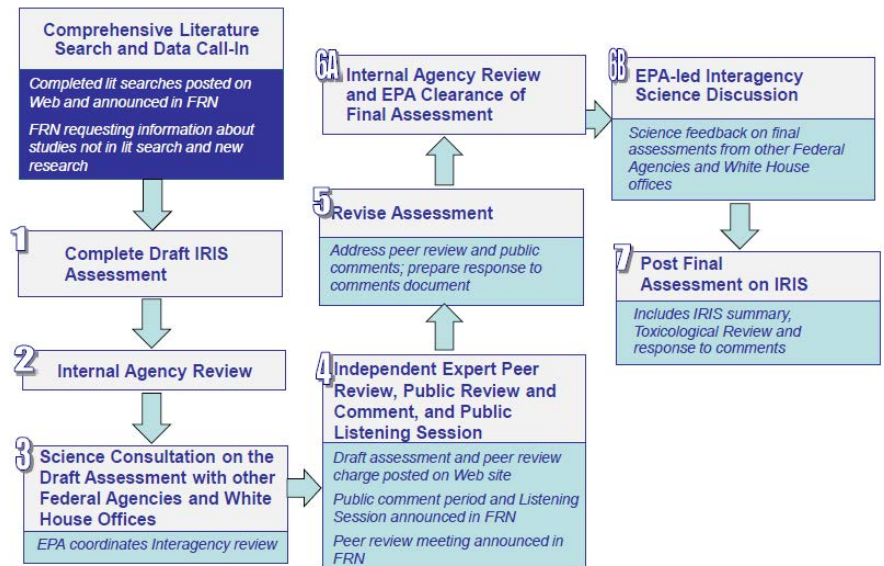


## Enhancements to EPA’s Integrated Risk Information System Program

Science is the most important factor in EPA’s work and is critical to protecting people’s health and the environment. It is with a commitment to scientific rigor and integrity in mind that EPA is taking steps to improve the Agency’s Integrated Risk Information System (IRIS) assessments.

### Background

The IRIS Program provides information about the health effects associated with chemicals to which people may be exposed. IRIS is a primary source of information used by EPA and states in environmental health decision-making. EPA is committed to producing high quality IRIS assessments in a timely and transparent manner to meet the needs of the Agency and the public. By combining IRIS toxicity values with exposure information, government and others use IRIS to characterize health risks of chemical substances to support decisions to protect public health.



### Why is EPA Making Changes to IRIS?

A strong, scientifically rigorous IRIS Program is of critical importance, and EPA is making changes to: 1) improve the scientific integrity of assessments; 2) improve the productivity of the Program; and 3) increase transparency so issues are identified and debated early in the process. In 2009, EPA made significant improvements to IRIS by announcing a new 7-step assessment development process. Since that time, the National Research Council (NRC) has made recommendations related to improving the development of IRIS assessments<sup>1</sup> and advancing risk assessment in general, including the importance of up front planning and scoping in the risk assessment process<sup>2</sup>. EPA is making changes to the IRIS Program to implement the NRC recommendations. These changes will help EPA produce more high quality IRIS assessments each year in a timely and transparent manner to meet the needs of the Agency and the public.

### Enhancements to Improve the Science of IRIS Assessments

EPA is making the following changes to improve the science of IRIS assessments:

- Using a new document structure for IRIS assessments that is clearer, more concise and more systematic;
- Adopting systematic review methods and information management tools (as they are developed) for study selection and analysis;
- Adopting “data integration” or “weight-of-evidence” approaches (as they are developed) to develop overall findings; and
- Strengthening its practices for peer review and protections against conflicts of interest.

<sup>1</sup> National Research Council, 2011. Review of the Environmental Protection Agency’s Draft IRIS Assessment of Formaldehyde.

<sup>2</sup> National Research Council, 2009. Science and Decisions: Advancing Risk Assessment

## Enhancements to Improve Productivity and Transparency in the IRIS Program

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EPA is making changes to improve productivity in the IRIS Program:

- Implementing improved workforce planning to help increase assessment output and improve scientific quality;
- Conducting a needs assessment to better understand client needs for IRIS assessments;
- Focusing staff attention on a smaller overall number of assessments and ultimately increasing efficiency and output of the Program;
- Implementing new stopping rules;
  - *For new data:* All published and ongoing studies relevant to the assessment should be identified by the end of the Step 1 public meeting to discuss the literature search, evidence tables, and exposure-response figures. Exceptions may be made when new information appears that could change the major findings of an assessment or when the peer review panel explicitly recommends that EPA incorporate recent research before completing an assessment<sup>3</sup>.
  - *For scientific issues:* Alternative interpretations of the science and perspectives on how to bridge scientific uncertainty should be raised early in the assessment development process. Opportunities to propose scientific approaches and interpretations are available at: Step 1 during the public meeting to discuss the literature search and evidence tables; Step 4 during the public comment period and public meeting to discuss the draft IRIS assessment and draft peer review charge; or Step 4 during the public external peer review process. Scientific issues that are raised, but not resolved, will be highlighted for the peer review panel for their input.
- Improving transparency in additional ways, such as providing more detailed information on the IRIS website about assessment schedules, stakeholder meetings and the progress of assessments.

## Enhancements to the IRIS Assessment Development Process

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EPA is making the following changes to the IRIS process. These changes will ultimately help EPA meet the goal of producing high quality scientific IRIS assessments in a timely and transparent manner:

- Before beginning to develop a draft assessment, the IRIS Program will conduct an internal planning and scoping meeting to identify EPA needs for the assessment; the IRIS Program will then release a planning and scoping summary and convene a public meeting focused on identifying the scientific information available for the chemical under assessment.
- In the early stages of developing the draft assessment, EPA will release the literature search and a search strategy, evidence tables, exposure-response figures, and, as appropriate, information on anticipated key scientific issues for the chemical. Evidence tables summarize the critical scientific literature and exposure-response figures graphically depict the responses at different levels of exposure for each study in the evidence table. We will also hold a public meeting to present these materials and receive comments.
- In step 4, EPA will release the draft assessment and draft peer review charge for public comment and hold a public meeting. In some cases, the IRIS Program may revise the draft assessment and peer review charge after hearing the public's comments about these materials.

## Summary

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Strengthening and streamlining the IRIS Program is an ongoing priority for EPA. Enhanced stakeholder and public engagement will help ensure transparency and the use of the best available science in IRIS assessments.

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<sup>3</sup> New information refers to newly published peer reviewed studies and should be distinguished from studies that are underway or anticipated and not yet complete, peer reviewed, and published. To consider unpublished studies would be a very high hurdle.