IRIS Frequently Asked Questions

July 12, 2011

Q: What is IRIS?

A: IRIS provides high quality science-based human health assessments that inform the Agency's decisions to protect public health.

The IRIS database includes more than 540 chemical substances, containing crucial information about how they impact human health. Combined with specific exposure information, government and private entities use IRIS to help characterize public health risks of chemical substances, thereby supporting risk management decisions designed to protect public health.

Q: Why is IRIS important?

A: It is very important that high-quality, and accessible human health risk information on environmental contaminants that may endanger the health of the American public is available so that decisions can be made to reduce exposures to these contaminants.

IRIS assessments provide a scientific foundation for EPA decisions to protect public health across EPA's programs and regions under an array of environmental laws. While not regulations, IRIS assessments are critical to many Agency decisions.

IRIS is also a resource for risk assessors and environmental and health professionals in state and local governments and other countries.

Q: Are IRIS health assessments regulations?

A: No. IRIS health assessments contain toxicity values that are used along with other factors, such as the extent of human exposure and the availability and cost of mitigation technologies, that EPA considers during the development of its decisions.

Q: How are IRIS health assessments used in regulations?

A: IRIS assessment toxicity values are combined with information on potential human exposures to develop risk assessments. EPA uses risk assessment to characterize the nature and

magnitude of health risks to people (e.g., residents, workers, recreational visitors) from chemical contaminants and other stressors that may be present in the environment. Risk assessment information is combined with other factors, such as cost and technical feasibility during the development of EPA regulations.

Q: **Do IRIS health assessment values always result in changes in EPA regulation and other decisions?**

A: No, as indicated above, IRIS assessments are only one of many considerations EPA uses to make decisions.

IRIS assessments can be used in a number of ways. They can be used to conduct site-specific screening level assessments to determine if an action such as cleanup or monitoring of contamination from air, soil or water is needed; to develop risk assessments for Superfund sites; and to inform decision-making.

Q: Are new IRIS health assessment values always more conservative than the values they replace?

A: No. When EPA re-evaluates an older value, it considers the latest scientific data and applies the most recent risk assessment guidelines in developing the new assessments. The values can increase or decrease depending on the science.

IRIS PROCESS

Q: In 2009 the Agency made significant changes to the IRIS process. What were those changes?

A: The following changes were made in 2009:

- We shortened the development time for most assessments to 23 months, speeding the availability of IRIS assessments for use by the risk assessment community and public.

- We implemented multiple opportunities for public review and comment and, very importantly, we now document and explain changes in assessments that occur during the public process, ensuring a transparent final product.

- We expanded the role of program and regional offices in nominating and prioritizing chemicals

- We developed the Health and Environmental Research Online (HERO), a web-based database which promotes transparency in risk assessments and makes the scientific studies used by EPA to develop assessments available to the public.

Q: Why did the Agency make changes to the IRIS process in 2009?

A: In their March 2008 report, *Chemical Assessments: Low Productivity and New Interagency Review Process Limit the Usefulness and Credibility of EPA's Integrated Risk Information System,* the U.S. Government Accountability Office (GAO) 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 70 ongoing assessments—a total of 4 were completed in fiscal years 2006 and 2007. To address these and other issues, in May 2009, Administrator Jackson announced a new IRIS process that would revitalize the program and make it ever more responsive to the needs of the Agency and other environmental decision makers. The aim of the new process was to ensure the highest level of scientific quality, integrity, transparency, and timeliness.

Q: What are the results of the new IRIS process adopted in 2009?

A: The new process has resulted in the following improvements since 2009:

- EPA has completed 16 assessments, more than the number of assessments that were completed in the previous four years.

- EPA has reduced the IRIS backlog and is currently working on 70 active assessments.

- In FY 2010, EPA completed 10 IRIS assessments and released nine for external peer review and public comment.

- The new process resulted in more input from EPA scientists, federal agency reviewers, and the public.

Q: In April 2011, the NAS released its review of EPA's draft IRIS risk assessment of formaldehyde and included comments and recommendations to improve both the

assessment and the IRIS process overall. What did the NAS recommend to EPA regarding the IRIS process in its April 2011 review of the IRIS assessment of formaldehyde?

A: In April 2011, the NAS released its review report of EPA's draft IRIS assessment of formaldehyde and included comments and recommendations to improve both the assessment the IRIS process overall. The NAS specifically focused their comments on the development of draft IRIS assessments, and intentionally did not advise EPA regarding the existing "multiple layers of peer review" in later parts of the IRIS process.

Q: What is EPA doing to address the recommendations to improve the IRIS process overall?

A: EPA welcomes those recommendations and has already taken steps to implement these changes. These steps include:

- rigorously edit assessment documents to substantially reduce the volume of text and address redundancies and inconsistencies

- build on existing IRIS guidelines and process to enhance the clarity and transparency of data evaluation and the presentation of findings and conclusions

- consolidate related discussions to eliminate redundancies and increase the use of tables and figures to improve communication of information

- provide a fuller discussion of the methods used in the IRIS assessments, and concise statements of the criteria used to include the highest quality studies for hazard assessment and for the derivation of toxicity values

- streamline IRIS assessment documents and more fully document our approach for assembling and evaluating the range of scientific data similar to how scientific evidence is presented in the Integrated Science Assessments for the criteria air pollutants

- implement a more uniform approach to evaluation the strengths and weaknesses of critical studies to increase the clarity of the rationale for selecting the studies used to calculate toxicity values.

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 scientific conclusions of all IRIS assessments.

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

Q: What is EPA doing to address the NAS recommendations to improve the formaldehyde assessment?

A: The formaldehyde assessment will:

- be prepared in a consistent fashion,
- include clear links to an underlying conceptual framework, and
- 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 the derivation of toxicity values.

Q: What is the timing for implementing these actions?

A: EPA's overriding goal is to continually improve IRIS assessments, recognizing that these improvements will have a greater impact on our new assessments as opposed to those already in the pipeline. It is important to note that the NAS report stated, "it is not recommending that EPA delay [the review of the formaldehyde assessment] to implement a new approach." EPA is doing the following:

- ***Assessments that have already been peer-reviewed or released for peer review:*** We are revising these assessment to address peer-review comments, especially those that call for increased transparency of study selection and evidence evaluation.
- ***Assessments currently under development but not yet released for peer review:*** We are re-examining these assessments to ensure that the rationale for study selection and evidence evaluation is clear; these assessments will also be edited to reduce redundancy.

- ***New assessments that have not yet been started:*** We will fully implement NAS recommendations for new assessments, including a tighter document structure, evidence tables to summarize details from pertinent studies, transparency in study selection and evaluation criteria, and emphasis on clear analysis and synthesis.

Q: Did the NAS recommend that EPA stop all IRIS assessments while implementing their recommendations?

A: No. The NAS did not tell EPA to stop reviewing existing assessments or to stop producing assessments. The NAS discussed their expectation that additional changes to the IRIS process would take time to implement. In addition, the NAS encouraged EPA to finish its formaldehyde assessment as expeditiously as possible.

Q. There is important and relevant research underway for many chemicals on the IRIS agenda. Why doesn't EPA wait for the results of this research before completing an IRIS assessment?

A. EPA is committed to ensuring that all of its IRIS human health assessments are based on the most current and best available, independently peer-reviewed, published scientific information. Because the scientific information available on any chemical continues to evolve over time, EPA cannot postpone assessments to wait for ongoing research to be published, especially when there is already a good database available. In order for information to be considered for inclusion in a draft assessment, it would have to appear in the published, peer-reviewed scientific literature during draft development of an assessment prior to Agency review.

Q. What type of peer review are IRIS health assessments subject to?

A. The standards to which IRIS assessments are held are second to none in the federal government and the scientific community. Every draft IRIS assessment is subject to rigorous independent, external scientific peer review. For most assessments, this is a contractor-led peer review. For a smaller group of complex assessments, EPA's Science Advisory Board or the National Academy of Sciences conducts the peer review.