Revised IRIS Process Q&A's

Question 1. What is IRIS?

Answer: EPA's Integrated Risk Information System (IRIS) is a database maintained by the Office of Research and Development (ORD) that contains the Agency's science and science policy positions on chronic human health effects that could result from exposure to environment contaminants. Through IRIS, EPA provides the highest quality, science-based, human-health assessments to support EPA's policymaking activities.

Question 2. Why were revisions made to the IRIS process?

Answer: Revisions to the IRIS process were made to provide greater transparency, objectivity, balance, rigor and predictability in IRIS assessments. For example, the improvements to the IRIS process help to define critical and appropriate roles for public and interagency comments and interactions, and promote greater communication and sharing of information between all interested parties and EPA. The outcome of these improvements are expected to result in a more predictable, streamlined, and transparent process for conducting IRIS assessments, which will ultimately lead to assessments that are of the highest quality and rigor. The revised process is also expected to result in a much more timely completion of IRIS assessments than has occurred in the past. Reforming the IRIS process has been an important goal of EPA Administrator, Stephen Johnson, as reflected in his Action Plan.

Question 3. What was the process for making these revisions to IRIS?

Answer: ORD drafted the revised IRIS process in consultation with EPA's other Program and Regional Offices. ORD also sought input from other federal agencies early on in the process. The final version of the revised IRIS process was developed and released by ORD. Additionally, ORD will host a public workshop to discuss the revised IRIS process in the coming months.

Question 4. Are all of the steps in the "revised IRIS process" new?

Answer: No, many of the steps were in place in the previous version of the IRIS process, including those that existed since the beginning of the IRIS program as well as some that were adopted by ORD during the past few years. New steps to the process include opportunities for the public to bring forth additional scientific information and to comment on the scope of an assessment early in the IRIS process. ORD will also host new "listening sessions" during public review and comment periods to allow for broader participation and engagement of all interested parties. Additionally, the revised process creates a limited opportunity for other agencies to collect data to fill significant data gaps for "mission critical" chemicals.

Question 5. What is a "mission critical" chemical?

Answer: A "mission critical" chemical is one that is an integral component to the successful and safe conduct of an agency's mission in any or all phases of its operations. Impacts on use of mission critical chemicals include cessation or degradation of the conduct of the mission and/or unacceptable resource constraints. Agencies must identify to ORD those chemicals on the IRIS Program Annual Agenda that they determine meet this definition.

Question 6. What is the role of public in the revised IRIS process?

Answer: EPA recognizes that significant knowledge and expertise exists outside the Agency, and has created several important opportunities for the public to share information and comment on EPA's IRIS assessment during the nomination and assessment portions of the process. For example, the public has an opportunity to comment on ORD's initial literature review results and to submit additional scientific information on a chemical to EPA. In addition, the public can comment on ORD's Draft Qualitative Assessment and participate in an EPA-sponsored "listening session" during the public review process. The public can also arrange for a meeting with ORD if they want to discuss a particular comment or set of comments. Finally, the public can comment on ORD's draft IRIS Toxicological Review and participate in a second "listening session" during the public comment process.

Question 7. What is the role of EPA Program and Regional Offices and other agencies in the revised IRIS process?

Answer: Because EPA Program and Regional Offices and other agencies also have significant knowledge and expertise, they too have opportunities to share information and comment on EPA's IRIS assessment during the nomination and assessment activities. This includes opportunities to nominate chemicals for consideration by EPA, comment on literature review results and submit additional scientific information on a chemical, comment on ORD's Draft Qualitative Assessment and draft IRIS Toxicological Review, participate in "listening sessions" during public comment and review processes, and request a meeting with ORD to discuss a particular comment or set of comments. Additionally, other agencies may express an interest in filling significant data gaps for "mission critical" chemicals, and can submit a detailed research plan to ORD. If approved by ORD, in consultation with an intra-Agency IRIS Review Committee, the sponsoring Agency may design and implement these new studies prior to ORD's completion of the draft Toxicological Review.

Question 8. What is the specific role of OMB in the revised IRIS process?

Answer: OMB has all of the same opportunities as other federal agencies to share information and comment on EPA's IRIS assessment during the nomination and assessment activities (see response to Question 6 above), although OMB is not expected to initiate any new studies. Additionally, OMB is responsible for distributing the draft

and final IRIS Toxicological Review to other agencies during interagency review steps, and compiling and providing all interagency comments on the draft and final assessments to ORD. If other agencies wish to call a meeting with ORD to discuss and resolve critical issues and significant areas of disagreement on the draft assessment, OMB will also serve as the facilitator for this meeting.

Question 9. What is role of independent external peer review in the revised IRIS process?

Answer: Independent external peer reviews are a hallmark of EPA's commitment to ensuring we have high quality science that has been vetted by a panel of experts. All draft IRIS Toxicological Reviews will undergo independent, external peer review. Most reviews will be conducted by an external peer review panel, and all peer reviews are public meetings. External peer reviewers will also have an opportunity to review the revised IRIS Toxicological Review and comment on ORD's response to the peer reviewer and public comments.

Question 10. Will the revised IRIS process allow for new research to be conducted and under what conditions?

Answer: Yes, for a small number of chemicals that are identified as being critical to the mission of an agency, a detailed research plan may be submitted by the agency indicating its planned research to fill significant data gaps for these "mission critical" chemicals. If approved by ORD, in consultation with an intra-agency IRIS Review Committee, the sponsoring agency may then design and implement the proposed new studies prior to ORD's completion of the draft Toxicological Review within 12 to 18 months. This step does not include the public, because it is intended to be reserved for those few chemicals that are of the highest importance to the Federal government.

Question 11. Under the revised IRIS process will toxicity values be included in the draft chemical assessments?

Answer: Yes, consistent with past practices, toxicity values (e.g., reference dose or reference concentration values, cancer potency values, unit risk values) will be included in the draft and final IRIS Toxicological Reviews. However, toxicity values will not be included in the Draft Qualitative Assessment, which will be developed prior to the draft IRIS Toxicological Review.

Question 12. Why is the revised IRIS more transparent than before?

Answer: The revised process helps define critical and appropriate roles for public and interagency comments and interactions, creates several important opportunities for the public and EPA Program and Regional Offices and other agencies to share information and comment on EPA's IRIS assessments, and establishes clear timeframes for the completion of each step. These improvements will ensure greater transparency,

objectivity, fairness, and balance in the IRIS process than has occurred historically, which will ultimately lead to assessments that are both timely and of the highest quality.

Question 13. How long will assessments take to complete under the revised IRIS process?

Answer: For most chemicals, the assessment process will take about 3-4 ½ years under the new process. For a small number of mission critical chemicals, it could take an additional 1-2 ½ years. Prior assessments took an average of 5 years, with some taking as long as 10 years, although recent efforts have been made to accelerate the process (e.g., by increasing resources and staffing). Because the revised process attempts to streamline and set specific time frames for each step, it is expected to reduce the amount of time to complete assessments.

Question 14. Will the revised IRIS process increase the number of assessments performed by EPA each year?

Answer: The revised IRIS process does not require any change in the number of annual assessments performed by EPA. However, the various improvements to the process, including specific milestones for completing chemical reviews, is expected to increase the efficiency of the IRIS program which may result in the completion of more assessments each year.

Question 15. Are any decisions on the content of IRIS assessments taken away from EPA in the revised process?

Answer: No, despite increased opportunities for public and other agency involvement, the revised process makes it clear that all final decisions on content will remain within EPA.

Question 16. Will EPA respond to public, other agency, and peer reviewer comments on the draft Toxicological Review and will these be made available to public?

Answer: Yes, EPA will review and respond to comments on the draft Toxicological Review by creating "disposition of comments" documents. All public comments received via the Federal Register will be made part of the official public record. However, all intra-Agency and interagency comments and disposition documents will be considered "deliberative" and will not become a part of the public record. This protection is the same as that afforded any other policymaking setting at EPA to ensure that scientists and policymakers are able to have full and frank discussions without being concerned about how these discussions may be viewed or misrepresented in the future. However, once ORD comes to a conclusion and requests public comment on its decision, then all subsequent comments or discussions on that decision will be open to the public.

Question 17. Where can I learn more about the revised IRIS process?

Answer: The revised IRIS process is posted at http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=190045. Recent updates to the IRIS website also provide greater public access to final documents and allow for the status of specific assessments to be tracked over time. Additionally, ORD will host a workshop to discuss the revised IRIS process in the coming months. In the meantime, ORD is implementing the new process now.

Question 18. Who can I contact if I have additional questions about the revised IRIS process?

Answer: ORD News Director, Melissa Anley-Mills 202.564.5179