UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

MAY 21 2009

THE ADMINISTRATOR

MEMORANDUM

SUBJECT: New Process for Development of Integrated Risk Information System Health Assessments

TO: Assistant Administrators
General Counsel
Inspector General
Chief Financial Officer
Chief of Staff
Associate Administrators
Regional Administrators

I have long recognized the critical role that EPA plays in disseminating timely, high-quality, and accessible human health risk information on environmental contaminants that may endanger the health of the American public. Central to this aspect of EPA's mission is its highly regarded Integrated Risk Information System program that provides health effects information on chemicals to which the public is exposed from releases to air, water, and land at contaminated sites and through use and disposal of products. IRIS assessments provide a scientific foundation for actions to protect public health across EPA's programs and regions under a broad array of environmental laws. IRIS is also a critical resource for risk assessors and environmental and health professionals in state and local governments and other countries.

It is of utmost importance that the process used to develop the IRIS risk information, and the resulting assessments posted on IRIS, reflect the highest possible standards for scientific quality and integrity and provide a timely basis for government actions to protect public health. Unfortunately, recent changes to the IRIS process, including the procedures formalized in an April 10, 2008, memorandum from the former Deputy Administrator, have reduced the transparency, timeliness, and scientific integrity of the IRIS process. The President's strong emphasis on the importance of transparency and scientific integrity in government decision-making compelled a rethinking of the IRIS process.

Therefore, after consulting with EPA scientists, I have asked the Office of Research and Development to immediately implement a new IRIS process that will be more responsive to the needs of the Agency and its government partners in protecting the health of Americans. This new IRIS assessment development process is reflected in the enclosed chart and background paper. It will be more transparent and timely, and it will ensure the highest level of scientific

integrity. The process will be entirely managed by EPA, which will have final responsibility for the content of all IRIS assessments after considering the scientific input of experts at other agencies and White House offices. To guarantee the scientific quality of the IRIS assessments, the process will include the opportunity for public comment and rely on a rigorous, open, and independent external peer review. Changes in EPA's scientific judgments during this public process will be clearly documented and explained, maximizing the transparency of the final product. While still robust, the assessment development process will be shortened to 23 months, speeding the availability of IRIS assessments to the risk assessor community and the public and providing for more timely action to protect public health. In addition, to give this new process an added boost, I have directed that for fiscal year 2010, resources for the IRIS program will be increased. I am pleased to announce that the President's budget request includes an additional $5 million and 10 FTEs for the IRIS program.

EPA remains dedicated to listening and being responsive to the public, independent experts, and scientists in other federal agencies as it develops IRIS human health assessments. I believe the new process will achieve this goal while providing timely and high-quality human health risk information to EPA's programs and regions that ensures that the Agency's actions protect the public health.

Lisa P. Jackson

Attachment

EPA's Integrated Risk Information System

Assessment Development Process

Introduction:

The Integrated Risk Information System (IRIS) is an U. S. Environmental Protection Agency (EPA) database that contains quantitative and qualitative risk information on human health effects that may result from exposure to environmental contaminants.

Through IRIS, EPA provides the highest quality science-based human health assessments to support Agency regulatory activities. IRIS is a key program in EPA's Office of Research and Development (ORD).

The Assessment Development Process:

Prior to the start of the development of the draft IRIS assessment, EPA conducts a scientific literature search and initiates a data call-in:

- Scientific Literature Search
  - ORD appoints a chemical manager for each chemical on the proposed Agenda.
  - The chemical manager(s) direct an EPA contractor to conduct and complete a comprehensive search of the scientific literature for the chemical.
  - Completed literature searches are posted on the EPA's Web site
- Data Call-In
  - After the literature search has been completed for each chemical, EPA publishes a Federal Register Notice (FRN) that notifies the public that completed literature searches for a set of chemicals are available on the IRIS Internet site.
  - FRN invites the public and other agencies to submit additional scientific information (peer reviewed studies, reports, other assessments, etc.) on the chemical.
  - FRN requests information on new research that may be planned, underway, or in press.
  - FRN includes information on how and where to submit scientific information.

After the literature search and data call-in are complete, EPA begins development of the IRIS human health assessment.

All draft human health assessments developed in the IRIS Program are subjected to rigorous, open, independent external peer review. Selected IRIS assessments considered being of major importance or high profile may be peer reviewed by panels of experts convened by EPA's Science Advisory Board or by the National Academy of Sciences. In addition, IRIS assessments developed under the seven step process outlined below, are expected to be completed within approximately two years from the Step 1 start date. Some IRIS assessments, however, because of their complexity, large scientific literature base, or high profile may take longer.

1. EPA Develops and Completes a Draft IRIS Toxicological Review (Duration 345 days)

A. ORD assembles an IRIS assessment team.

B. ORD assesses the data in the scientific literature and any information submitted as a result of the data call-in and develops a draft assessment for the chemical being assessed, including:

   a. summary of potentially important health effects;

   b. summary of information on potential mode(s) of action;

   c. summary of information about potentially susceptible populations;

   d. a quantitative assessment, including application of uncertainty factors, default approaches, mode of action information, and dose-response modeling; and

   e. identification of potential uncertainties that impact the qualitative and quantitative aspects of the assessment.

C. ORD completes the draft IRIS Toxicological Review.

2. Internal EPA Review (Duration 60 days)

A. ORD submits the draft IRIS Toxicological Review for internal Agency review.

B. Internal Agency review includes scientists from EPA programs and regions.

C. Internal agency review identifies any scientific issues to determine the level of peer review, needed panel member disciplines, and the scope of the review.

3. EPA Initiates Interagency Science Consultation on Draft IRIS Toxicological Review (Duration 45 days)

A. EPA sends the draft IRIS Toxicological Review and draft external peer review charge to other Federal agencies and White House offices for a science consultation.

B. The science consultation step is managed and coordinated by EPA

   a. EPA provides a specified date for receipt of written comments.

   b. EPA hosts meeting of other agencies and White House offices to discuss issues raised by comments.

C. All written comments received during Interagency Science Consultation become part of the public record

D. ORD revises the draft assessment documents, as appropriate.

E. If EPA considers appropriate, science questions that arise during science consultation may be included as part of a charge question to the peer review panel.

4. EPA Initiates Independent External Peer Review of Draft IRIS Toxicological Review, Public Review and Comment on Draft IRIS Toxicological Review, and Holds a Public Listening Session (Duration 105 days)

A. External Peer Review

a. EPA provides the draft IRIS Toxicological Review and peer review charge questions for independent external peer review.

b. EPA publishes an FRN at least 30 days prior to the peer review meeting notifying the public about the time and place of the meeting.

c. Peer reviews are public meetings, generally through a face-to-face meeting of panelists, though some may be held via public teleconference.

d. The report of the external peer review panel becomes part of the official public record for the IRIS assessment

B. Public Review and Comment

a. EPA releases the draft IRIS Toxicological Review for public review and comment.

b. ORD prepares an FRN announcing a public comment period of 60 days.

i. The draft IRIS Toxicological Review is released on EPA's Web site on the day that the FRN is published.

ii. The FRN includes detailed instruction for submitting public comments.

iii. The public comment period is open to all stakeholders, including other Federal Agencies and White House offices.

c. Public comments are submitted to ORD

i. All comments received during the official public comment period will be submitted through E-Gov (www.regulations.gov).

ii. All public comments will be part of the official public record.

iii. Public comments submitted by the close of the comment period will be provided to the peer reviewers at least 10 working days prior to the peer review meeting.

iv. Only those comments received by the close of the public comment period are guaranteed of being provided to the external peer review panel in advance of the peer review meeting.

v. If an extension of a comment period is requested and granted, and a second FRN is published, the comments submitted during the extension may not be able to be provided to the peer reviewers before the meeting.

C. Public Listening Session

a. EPA holds a Public Listening Session after the public release of the draft assessment and before the peer review meeting.

b. The Listening Session provides an opportunity for interested parties to present scientific and technical comments on the draft IRIS health assessment to EPA and other interested parties.

c. An FRN announcing the Listening Session is generally published as least 30 days prior to the Listening Session meeting.

d. FRN includes all logistical information regarding the meeting.

e. All Listening Sessions are held in the Washington, DC metropolitan area.

5. EPA Revises IRIS Toxicological Review and Develops IRIS Summary (Duration 60 days)

A. ORD evaluates the external peer review panel report and all public comments.

B. ORD revises the draft IRIS Toxicological Review, as appropriate, and develops the IRIS Summary.

C. Length of revision process may depend on the complexity of the IRIS Toxicological Review and complexity and number of peer reviewer and public comments.

D. ORD develops a disposition of peer reviewer and public comments and provides these as an appendix to the IRIS Toxicological Review.

6A.Internal EPA Review of Final IRIS Toxicological Review and IRIS Summary (Duration 45 days)

A. ORD sends the IRIS Toxicological Review and IRIS Summary for final internal Agency review.

B. This review is intended as a final check-in with Agency program and regions.

6B. EPA-led Interagency Science Discussion (Duration 45 days – concurrent with Step 6A.)

A. EPA provides other agencies and White House offices with the final draft of the IRIS Summary and Toxicological Review and appendix describing disposition of peer review and public comments.

B. Other agency and White House Office scientists have opportunity to provide written scientific feedback.

C. EPA hosts meeting with White House offices and other agencies to discuss any scientific issues related to the final draft of the IRIS Summary and Toxicological Review and appendix.

D. All written comments by other agencies and White House offices documented in the record.

7. EPA Completion of IRIS Toxicological Review and IRIS Summary (Duration 30 days)

A. ORD completes the IRIS Toxicological Review and IRIS Summary.

B. ORD prepares the final assessment for Agency's Web site posting.

C. ORD insures 508 Compliance and EPA Web site compliance.

D. ORD posts the assessment to the IRIS data base.

E. ORD completes and maintains the public record.

TOTAL: 23 Months

Assessment Development Process for New IRIS