

Committee on Science and Technology
Subcommittee on Investigations & Oversight
U.S. House of Representatives

Hearing Charter

Fixing EPA's Broken Integrated Risk Information System

Thursday, June 11, 2009
1:00 to 3:00 p.m.
2318 Rayburn House Office Building

Purpose

On Thursday, June 11, 2009, the Subcommittee on Investigations and Oversight of the House Committee on Science and Technology will hold a hearing entitled "Fixing EPA's Broken Integrated Risk Information System." We will receive testimony from two witnesses at this hearing: Mr. John Stephenson, Director, Natural Resources and Environment, U.S. Government Accountability Office, and Dr. Kevin Teichman, the Deputy Assistant Administrator for Science, Office of Research and Development, the Environmental Protection Agency. They will testify about the new Integrated Risk Information System (IRIS) process announced by EPA Administrator Lisa Jackson on May 21, 2009.

Background

By the end of the Bush Administration, the Environmental Protection Agency's (EPA) IRIS process was broken. What began two decades ago as an initiative at EPA to establish a reliable database on what science said about the risks of particular chemicals devolved by the end of the Bush Administration into a tortured round of interagency bickering, mediated by the Office of Information and Regulatory Affairs (OIRA). As a result of the IRIS process breaking down, public health offices across the country and around the world, as well as concerned citizens, were left without the reliable, expanding, up-to-date database of chemical risks that they had come to count on.¹

¹. The Subcommittee has carried out extensive work on OIRA's role in relationship to IRIS. In 2008, the Subcommittee held two hearings on this subject. The first of these hearings was on May 21, 2008, when the Subcommittee took testimony from Dr. George Gray, the then-Assistant Administrator for Research and Development at EPA, and Ms. Susan Dudley, the then-Administrator of the Office of Information and Regulatory Affairs (OIRA) at the Office of Management and Budget. Additionally, Mr. John Stephenson of GAO testified on findings regarding the lack of productivity in the IRIS process. In the second hearing, on June 12, 2008, the Subcommittee received testimony from Mr. Jerry Ensminger (U.S.M.C., retired), Mr. Lenny Seigel (Executive Director, Center for Public Environmental Oversight), and Dr. Linda Greer (Director of the Health Program at the Natural Resources Defense Council). On June 11, 2008 Chairman

A chemical's entry in the IRIS database is nothing more than a science-based assessment of risks associated with a particular chemical. IRIS entries are produced in the Office of Research and Development (ORD) of EPA, and those entries are not an expression of regulatory intent or advice. The entries are not even all that is required of a complete risk assessment as defined in the seminal National Academies of Science report, *Risk Assessment in the Federal Government: Managing the Process* (1983).² And risk assessment is a long step away from a regulatory effort, which is described in the terminology of the panel as "risk management." However, the absence of IRIS entries for widely used, toxic chemicals leaves state and local regulators, first responders, and citizens without crucial information that can guide their response to an emergency or an emerging health or environmental threat.

OIRA has been involved in the IRIS process since the closing years of the Clinton Administration. Initially OIRA was pulled into the process to facilitate interagency discussions about particular chemicals proposed for IRIS listings. Agencies that had a record of pollution with certain chemicals were concerned that new IRIS standards would trigger the long march to new regulations and the end result would be that the polluting agencies would have to change their practices and clean up legacy wastes. Those who polluted saw that disputing what scientific research had found about the risks of a particular chemical could become the first line of defense against the distant possibility of regulation.³ By the late 1990s, OIRA was playing a role as facilitator for contentious

Miller sent a document request to OMB asking for all materials relating to OIRA's involvement in the proposed IRIS entry for trichloroethylene (TCE). In response, the Committee received a few boxes of materials. The great majority of those materials were either peer reviewed articles, articles done by EPA staff, or research reports done under contract to industry or polluting agencies. Subcommittee staff were obliged to visit OMB's office to review thousands of pages of documents and take notes because the office refused to provide copies. A clear picture of OIRA's almost daily involvement on TCE emerged from that review. However, OIRA refused to provide access to most documents regarding interagency communications or internal communications surrounding TCE. Because the 110th Congress was drawing to a close, it was not practical to push for a subpoena for these records. We were never shown any document that could have been construed as having Executive Privilege attached to it. OIRA's entire approach appeared to amount to little more than obstruction of the work of the Subcommittee; in a sense, OIRA did to the Subcommittee's investigation what they have perfected in terms of slow-rolling IRIS proposals.

². In that 1983 report, "Risk Assessment in the Federal Government: Managing the Process," the National Research Council panel identified four components of a complete risk assessment: hazard identification, dose-response evaluation, exposure assessment, and risk characterization. IRIS reflects science that addresses the first two conditions. In discussing the difference between risk assessment and risk management, the Academy panel wrote: "Risk assessment is the use of the factual base to define the health effects of exposure of individuals or populations to hazardous materials and situations. Risk management is the process of weighing policy alternatives and selecting the most appropriate regulatory action, integrating the results of risk assessment with engineering data and with social, economic and political concerns to reach a decision." See the discussion on page 3 of the 1983 report.

³. This effort by polluters, or those who fear regulation of whatever stripe, of pushing the struggle back to what the science says about a particular risk rather than arguing over how to structure a regulation has been described as "paralysis by analysis." Science lends itself to endless study because there is never an absolute, final answer to any question, but always another layer of research that could add to the body of accumulated knowledge. If those who want to avoid regulation can shift the terms of discussion from the risk management end of the spectrum to the science and what uncertainties remain, a regulatory struggle

interagency discussions for some particular proposed IRIS listings.⁴

Suppressing IRIS entries essentially shuts down the flow of coherent, reliable information about what chemicals pose what kinds of risks. Testimony received by the Subcommittee at the second day of hearings on this subject in 2008 emphasized the important role of IRIS as a public health and safety resource. That hearing, entitled, “Toxic Communities: How EPA’s IRIS Program Fails the Public,” took testimony from U.S.M.C. (retired) Master Sergeant Jerry Ensminger, the Executive Director of the Center for Public Environmental Oversight, Mr. Lenny Siegel, and Dr. Linda E. Greer, Director for Health Programs at the Natural Resources Defense Council. Mr. Ensminger was particularly compelling in making a case for why polluting agencies such as DOD should not be allowed privileged access to discussions about the science of potential pollutants.

It is a known fact that the United States Department of Defense is our nation’s largest polluter. It is beyond my comprehension why an entity with that type of reputation and who has a vested interest in seeing little to no environmental oversight would be included in the scientific process. Not only are they obstructing science, they are also jeopardizing the public health for millions of people all around the world... and yet this Administration and past Congresses have allowed DOD’s tentacles to infiltrate the realm of science.⁵

Mr. Ensminger was stationed at Camp LeJeune. His daughter, Janey, died of acute lymphocytic leukemia. Water at the Camp was contaminated with trichloroethylene (TCE) and perchlorate (perc) and these chemicals, as well as other volatile organic compounds in the water system at the Camp, may have caused Janey’s condition. DOD has been working for many years to block new IRIS standards on TCE and perc.

During the Bush Administration, OIRA’s involvement changed in scope and kind from what it had been in the Clinton Administration. John Graham, the first director of OIRA in the Bush Administration, brought in technical specialists—including toxicologists—to tend to science-based discussions of proposed environmental regulations, guidance and IRIS entries. Graham also oversaw a complete overhaul—some might describe it as an endless evolution—of the review and approval process for IRIS proposals.

need never begin. For analysis of how this process has unfolded among regulated industries, see, David Michaels, Doubt Is Their Product: How Industry’s Assault on Science Threatens Your Health, Oxford University Press, New York, 2008.

⁴ . The Subcommittee was also able to review records from 1998 when OIRA first began to push into the interagency struggles over characterizing risks to former marines and their families from TCE and other chemicals at Camp LeJeune. At that time, OIRA’s interest was more in the costs of the studies and making sure the then-proposed survey study met OIRA quality standards. OIRA reviews all survey instruments as part of its authority under the Paperwork Reduction Act of 1980.

⁵ . “Toxic Communities: How EPA’s IRIS Program Fails the Public,” Hearing before the Subcommittee on Investigations and Oversight, Committee on Science and Technology, June 12, 2008, p. 132.

IRIS Process Reforms Past and Present

On April 10, 2008, EPA announced a new IRIS review process for future entries into the IRIS database. In testimony before the Subcommittee, the then Assistant Administrator for Research and Development at EPA, Dr. George Gray, described this new process as “streamlined.” Comparing the process as it existed before 2004 and the process announced on April 10, 2008, it is hard to understand in what sense the process could be described as “streamlined” (see attachments 1 and 2). The fruits of this new process were exactly four new IRIS entries in the years since that process was announced (actually, they had gone through as a single proposal as they were four variants on one chemical compound so this could be counted as “one” new entry and not distort the record). In the two years prior to announcing this new process, EPA had been allowed to post four new entries (two each year).

GAO issued a very strong report concerning mismanagement of the IRIS program in a March, 2008 report (“Chemical Assessments: Low Productivity and New Interagency Review Process Limit the Usefulness and Credibility of EPA’s Integrated Risk Information System,” GAO-08-440). In addition, GAO added the IRIS program to its “High Risk” report in January of 2009—placing additional pressure on EPA and the new Administration to take steps to fix this broken process.

On May 21, EPA Administrator Lisa Jackson announced a new IRIS process that appears to be much improved over the system she inherited (see attachment 3). It imposes transparency on interagency comments concerning proposed IRIS entries; it eliminates the ability of polluting agencies (such as the Department of Energy, NASA, or the Department of Defense) to further drag out assessments by declaring particular chemicals as “mission critical”; it puts EPA solidly in charge of the entire process with a timeline for each step in the process.

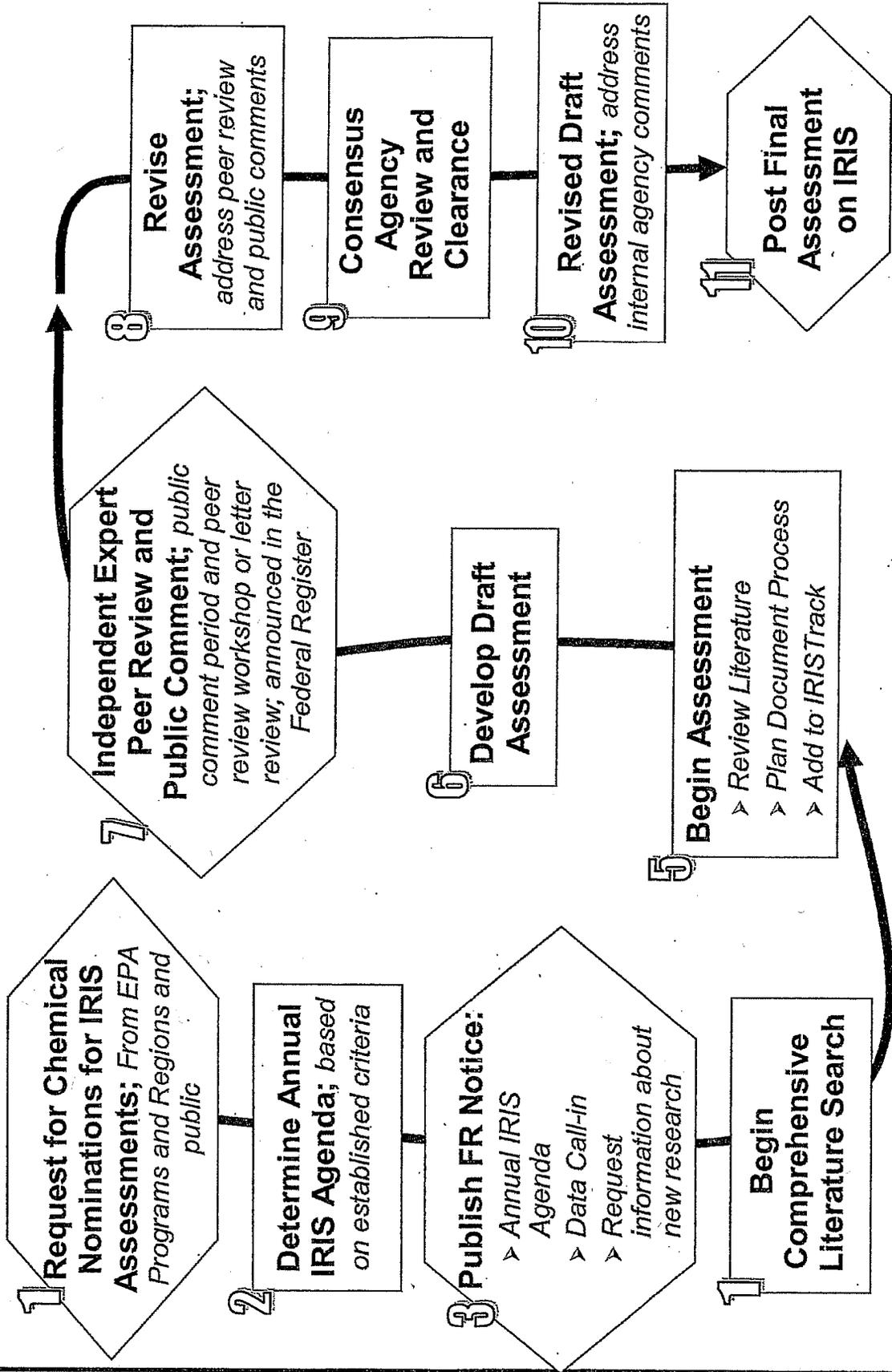
All of these steps away from an OIRA-dominated system are positive. However, questions still remain about how this process will perform in actual practice.

1. Control: Will EPA really have the muscle to stand up to pressure from more powerful agencies that have historically obstructed IRIS entries as a way of strangling potential regulation? Will EPA be able to withstand pressure from offices inside the White House should those offices mobilize to block or significantly redo a proposed IRIS listing? EPA fared badly during the prior Administration in struggles over science and regulation. Some of those problems reflected the political preferences of the Bush Administration, but some of those problems reflect the ingrained institutional interests of other agencies who do not want to be regulated and White House offices that want to have a great measure of control over what EPA (among many agencies) can and cannot do. Institutional interests do not change with elections, and EPA will still face some pressure on that front. The Chairman’s position has been that EPA scientists should be in charge of EPA science products.

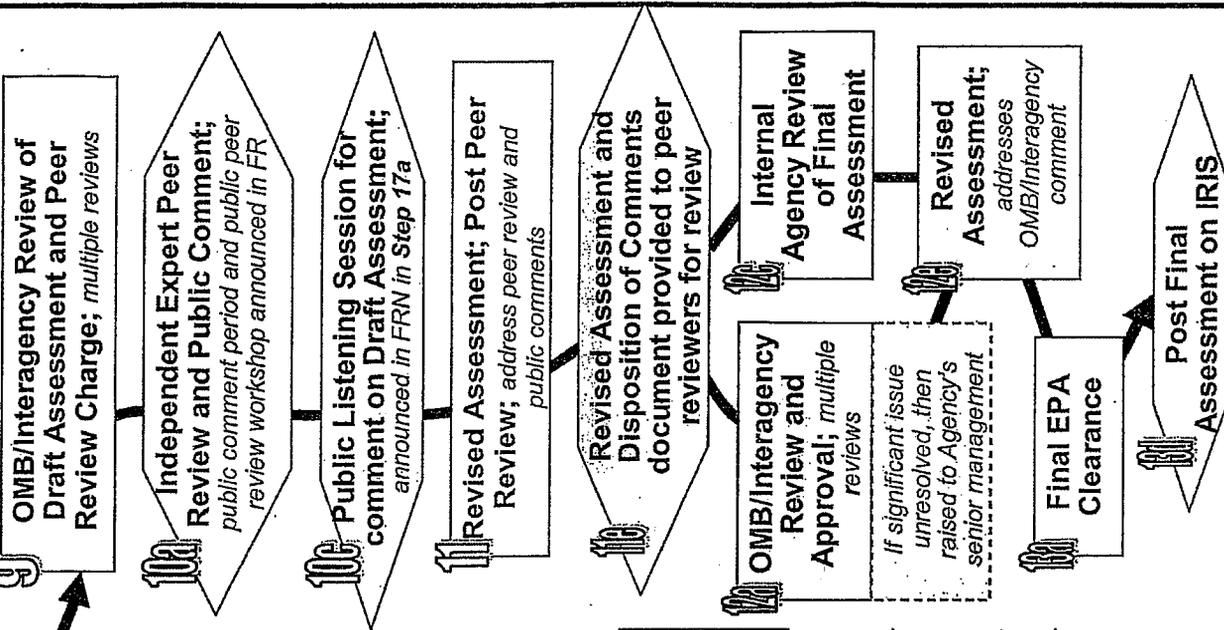
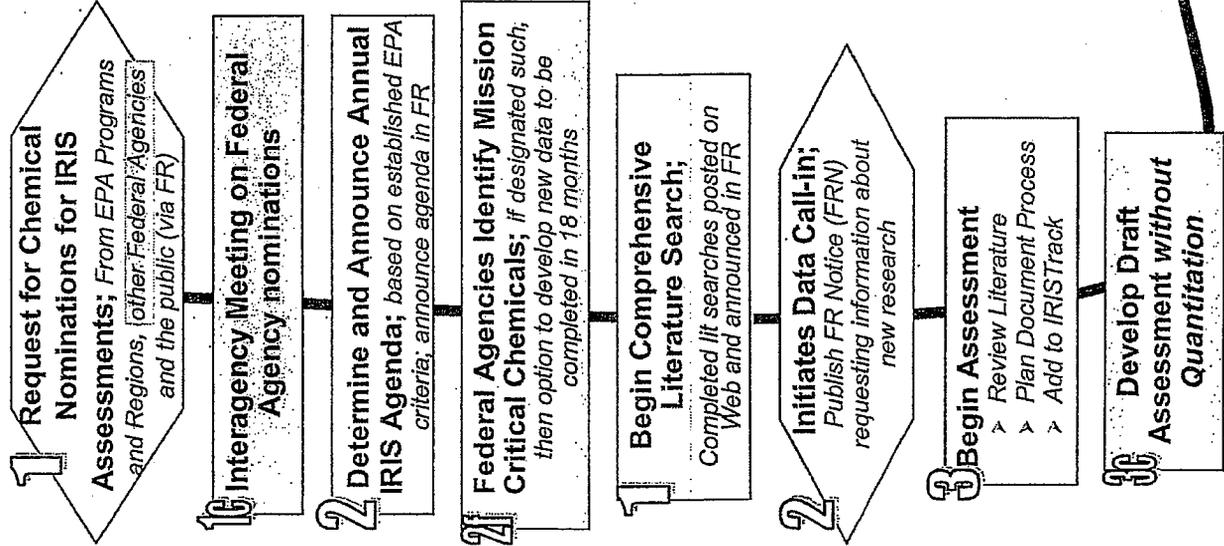
2. What role will OIRA play? This is really a more specific observation related to control, but the new plan announced by Administrator Jackson is ambiguous about what White House offices will be involved in reviews of EPA IRIS proposals. Because discussion of proposed listings is supposed to be limited solely to “science” matters, it is hard to imagine any White House office actually having the time or resources to appropriately weigh in on science matters—even the Office of Science and Technology Policy. There is no office in the White House that does “science” per se. OIRA is really designed to weigh in on the “risk management” side of the regulatory equation, not the “risk assessment” or science side which comes well before any regulatory proposal is even contemplated. No office in the White House is more influential with agencies than is the Office of Management and Budget (OMB) precisely because OMB controls every agency’s budget request. OIRA is housed at OMB and that location gives them a very powerful voice, when they raise it, in the work of the line agencies. Is it appropriate to let OIRA play any role at all in science matters?
3. Productivity: While the newly announced process does eliminate some steps in the IRIS approval process, it remains to be seen whether it will allow for a substantial increase in IRIS entries being finalized by EPA. With 700 new chemicals entering the marketplace each year, and a backlog of needed updates and new entries, the bare minimum standard for success of IRIS is probably 20 entries a year—which is what the new process promises to deliver.

The Subcommittee will pursue these matters, and others, during the hearing. If IRIS is unable to function effectively, public health and safety will ultimately suffer. Getting this program right is a high priority for the Subcommittee and the country. The Subcommittee Chairman expects to send a request letter to the Government Accountability Office to have them continue to monitor the new IRIS process.

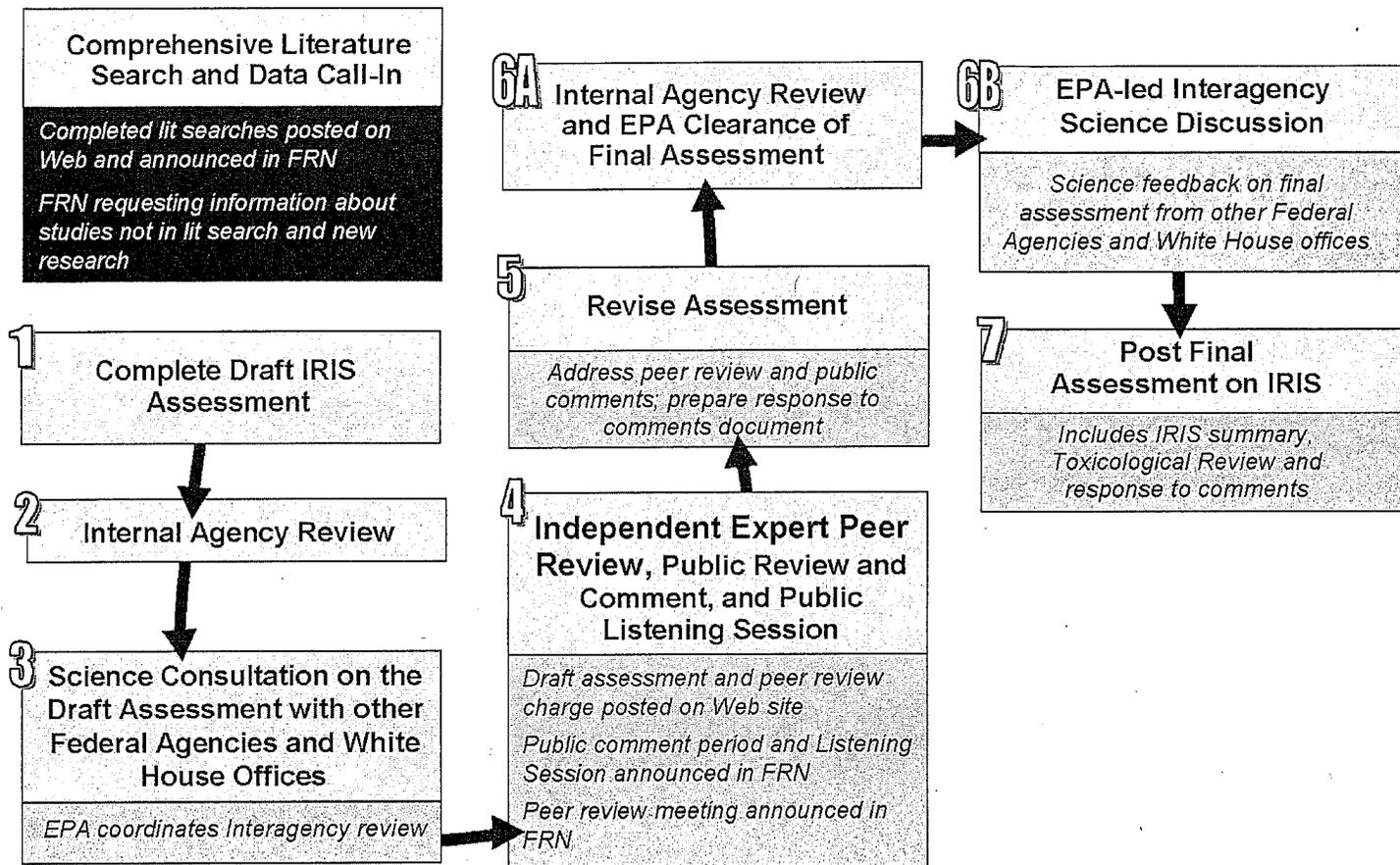
IRIS PROCESS: Pre-2004



DRAFT Revised IRIS PROCESS: Post April 10, 2008



Assessment Development Process for New IRIS



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 **1. EPA Develops and Completes a Draft IRIS Toxicological Review (Duration**
2 **345 days)**

- 3 A. ORD assembles an IRIS assessment team.
- 4 B. ORD assesses the data in the scientific literature and any information submitted as a result of the
5 data call-in and develops a draft assessment for the chemical being assessed, including:
- 6 a. summary of potentially important health effects;
- 7 b. summary of information on potential mode(s) of action;
- 8 c. summary of information about potentially susceptible populations;
- 9 d. a quantitative assessment, including application of uncertainty factors, default approaches,
10 mode of action information, and dose-response modeling; and
- 11 e. identification of potential uncertainties that impact the qualitative and quantitative aspects of
12 the assessment.
- 13 C. ORD completes the draft IRIS Toxicological Review.
- 14

15 **2. Internal EPA Review (Duration 60 days)**

- 16 A. ORD submits the draft IRIS Toxicological Review for internal Agency review.
- 17 B. Internal Agency review includes scientists from EPA programs and regions.
- 18 C. Internal agency review identifies any scientific issues to determine the level of peer review, needed
19 panel member disciplines, and the scope of the review.
- 20

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

- 23 A. EPA sends the draft IRIS Toxicological Review and draft external peer review charge to other
24 Federal agencies and White House offices for a science consultation.
- 25 B. The science consultation step is managed and coordinated by EPA
- 26 a. EPA provides a specified date for receipt of written comments.
- 27 b. EPA hosts meeting of other agencies and White House offices to discuss issues raised by
28 comments.
- 29 C. All written comments received during Interagency Science Consultation become part of the public
30 record
- 31 D. ORD revises the draft assessment documents, as appropriate.
- 32 E. If EPA considers appropriate, science questions that arise during science consultation may be
33 included as part of a charge question to the peer review panel.
- 34
- 35
- 36
- 37

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

4 A. External Peer Review

- 5 a. EPA provides the draft IRIS Toxicological Review and peer review charge questions for
6 independent external peer review.
- 7 b. EPA publishes an FRN at least 30 days prior to the peer review meeting notifying the public
8 about the time and place of the meeting.
- 9 c. Peer reviews are public meetings, generally through a face-to-face meeting of panelists,
10 though some may be held via public teleconference.
- 11 d. The report of the external peer review panel becomes part of the official public record for the
12 IRIS assessment

13 B. Public Review and Comment

- 14 a. EPA releases the draft IRIS Toxicological Review for public review and comment.
- 15 b. ORD prepares an FRN announcing a public comment period of 60 days.
- 16 i. The draft IRIS Toxicological Review is released on EPA's Web site on the day that
17 the FRN is published.
- 18 ii. The FRN includes detailed instruction for submitting public comments.
- 19 iii. The public comment period is open to all stakeholders, including other Federal
20 Agencies and White House offices.
- 21 c. Public comments are submitted to ORD
- 22 i. All comments received during the official public comment period will be submitted
23 through E-Gov (www.regulations.gov).
- 24 ii. All public comments will be part of the official public record.
- 25 iii. Public comments submitted by the close of the comment period will be provided to
26 the peer reviewers at least 10 working days prior to the peer review meeting.
- 27 iv. Only those comments received by the close of the public comment period are
28 guaranteed of being provided to the external peer review panel in advance of the peer
29 review meeting.
- 30 v. If an extension of a comment period is requested and granted, and a second FRN is
31 published, the comments submitted during the extension may not be able to be
32 provided to the peer reviewers before the meeting.

33 C. Public Listening Session

- 34 a. EPA holds a Public Listening Session after the public release of the draft assessment and
35 before the peer review meeting.
- 36 b. The Listening Session provides an opportunity for interested parties to present scientific and
37 technical comments on the draft IRIS health assessment to EPA and other interested parties.
- 38 c. An FRN announcing the Listening Session is generally published as least 30 days prior to the
39 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



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**COMMITTEE ON SCIENCE AND TECHNOLOGY
SUBCOMMITTEE ON INVESTIGATIONS AND OVERSIGHT
U.S. HOUSE OF REPRESENTATIVES**

HEARING CHARTER

“Toxic Communities: How EPA’s IRIS Program Fails the Public”

Thursday, June 12, 2008
10:00 a.m. – 12:00 p.m.
2318 Rayburn House Office Building

The Subcommittee on Investigations and Oversight will hold the second hearing on the Integrated Risk Information System (IRIS) at the Environmental Protection Agency (EPA).

On May 21, 2008, the Subcommittee heard the Government Accountability Office’s (GAO) evaluation of the Administration’s new process for reviewing and approving chemical assessments for inclusion in the IRIS database. In their March 2008 review of EPA’s IRIS program GAO found that the IRIS database was at serious risk of becoming obsolete because the Agency has not been able to complete credible assessments in a timely manner or to reduce the backlog of 70 assessments that were in the development, review or approval process.¹ In their subsequent examination of the process implemented by the Administration on April 10, 2008, GAO testified that the recent assessment process changes and the other process changes being implemented by EPA were likely to increase the time needed to finalize IRIS assessments and to further reduce the credibility of IRIS assessments.²

The witnesses will address the role of IRIS assessments in the regulatory process for implementing environmental statutes administered by EPA and by state, territorial, and tribal governments and the consequences of extended delay in the IRIS assessment process for public health. They will also address questions regarding the Bush Administration’s evolving system to draft and review IRIS entries. Witnesses include:

- **Mr. Jerome Ensminger**, *Master Sergeant U.S. Marine Corps (ret.)*
- **Mr. Lenny Seigel**, *Center for Public Environmental Oversight*
- **Dr. Linda Greer**, *Senior Scientist, Natural Resources Defense Council*
- **Dr. David G. Hoel**, *Professor, Medical University of South Carolina*

¹U.S. Government Accountability Office (GAO). 2008. *Chemical Assessments Low Productivity and New Interagency Process Limit the Usefulness of EPA’s Integrated Risk Information System*. GAO-08-440.

²U.S. Government Accountability Office (GAO). 2008. *Chemical Assessments EPA’s New Assessment Process Will Further Limit the Productivity and Credibility of Its Integrated Risk Information System*. Testimony before the Subcommittee on Investigations and Oversight, Committee on Science and Technology, House of Representatives.