

IRIS Progress Report

IRIS Program Overview

EPA's Integrated Risk Information System, commonly called the IRIS program, provides health effects information on chemicals to which the public may be exposed from releases to air, water, and land and through the use and disposal of chemicals. IRIS assessments provide a scientific foundation for 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 Agency decisions. IRIS is also a resource for risk assessors and environmental and health professionals in state and local governments and other countries. Because of the critical importance of IRIS for the Agency and beyond, a strong, vital and scientifically sound assessment development process is key to providing needed health risk information. Over the past two years, EPA has strengthened and streamlined the IRIS program, improving transparency and increasing the number of final assessments added to the IRIS database. Continually improving the IRIS program is an ongoing priority for the Agency, and efforts are underway to further strengthen and streamline this important program.

Background

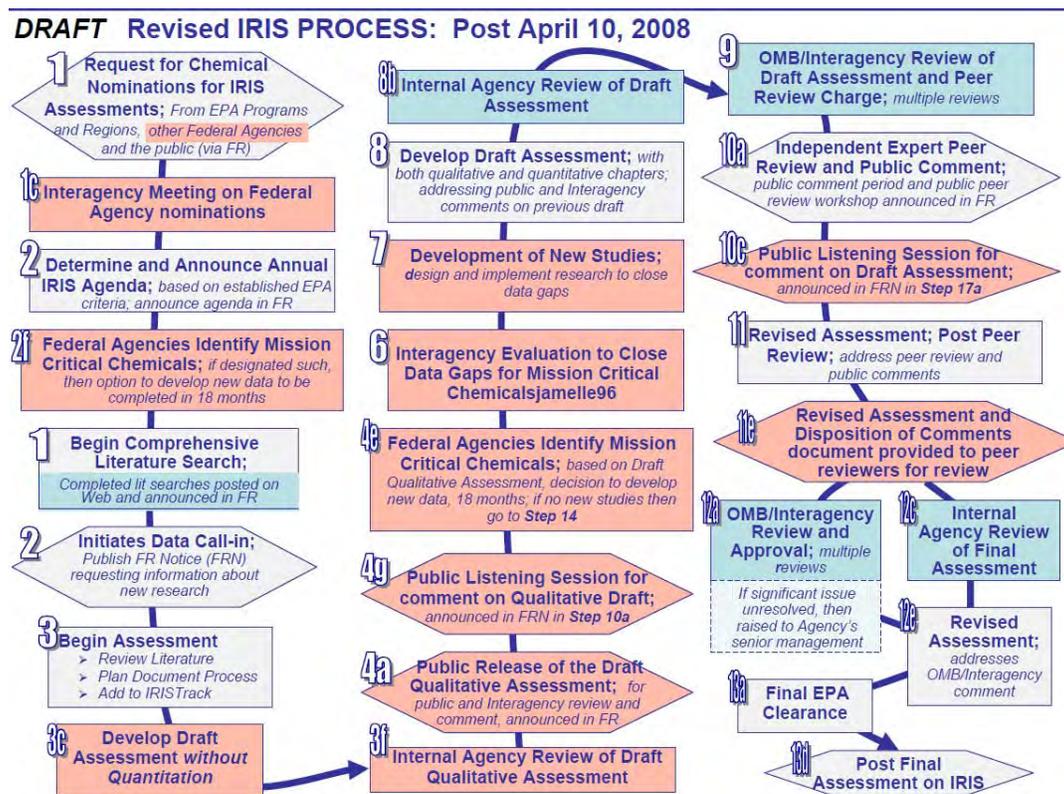
In March, 2008, the Government Accountability Office (GAO) submitted the report, "Chemical Assessments-Low Productivity and New Interagency Review Process Limit the Usefulness and Credibility of EPA's Integrated Risk Information System," to Congress, criticizing several aspects of the IRIS program. With a backlog of 70 ongoing assessments, in FY2006 and 2007 EPA sent 32 assessments for the first of three required interagency reviews; however, EPA finalized only 4 assessments. As of December 2007, most of the 70 ongoing assessments had been in progress for over 5 years.

In their report, GAO found that the IRIS database was at serious risk of becoming obsolete, concluding that EPA's efforts to finalize assessments had been thwarted by a

combination of factors, including two new interagency reviews, the involvement of other federal agencies in the IRIS assessment process in a manner that limited the credibility of the program and EPA's ability to manage it, the lack of transparency surrounding the interagency review, and delaying assessments to await new research.

In April 2008, EPA issued a revised IRIS assessment process that codified the new interagency reviews (See Figure 1), as well as a number of additional steps. A subsequent September 2008 GAO investigation found that the new process included key changes that were likely to further exacerbate the productivity and credibility concerns they had previously identified. For example, comments from other federal agencies on IRIS assessments were deemed "deliberative" and excluded from the public record. Additionally, GAO estimated the time frames under the new process, especially for chemicals of key concern, would take 6 to 8 years from the start of an assessment to completion.

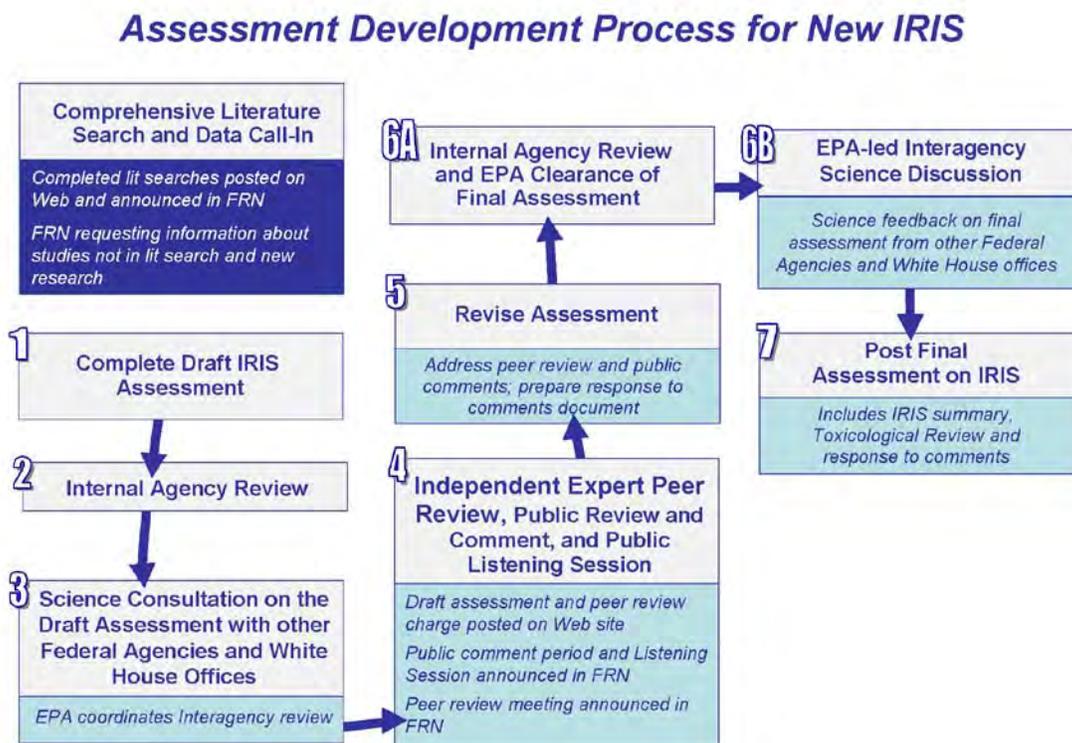
Figure 1. IRIS Process April 2008 to May 2009.



Changes to the IRIS Process under Administrator Lisa Jackson

Recognizing the importance of the IRIS program, and taking seriously the GAO recommendations, EPA Administrator Lisa Jackson undertook a thorough review of the IRIS process. In May 2009, she announced a new IRIS assessment development process (Figure 2) that would streamline, strengthen and improve transparency within the program while ensuring the highest level of scientific quality and integrity and a renewed commitment to rigorous independent peer review.

Figure 2. IRIS Process After May 2009



The May 2009 process included the following key features:

- EPA would manage the IRIS program and have final responsibility for the content of all IRIS assessments

- The assessment development time was shortened to 23 months, a reduction of more than half the estimated time for an assessment to be developed under the previous process
- The number of steps in the assessment development process was reduced from 14 to 7
- Other federal agencies and White House offices would have the opportunity to provide scientific input at two points in the assessment development process, and the comments would be made publicly available
- The assessment development process would include the opportunity for public comment and rely on an open, rigorous and independent external peer review
- A public listening session would be offered for each chemical assessment
- Changes in EPA's scientific judgments during the process would be clearly documented and explained

While these changes streamlined the IRIS assessment development process, EPA has remained strongly committed to scientific integrity, public involvement, rigorous independent external peer review, and full consultation with scientists at White House offices and other federal agencies. For example, there are multiple opportunities for public involvement throughout the IRIS process:

- Opportunity for public nominations for substances to be considered for an assessment or reassessment through the IRIS program
- Public availability of a completed literature review on a chemical at the beginning of the assessment development process
- Request for information from the public on studies not included in the literature review as well as new research
- Public availability of a draft IRIS assessment document for review and comment
- Listening session, where any member of the public can make comments or present information about or related to the draft assessment
- Independent expert peer review meeting, which is open to the public and where members of the public may make formal comments and presentations

Further changes to IRIS since the new May 2009 process

Since announcing this new process, EPA has continued to make improvements to the IRIS program. For example, EPA's program and regional offices now have an extended role in nominating and prioritizing chemicals for assessment to ensure that the IRIS program is focused on the highest Agency needs. Additionally, IRIS program managers regularly meet with EPA's programs and regions to discuss individual IRIS assessments and the IRIS process. EPA has created an IRIS logistics team to help further streamline the assessment development process; this team is charged with coordinating all administrative support, freeing up scientific staff to focus on the science of the assessments.

EPA has also maintained and strengthened a commitment to rigorous independent peer review. Every draft IRIS assessment is subjected to rigorous, open, independent external peer review by a panel with relevant scientific expertise. Peer review panels are organized by EPA's Science Advisory Board (SAB), EPA's contract peer review mechanism, or the National Academy of Sciences (NAS). Regardless of their origin, all IRIS peer reviews follow the same rules regarding balance, transparency, and scientific rigor, and all peer review panel members are required to disclose any real or perceived conflicts of interest. All peer review meetings are open to the public and allow the public to make formal comments and presentations. Assessments that are considered high profile may be peer reviewed by panels of experts convened by the SAB or the NAS. In fact, in the past two years, EPA has gone to extraordinary lengths to accommodate requests for additional expert peer review for our most scientifically complex assessments. For example, the draft IRIS formaldehyde assessment was recently reviewed by the NAS rather than by contractor-led external peer review because of the complexities of evaluating the toxicity of inhalation exposures to the chemical. Additionally, in 2010 EPA asked the SAB to conduct an additional round of peer review of the draft IRIS assessment for arsenic, the culmination of a long history of efforts by EPA which included several high quality peer reviews of the draft assessment by the NAS in 1999 and 2001 and the SAB in 2007.

EPA also developed the Health and Environmental Research Online – or HERO – database, which promotes transparency in risk assessments by capturing the scientific literature used in Agency health and environmental assessments and making the scientific studies selected and used by the Agency to develop assessments available to the public. The HERO database is web-based and accessible to everyone. Additionally, EPA has developed Memoranda of Understanding with the California Environmental Protection Agency’s Office of Environmental Health Hazard Assessment and the Agency for Toxic Substances and Disease Registry to cooperate in the development of health assessments, paving the way to sharing data and avoiding duplication of effort. The overarching goal of these cooperative efforts is to further increase efficiency and assessment output. Finally, EPA has recently hired a highly respected risk assessor with national and international risk assessment experience to serve as the IRIS Program Director.

In addition to these process changes, EPA has increased the resources dedicated to the IRIS program. From Fiscal Year 2009 to 2010, the number of staff assigned to the IRIS program has increased by more than 25 percent, and funding has increased by more than 50 percent.

2009 IRIS process and improved results

Since the new process was instituted in 2009, EPA has completed 16 assessments, more than the number of assessments that were completed in the previous four years. The IRIS backlog has been significantly reduced, and the Agency has 70 assessments in the IRIS process at various stages. In FY 2010, EPA completed 10 IRIS assessments and released nine for external peer review and public comment, seven of which were major assessments. In FY 2011, we anticipate releasing a total of 13 completed assessments, including a number of major assessments, such as trichloroethylene, tetrachloroethylene, arsenic, and ethylene oxide. In addition, we have a number of assessments that will be released for external peer review, including Polychlorinated biphenyls (PCBs) and Libby amphibole asbestos.

	Draft Assessments Start Interagency Review/Consultation	Draft Assessments Start Independent External Peer Review	Final Assessments Posted on IRIS
FY2006	11	1	2
FY2007	16	12	2
FY2008	5	12	5
FY2009 1 st - 3 rd qtrs.	9	3	1
FY2009 4 th qtr. (May 21, 2009 – New IRIS Process)	1	7	6
FY2010	5	9	10
FY2011 (projected)	17	9	13

	Draft Assessments Start Interagency Review/Consultation (Points)	Draft Assessments Start Independent External Peer Review (Points)	Final Assessments Posted on IRIS (Points)
FY2009	25	14	9
FY2010	21	37	19
FY2011 (projected)	32	20	30

NAS Recommendations to Further Improve IRIS

In April, 2011, the NAS released its “Review of the Environmental Protection Agency’s Draft IRIS Assessment of Formaldehyde.” In addition to offering comments about EPA’s draft formaldehyde assessment, the NAS included comments and recommendations to improve IRIS documents. EPA welcomed those recommendations and will fully implement the recommendations over the coming months.

The NAS focused their comments on the development of draft IRIS assessments and did not recommend changes to the overall IRIS process. The NAS recommended that EPA improve the clarity, readability, and transparency of IRIS assessment documents, specifically noting that EPA should rigorously edit assessment documents to reduce the text volume and address redundancies and inconsistencies. EPA is doing this, and the Agency is building on existing

IRIS guidelines to enhance the clarity and transparency of data evaluation and presentation of findings and conclusions. We are also consolidating related discussions to eliminate redundancies, increasing the use of tables and figures to improve communication of information, and providing reference information for all studies considered on the IRIS website.

The NAS also recommended that IRIS assessment documents include a fuller discussion of methods and a concise statement of the criteria used to exclude or include studies for hazard evaluation and derivation of toxicity values. EPA is doing this, and the Agency is also working towards replacing text study descriptions with standardized evidence tables that provide the methods and results of each study for all health outcomes.

Additionally, the NAS recommended that EPA more clearly articulate the rationale and criteria for screening studies. To do this, EPA is enhancing the sequential approach for focusing on the most pertinent information by searching the literature, identifying the relevant studies, and evaluating study characteristics. In addition, EPA will evaluate the overall weight of evidence for each health outcome; identify plausible approaches for developing toxicity values; select the most pertinent data and develop toxicity values for each health hazard; and portray toxicity values graphically.

The NAS also recommended that EPA use uniform approaches to thoroughly evaluate the strengths and weaknesses of critical studies, summarize its findings in tables, and clearly articulate the rationale for selecting studies used to calculate toxicity values. To accomplish this, EPA is streamlining IRIS assessment documents and more fully documenting the approach taken to assemble and evaluate the range of scientific data. EPA has already made similar changes to how it presents scientific evidence on the criteria air pollutants in the Integrated Science Assessments (ISA), and we are confident we can make comparable improvements for the IRIS program.

Finally, the NAS recommended that EPA describe the various determinants of weight of evidence to promote understanding of the elements that were emphasized in synthesizing the

evidence. EPA is augmenting its current analysis of data to indicate which criteria were most influential in evaluating the weight of the evidence.

In making these changes that address the NAS recommendations, EPA's goal is to continually improve IRIS assessment without taking any assessment backwards to earlier steps of the process, a point that the NAS emphasized. Therefore, consistent with the advice of the NAS, these recommendations will be implemented in a tiered approach, making the most extensive changes to documents that are in the earlier stages of the assessment development process. For draft assessments that are in the later stages of development, EPA will implement the recommendations as feasible without taking the assessments backwards to earlier steps of the process. This is the same approach EPA took when it made similar changes to the ISA process.

The changes to the IRIS process announced by the Administrator in 2009 have substantially improved the program and its ability to generate timely and credible scientific health assessments. Changes made since 2009 have further strengthened and streamlined the program. EPA is confident that implementing the recent recommendations from the NAS will continue to improve IRIS assessments. To further ensure a strong, scientifically sound and efficient program, EPA is working with the Science Advisory Board to create a standing IRIS Advisory Committee, similar to the Clean Air Science Advisory Committee. The purpose of this standing peer review committee will be to provide independent, expert scientific peer review for IRIS assessments. A clear benefit of this standing committee is that it will serve as an additional quality control measure, ensuring that any IRIS process improvements are successfully implemented and truly enhance the program. EPA will also add an early peer consultation step to the IRIS draft development process for major assessments. This will facilitate the early involvement of scientists in the draft development process, informing the development of early drafts of IRIS assessments. Overall, by taking these steps, EPA believes we will be able to even further accelerate the pace of IRIS assessment development.

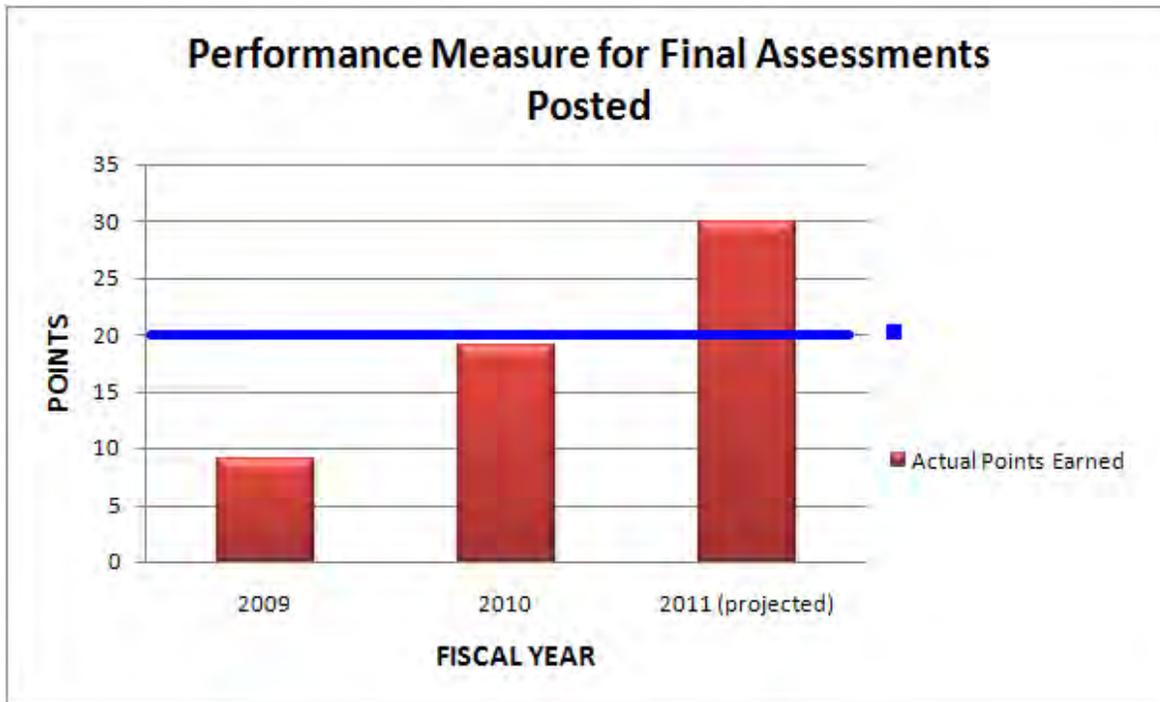
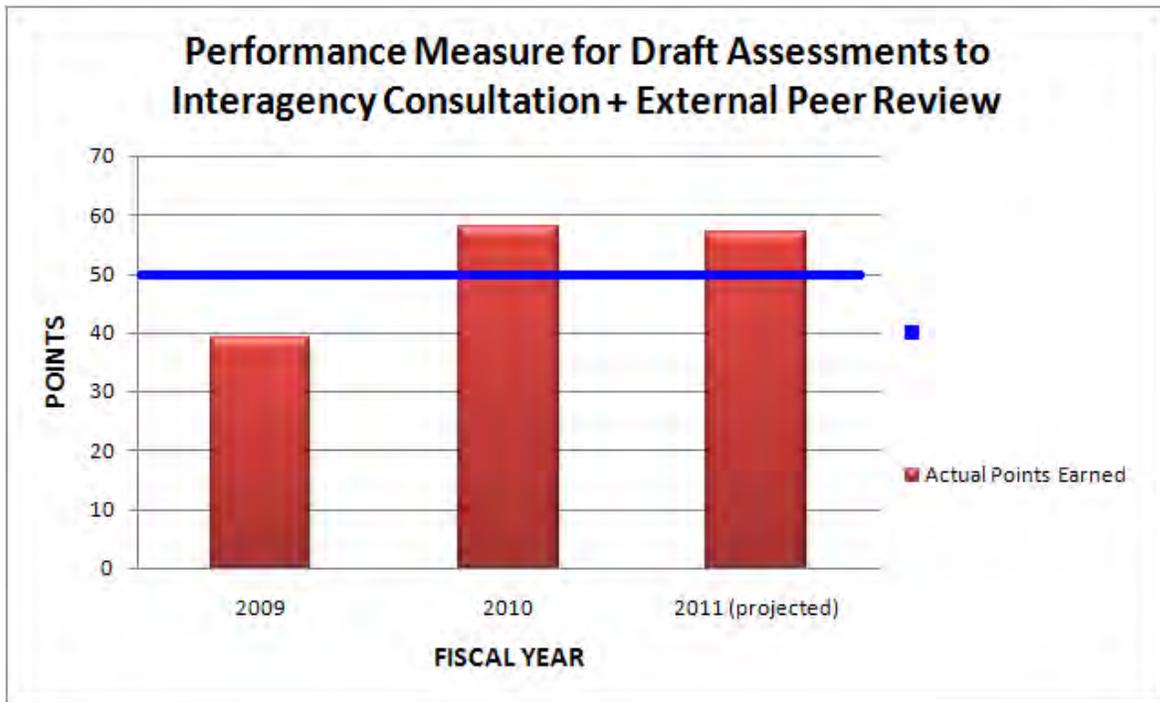
Conclusion

The standards to which IRIS assessments are held, including the rigorous independent external peer review for every draft IRIS assessment, are second to none in the federal government and the scientific community. Over the coming months, the IRIS program will fully implement the NAS recommendations and continue to improve the IRIS process to reflect the highest standards of scientific integrity and credibility. Strengthening and streamlining the IRIS process is a continuing and ongoing priority for EPA.

Appendix A. Summary of NAS Recommendations and EPA’s Actions

NAS Recommendation	EPA Action
<p>Improve clarity, readability, and transparency of IRIS assessment documents. Rigorously edit to reduce text volume and address redundancies and inconsistencies.</p>	<p>EPA is building on existing IRIS guidelines to enhance clarity and transparency of data evaluation and presentation of findings and conclusions. EPA is consolidating related discussions to eliminate redundancies, increasing use of tables and figures to improve communication of information, and providing reference information for all studies considered on the IRIS website.</p>
<p>Include a fuller discussion of methods and a concise statement of the criteria used to exclude, include and advance studies for hazard evaluation and derivation of toxicity values.</p>	<p>EPA is doing this, and the Agency is working towards replacing text study descriptions with standardized evidence tables that provide the methods and results of each study for all health outcomes.</p>
<p>More clearly articulate the rationale and criteria for screening studies.</p>	<p>EPA is enhancing the sequential approach for focusing on the most pertinent information by searching the literature, identifying the relevant studies, and evaluating study characteristics. EPA will evaluate the overall weight of evidence for each health outcome; identify plausible approaches for developing toxicity values; select the most pertinent data and develop toxicity values for each health hazard; and portray toxicity values graphically.</p>
<p>Use uniform approaches to thoroughly evaluate the strengths and weaknesses of critical studies, summarize findings in tables and clearly articulate the rationale for selecting studies used to calculate toxicity values.</p>	<p>EPA is streamlining IRIS assessment documents and more fully documenting the approach taken to assemble and evaluate the range of scientific data. EPA has already made similar changes to how it presents scientific evidence on the criteria air pollutants in the Integrated Science Assessments, and we are confident we can make comparable improvements for the IRIS program.</p>
<p>Describe the various determinants of weight to promote understanding of the elements that were emphasized in synthesizing the evidence.</p>	<p>EPA is augmenting its current analysis of data to indicate which criteria were most influential in evaluating the weight of the evidence.</p>

Appendix B.



Appendix C. Detailed description of the current IRIS assessment development process

Prior to the start of the draft human health assessment development, EPA conducts a scientific literature search. All draft assessments are subjected to rigorous, open, independent external peer review. Selected assessments considered high profile may be peer reviewed by panels of experts convened by EPA's Science Advisory Board or by the National Academy of Scientists. Also, IRIS assessments developed under this 7-step process (described below) are expected to be completed within approximately 2 years from the Step 1 start date. Some assessments, because of their complexity, extensive literature base, or public visibility, may take longer.

Step 1 – EPA develops and completes a draft toxicological review in a period of 345 days.

Step 2 – EPA submits this draft throughout the Agency to appropriate program and regional offices for internal Agency review. This is accomplished in 60 days.

Step 3 – The Agency initiates science consultation on this draft assessment, i.e. the assessment and draft external peer review charge are sent to other Federal agencies and White House offices requesting written comments, which become part of the public record. EPA revises the draft assessment based on these comments. This step in the process takes 45 days.

Step 4 – EPA initiates independent external peer review, provides the opportunity for public review and comment of the draft assessment and conducts a public listening session during a period of 105 days.

Step 5 – The Agency evaluates the external peer review panel report and the public comments, revises the draft toxicological review, as appropriate, into a final review and develops a summary. This is done in 45 days.

Step 6 has two parts that occur concurrently:

6A – EPA submits the final toxicological review and summary for the second and final internal Agency (program and regional offices) 45-day review.

6B – EPA conducts and leads a 45-day interagency science discussion with other Federal agencies and White House offices, affording the opportunity to both to provide written feedback to EPA on the science in the assessment. All written comments are publicly documented.

Step 7 – The Agency completes the toxicological review and summary in 30 days and posts the assessment to the public IRIS data base.

The total time for this 7-step IRIS process is 23 months.

Appendix D. Description of peer review process

EPA releases all draft IRIS assessments for public review and comment and publishes an FRN announcing a public comment period of 60 days. The draft IRIS Toxicological Review is released on EPA's Web site on the day that the FRN is published. The FRN includes detailed instruction for submitting public comments. The public comment period is open to all stakeholders, including other Federal Agencies and White House offices.

EPA holds a Public Listening Session after the public release of the draft assessment and before the peer review meeting for the purpose of providing an opportunity for interested parties to present scientific and technical comments on the draft assessment. An FRN announcing the Listening Session is published at least 30 days prior to the Listening Session meeting and includes logistical information regarding the meeting. All public comments submitted to EPA during the official public comment period are submitted through E-Gov (www.regulations.gov) and become part of the official public record and are provided to the peer reviewers at least 10 working days prior to the peer review meeting.

During the external peer review, EPA provides the draft IRIS Toxicological Review and peer review charge questions for independent external peer review. This is followed by a Federal Register Notice (FRN) at least 30 days prior to the peer review meeting notifying the public about the time and place of the meeting. Peer reviews are public meetings, generally through a face-to-face meeting of panelists, though some may be held via public teleconference. The report of the external peer review panel becomes part of the official public record for the IRIS assessment