

IRIS STOPPING RULES

The review period for IRIS assessments (consisting of Agency Review, Interagency Science Consultation, Public Comment, Peer Review, Final Agency Review, and Interagency Science Discussion) is projected to take between 15 and 24 months, depending on the complexity of the assessment and the mechanism for obtaining peer review. During this time, it is expected that new scientific studies will be published. Accordingly, it is important to have a process for determining how to include new studies in an assessment without introducing delay or cycling through repeated revisions and re-reviews.

The IRIS Program has begun to announce annually which assessments will be started during the following 2-3 years. In addition, the enhanced IRIS process includes a public problem formulation meeting before work on an assessment begins. By allowing this time for interested parties to conduct and complete research in progress, the IRIS Program hopes to minimize the need for delaying a draft assessment to wait for new studies.

Nonetheless, late studies will sometimes have an important impact on an assessment, and the IRIS Program would like completed assessments to reflect the published scientific record. At the same time, the IRIS Program is expected to complete assessments without undue delay in order to meet the needs of Agency program and regional offices who have time critical needs for the results of completed IRIS assessments.

In general, new studies can be included until a few months before an assessment is released for review. During the early review steps and before the public peer review meeting, new studies may be included, though it is important not to delay the assessment's progress by adding new studies or analyses that do not affect the assessment's conclusions. It is also important that an assessment not become out of date by repeating the early review steps.

After peer review, the presumption shifts to not including new studies unless they have an impact on the credibility of an assessment's conclusions. Examples might be a strong new study that indicates a heretofore undiscovered health effect, or a strong new study that might change, in either direction, a major conclusion. Quantitatively, such a study would likely have the ability to significantly influence the selection of health effect or uncertainty factors for deriving a toxicity value, or to provide important mechanistic insights that would change the approach to dose-response assessment. On the other hand, a new study that merely confirms existing studies would not need to be added to an assessment that has undergone public peer review.

These principles are further described in the table on the next page.

Step in IRIS Process		For Studies Published or Accepted for Publication After EPA's Initial Literature Search, EPA will:	For Studies Submitted but Not Yet Accepted for Publication After EPA's Initial Literature Search, EPA will:	For Research in Progress, EPA will:
–	Before public problem formulation meeting	Fully consider the studies in Step 1 draft documents and in Step 4 draft assessment.	Fully consider the studies in Step 1 draft documents (if published in advance of the release of the documents for public comment) and in Step 4 draft assessment.	Review the written research plan and discuss it with the researcher. If the study promises to be critical, EPA may adjust the start of the assessment to accommodate the research plan timeline.
1a	After problem formulation and before Step 1 public meeting	Fully consider the studies in Step 1 draft documents and in Step 4 draft assessment.	Fully consider the studies in Step 1 draft documents (if published in advance of the release of the documents for public comment) and in Step 4 draft assessment.	Review the written research plan and determine whether delay is warranted. The research must promise to be a highly critical addition to the existing data.
1b, 2, 3	After Step 1 public meeting and before release of Step 4 public comment draft	Review the studies for pertinence and quality. From this step forward, new studies that have been accepted for publication will be considered in a manner that does not delay the assessment development and review process. The use of new studies in the assessment will be discussed in the LitSearch section. If added to the assessment after Steps 2 or 3, those steps need not be repeated. Step 2 and 3 reviewers will be informed of the implications of the new studies, as appropriate.	At this point, EPA will no longer consider studies unless they have been accepted for publication as described at left. It is expected that research in progress will have been discussed prior to the Step 1 public meeting.	
4a	After release of public comment draft and before release of peer review draft	Review the studies for pertinence and quality. The study may be added to the peer review draft without repeating earlier steps.		
4b	After release of peer review draft and before peer review meeting	Review the studies for pertinence, quality, and impact on the conclusions. EPA will present its determination orally at the peer review meeting. The study will be added to the assessment if recommended in the Final Peer Review Report by the peer review panel.		
5, 6, 7	After peer review meeting and before posting	Review the studies for pertinence, quality, and impact on the credibility of the assessment's conclusions. EPA will discuss its determination with the chair of the peer review panel.		