

Legal Lookout: EPA Updates IRIS Process, Again

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As EPA works to get its toxicological database back on track after lapsing for years, big questions arise as to the process' integrity.

EPA announced in a May 21, 2009, memorandum that it has reformed the Integrated Risk Information System (IRIS), again. According to the agency, the revisions are intended to "revitalize the program and ensure its scientific quality, integrity, transparency and timeliness." In the memo, Administrator Jackson stated that recent changes, including procedures formalized in an April 21, 2008, memorandum, "have reduced the transparency, timeliness, and scientific integrity of the IRIS process."

The new process will be entirely managed by EPA, which will have final responsibility for the content of all IRIS assessments. To ensure the scientific quality of IRIS assessments, the process will include the opportunity for public comment and rely on "a rigorous, open, and independent external peer review." The IRIS 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." Jackson's memo and other materials are available at <http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=190045>.

Prior to the development of a draft IRIS assessment, EPA will conduct a scientific literature search and initiate a data call-in. EPA will post the completed literature search on its website. Once the agency has completed literature searches for a set of chemicals, they will publish a Federal Register notice announcing its availability and requesting the submission of additional scientific information. Once the literature search and data call-in are complete, EPA will develop the IRIS human health assessment, using the seven steps described below. The agency states that although IRIS assessments are expected to be completed approximately two years from the Step 1 start date, some may take longer "because of their complexity, large scientific literature base, or high profile." The seven steps are:

1. EPA develops and completes a draft IRIS toxicological review (duration: 345 days)
2. Internal EPA review (60 days)
3. EPA initiates interagency science consultation on draft IRIS toxicological review (45 days)
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 (105 days)
5. EPA revises IRIS toxicological review and develops IRIS summary (60 days)
- 6A. Internal EPA review of final IRIS toxicological review and IRIS summary (45 days)

- 6B. EPA-led interagency science discussion (concurrent with Step 6A)
7. EPA completion of IRIS toxicological review and IRIS summary (30 days)

Total: 23 Months

The House Committee on Science and Technology's Subcommittee on Investigations and Oversight convened a hearing on June 11, 2009, to review the changes. The subcommittee expressed its interest in knowing "how many new listings the EPA expects to post each year, how many staff will be assigned to the process, and whether OMB will still be involved if the only issue is a scientific determination," according to Subcommittee Chair Brad Miller, D-N.C.

The subcommittee convened two hearings on IRIS last year, and introduced legislation to address what it regarded as a loss of control by EPA over the scientific process, and a lack of speed with regard to the number of IRIS assessments produced each year. Under the draft legislation, EPA would be required to issue a minimum of 15 assessments and five updated assessments each year.

Some in industry have expressed concern with a noticeable lack of checks and balances in the new process. The concern is that without more independent review by others, the process may suffer from a lack of objectivity.

Regardless of which side of the debate on which you sit, most would agree the IRIS process is broken. Whether the repairs most recently offered by EPA will fix the program remains to be seen. PE

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