

Legal Lookout: IRIS Redux

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After years of falling behind, EPA updates the IRIS process.

EPA announced on May 21, 2009, that it has reformed the Integrated Risk Information System (IRIS). According to the agency, the revisions are intended to "revitalize the program and ensure its scientific quality, integrity, transparency and timeliness."

The new administration

In a May 21, 2009, memorandum, EPA Administrator Lisa P. 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." According to Jackson, the importance of transparency and scientific integrity in government decision-making "compelled a rethinking of the IRIS process."

The new process will be managed by EPA. 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 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 memorandum and other materials are available at <http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=190045>.

The new process

Prior to a draft IRIS assessment, EPA will conduct a scientific literature search and initiate a data call-in. The agency will post the completed literature search on its website. Once EPA has completed literature searches for a set of chemicals, the agency will publish a Federal Register notice and ask for additional scientific information. The agency will then develop the IRIS human health assessment, using the seven steps described below. EPA 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 (345 days)
2. Internal EPA review (60 days)
3. Interagency science consultation on draft review (45 days)
4. Independent external peer review of draft IRIS toxicological review, public review and comment, public listening session (105 days)
5. EPA revises toxicological review and develops IRIS summary (60 days)
6. Internal EPA review of final review and summary, and interagency science discussion (45 days)

days)
7. Completion (30 days)

Congressional concern

On June 11, 2009, the House Committee on Science and Technology's Subcommittee on Investigations and Oversight held a hearing entitled Fixing EPA's Broken Integrated Risk Information System. Witnesses included John Stephenson, Director, Natural Resources and the Environment, the Government Accountability Office (GAO), and Kevin Teichman, Deputy Assistant Administrator for Science, ORD, EPA. Opening statements and witness testimony are available at

http://science.house.gov/publications/hearings_markup_details.aspx?NewsID=2485.

The hearing was intended to explore the effectiveness of the restructured IRIS process implemented by Jackson and to explore some concerns GAO had expressed earlier about deficiencies in the IRIS process. According to GAO, some files have taken over 10 years to complete. Witnesses agreed that the new IRIS process was an improvement, but Stephenson remained uncertain about the effectiveness of the 23-month schedule for IRIS, as well as the purposes of some of the scheduled interagency consults.

Implications

The IRIS database is internationally recognized and respected. Because IRIS health values are cited and relied upon by other federal, state, and local regulatory agencies, it is critical that stakeholders ensure that the process is open, transparent and scientifically defensible.

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