

Developments in Hazard and Risk Communication: The Integrated Risk Information System (IRIS)

EPA decision making in all of its programs depends on a central science database known as the Integrated Risk Information System (“IRIS”). IRIS attracted strong criticism under the Bush Administration. Newly announced changes to the IRIS process by the Obama Administration signal important developments affecting all EPA chemical risk assessments.

I. Introduction

The Integrated Risk Information System, or IRIS, is an influential database of electronic reports intended to allow quick access by EPA and the public to information on assessments describe and quantify hazard and dose-response data on the effects of several hundred selected chemicals. The Environmental Protection Agency (“EPA”) uses IRIS reports in its risk assessments under the Toxic Substances Control Act, Clean Air Act, Clean Water Act, and other statutory authorities.

The IRIS assessment process has become a flashpoint for controversy and a subject of Congressional scrutiny. One point of contention has been the program’s extraordinary backlog of assessments. In addition, critics alleged politicization of IRIS under the Bush Administration. New attempts by EPA under the Obama Administration to fix IRIS, reviewed by recent hearings in both houses of Congress, will greatly impact the regulated community.

II. Background: Clinton and Bush Administration Problems

EPA established IRIS in 1985 as a way to integrate and communicate human toxicology research on chemicals. Since then, EPA has used IRIS as a basis for many regulatory decisions regarding drinking water, air toxics, contaminated site cleanups, and other topics. The IRIS database is prepared and maintained by EPA’s National Center for Environmental Assessment (“NCEA”). The IRIS program requests nominations for new or updated assessments annually. EPA then drafts assessments based on scientific literature review, solicited data, and other inputs. The final assessment is published after a series of reviews. It provides weight-of-the-evidence descriptors and unit risks for chemicals not considered to have threshold effects, such as carcinogens, and a reference dose (“RfD”) and/or reference concentration (“RfC”) for the chemicals considered to have threshold effects.

However, the IRIS program has amassed a large and growing backlog of unfinished assessments, to the point that the Government Accountability Office (“GAO”) considers the program “at serious risk of becoming obsolete.” The sluggish pace of IRIS prompted the GAO to strenuously recommend a number of major procedural improvements in 2008.¹ Preparation of assessments often takes years, over which time new research may arise leading to yet more

¹ GAO, GAO-08-1168T, NEW ASSESSMENT PROCESS FURTHER LIMITS THE CREDIBILITY AND TIMELINESS OF EPA’S ASSESSMENTS OF TOXIC CHEMICALS 5 (2008), available at <http://www.gao.gov/new.items/d081168t.pdf>.

delays; for example, the assessment for trichloroethylene (“TCE”) was initiated in 1998 and has not yet been finished. In light of these delays, EPA’s ability to update prior assessments is also limited, despite the average age of most assessments being well over a decade.

Moreover, the Bush Administration revised the IRIS process in April, 2008,² adding further delays despite harsh criticisms by the GAO and others.³ Prior to the revisions, the IRIS assessment process released draft qualitative and quantitative assessments for peer review and for review by the public and other interested federal agencies at the same time. The revised process separated out the initial qualitative draft for its own review cycle, added additional non-public consultations with agencies such as the Department of Defense prior to public availability of the draft assessment, and allowed those agencies to identify a wide range of “mission critical” chemicals for which the process could be stalled for further study for an additional year and a half or more. Typical assessments would take many years even on schedule. Moreover, the revised process greatly increased the involvement of the White House Office of Management and Budget (“OMB”) and coordination of inter-agency reviews, while simultaneously making this involvement largely non-public.

III. Responses by the Democratic Congress and the Obama Administration

A. Oversight of the Bush Administration IRIS Process

The problems with IRIS, and in particular the perceived harms from Bush Administration’s 2008 revisions, prompted a great deal of attention from Congress and the GAO. In June 2008, the Subcommittee on Oversight and Investigations of the House Committee on Energy and Commerce held a hearing entitled “Toxic Communities: How EPA’s IRIS Process Fails the Public.”⁴ In September, the same Subcommittee held a hearing on the IRIS changes entitled “Science Under Siege: Scientific Integrity at the Environmental Protection Agency.”⁵ Rep. Bradley Miller (D-N.C.) introduced a bill in late 2008 to speed IRIS assessments and reduce agency reviews.⁶ Rep. Miller also commissioned a report from the majority staff of the House Committee on Science and Technology’s Subcommittee on Investigations and Oversight. The report, entitled “Nipping IRIS in the Bud: Suppression of Environmental Science by the Bush Administration’s Office of Management and Budget,” details instances of what the authors deem inappropriate secret interference with EPA science by the OMB.⁷

² EPA National Center for Environmental Assessment, IRIS Process (2008 Update), <http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=190045>.

³ See, e.g., GAO, *supra* note 1.

⁴ *Toxic Communities: How EPA’s IRIS Process Fails the Public, Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy & Commerce*, 110th Cong. (2008), available at http://science.house.gov/Publications/hearings_markups_details.aspx?NewsID=2217.

⁵ *Science Under Siege: Scientific Integrity at the Environmental Protection Agency: Hearing before the Subcomm. on Oversight & Investigations of the H. Comm. on Energy & Commerce*, 110th Cong. (2008), http://energycommerce.house.gov/index.php?option=com_content&task=view&id=1396&Itemid=106.

⁶ H.R. 7234, 110th Cong. (2008).

⁷ MAJORITY STAFF OF H. SUBCOMM. ON INVESTIGATIONS & OVERSIGHT OF THE H. COMM. ON SCI. & TECH., 111TH CONG., *NIPPING IRIS IN THE BUD: SUPPRESSION OF ENVIRONMENTAL SCIENCE BY THE BUSH ADMINISTRATION’S OFFICE OF MANAGEMENT AND BUDGET*, available at http://science.house.gov/publications/caucus_detail.aspx?NewsID=2499.

This year, the GAO added the IRIS assessment process to its 2009 *High Risk Series* list in January.⁸ Also, in the report accompanying the omnibus appropriations bill for fiscal year 2009, Congress urged EPA to complete pending IRIS assessments: “Given concerns that the newly revised IRIS process will exacerbate delays and reduce transparency, the Agency is directed to aggressively pursue completion of pending IRIS assessments and to report to the Committees the steps it will take to revise the IRIS process in accordance with recommendations [by the GAO].”⁹

B. The Obama EPA’s Overhaul of the IRIS Process

On May 21, 2009, EPA announced that it is largely overturning the Bush Administration’s procedural reforms to IRIS assessments and instituting new reforms.¹⁰ Under the current streamlined process, the quantitative and qualitative drafts are not separated for review, all comments (including from other agencies) must be public and science-based, and other agencies cannot delay the process. All told, the new process comprises advanced notice of chemicals to be assessed; data call-in and literature search; completion of a draft assessment and internal and inter-agency review; expert peer review and public comment on the draft; revision of the assessment and additional internal and inter-agency review; and issuance of a final assessment, generally within approximately 23 months after first assembling the assessment team for the chemical and beginning data review.¹¹ The Obama Administration has also requested a substantial funding increase for the IRIS program in its proposed Fiscal Year 2010 budget and plans to add more full-time staff to the program.¹²

C. Oversight of the Obama Administration IRIS Process

Recent hearings in both the Senate and the House of Representatives have investigated these updates to the IRIS program. On June 9, 2009, a joint hearing of the Senate Environment and Public Works Committee and its Oversight Subcommittee examined scientific integrity and transparency reforms at EPA.¹³ At the hearing, Democratic Senators repeatedly used the Bush Administration’s IRIS process as a prime example of lack of scientific integrity and transparency and the Obama Administration’s reforms as a prime example of progress. John B. Stephenson, Director for Natural Resources and Environment at the GAO, testified that the GAO’s

⁸ GAO-09-271, HIGH RISK SERIES: AN UPDATE (2009), available at <http://www.gao.gov/new.items/d09271.pdf>.

⁹ Statement: Appropriations Act of 2009, H.R. 1105, 111th Cong. Div. E, Title II, at 36 (2009), http://appropriations.house.gov/pdf/2009_Con_Statement_DivE.pdf. Similar direction “to aggressively pursue completion of pending IRIS assessments, such as trichloroethylene” was given in the House Appropriations Committee report for the prior appropriations bill in December as well. H. Rep. 110-920 at 41 (2008), available at http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=110_cong_reports&docid=f:hr920.110.pdf.

¹⁰ EPA Press release, EPA Announces New IRIS Assessment Development Process, May 21, 2009, available at <http://yosemite.epa.gov/opa/admpress.nsf/0/065E2C61AFE0917852575BD0064C9DB>.

¹¹ EPA’s Integrated Risk Information System Assessment Development Process, May 20, 2009, available at http://oaspub.epa.gov/eims/eimscomm.getfile?p_download_id=489351.

¹² Memorandum from Lisa P. Jackson, EPA Administrator, to Assistant Administrators et al., re: New Process for Development of Integrated Risk Information System Health Assessments, May 21, 2009, at 2, available at http://oaspub.epa.gov/eims/eimscomm.getfile?p_download_id=489350.

¹³ *Scientific Integrity and Transparency Reforms at the Environmental Protection Agency: Hearing Before the S. Comm. on the Environment and Public Works*, 111th Cong. (2009), http://epw.senate.gov/public/index.cfm?FuseAction=Hearings.Hearing&Hearing_ID=a3282f69-802a-23ad-4b7b-256cc6378cf1.

preliminary review of EPA's May 2009 revisions to the IRIS process indicated that "if effectively implemented, the new process would be largely responsive to [the GAO's 2008] recommendations."¹⁴

At a hearing held June 11, 2009 before the House Science and Technology Committee's Investigations and Oversight Subcommittee,¹⁵ Chairman Bradley Miller (D-N.C.) and Ranking Member Paul Broun (R-Ga.) delved deeper into the IRIS process changes, which were summarized by Dr. Kevin Teichman, Deputy Assistant Administrator for Science at EPA's Office of Research and Development. Rep. Miller reiterated harsh criticisms of the Bush Administration's IRIS process revisions, while Rep. Broun criticized the criticisms. However, both Congressmen advocated for public availability of all materials, including records of meetings and important oral discussions. The GAO's John Stephenson testified at this hearing as well, expanding on the GAO's assessment of the IRIS changes in the earlier Senate hearing. He noted some skepticism of EPA's ability to meet its stated timelines, and offered a number of suggestions, including:¹⁶

- EPA should provide at least two years advance notice of planned assessments in order to allow stakeholders to complete relevant research.
- The nature and role of the consultations with OMB and other agencies should be clarified, and such meetings should be documented. Also, EPA could solicit comments from other federal agencies at the same time it provides the draft assessment to peer reviewers and the public for comment.
- EPA should provide time frames for the literature search and data call as well as other pre-assessment steps, as their omission tends to understate the amount of time the overall process would take; "when assessments take longer than 2 years, they can become subject to substantial delays stemming from the need to redo key analyses to take into account changing science and assessment methodologies."
- Congress should consider enacting enforceable statutory deadlines, and EPA should consider establishing its IRIS process in formal regulations to limit the frequency of changes.

The Subcommittee asked the GAO to formally "undertake a review of how the new IRIS process performs in practice."¹⁷

IV. Implications

A revitalized IRIS program promises greater and more up-to-date information for the public and for regulators, and both benefits and costs to industry. Industry should be prepared for the faster assessments and reduced consideration of important chemical uses (i.e., "mission

¹⁴ *Id.* (statement of John B. Stephenson, GAO), available at <http://www.gao.gov/new.items/d09773t.pdf>.

¹⁵ *Fixing EPA's Broken Integrated Risk Information System: Hearing Before the Subcomm. on Investigations and Oversight of the H. Comm. on Sci. & Tech.*, 111th Cong. (2009), http://science.house.gov/publications/hearings_markups_details.aspx?NewsID=2485.

¹⁶ *Id.* (statement of John B. Stephenson, GAO), available at <http://www.gao.gov/new.items/d09774t.pdf>.

¹⁷ Letter from Rep. Brad Miller to Gene L. Dodaro, Acting Comptroller General, GAO (June 10, 2009), available at http://democrats.science.house.gov/Media/file/Commdocs/hearings/2009/Oversight/11jun/Miller%20Letter_Dodaro_IRIS.pdf.

critical” chemicals) leading to some more chemicals being found hazardous and thereby regulated. Conversely, more up-to-date information may lead to reduced hazard findings for some chemicals, particularly in light of advances in the science and technologies of toxicology. While the timeline for stakeholder input has been shortened, slightly expanded “listening sessions” during the public comment period and possible improvements to the advanced notice given regarding impending chemical assessments retain some opportunity for industry to provide important information for timely use by peer reviewers. Increased government transparency may also cut both ways: the possibility of greater public availability of meeting records may end up hindering some stakeholder communications due to privacy concerns, but both industry stakeholders and the public could also benefit from the additional information on how EPA has reached its conclusions.

In addition, an improved IRIS database and assessment process could serve to alleviate one of the main concerns driving calls for reform of the Toxic Substances Control Act (“TSCA”):¹⁸ lack of information regarding chemicals, especially “existing” chemicals listed on the TSCA Inventory.¹⁹ A noticeable reduction in the backlog of IRIS assessments could reassure the public and non-governmental organizations, at least to some extent, that the basic shape of chemicals management in the United States is sound and that improved implementation and information gathering can adequately protect public health. Affected entities should consider both how to contribute productively to the IRIS assessments under the revised process and how to ensure that these changes effectively shape policy debates regarding chemicals management.

* * * * *

This report was written by Mark N. Duvall and Alexandra M. Wyatt. Mr. Duvall is a Principal, and Ms. Wyatt is an Associate in the Washington, DC office of Beveridge & Diamond, P.C. For more information, please contact Mr. Duvall at mduvall@bdlaw.com, (202) 789-6090.

1241785v2 Washington 009250

¹⁸ 15 U.S.C. §§ 2601-2692.

¹⁹ See, e.g., Press release, Sen. Frank R. Lautenberg, Lautenberg, Solis, Waxman Introduce Legislation To Protect Americans From Hazardous Chemicals In Consumer Products (May 20, 2008), available at <http://lautenberg.senate.gov/newsroom/record.cfm?id=298072>.