

OMB Interferes in IRIS Assessments of Toxic Chemicals: Questions and Answers

What is IRIS?

IRIS stands for Integrated Risk Information System and is managed by the U.S. Environmental Protection Agency (EPA). IRIS serves as a publicly searchable database for studies on the human health effects of hundreds of industrial chemicals and other chemical substances.

The studies in the database, conducted by EPA and referred to here as IRIS assessments, can lead to regulatory actions which protect humans from the harmful effects of certain substances. The studies are technical documents based on the latest and best available research. During the IRIS assessment process, EPA scientists and independent experts look at human exposure levels and the potential effects on the human body those exposures can have.

Recently, political forces have taken hold of the process for EPA's work on IRIS assessments. In 2004, the White House directed EPA to begin routinely submitting draft assessments to the White House Office of Management and Budget (OMB) for review. (Previously, the need for these reviews had been determined on a case by case basis.)¹ On April 10, 2008, EPA announced additional changes to the IRIS assessment process which further involve OMB and make other important – and potentially damaging – changes.

How does OMB interfere in IRIS assessments?

OMB is an office within the White House overseeing and managing numerous aspects of executive branch decision making. OMB's Office of Information and Regulatory Affairs reviews drafts of agency regulations, some risk assessments (such as EPA's IRIS assessments) and other agency documents. OMB's staff is comprised mostly of policy analysts and economists, and the office is widely considered to be the political arm of the White House.

Interference

At two points in the IRIS assessment process, EPA must submit drafts of chemical assessments to OMB for review.² OMB does the bulk of its interfering during these review periods. OMB voices its own opinions on the chemicals EPA is studying and solicits the opinions of other federal agencies such as the Department of Defense (DOD), the Department of Energy, and NASA. EPA is prohibited from proceeding with the IRIS assessment until it receives explicit approval from OMB.³

OMB can interfere with IRIS assessments by foisting upon EPA its own scientific judgments or forcing EPA to consider scientific studies that fit the White House's preconceived policy notions, regardless of the studies' integrity.



FACT: OMB forced EPA to halt work on five IRIS assessments because it disagreed with the agency's decision to study short-term (acute) exposure to those chemicals.⁴

Delay

Alternatively, or additionally, OMB can delay completion of an IRIS assessment. Because EPA must wait for OMB approval before moving forward with an IRIS assessment, OMB has full control over the process while the assessment is under review. EPA's stated procedures for IRIS assessments contain no time limits for the OMB review period.

FACT: OMB review typically adds almost one year to the completion of an IRIS assessment.⁵

The IRIS assessment of naphthalene proves an example of both interference and delay. In 2004, EPA submitted to OMB a draft assessment for naphthalene, a chemical found in jet fuel, moth balls, and a variety of other products. OMB, consulting with DOD, objected to EPA's findings and forced the agency to suspend the assessment, citing the need for additional research. OMB then forced EPA to form an ad hoc scientific panel to research the issues related to OMB and DOD's objections. After continued delays, the initial studies upon which EPA had formed its opinion had become outdated, and the agency was sent back to the drawing board.⁶



How does the new IRIS assessment process make matters worse?

On April 10, 2008, EPA unveiled a revised IRIS assessment process. The new process had been developed by a working group consisting of officials from EPA, OMB and other federal agencies including DOD. The revised process adds several requirements to an already protracted process and may ultimately undermine the role of EPA scientists and delay the completion of IRIS assessments.

Mission-critical designations

One new and complicated facet of the IRIS process involves asking other federal agencies whether an industrial chemical is critical to

that agency's mission. EPA included this step at the behest of agencies like DOD and NASA – agencies that use substances like jet and rocket fuel, which may contain controversial and potentially harmful chemicals. If an IRIS assessment determines these chemicals to be harmful, the regulatory actions that often spring forth from the findings may force those agencies or their contractors to change their habits.

OMB will coordinate the agencies' negotiations over mission-critical designations. If OMB and other agencies determine the chemical in question to be mission critical, the other agencies will have the opportunity to conduct their own research to fill any identified data gaps or address any uncertainties. The addition of the mission critical designation step will give other federal agencies opportunities to undermine or delay IRIS assessments.

FACT: Designating a chemical mission critical could add two or more years to the completion of an IRIS assessment.⁷

Industry access

Critics also fear the new process may provide a means for special interests to co-opt IRIS assessments.⁸ The new IRIS process includes an opportunity for public submission of data relevant to the chemicals EPA is studying. EPA will now pause IRIS assessments for up to 60 days while the public identifies additional research it does not believe EPA has considered. But big polluters and industry trade groups, with their staff scientists and ability to fund their own studies, are more likely to take advantage of this opportunity than are the general public.

Industry representatives may also use OMB to funnel their concerns into the IRIS process. During its reviews of agency regulations, President Bush's OMB has frequently held closed-door meetings with special interests. If this trend continues with OMB's review of IRIS assessments, industry representatives could use OMB as a conduit to quietly inject their opinions into the scientific studies. By controlling the data EPA uses for IRIS assessments, industry groups can ultimately affect the assessments' findings.

A Pattern of Interference

Under the administration of George W. Bush, the White House Office of Management and Budget (OMB) has expanded its reach into the scientific work of federal agencies in unprecedented ways. In addition to reviews of IRIS assessments, here are two other examples of systemic scientific interference conducted or coordinated by Bush's OMB:

Data Quality Act⁹

In implementing the Data Quality Act, OMB gave itself wide latitude and released controversial implementation guidelines in 2002.¹⁰ OMB created a system in which industry groups can easily challenge any scientific information produced by a federal agency and delay or obstruct public dissemination of that information. For example, chemical and manufacturing groups used Data Quality Act challenges to delay the release of the Report on Carcinogens – a critical government study of cancer-causing substances – for more than one year.¹¹

Peer Review

Shortly after establishing the Data Quality Guidelines, OMB pushed to expand political control and influence over the scientific work of federal agencies by proposing government-wide standards for scientific peer review. Through its Peer Review Bulletin,¹² OMB micromanages agency peer review practices, including selection of peer reviewers.

FACT: The revised IRIS assessment process explicitly allows EPA, OMB, or other agencies to call in “third-party consultants” when discussing mission critical designations.

Lack of transparency

One unchanged aspect of the IRIS process allows all communications among EPA, OMB, and other agencies to evade public scrutiny. Although EPA had hoped to make these back-and-forths part of the public record, OMB persuaded the agency to designate the communications as deliberative.¹³ As a result, the communications will not be subject to Freedom of Information Act requests, nor will they be subject to review by Congress, unless subpoenaed.

The Government Accountability Office says classifying communications about IRIS assessments as deliberative is “inconsistent with the principle of sound science” and limits the credibility of the assessments due to suspicions of bias.¹⁴



FACT: Scientific research offered by OMB or other federal agencies will not be disclosed to the public – a gross violation of the basic scientific principles of transparency and reproducibility.

Why is the IRIS assessment process important?

IRIS assessments are crucial for informing the decisions that protect us from the harmful effects of industrial chemicals. EPA scientists must be able to conduct these scientific studies without feeling weighed down by the heavy hand of political interference. Moreover, the IRIS assessment process must be as transparent as possible to ensure accuracy and objectivity.

A smooth IRIS assessment process is also important for public health. Scientists and regulators still don't know the effects of countless chemicals the public comes in contact with everyday. Therefore, expeditious completion of scientific studies is critical to providing the public with the information it has a right to know and to protecting public health when necessary.

Unfortunately, by attacking or delaying the scientific basis for future regulatory decisions, OMB will be able to erode the very foundations upon which public protection standards are built.



FACT: The IRIS assessments for chemicals such as arsenic, mercury, and others led to national drinking water standards that continue to protect public health.¹⁵

Endnotes

1. John B. Stephenson, "Chemical Assessments: Low Productivity and New Interagency Review Process Limit the Usefulness and Credibility of EPA's Integrated Risk Information System," United States Government Accountability Office, GAO-08-440, March 2008, 22. Available electronically at www.gao.gov/new.items/d08440.pdf (last accessed May 14, 2008). (hereinafter "GAO report")

2. U.S. Environmental Protection Agency, "EPA's Integrated Risk Information System: Assessment Development Procedures." Available electronically at cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=190045 (last accessed May 14, 2008).

3. GAO report, 23.

4. GAO report, 16.

5. Based on information in EPA's IRIS Track database, the mean review time for IRIS assessments sent to OMB for the first OMB/Interagency review is 264.33 days, as of May 5, 2008. The GAO report found the five assessments that had completed the second OMB/Interagency review, as of Dec. 1, 2007, were under review "for periods ranging from 10 days to almost 4 months.

6. GAO report, 35-37.

7. GAO report, 44.

8. Speaking at an April 29, 2008 hearing of the Senate Environment and Public Works Committee titled, "Oversight on EPA Toxic Chemical Policies," Sen. Sheldon Whitehouse, Democrat of Rhode Island and committee member, said, "The worst-case scenario is that a polluter comes to the White House, makes big camp contributions...and says that they want OMB to put the word in for them through this process, there is nothing in the process itself that would ever disclose that, or surface that, or prevent that from happening."

9. The Data Quality Act (P.L. 106-554), sometimes called the Information Quality Act, was passed by Congress as part of the Fiscal Year 2001 Treasury and General Government Appropriations Act. The Act instructs OMB to develop guidelines for agencies that will maximize "the quality, objectivity, utility, and integrity" of government information. It also requires the establishment of "administrative mechanisms allowing affected persons to seek and obtain correction" of government information.

10. White House Office of Management and Budget, "Information Quality Guidelines," October 1, 2002. Available electronically at www.whitehouse.gov/omb/inforeg/iqg_oct2002.pdf (last accessed May 14, 2008).

11. OMB Watch, *An Attack on Cancer Research: Industry's Obstruction of the National Toxicology Program*, August 2007. Available electronically at www.ombwatch.org/info/NTPDataQuality.pdf (last accessed May 14, 2008).

12. White House Office of Management and Budget, "Final Information Quality Bulletin for Peer Review," December 16, 2004. Available electronically at www.whitehouse.gov/omb/memoranda/fy2005/m05-03.pdf (last accessed May 14, 2008).

13. GAO report, 53.

14. GAO report, 5.

15. Barbara Boxer, speaking in the Senate Environment and Public Works Committee hearing "Oversight on EPA Toxic Chemical Policies," April 29, 2008.

16. Image by Flickr user Darwin Bell, "drinking water." Used under a Creative Commons license. Available electronically at flickr.com/photos/darwinbell/286131360/ (last accessed May 14, 2008).