

Appendix V: Comments from the Office of Management and Budget



EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
WASHINGTON, D.C. 20503

FEB 11 2008

Mr. John B. Stephenson
Director, Natural Resources and Environment
U.S. Government Accountability Office
441 G Street, N.W., Room 2075
Washington, D.C. 20548

Dear Mr. Stephenson,

Thank you for the opportunity to comment on the Government Accountability Office's (GAO) draft report titled, "Chemical Assessments: Low Productivity and Lack of Transparency Limit the Usefulness and Credibility of EPA's Integrated Risk Information System" (GAO-08-440).

We applaud your efforts to evaluate the EPA Integrated Risk Information System (IRIS) as we believe this is a very important EPA program. As your report states, funding for the IRIS program has increased—from \$1.7 million in FY 2000 to \$9.6 million in FY 2007; OMB has supported changes that will improve the quality and efficiency of the IRIS program.

However, the draft GAO report fundamentally misunderstands the purpose of interagency review and, unfortunately, could leave readers with a false impression of the role of OMB/interagency review in the IRIS process. We discuss below our most important concerns with the draft report.¹

First, the draft report mischaracterizes OMB's role by alleging that OMB has imposed an OMB-managed interagency review process of IRIS risk assessment documents that has resulted in a loss of EPA control.² In fact, however, only EPA has the authority to finalize an EPA assessment and only EPA has authority to determine when a draft may be sent for external peer review. The interagency review process is a dialogue that helps to ensure the quality (including objectivity and transparency) of agency documents. Input from scientists throughout the Federal government (including, for example, HHS, DOD, DOE, NASA, DOL, and USDA within the context of the IRIS process) helps inform and improve the quality of IRIS assessments. These reviews address the objectivity, clarity, and transparency of the work, identifying key science policy issues for EPA's consideration, and scientific issues for external peer review.³ Simply

¹ In January 2008, GAO provided OMB staff with the opportunity to provide comments on the draft report titled "Statement of Facts for GAO's Review of EPA's Integrated Risk Information System." As you were aware, from our discussion on January 18, 2008, OMB staff had a number of concerns about the draft statement of facts, which were discussed in the January 22, 2008 comments that were sent to you. It appears that many of those comments have not been incorporated into the current draft report and our concerns remain. But rather than reiterating them all here, I will highlight our overarching comments on the draft report.

² Draft report, pp. 22-27.

³ OMB has a broad interest in the quality, objectivity, utility and integrity of information disseminated by Federal Agencies. See OMB's Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies (2002), 67 Fed. Reg. 8452 (Feb. 22, 2002), available at

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put, the interagency review process works as follows: OMB oversees an interagency process that is part of a broader EPA process. During the interagency process, EPA works collaboratively with OMB and other agencies to achieve resolution and completion of interagency reviews. These discussions have sometimes required resolution by the EPA Science Advisor, who is also the EPA Assistant Administrator of the Office of Research and Development. When this review process is complete, OMB concludes interagency review. At that time, EPA moves to the next step – generally, release of the risk assessment for public comment and an external peer review by a group of independent experts.⁴ To be clear, EPA is entirely responsible for the content of information on IRIS.

See comment 3.

Second, the draft report alleges that the fact that OMB manages and directs the review process has “made it more difficult for EPA to complete IRIS assessments in a timely manner.”⁵ The draft report asserts that the OMB/interagency review adds significant time to IRIS time frames. It is our experience, however, that the interagency commenters have generally provided comments in a very timely manner. We are not aware of delays over “nonsubstantive issues” as alleged in the draft report.⁶ We also note that the draft report does not provide specific examples on which we can comment.⁷ In addition, we believe the draft report is seriously flawed in that it does not consider whether interagency review operates to improve the quality of IRIS assessments, both by addressing the objectivity, clarity, and transparency of the work as well as identifying key science policy issues for EPA consideration and technical issues for peer review.⁸ The draft report’s focus on timeliness, without consideration of quality of the end product, presents a misleading and incomplete picture.

See comment 4.

See comment 5.

Third, the draft report alleges that “the OMB/interagency review process also affects the credibility of assessments primarily because the review process lacks transparency.”⁹ To address this supposed issue, the draft report recommends that EPA make public comments by OMB and other Federal agencies to decision makers, the Congress, and the public. However, the draft report fails to acknowledge that, in the case of documents that involve interagency deliberations, these documents are covered by the deliberative process privilege, a well-recognized privilege that has been affirmed by the Congress in the Freedom of Information Act (5 U.S.C. 552(b)(5)) and by the Supreme Court in such cases as *NLRB v. Sears, Roebuck & Co.*, 421 U.S. 132 (1975),

See comment 6.

<http://www.whitehouse.gov/omb/fedreg/reproducible2.pdf>; OMB’s Final Information Quality Bulletin for Peer Review (2002), 70 Fed. Reg. 2664 (Jan. 14, 2005), available at http://www.whitehouse.gov/omb/fedreg/2005/011405_peer.pdf; and the OMB/OSTP Updated Principles for Risk Analysis, available at <http://www.whitehouse.gov/omb/memoranda/fy2007/m07-24.pdf>.

⁴ OMB recognizes that there is also a second round of interagency review in the current IRIS process. This review seeks to ensure that comments from expert reviewers and the public have been transparently and objectively addressed.

⁵ Draft report, p. 22.

⁶ Draft report, p. 25.

⁷ In fact, when the draft report does provide a specific example, such as its discussion of naphthalene, it does so inaccurately. Draft report, pp. 36-38. OMB staff does not agree with the characterizations as presented in the draft report and suggests that readers would benefit from looking at the EPA documentation: (i) the EPA charge for the peer consultation, which resulted from interagency dialogue, available at http://oaspub.epa.gov/eims/eimscomm.getfile?p_download_id=46877; and (ii) the peer consultation report, available at http://oaspub.epa.gov/eims/eimscomm.getfile?p_download_id=442588.

⁸ In fact, the draft report recognizes that it “did not evaluate the scientific content or quality of IRIS assessments.” Draft report, p. 3.

⁹ Draft report, p. 26.

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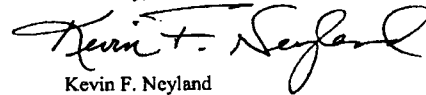
and *EPA v. Mink*, 410 U.S. 73 (1973).¹⁰ Accordingly, protection of internal Executive Branch communications is not "inconsistent with the principle of sound science," contrary to the erroneous conclusions of the draft report.¹¹ In fact, the National Academy of Sciences, which is recognized as a leader in scientific reviews, uses a multi-step review process that includes deliberations that are withheld from the public.¹²

See comment 7.

Finally, the draft report discusses at some length a draft document that it alleges serves to establish a "formal IRIS assessment process" that EPA has been developing over the past two years.¹³ The discussion in the draft GAO report is misleading to readers; EPA's draft document is not a final document.¹⁴ EPA has not completed the development of this process. Indeed, the process will not be complete until EPA circulates its draft to the public for comments and then releases a final product that is responsive to those comments.

Thank you again for the opportunity to review and comment on your draft report. We hope you take these comments into account in preparing your final report.

Sincerely,



Kevin F. Neyland
Deputy Administrator
Office of Information
and Regulatory Affairs

See comment 8.

¹⁰ We do not consider the interagency process to constitute peer review; rather the document that EPA releases at a later step in the process will be subject to external peer review and public comment. EPA has a very transparent process by which draft IRIS assessments are released for public comment and external peer review before they are issued as final documents. The credibility of IRIS assessment is in part based on this rigorous and transparent external peer review and public comment process.

¹¹ Draft report page 6.

¹² See <http://www.ion.edu/CMS/6008.aspx> and <http://www.nationalacademies.org/studycommittee/process.pdf>. In 1997, Congress ensured that NAS deliberations have heightened confidentiality protections, when Congress passed stand-alone legislation that added a new section (Section 15) to the Federal Advisory Committee Act (5 U.S.C. App.) which specifically, and solely, addresses NAS and the National Academy of Public Administration. See the Federal Advisory Committee Act Amendments of 1997, Public Law 105-153, 111 Stat. 2689. The legislative history explains that Congress granted this protection "to preserve the quality of the research provided to the Federal Government through the National Academy of Sciences and the National Academy of Public Administration." Statement of Rep. Horn, Cong. Rec. H10579 (daily ed. November 9, 1997). Representative Horn explained that "[t]he administration, the House and the Senate, both the majority and minority, all agree the academy should not be subject to the full process of the Federal Advisory Committee Act." *Id.* As Rep. Horn also noted, *id.*, Congress passed this legislation in response to the court decision earlier that year in *Animal Legal Defense Fund, Inc. v. Shalala*, 104 F3d 1209 (D.C. Cir.), *cert. denied*, 522 U.S. 949 (1997), in which the court held that NAS panels were subject to the full range of FOIA disclosure requirements. In its decision, the court stated that NAS, in arguing for why it should not be subject to these requirements, referred to "the deleterious effects of FOIA's requirements on its deliberative processes: As the NAS sees it, open meetings and records would compromise its internal review procedures and inhibit candid exchange among its members." *Id.* at 428.

¹³ Draft report, pp. 45-52.

¹⁴ By way of comparison, we note that, in providing to us the draft report for our comment, your cover page stated that the draft "is restricted to official use only"; is "subject to revision"; and "must be safeguarded to prevent improper disclosure."

See comment 10.