

**From:** Hardy, Catherine H.  
**Sent:** Wednesday, May 19, 2004 2:50 PM  
**To:** 'ombpeer\_review@omb.eop.gov'  
**Subject:** FW: OMB Comments

Mark Greenwood's comments on behalf of CEEI as filed on May 14, 2004. If you have any questions, or require anything further of us, please feel free to contact me.

CATHERINE H. HARDY  
Legal Secretary

ROPES & GRAY LLP  
One Metro Center  
700 12th St., NW, Suite 900  
Washington, DC 20005-3948  
202-508-4600 (main)  
202-508-4635 (direct)  
202-508-4650 (fax)



OMB Comments.pdf  
(297 KB)

- OMB Comments.pdf



ROPE & GRAY LLP  
ONE METRO CENTER 700 12TH STREET, NW SUITE 900 WASHINGTON, DC 20005-3948 202-508-4600 F 202-508-4650  
BOSTON NEW YORK SAN FRANCISCO WASHINGTON, DC

May 14, 2004

Mark A. Greenwood  
(202) 508-4605

**VIA FACSIMILE**

Dr. John D. Graham  
Office of Information and Regulatory Affairs  
Office of Management and Budget  
Eisenhower Executive Office Building  
17<sup>th</sup> Street & Pennsylvania Avenue, N.W.  
Washington, DC 20503

Re: Revised Bulletin on Peer Review

Dear Dr. Graham:

On behalf of the Coalition for Effective Environmental Information (CEEI), we are submitting additional comments on the Revised Bulletin on Peer Review that was issued for comment on April 15, 2004 by the Office of Management and Budget (OMB).

CEEI is a group of major companies and business organizations, representing a wide array of industry sectors, that share a common interest in improving how government collects, manages, uses and disseminates environmental information.<sup>1</sup> CEEI supports public policies that encourage information quality, governmental accountability, efficient information collection, alignment of information with strategic goals and consistent management of environmental information resources. Given this agenda, CEEI has maintained a continuing interest in the implementation of OMB's Information Quality Guidelines (IQG).<sup>2</sup> The Revised Bulletin on Peer Review was developed by OMB to implement the "pre-dissemination review" provisions of the IQG.

---

<sup>1</sup> CEEI includes representatives from the aerospace, chemical, energy, automobile, pharmaceutical, forest products, petroleum, electronics and consumer products industries.

<sup>2</sup> These Guidelines were issued under Section 515 of the Treasury and General Government Appropriations Act for Fiscal Year 2001 (Pub. L. 106-554; H.R. 5658); 44 U.S.C. 3504(d)(1), 3506 (a)(1)(B).

CEEI believes that OMB's Bulletin on Peer Review is an important and precedential document. It is establishing a consistent government-wide set of principles in an area that has needed guidance. CEEI is particularly supportive of the Bulletin's emphasis on making peer review processes transparent, recognizing that the peer reviews conducted by federal agencies shape important public policies that should be developed through open and participative processes.

The revised version of the Bulletin has made substantial efforts to address concerns raised by commenters, while maintaining the general principles of the proposed Bulletin. CEEI believes that OMB has done a reasonable job balancing the various perspectives reflected in the comments. We urge OMB to adopt this version of the Bulletin.

In part, our recommendation to maintain this version of the Bulletin is driven by the need to clarify the true meaning of the Bulletin's provisions through implementation activities. Experience suggests that the implementation phase of public policy provides much greater clarity about whether particular policies achieve their objectives or are counterproductive.

Nowhere are the benefits of proceeding with implementation activity more evident than in the area of information policy. For example, the debate that surrounded OMB's original IQG suggested that the "correction process" would be used by industry, on a large scale, to frustrate – even ossify – the federal government's regulatory process. This scenario never materialized. A modest number of correction requests have been filed, and the agencies have not found that the correction process has stymied their regulatory programs. As always, the substantive issues and overall societal impact of individual rules tend to drive the time and resources that agencies must invest to complete their rulemakings.

While CEEI supports this version of the Bulletin, we have identified some issue areas that we will be watching as the Bulletin is implemented. We urge OMB and the agencies to consider these matters as they move forward:

*1. Agenda of Planned and Ongoing Peer Reviews* - Section V. of the Bulletin calls for the creation of an "agenda" of planned and ongoing peer reviews that would be posted on each agency's Internet Website. CEEI believes this is an excellent addition to the Bulletin. Such an agenda should help the public participate more effectively in the development of high-quality, credible scientific information.

As agencies post this information, however, it will be important for agencies to give this agenda sufficient visibility so that it will be noticed by the public. The Websites of federal agencies are now very complex networks of information that are often difficult to navigate. Our members have also found that the browser functions of federal agency Websites often do not yield helpful information very easily.

Since each agency has adopted a different architecture for its information systems and its Website, there is no one solution to assure adequate visibility of the agenda. As a general principle, however, the agenda of planned and ongoing peer reviews should be at least as accessible as each agency's explanation about access to information through the Freedom of Information Act. In addition, OMB should use federal government portal sites like FirstGov to provide reliable access to the agency Websites on peer review.

2. *Improving Transparency* – As OMB and the agencies refine the peer review planning process and the peer review agenda, it will be important to provide public access to the documents that frame the nature and scope of the peer review. For example, we assume that the charge to a peer review panel, as well as any other documents that frame the scientific assessment to be reviewed, will be made available to the public in a timely way. This will allow the public to track the scientific assessment more effectively and offer appropriate comments when needed. We believe that this aspect of transparency does not affect the concern expressed by commenters about the attribution of specific comments to specific peer reviewers that appears in other sections of the Bulletin.

We also recommend that OMB and the agencies favor opportunities for public participation in the peer review process. The Bulletin appears to reserve some agency discretion to avoid public comment on scientific assessments undergoing peer review. Experience shows, however, that closed reviews of the scientific aspects of important public policy issues are almost always a mistake.

3. *Value of the Two Tiers of Peer Review* - As the Bulletin has developed, commenters have engaged in significant debate about the criteria used to distinguish between “influential” information subject to Section II and “highly influential” information subject to Section III of the Bulletin. The revised version of the Bulletin, however, has given agencies greater flexibility in deciding what additional measures are needed for a Section III peer review. As a result of these changes, it is not clear that a Section III peer review is substantially more constraining or resource-intensive for agencies than a Section II peer review.

For example, in a Section III review agencies are supposed to provide peer reviewers with sufficient background information to allow them to understand the draft assessment. We do not understand why such a principle would not be equally important, and not overly burdensome, for a Section II review. Similarly, as currently drafted, Section III calls for better coordination between public participation opportunities and peer review processes to allow the peer reviewers to understand what issues have been raised in public comments. We assume such coordination is just as viable in a Section II peer review.

At this time CEEI is not requesting elimination of the distinction between Section II and Section III peer reviews. We do recommend that OMB and the agencies *evaluate* the significance of the

two tiers of peer review. Based on agency experience with the Bulletin, what measures add significant cost or complexity to the task of conducting high-quality peer reviews? Such information can and should inform the evolution of the peer review Bulletin over time.

4. *Scope of the Exemptions* - The Revised Bulletin contains a significant number of exemptions. Some of the exemptions are tailored to specific situations that should not raise many issues. A few of the exemptions are broadly drawn and may, depending on how agencies interpret them, create loopholes that would frustrate the general intent of the Bulletin.

As an example, the exemption for “adjudications”, which includes the granting of licenses, could be interpreted too broadly. Under some statutes, broad policymaking on scientific issues can occur in the context of licensing action rather than rulemaking. At the Environmental Protection Agency (EPA), for example, the pesticide program is primarily a licensing program. EPA’s risk assessments of major active ingredients in commerce occur in the context of decisions about whether that active ingredient should be “re-registered” or removed from the market. Yet these assessments are precisely the type of influential, even highly influential, scientific information that the Bulletin should cover. We assume that such assessments should not qualify for the “adjudication” exemption.

As another example, the preamble to the Bulletin indicates that it “does not impose new peer-review requirements on information that has already been peer reviewed.”<sup>3</sup> Certainly CEEI does not favor repetitive reviews of the same information. On the other hand, prior peer review of one piece of a larger scientific assessment does not substitute for a review of the whole assessment. Situations arise where an agency has constructed a scientific model, made up a several separate analytical modules, to characterize a current condition or predict future scenarios. Prior peer review of the separate modules is usually insufficient because a variety of scientific issues (e.g., incompatible technical assumptions) can arise when these modules are combined in a larger model.

As OMB and the agencies interpret the various exemptions, it will be important to keep the larger objectives of the Bulletin in mind and provide for peer review of assessments that meet common sense understandings of “influential scientific information.”

---

<sup>3</sup> Peer Review Bulletin, at 28.

ROPES & GRAY LLP

Dr. John D. Graham

- 5 -

May 14, 2004

*Transparency of the Correction Process*

The first version of the Bulletin, proposed on September 15, 2003, included a discussion of how agencies should make the correction request process under the Information Quality Act more transparent. In particular, the Bulletin indicated that an agency should notify OMB of correction requests received or post those requests on the agency's Website. CEEI commented that the latter option provided the greatest value to the public.

The revised version of the Bulletin does not address this issue. We ask OMB to address this question in the Bulletin, or in some other context, and urge all agencies to provide easy and timely Web access to the documents filed in conjunction with correction requests.

CEEI appreciates the opportunity to comment on the Revised Bulletin, and we would be happy to answer any questions related to these comments. Thank you for your attention to this matter.

Best regards,

A handwritten signature in cursive script, appearing to read "Mark A. Greenwood".

Mark A. Greenwood