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BY FACSIMILE

Dr. Margo Schwab
Office of Information and Regulatory Affairs
Office of Management and Budget
725 17th Street, N.W.
New Executive Office Building, Room 10201
Washington, DC 20503

Re: Bulletin on Peer Review and Information Quality

Dear Dr. Schwab:

On behalf of the Coalition for Effective Environmental Information (CEEI), I am submitting comments on the draft Bulletin on Peer Review and Information Quality (Bulletin) that the Office of Management and Budget (OMB) issued for comment on September 15, 2003 (68 Fed. Reg. 54023).

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.¹ 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.²

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

² 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 views the Information Quality Guidelines as a tool to create greater transparency in the information products that government agencies disseminate to the public. Under the Guidelines, agencies must provide better explanations of their policy decisions. Information resources offered to the public need to disclose the strengths and weaknesses of the underlying data. Agencies are responsible for helping the public understand the significance of information carrying the government's imprimatur. All of these principles serve the larger objective of making government more accountable and responsive, resulting in better information for the public.

We see the Bulletin as contributing to these objectives by directing agencies to provide greater transparency in their processes for developing major scientific assessments.³ We also are supportive of the Bulletin's intent to improve the public visibility of the information correction process under the Guidelines.

The Bulletin Encourages Transparency

CEEI supports the Bulletin because several of its aspects will make the agencies' processes for scientific assessment more open for public review and understanding. In particular, the provisions in Section 3 of the Bulletin, which apply to "especially significant regulatory information", establish important principles that facilitate transparency.

The provisions addressing "conflict of interest" among peer reviewers recognize that concern about potential bias arises not just from the financial relationship of the reviewers to private companies. Other factors, such as the strength of the reviewer's relationship to a sponsoring agency, are also relevant considerations.

The net effect of the Bulletin will be to create greater public disclosure about the background of scientists who are chosen for peer review panels. This is a healthy development. The parties interested in a particular scientific assessment, as well as the general public, will know more about the backgrounds of the peer reviewers and will be able to weigh their potential bias.

The Bulletin also provides for public disclosure of the comments from peer reviewers. Agencies are then expected to respond to those comments and provide that response for the public record. This is an important policy because some peer reviews conducted by federal agencies have not been visible to the public. Under the Bulletin, the public will now have a better ability to

³ CEEI is not addressing the interplay between the Bulletin and regulatory or science policy. Several members of CEEI will address those aspects of the Bulletin through separate comments.

understand the range of scientific perspectives, including the areas of disagreement among the experts.

The Bulletin indicates that an opportunity for public comment should be provided in conjunction with peer reviews. These public comments are to be provided to the peer reviewers with "ample time for consideration" before the peer review is completed. Historically, agency peer review processes and public comment opportunities have not been coordinated in this way and often were parallel processes. As a result, peer reviewers did not have the benefit of knowing the issues of concern to stakeholders or the potential impacts of an assessment. This knowledge would have allowed the peer reviewers to give particular attention to the scientific questions that are likely to have the biggest impacts on public policy. The process outlined in the Bulletin should better serve both the peer reviewers and the governmental decision-makers who are seeking the advice of the peer review panel. CEEI further suggests that agencies seek public comment on the charge to the peer review panel to ensure that the appropriate questions are posed to the panel.

The Bulletin also makes it clear that peer reviewers must have full access to relevant background information. It is unfortunate that this right has not always been clear. The need for access to background information is often particularly important where agencies have relied on analytical models to justify a conclusion. A peer reviewer must understand the critical assumptions and algorithms for such models in order to evaluate an agency's analysis.⁴ For the same reason, this information should also be available to the public, so that public comments can be based upon a complete record.

While CEEI supports all of these measures as a means to improve the quality of peer review, we would also express a note of caution about the role of peer review itself. Under the Guidelines, peer review is identified as a procedural step that improves the likelihood that a study or an analytical document meets the "objectivity" standard. Peer review, however, cannot guarantee the quality of information. Errors do occur in peer-reviewed studies. Moreover, the quality of peer review varies. Situations do arise where groups of like-minded researchers collaborate to publish articles that are peer-reviewed among scientists who share common perspectives. In these cases, "peer" review is not always independent review.

Peer review does not substitute for transparency of analysis and other assurances of information accuracy. We urge OMB to emphasize this point as it refines the Bulletin. In particular, OMB should clarify that peer review does not assure the objectivity of information where questions arise about the transparency of the data or analysis considered in the peer review.

⁴ As a more general matter, CEEI questions whether agencies should be using proprietary models that cannot be freely and fully disclosed to the public as the basis for major policy decisions.

Importance of a Pragmatic Approach Toward Implementation of the Bulletin

In issuing the Bulletin, OMB is providing further guidance to agencies on an aspect of "pre-dissemination review" under the Guidelines. This is very useful because effective action at an early stage of the information development process can lead to better information, and thus fewer disputes about correction of information. Further clarification by OMB and the agencies about the policies and procedures that guide "pre-dissemination review" would be helpful because the intent of the Guidelines in this area is not well-understood by the public.

We read the Bulletin as providing the flexibility and pragmatism that is needed for effective implementation of peer review. For example, the Bulletin recognizes that the conflict of interest provisions can create difficulties when the pool of experts on a scientific topic is relatively small. Where it is not possible to find an adequate set of experts that have had little contact with the parties affected by a scientific issue, the Bulletin recognizes that agencies will need to draw upon the available expertise. In those situations, the Bulletin indicates that agencies should seek a balance of perspectives on the peer review panel.

The Bulletin also recognizes the importance of upfront planning and consultation within the government to implement these peer review policies. We assume, and would urge, that OMB and the agencies develop a practical agenda of matters where the procedures anticipated in Section 3 would occur. Many scientific assessments that agencies conduct will not require a Section 3 peer review. Development of a reasonable plan for Section 3 peer reviews will focus attention on the actions where such review is needed and reduce anxiety among some groups that the Bulletin will cause unwarranted delay in agency decisions.

As an important corollary to this planning process, CEEI urges OMB and the agencies to avoid premature decisions about categorical exclusions from the provisions of the Bulletin. When new policies of this nature raise concerns about delays in agency processes, it is very common for operating agencies to propose a plethora of exclusions. Instead of creating potentially unwarranted exclusions from the Bulletin at this time, we believe that it makes more sense to proceed with reasonable implementation of these peer review policies and determine whether particular exclusions are justified based on experience. In fact, experience may demonstrate that it is more reasonable to *expand*, rather than limit, the application of the Section 3 procedures to agency peer reviews.

We also support the idea of notifying the public about important scientific issues under consideration at the agencies through a roster of major pending or planned risk assessments. Ideally, such a roster could be set up as a docket of documents relevant to the risk assessment. The roster would provide transparency about scientific reviews of significant regulatory information in the federal government, allowing members of the public to track these reviews and make effective use of the comment opportunity anticipated by the Bulletin. Several years

ago, EPA developed an Information Products Bulletin (IPB) that provided quarterly notices to the public about major information products that were under development by various parts of the Agency.⁵ Our members have found the IPB to be a useful tool in understanding new developments in information policy at EPA.

Greater Transparency of IQA Corrections Process

Under the Bulletin, agencies would be offered a choice to send correction notifications to OMB or post the notifications on their Websites. From the perspective of the public, the latter approach is clearly preferable because it enhances the overall transparency of corrections to the public.

We have found the EPA Website, which posts IQA correction requests, responses and appeal documents, a very useful resource. Since the level of activity on correction requests has been fairly modest, we assume that posting of these documents has not presented any undue hardship on EPA. Therefore, we urge OMB and the agencies to establish a general policy in favor of timely Web posting of the correction request documents.

Agencies also should establish an effective link between their IQA guidelines and policies, their IQA corrections information and their home pages. We have found it difficult to locate the IQA policies of some agencies on their Websites. The IQA information should be at least as accessible as each agency's Freedom of Information Act Website. In addition, the government should establish a link in the FirstGov Website to the IQA corrections information of the various agencies.

We appreciate the opportunity to comment on the draft Bulletin and would be happy to answer any questions you might have for us. Thank you for your attention to this matter.

Sincerely,



Mark A. Greenwood

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⁵ As OMB is well aware, the Regulatory Agenda that the federal government issues every six months is a very helpful overview of regulatory activity in the agencies. The issuance of such a document greatly assists the public's ability to participate effectively in those proceedings.