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cc:

Subject: Comments on OMB Peer Review Bulletin

- OMB Peer Review Bulletin Comments.doc



December 15, 2003

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

RE: Proposed Office of Management and Budget Bulletin and
Supplemental Information Quality Guidelines, 68 Fed. Reg.
54023 (2003).

Dear Dr. Schwab:

*A
Council
of the
American
Chemistry
Council*

The Chlorine Chemistry Council (CCC) appreciates this opportunity to comment on the Office of Management and Budget's (OMB) Bulletin on Peer Review and Information Quality. CCC, a business council of the American Chemistry Council (ACC), is dedicated to addressing public policy issues affecting the chlorine industry. Because the guidance laid out in OMB's Bulletin will directly impact the federal government's policies on several important scientific and technical issues, CCC has a strong interest in the Bulletin.

CCC commends OMB's efforts to instill more independence, transparency, and reliability in the federal government's peer review process for scientific and technical regulatory policies. The Bulletin, however, raises several concerns which are addressed below. Many of the comments are general in nature. Other comments are specific to peer review of "Especially Significant Regulatory Information" which should be subjected to closer scrutiny during the review process.

In addition to the issues laid out below, CCC supports the comments submitted separately by ACC, including in particular the following points:

- OMB should not presume that publication in a peer reviewed journal equates to government peer review. As stated by ACC, the peer review process for journal publications and the government agency peer review process are different proceedings with different goals. Because the results of government peer review impact important policy decisions, the often cursory journal peer review process should not be a equivalent substitute.

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- OMB should broaden the scope for work products considered “Especially Significant Regulatory Information” to more closely follow EPA’s *Peer Review Handbook*. Thus, OMB should require application of more stringent peer review requirements to all information that is precedential or novel, particularly controversial, or highly complex.
- OMB should consider adopting the procedures of the National Academies and EPA’s Science Advisory Board for addressing conflict of interest issues. As governed by the Federal Advisory Committee Act (FACA), in selecting members of Academy panels, “[t]he Academy shall make its best efforts to ensure that...no individual appointed on the committee has a conflict of interest that is relevant to the functions to be performed, unless such conflict is promptly and publicly disclosed and the Academy determines that the conflict is *unavoidable*.” 5 U.S.C. app. § 15(B)(1) (2003) (emphasis added). FACA also requires potential reviewers to inform the Academy of any conflicts relevant to the individual’s functions as a reviewer.

I. General Comments on OMB’s Proposed Peer Review Guidelines

A. OMB should ensure that agencies allot adequate time to peer review.

Although several of the constraints put on peer reviewers are addressed by the OMB Bulletin, the critical factor of time is omitted. In order for reviewers to conduct a thorough and reliable review, they should be given adequate time to both prepare for and conduct the review. While still recognizing that reviewers cannot be given an infinite amount of time, subjecting them to unreasonable time constraints jeopardizes the quality of the review. Sufficient time should be allotted for peer reviewers to read the necessary documents and conduct a thorough review. In the case of “Especially Significant Regulatory Information,” reviewers should also be given sufficient time to meet, consider public comments, and conduct other necessary activities culminating in a peer review report. To facilitate the timely release of work-product, the OMB Bulletin should provide a suggested timeframe within which peer review should be conducted.

As illustrated in the following examples, agencies do not always provide sufficient time for peer review.

Peer reviewers such as the National Toxicology Program’s (NTP) Board of Scientific Counselors are often given limited time constraints to review data and make recommendations on which substances to include and how to classify substances in NTP’s biennial *Report on Carcinogens*. The inclusion of a substance and its classification can significantly impact how that substance is regulated. Therefore, stringent time limits should be avoided to limit hasty decisions.

EPA’s SAB was faced with its own time constraints when conducting its November 2000 review of the draft dioxin reassessment. Less than one month before the review was to begin, EPA released a new version of the reassessment, asking SAB to review three substantial sections of the document, a previous peer review report, and public comments. To review sections of the

document as requested by EPA, the SAB would also have to review the other supporting sections of the document, which numbered over 3000 pages. Giving the SAB less than a month before its two-day meeting to give a proper and meaningful review was unreasonable.

B. OMB should ensure that peer reviews are conducted in environments conducive to optimal peer review and free from intimidation.

Individuals participating in a government peer review should not be subjected to harassment, intimidation, or other unnecessary disturbances. These disturbances interrupt the review process, preventing reviewers from contributing their honest opinions or even discouraging participation altogether. The November 2000 EPA Science Advisory Board (SAB) review of the dioxin reassessment serves as an example of an intimidating peer review atmosphere. During the SAB review, representatives of the Center for Health, Environment and Justice distributed materials debasing certain scientists on the review panel and held up slanderous signs when those scientists spoke. SAB staff did nothing to discourage this behavior. The OMB guidelines should strongly encourage the fostering of peer reviews in optimal environments, free from intimidation. The right to free speech for all parties is critical and intimidation to deter the free exercise of another's right is not justified.

C. The necessity to conduct peer review should not be an excuse for missing deadlines.

The importance of meeting deadlines, both statutory and those set by consent decrees, should be stressed by the OMB guidelines. When deadlines are missed, agencies are forced to delay the development of important policy decisions. Such delays often result in lawsuits and the considerable expenditure of agency resources. Agencies need to ensure that adequate time is allotted for peer review, taking critical deadlines into account. Thus, OMB guidelines should admonish agencies to provide sufficient time for peer reviewers to conduct a thorough review.¹

D. Asking peer reviewers to refrain from reviewing policy matters is not always possible.

The OMB Bulletin states, “[p]eer reviewers shall be asked to review scientific and technical matters, leaving policy determinations for the agency. This must be clearly stated and adhered to during the peer review process so the review is based solely on the science being evaluated.” This objective is unrealistic. Although asking for policy determinations to be left to the agency is ideal, science and policy issues are often intertwined, frustrating efforts to cleanly separate them. For example, the magnitude of uncertainty factors is both a policy *and* scientific inquiry. Asking peer reviewers to give their opinion on suggested uncertainty factors will inevitably appear as a policy recommendation. Asking reviewers not to opine on the policy

¹ Similarly, the inability to conduct peer review because of time constraints should not be an excuse for failing to use the best available science. EPA's failed to consider best available science that had not been peer reviewed in order to meet a deadline in its issuance of a maximum contaminant level goal for chloroform. In its decision on the resulting lawsuit, the U.S. Court of Appeals for the D.C. Circuit stated, “however desirable it may be for EPA to consult an SAB and even to revise its conclusion in the future, that is no reason for acting against its own science findings in the meantime.” *Chlorine Chemistry Council v. EPA*, 206 F.3d 1286, 1290 (2000).

regarding uncertainty factors would force the reviewers not to opine on uncertainty altogether. The OMB guidelines should make clear that peer review of the science underlying policy decisions is entirely appropriate. Thus, in the context of uncertainty factors, an agency could seek peer review of its scientific basis for particular uncertainty factors.

II. Comments Specific to “Especially Significant Regulatory Information”

A. Government agencies should not manage their own peer review process.

CCC emphasizes its support for OMB’s intention that “Especially Significant Regulatory Information” should be examined by “external peer reviewers who possess the requisite experience and independence from the agency.” However, to truly maintain the independence of the review, the agency managing a project should not also manage peer review of that project. The National Research Council’s report *Strengthening Science at the U.S. Environmental Protection Agency* recommended that “EPA change its peer-review practices to more strictly separate the management of a work product from the management of the peer review of that work product. ...[T]he decision-maker and peer review leader for a work product should never be the same person.” (p. 124). Because of the potential impact of “Especially Significant Regulatory Information,” it is particularly important that peer review of such information remain independent of and external to the agency personnel managing the product under review.

The November 2000 SAB review of the draft dioxin reassessment serves as a prime example where managers of a project were intimately involved in the project’s peer review. Two EPA staff members managing the dioxin reassessment actively participated throughout the SAB review meetings to the point where the EPA staff could have been mistaken for actual members of the review committee. In this situation, agency staff can too easily push their opinions on the review committee. Such commingling of agency staff and peer reviewers during the review process disrupts the objectivity and independence of the peer review. To create more independence and objectivity, managers of a project should not be involved in the review process.

B. OMB should emphasize the importance of having peer reviewers consider public comments as part of the peer review process.

As stated in the OMB Bulletin, “openness enhances the credibility of the peer review of regulatory science.” For “Especially Significant Regulatory Information” the importance of providing peer reviewers with public comments is even more evident. At a minimum, relevant synopses of public comments with access to the complete comments should be made available. Allowing submission and consideration of public comments enhances the transparency of the peer review process. For example, in 1994 EPA accepted public comments and held public hearings on the draft dioxin reassessment. The comments received were considered and responded to by SAB during its review of the document. According to EPA’s Federal Register notice seeking comments on the reassessment, “the draft documents or chapters were made available in keeping with the Agency’s continuing commitment to conduct the reassessment of dioxin in an open and participatory manner, to keep the public informed of its progress, and to

encourage public participation in the document development process.” To maintain openness, OMB should recommend that comment opportunities similar to those offered by EPA in 1994 are available during peer review of “Especially Significant Regulatory Information.”

C. The OMB guidelines should emphasize the importance and encourage the use of oral presentations by interested parties to the reviewers.

For “Especially Significant Regulatory Information,” commenters should be given the opportunity to make oral presentations to the peer reviewers. While recognizing the value of written comments, the ability of reviewers to interact with commenters can only be fostered through oral presentations. Such interaction gives reviewers the opportunity to clarify points and ask questions in order to gain a better understanding of the information provided by the commenter. Furthermore, oral presenters should be allowed adequate time to give their presentation and, more importantly, respond to questions by the reviewers. Recommending the opportunity for oral presentations will further enhance the quality of the peer review while increasing transparency of the review process.

We appreciate this opportunity to comment on the OMB Bulletin. If you have any questions concerning our comments or if we can provide further information, please do not hesitate to call me or David Fischer at (703) 741-5179.

Sincerely,



Clifford T. “Kip” Howlett, Jr.
Executive Director,
American Chemistry Council,
Vice President