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California Environmental Protection Agency

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Governor



Air Resources Board | Department of Pesticide Regulation | Department of Toxic Substances Control

Integrated Waste Management Board | Office of Environmental Health Hazard Assessment | State Water Resources Control Board | Regional Water Quality Control Board

October 28, 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

Dear Dr. Schwab:

Enclosed please find comments on the Office of Management and Budget's (OMB) draft peer review guidance for regulatory science disseminated by the federal government, as contained in the Proposed Bulletin under Executive Order 12866.

The California Environmental Protection Agency (Cal/EPA) extensively uses information generated by federal agencies to support implementation and enforcement of California and federal laws within the state. The importance of timely, objective, reliable scientific information of high quality cannot be over-emphasized. Thus, we appreciate OMB's intent to provide a more uniform peer review policy toward improving the quality and utility of information disseminated by the federal government. However, we believe the prescriptive procedures proposed in the OMB guidance would likely impede the timely release of information necessary for science-based regulation. The peer review guidance also does not contain adequate provisions to address potential conflicts of interest that could result in biased information unsuitable for regulatory purposes. If implemented as proposed, OMB's policy could negatively impact the quality and extent of information available to the states for their regulatory programs. These issues are discussed in the enclosure, which contains comments on the draft OMB guidance from the various boards, departments and science office within Cal/EPA.

Thank you for the opportunity to comment on this important matter. If you have any questions or need further assistance please contact Ms. Tam Doduc, Assistant Secretary, Cal/EPA, at (916) 445-1399.

Sincerely,

Winston H. Hickox

Winston H. Hickox
Agency Secretary

Enclosure

The energy challenge facing California is real. Every Californian needs to take immediate action to reduce energy consumption. For a list of simple ways you can reduce demand and cut your energy costs, check out www.flexyourpower.ca.gov.

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**California Environmental Protection Agency
October 2003**

**Comments on the Office of Management and Budget's
Scientific Peer Review Guidance in the
Proposed Bulletin under Executive Order 12866**

The California Environmental Protection Agency (Cal/EPA) extensively utilizes information generated by federal agencies in evaluating health risks and regulatory issues. These evaluations support enforcement of California and federal laws within the state. The importance of timely, objective, reliable scientific information of high quality cannot be over-emphasized. Peer review is one of the main tools used by the scientific community to improve the quality of scientific information. However, peer review in and of itself is not sufficient to ensure scientific quality, and inappropriate peer review processes can negatively impact the release, quality and extent of information available to the states for their regulatory programs. The following are comments from Cal/EPA's various boards, departments and science office on the peer review guidance proposed by the Office of Management and Budget's (OMB) Office of Information and Regulatory Affairs (OIRA).

1. Economic Conflict of Interest

OMB should provide additional guidance to address conflict of interest that may influence scientific peer review. A major concern regarding peer review and other scientific activities has been allegations of undue influence of economic interests in scientific peer review processes. OMB's proposed guidance discusses financial conflict of interest as a factor to consider in selecting peer reviewers (Proposed Bulletin, Section 3, Selection of Peer Reviewers), but the emphasis in the preface to the Proposed Bulletin is on the potential conflicts of reviewers that have a history of service to an agency, or could be receiving a grant from the agency. Under federal law, financial conflict has very specific and narrow meaning in terms of excluding an individual from scientific peer review. A broader consideration of conflict is needed to address more generic issues regarding influence of economic interests on agency peer reviews. Models for evaluating such conflicts of individuals and selection for peer review are given in policies of the Institute of Medicine and National Research Council, both of which are institutions of the National Academies.

2. "Balance" of Peer Reviewer Biases

The guidelines for peer reviewer selection (Proposed Bulletin, Section 3, Selection of Peer Reviewers) state: "If it is necessary to select a reviewer who is or appears to be biased in order to obtain a panel with appropriate expertise, the agency shall ensure that another reviewer with contrary bias is appointed to balance the panel." A balanced, well-considered scientific peer review is a worthy goal, but a simple balancing of extreme viewpoints may not serve the agency well. Establishing a committee that cannot achieve consensus in the interest of having depth of expertise in a specific matter will not achieve OMB's objective of an independent, objective review.

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Experienced scientists are capable of evaluating specific scientific matters falling outside their specific area of deep expertise, if given sufficient time for preparation. Instead of accepting biased reviewers, agencies should focus on identifying the best scientists capable of performing credible peer reviews.

3. Agency Discretion in Peer Review

The proposed guidelines include extensive OMB involvement and oversight at all levels in agency peer review processes. Examples include:

- Agencies are required to provide to OMB/OIRA for review a description of "any existing, ongoing, or contemplated scientific or technical studies that might (in whole or in part) constitute or support significant regulatory information the agency intends to disseminate within the next year," its plan for peer review of such studies, and a contact within the agency to discuss the plan (Proposed Bulletin, Section 6).
- OMB may identify agency information to undergo formal external peer review (Proposed Bulletin, Section 3).
- OMB intends to intervene in peer reviews of specific documents it finds of interest (Proposed Bulletin, Section 3) and also reserves the right to require interagency review of agency documents (proposed Bulletin, Section 8). Any waiver of the peer review requirement is granted by the OMB/OIRA Administrator, and not the agency (Proposed Bulletin, Section 4, part c).
- OMB intends to review all agency responses to public requests for correction of agency information. Copies of each and every draft response to such requests to agencies are to be provided to OMB, and responses cannot be issued until after consultation with OMB/OIRA (Proposed Bulletin, Section 7).

Such overly prescriptive measures will be costly to agencies in time and staff resources. They also distract agencies from mission critical matters and further burden the complicated regulatory process. Instead, agencies should have more discretion in peer review, while OMB focuses on particular recurring problems, if warranted (e.g., allegations of conflict of interest in an agency's peer reviews), and the general approach to and policies concerning peer review.

4. Exemptions

Some science-based documents should be exempt from the OMB peer review requirements, including those for which peer review processes have been ongoing and are well established and are required by law. An example is the review by the

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U.S. Environmental Protection Agency (U.S. EPA) Science Advisory Board's Clean Air Scientific Advisory Committee (CASAC) of Criteria Documents. Regulations and information supporting them that are reviewed by mandated peer review groups such as CASAC should be exempt from additional review requirements. Other items that should be exempt include: information supporting actions that are ministerial in terms of explaining or clarifying promulgated regulatory actions; background information supporting actions that are entirely policy oriented, such as compliance re-designation for an area based on new ambient monitoring data; and data collected following standard, generally accepted protocols.

5. Standing or Semi-Permanent Committees

The guidance should explicitly support the use of standing committees to peer review similar types of agency documents. CASAC is one example of a standing agency committee whose members over time have developed an understanding of the information needs of the agency and which has the breadth and depth of expertise needed to review the agency information supporting a specific type of regulatory action, in this case the U.S. EPA's Criteria Documents. There are many such standing committees within the federal government, under agencies excluded and included by the proposed guidance. The proposed guidance appears to question the credibility of standing committees (Proposed Bulletin, Section 3, Selection of Peer Reviewers) by identifying, as a factor relevant to judging an individual as having perceived or real conflict of interest, whether he or she "has conducted multiple peer reviews for the same agency in recent years, or has conducted a peer review for the same agency on the same *specific* matter in recent years." Construction of a separate committee to peer review each specific item can be wasteful of agency resources and carry opportunity costs associated with use of experts with an understanding of the informational needs of the agency or deep expertise in certain subject areas. The standing committees within Cal/EPA have served the public well, having developed standards of evidence for peer review and ensured scientific quality of agency documents.

6. Administrative Correction Process

The OMB guidelines for administrative mechanisms for correcting disseminated information in response to public requests (Proposed Bulletin, Section 7) should be directed at ensuring closure to agency scientific analyses and other informational materials. While detailed guidance is not provided, the administrative corrections process proposed may be used by those not satisfied with the scientific positions of the agency to prevent drafts from being finalized, encourage a state of uncertainty in agency findings, and facilitate a continuous process of editing, science review, and redrafting. The OMB process should facilitate the closure and release of final

documents, and if the scientific underpinnings change significantly, leading to different interpretations of a large body of scientific data, the agency may then begin the process of revision. The mandated process for development of Criteria Documents by the U.S. EPA is a particularly good example of a stable approach to revisiting and revising scientific findings as the science evolves. The OMB/OIRA process already enables public comment in the peer review, and it is at this and earlier points in the process of developing scientific information that the public should be encouraged to bring errors and concerns of interpretation to agency attention.

7. Reports and Responses

The detailed requirements concerning peer review and agency response reports and their dissemination (Proposed Bulletin, Section 3, Peer Review Reports) can be overly burdensome and should be left to the discretion of the agency. The agency should be given both discretion to decide the extent of documentation needed and a dissemination plan. The requirement that the agency disseminate the peer review reports in the same manner the work product is distributed may not be feasible to implement, given the limited resources of some agencies. Where reviewers are in agreement with the agency, the requirement that the agency report on the basis for the agreement may lead to over-interpretation of peer reviewer findings.

8. Public Comments to Peer Reviewers

Federal agencies should be given discretion regarding dissemination of public comment to peer reviewers (Proposed Bulletin, Section 3, Opportunity for Public Comment) in order to maintain an efficient process focused on the scientific issues under consideration. Interested parties may submit voluminous comments, sometimes of little overall relevance, or non-scientific comments that have no place in a scientific peer review. If received, the agency should have the discretion to evaluate such comments for relevance to the peer review and distribute the comments as appropriate.

OMB should also provide federal agencies the flexibility to conduct the peer review before the public comment period. Under this option, the peer review report would be publicly available during the comment period, thus allowing interested parties to prepare their comments with the benefit of having seen the peer reviewers' conclusions. In California's experience, this process benefits many interested parties who otherwise would not be able to present comments based on an independent scientific evaluation.