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To: Mabel E. Echols OMB_Peer_Review/OMB/EOP@EOP

cc:

Subject: Comments on the Proposed Bulletin Under Executive Order 12866 and Supplemental Information Quality Guidelines

Attached are comments from the American Petroleum Institute on the OMB Peer Review Bulletin. As requested, I have also included the comments in email text, which follows.

- peerreview_comments_finalpdf_121003.pdf



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Dr. Margo Schwab
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725 17th Street, NW
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Room 10201
Washington, DC 20503

**RE: Proposed Bulletin Under Executive Order 12866 and Supplemental Information
Quality Guidelines**

Dear Dr. Schwab:

The American Petroleum Institute (API) is pleased to present comments to the Office of Management and Budget (OMB) on its *Proposed Bulletin Under Executive Order 12866 and Supplemental Information Quality Guidelines* ("Peer Review Bulletin").¹ API is the primary trade association of America's oil and natural gas industry, and represents more than 400 members involved in all aspects of the industry. API's members are significantly affected by the wide variety of information that federal government agencies disseminate and use when developing policy and rulemakings. API strongly supported OMB's publication and implementation of Information Quality Guidelines,² and we believe that peer review is an essential component for achieving information quality. OMB's Peer Review Bulletin will be a vital part of OMB's framework for overseeing and supporting agencies' implementation of the Information Quality Guidelines.

In the comments below, API agrees with the need for peer review guidance, and expresses its strong support for OMB's development of the Peer Review Bulletin. We also offer several suggestions for enhancing the Peer Review Bulletin in the following ways:

- Allowing public comment on the peer review charges;
- Specifying where in the peer review process public comments will be solicited;
- Providing guidance on when and how the peer review process should be integrated into the regulatory process;
- Allowing peer reviewers with potential conflict, but unique expertise, to serve as reviewers;
- Requiring a signed ethics statement for peer reviewers;
- Identifying a standard for scientific journal peer review;
- Encouraging or requiring the use of independent organizations to select and manage all peer reviews; and

¹ August 29, 2003.

² *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies*; 67 FR 8451-8460, February 22, 2002.

- Encouraging use of non-monetary criteria for requiring peer review that is required for “especially significant regulatory information”.

I. Need for Peer Review Guidance

API strongly supports OMB’s development of the Peer Review Bulletin. OMB states that it is proposing the new Bulletin to ensure that agencies conduct peer reviews of the most important scientific and technical information relevant to regulatory policies, and that the peer reviews are reliable, independent, and transparent. API supports these goals and believes that they are of paramount importance in achieving the overall objectives of the OMB Information Quality Guidelines.

In its discussion of the need for the Proposed Bulletin, OMB states that existing federal agency peer review mechanisms have not always been sufficient to ensure the reliability of regulatory information. OMB discusses the following deficiencies in existing peer review procedures:

- Most agencies have policies for peer review, but do not always conduct peer review according to their own policies.
- Peer reviewers are sometimes people who are not independent of the agencies, or are not perceived to be independent.
- When an agency initiates a program to select outside peer reviewers for regulatory science, it sometimes selects the same reviewers for all or nearly all of its peer reviews on a particular topic.
- Agencies do not sufficiently consider the relationship of the peer reviewers with the agency, including their funding history.
- Some agencies have sought peer review consisting of only narrow questions regarding a particular study or issue.

API agrees with OMB’s analysis of the current situation, and we have observed it over the course of many years—during various rulemaking processes and other agency activities. One current example is the information used to develop cleanup guidance used in Environmental Protection Agency (EPA) Office of Solid Waste and Emergency Response (OSWER) programs. Cleanup guidance and screening levels using risk-based concentrations (RBCs) vary among guidance documents and by region. It is not clear what the peer review process is for the RBCs and the technical information behind them, or for other aspects of the guidance.

Similarly, EPA has begun to conduct risk assessments for major stationary sources under section 112(f) of the Clean Air Act that requires EPA to assess the risk remaining after technology-based standards have been implemented for each source category. It is not clear whether the risk assessments for each source category will be peer reviewed, or whether consistent peer review methodology will be used for each source category.

We believe that strong peer review guidelines from OMB will address some of the concerns that API expressed in comments on the EPA draft Information Quality Guidelines.³ Two of our main concerns were as follows:

- Other than referencing existing policies and procedures, EPA said very little about how it would ensure and maximize data quality.
- Although OMB directed agencies to develop a pre-dissemination review process, EPA did not clearly outline one. A pre-dissemination review process, which includes peer review, is an absolute necessity for improving information quality.

We think that implementation of peer review guidelines, such as those set forth in OMB's draft Peer Review Bulletin, will be very helpful in addressing these concerns.

II. Peer Review Charges

API agrees with the directive in the proposed Peer Review Bulletin: agencies should provide peer reviewers an explicit, written charge statement describing the purpose and scope of the review.⁴ Creating an appropriate charge is one of the most important steps in the peer review process. If the charge does not adequately define the purpose and scope of review, then subsequent steps to promote quality peer review are largely wasted.

Given the importance of the charge statement, API suggests that OMB require agencies to publish each charge statement in the *Federal Register* and take public comments on each charge statement. Public comments will help agencies design charge statements that facilitate a probing and meaningful review of the work at issue. Commenters may have technical, practical, and other information about the subject that may not be known or understood by government officials.

III. Process for Public Comments

API supports the provision in the Peer Review Bulletin that directs agencies to provide an opportunity for other interested agencies and persons to submit comments, and to ensure that the comments are provided to peer reviewers with ample time for consideration. However, the current draft of the Peer Review Bulletin is not clear on *what* documents and actions require comment, and *when* in the process agencies should solicit comments. API suggests that OMB elaborate on its expectations for the public comment process for peer reviews.

The following are key points in the peer review process where agencies should solicit public comment:

- Selection of peer reviewers;
- Development of the charge to peer reviewers; and

³ *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency*; 67 FR 21234-21235; April 30, 2002.

⁴ Page 10.

- Agency written response to peer review reports.

In addition to public comments on aspects of the peer review process and charge, API suggests that OMB consider how to ensure that all public comments relevant to the issue at hand are available to and considered by peer reviewers. The draft Peer Review Bulletin states that if aspects of the work under review were likely to be controversial, agencies would be required to provide to reviewers background information on the controversy. OMB should state that background information provided to peer reviewers should include any public comments related to the issue under review. For example, if a peer review is conducted for technical information used to support a final rule, the peer reviewers should be provided with all comments on the proposed rule. Furthermore, in some cases, it may be appropriate to charge a peer review panel with reviewing an agency's response to public comments on an issue.

IV. Implementation and Timing of Peer Review

OMB's draft Peer Review Bulletin states that agencies shall have an appropriate and scientifically rigorous peer review conducted on all significant regulatory information that they intend to disseminate.⁵ For especially significant regulatory information, the draft Peer Review Bulletin contains guidelines that cover key steps in the peer review process including selection of peer reviewers, charge to peer reviewers, information access, opportunity for public comment, peer review reports, and so forth. What is not clear from the draft Peer Review Bulletin is *when* and *how* the peer review process should be integrated into the agency's regulatory process.

For instance, if technical information is used to support a rulemaking, at what point in the rulemaking process should peer review of that information occur: pre-proposal stage, proposed rule stage, final rule stage, other stage, or at multiple stages? Likewise, for agency analyses such as the Economic Analysis for a rulemaking, when is peer review expected to occur? API recommends that OMB outline some general guidelines for the timing of peer reviews, particularly for information used to support rulemakings, such as risk assessments that support regulatory decisions (e.g., EPA's Residual Risk Program), and widely used risk-based information such as toxicity values in EPA's Integrated Risk Information System (IRIS).

Our foremost concern regarding this issue is that peer review be conducted early enough to be appropriately considered in decision-making. This will be especially important when internal or external forces, such as court-ordered deadlines, are driving policymakers to issue rulemakings by a certain date. OMB should ensure that this issue is addressed when agencies consult with Office of Information and Regulatory Affairs (OIRA) and Office of Science and Technology Policy (OSTP) on their plans for peer reviews.

⁵ Page 9.

V. Reviewers with Potential Conflict, but Unique Expertise

OMB specifically requests comments on the possibility that agency employees could serve on peer review panels in certain circumstances and on whether any of the provisions would unnecessarily burden participating scientists or discourage qualified scientists from participating in agency peer reviews. API agrees with OMB that agencies should select peer reviewers who are independent of the agency and who do not possess real or perceived conflicts of interest. However, we acknowledge that in some cases there will be unique experts who are either not independent of an agency or do not meet other criteria for independence.

If the entity selecting the peer review panel can demonstrate that a candidate peer reviewer is a unique expert and is capable of approaching the subject matter in an open-minded and unbiased manner, then the person should be eligible to serve, as long as any conflicts are duly noted. We believe that the ethics statement idea presented directly below could help allay some of the concerns associated with choosing a unique expert who does not meet all criteria for independence (e.g., is not independent of an agency, or has past association with Agency advocacy or funding).

VI. Ethics Statement

API recommends that the Peer Review Bulletin require agencies to adopt an ethics statement to be signed by peer reviewers for each peer review. The statement would affirm each peer reviewer's commitment to serve independently and objectively, and to provide review that is technically accurate to the best of his or her ability.

VII. Scientific Journal Peer Review

The draft Peer Review Bulletin states that agencies need not have peer review conducted on studies that have already been subjected to adequate independent peer review. It states that, for purposes of the Bulletin, peer review undertaken by a scientific journal may generally be presumed to be adequate.⁶ This presumption is rebuttable based on a persuasive showing in a particular instance.

API recommends that OMB reconsider whether this provides a high enough standard for published information. The term "scientific journals" is broad and encompasses a large number of publications of varying quality. The extent and quality of peer review conducted on journal articles varies widely from publication to publication. OMB may wish to consider limiting the presumption of adequacy to information published in scientific journals that follow established standards for peer review. OMB may find it useful to consult with the National Academy of Sciences to identify any existing established standards regarding peer review for publication in scientific journals.

⁶ Page 9.

VIII. Independent Selection and Coordination of Peer Review Panels

API suggests that OMB encourage or require the use of independent organizations to select and manage peer reviews. Federal agencies commonly employ contractors to assist with the logistics of peer reviews and expert panels, so contracting with an independent party for peer review coordination may not necessarily require a large increase in budget or resources.

EPA's Voluntary Children's Chemical Evaluation Program (VCCEP) provides an example. The VCCEP program includes many peer consultations by groups of scientific experts with extensive experience in toxicity testing and exposure evaluations. An independent non-profit organization, Toxicology Excellence for Risk Assessment (TERA), organizes and facilitates peer consultations and forwards the results to EPA. Additional information on this program is available at:

<http://www.epa.gov/chemrtk/vccep/index.htm>

and

<http://www.tera.org/peer/VCCEP/VCCEPIntroduction.html>.

At the least, selection of peer reviewers should not be conducted exclusively by the program office that is producing and/or using the information at issue. OMB may want to consider requiring that agencies have a peer reviewer selection body that is independent of the program offices that are producing or using the information subject to peer review.

IX. Scope of the Peer Review Bulletin

API agrees with OMB's general framework of requiring appropriate and scientifically rigorous peer review for all significant regulatory information that an agency intends to disseminate, with a higher standard and level of guidance for "especially significant regulatory information." We agree with OMB's definition of "especially significant regulatory information," with the following caveat.

Only a limited number of agency actions will meet the monetary criterion of having a possible impact of more than \$100 million in any year. Applying only a monetary criterion would be particularly problematic if related rulemakings were divided into smaller ones that did not exceed the threshold, but when taken together, would exceed the threshold. Therefore, it is important that OMB and agencies not neglect the non-monetary criteria for "especially significant regulatory information," which include the following:

- Information that is of significant interagency interest or is relevant to policy priority;
- Information related to actions that adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health and/or safety, or community well-being; and
- Information related to actions that may create serious inconsistency or otherwise interfere with action of another agency, materially affect the budgetary impacts of entitlements, grants, etc., or raise novel legal or policy issues.

API appreciates the opportunity to comment on the draft Peer Review Bulletin and looks forward to continued cooperation with OMB in the process of developing it. Feel free to contact me at 202-682-8341 or barrettg@api.org, if you have any questions about our comments.

Sincerely,

A handwritten signature in black ink, appearing to read "Glen J. Barrett", with a horizontal line extending to the right from the end of the signature.

Glen J. Barrett
Senior Health Scientist
American Petroleum Institute

CC: Paul Noe, OMB
Lorraine Twerdok, API
Right-to Know/Environmental Information Task Force, API
Air Toxics Task Force, API
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