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12/15/2003 11:21:21 AM

Record Type: Record

To: Mabel E. Echols OMB_Peer_Review/OMB/EOP@EOP
cc: Lara Swett <LSwett@npra.org>
Subject: NPRA Comments on OMB's Proposed Bulletin on Peer Review and Information Quality

Comments submitted by:

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December 15, 2003

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

Dear Dr. Schwab:

NPRA, the National Petrochemical & Refiners Association, is pleased to present the attached comments on OMB's *Proposed Bulletin on Peer Review and Information Quality* which was published on September 15, 2003 (68 *FR* 54024).

NPRA represents almost 450 companies, including virtually all US refiners and petrochemical manufacturers. Our members supply consumers with a wide variety of products and services that are used daily in homes and businesses. These products include gasoline, diesel fuel, home heating oil, jet fuel and the chemicals that serve as "building blocks" in making everything from plastics to clothing to medicine to computers.

EPA and other Regulatory Agencies' information have a significant effect upon NPRA members' ability to do business and meet the goal of continuous environmental improvement in our facility operations and in our products. For this reason, NPRA has a direct interest in ensuring that peer reviews are conducted to ensure that the technical information underpinning regulatory policies meets the Data Quality Standards.

We support the effort by OMB as an excellent first step in ensuring that peer reviews conducted and disseminated to the public are reliable, independent, and transparent. We provide some suggestions below for improving the proposed OMB Peer Review Bulletin.

If you have any questions, please contact me at 202-457-0480.

Sincerely,

A handwritten signature in black ink that reads "Norbert Dee". The signature is written in a cursive, flowing style.

Norbert Dee, Ph.D.
Director Environment & Safety

**Comments by NPRA On OMB's
Proposed Bulletin on Peer Review and Information Quality
September 15, 2003**

1. NPRA Strongly Supports the Proposed OMB Bulletin on Peer Review and Information Quality

In the United States, the appropriate science based-studies and analyses are important elements in developing federal policies and regulatory actions. For this reason, it is essential that the public have confidence that those analyses receive an independent and objective review prior to their use. In the past, peer review of federal agency's analyses has often been non-existent or insufficient to ensure the reliability of included information.

For that reason, NPRA strongly supports OMB's proposed peer review Bulletin, which requires a peer review of all significant regulatory science to ensure that it is reliable, independent and transparent prior to public dissemination. The proposed OMB Bulletin supports Executive Order 12866. (Regulatory Planning and Review) Independent peer review is essential for regulatory policies that will impact the regulated community, the public, and the government. It is therefore necessary that these reviews be conducted without an actual or perceived conflict of interest. Further, independent peer review improves the quality of information that forms the basis for regulatory action. The Bulletin significantly improves the peer review process by establishing stringent public notice and participation requirements.

2. The OMB Bulletin Should Be an Amendment to the Data Quality Guidelines

The OMB Bulletin should be an integral part of the current Data Quality Guidelines to ensure consistent implementation across all Federal agencies. Because the current guidance only encourages peer reviews, but does not require them, in many cases agencies have narrowly defined the peer review process. This leads to a patchwork of decisions on when and how to incorporate peer review. Such arbitrariness does not provide public confidence in a process designed to ensure objectivity and transparency.

We believe amending the Data Quality Guidelines with the OMB Bulletin will correct the current variability in federal agency implementation of peer reviews by providing the needed guidance on process requirements. Consistent implementation will only occur if

the Bulletin is defined as an amendment to the Data Quality Guidelines and not as a separate document which may be ignored.

For example, NPRA is currently involved in an EPA rulemaking process on Residual Risk. The data and model used by EPA, which we believe are seriously flawed, have not been subjected to any review process.

Unless there is a consistent requirement for peer review across all agencies, EPA Offices are reluctant to conduct an independent peer review of their own staff work, such as in the Residual Risk rulemaking. Currently, points of contention or disagreement in science studies often can only be addressed through litigation instead of solving the problems within the agency at an earlier stage.

3. OMB Should Broadly Define Federal Actions Considered In the Peer Review Process

In Part II, Section 2 of the proposed Bulletin, OMB states that peer review is required for significant regulatory action. In addition, under Executive Order 12866 a significant regulatory action not only includes ones with regulatory impacts over 100 million dollars but also includes actions which would create or impact public policies.

NPRA suggests that for purposes of peer review as defined in Part II Section 2 and 3 of the proposed Bulletin, a significant regulatory action definition should include:

- Federal actions which establish a precedent by the agency for the use of scientific models or data in the development of regulations that individually may not meet the \$100 million threshold, but when totaled over all subsequent regulations developed by the Agency, may exceed the threshold. By its very nature, the aggregate cost total would not be reached in one year but over multiple years.
- Federal actions which use scientific models or data to establish a national policy or which may impact an existing national policy.

4. Required Action in Response to Requests for Correction

NPRA supports the process defined in Section 7 of the proposed OMB Bulletin, to correct data quality errors. However, it is our experience that often even after the Agency has agreed that there is a data quality issue, the time it takes to respond may be significant. We request that a time for correction be included in the response by the Agency. Further, the correction should include the removal of the data from the web page, if appropriate, rather than the practice of placing a simple statement on the web

page that the data is not supported by the Agency without removal of the incorrect data. The agency should also cease use of the data and any results based on it in future releases to the public.

5. Journal Peer Review May Not Be Adequate

In Part II Section 2 of the proposed Bulletin, OMB states that a peer review undertaken by a scientific journal may be generally be presumed to be adequate. NPRA is concerned about this approach. Not all scientific journals are of the same quality in the content of the articles nor are they all “scientific”. In addition, each scientific journal has its own criteria which define who is selected for the review panel, as well as depth of the review.

Therefore, instead of stating that all peer reviews are assumed to be adequate which presumption is rebuttable, NPRA suggests that the use of a journal peer review be presumed adequate only if the journal can provide the agency with sufficient documentation of the reviewers’ qualifications and the merits of the review.