



December 12, 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

Subject: Office of Management and Budget Proposed Bulletin on Peer Review and Information Quality under Executive Order 12866 and supplemental information quality guidelines [FR Doc. 03–23367] 68 FR 54023, September 15, 2003

Dear Dr. Schwab:

The American Phytopathological Society (APS) is pleased to respond to the request for comments on the subject Proposed Bulletin from the Office of Management and Budget (OMB).

APS, founded in 1909, is the premier educational, professional and scientific society dedicated to the promotion of plant health and plant disease control for the common good. The Society represents more than 5,000 plant pathologists, including scientists and science administrators in academic, industrial and government institutions working in a variety of areas, including applied and environmental plant pathology, food, horticultural and forestry science, and biotechnology, including basic and applied research on producing transgenic plants resistant to pathogens and abiotic stresses.

APS supports the intent of the Proposed Bulletin on Peer Review and Information Quality as a way to further improve the scientific review process as conducted by federal agencies for the most important scientific and technical information relevant to regulatory policies. As stated in the proposal, currently there is uncertainty and lack of consistency and transparency in the peer review process within and across federal agencies. Recognizing the need to improve the quality of information disseminated to the public by the Federal government, OMB was directed by Congress' Information Quality Act (IQA) to issue government-wide guidelines that *provide policy and procedural guidance to Federal agencies for ensuring and maximizing the quality, objectivity, utility, and integrity of information (including statistical information) disseminated by Federal agencies*. OMB directed Federal agencies to issue IQA guidance and indicated that the quality principles applied by Congress to the Safe Drinking Water Act (SDWA) amendments of 1996(42 U.S.C. § 300g1(b)(3)(A), (B)) should be adopted. Under that law an agency is directed, *to the degree an agency action is based on science, to use (i) the best available, peer-reviewed science and supporting studies conducted in accordance with sound and objective scientific practices....* Thus, OMB has already directed the use of peer review in satisfying the IQA standards, the proposed bulletin now provides a framework for achievement of such reviews and should be considered an

amendment to the government-wide IQA guidelines. Individual agencies should amend their specific guidelines to include the peer review bulletin framework.

APS would like to comment on some aspects of the proposed bulletin. The current proposal uses a multi-tiered system of categories (*significant regulatory information* and *especially significant regulatory information*) which are not consistent with the IQA guidance. OMB should eliminate the confusion that this causes and revise the proposal to reflect the two-tiered approach used in the IQA guidance (regular information and *influential* information).

The definition of a peer review in the proposal text is a scientifically rigorous review and critique of a study's methods, results, and findings by others in the field with requisite training and expertise. APS recommends that this definition be expanded to clarify that peer review must also be independent, objective (unbiased) and transparent. Transparency of all information used in the study is important, as is transparency of information on peer reviewers.

Section 2 of the proposal (Peer Review of Significant Regulatory Information) states: *Agencies need not, however have peer review conducted on studies that have already been subjected to adequate independent peer review. For purposes of this Bulletin, peer review undertaken by a scientific journal may generally be presumed to be adequate. This presumption is rebuttable based on a persuasive showing in a particular instance.* APS disagrees that publication by a scientific journal constitutes peer review in the context required for regulatory policy decision-making. The greater scientific community is not driven by science used in regulatory decision-making. In addition to issues about journal peer reviewers only being able to examine what the author(s) summarize (not the actual data), it is an established concern that journal peer review is not designed to detect fraud or lack of scientific integrity. APS would argue that journal review contributes to maintaining standards in published science, and results in placing the plausible research results in the hands of the scientific community where it will be validated or disproved in time. Reproducibility of data is a basic principle of scientific investigation. The presumption that journal review is adequate for regulatory decision-making should be removed from the proposed bulletin.

Additionally, APS disagrees with the concept that scientific research conducted by the National Institutes of Health (including the National Institute of Environmental Health Sciences and the National Cancer Institute), the National Science Foundation, the Environmental Protection Agency's Office of Research and Development, etc. is not directed toward regulatory issues. Much of the research generated by these organizations will indeed be used in regulatory decision-making and especially if such decisions set precedent, the underlying studies must be peer reviewed. APS suggest that OMB revise the proposal to reflect this requirement.

APS agrees with OMB that peer reviewers must be selected primarily on the basis of necessary scientific and technical expertise, and that when multiple disciplines are required, the selected reviewers should include as broad a range of expertise as is necessary. APS also agrees with OMB that in selection of qualified peer reviewers the agency sponsoring the review shall strive to appoint experts who, in addition to possessing the necessary scientific and technical expertise, are independent of the agency, do not possess real or perceived conflicts of interest and are capable of approaching the subject matter in an open-minded and unbiased manner. In order for an agency to achieve this standard, the selection must become completely transparent, encompassing relevant factors such as financial interests in the matter at issue (including whether the reviewer is currently receiving or seeking substantial funding from the agency through a contract or research grant) or recent advocating of a position on the specific matter at issue. If it is necessary to select a reviewer that is or appears to be biased in order to obtain a panel with

appropriate expertise, APS agrees that the agency shall ensure that another reviewer with contrary bias is appointed to balance the panel.

APS agrees that the charge to peer reviewer should be an explicit, written charge statement describing the purpose and scope of the review. The charge should be appropriately broad and specific to facilitate a meaningful critique of the science and the agency must make clear that it is the science alone being evaluated, not the policy determinations.

APS appreciates the opportunity to provide these comments and hop that the OMB finds them useful input from the scientific community.

Sincerely,

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