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To: OMB_peer_review@omb.eop.gov

cc:

Subject: OMB Revised Information Quality Bulletin on Peer Review

Please accept the attached document as our comments regarding OMB Revised Information Quality Bulletin on Peer Review.

If you have any difficulties opening the attachment please contact Marissa at 202/406-3681.

Thank you in advance for your time and consideration

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May 19, 2004

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

RE: OMB Revised Information Quality Bulletin on Peer Review

Dear Dr. Schwab:

The American Farm Bureau Federation (AFBF) is pleased to offer its comments in general support of the revised bulletin on Peer Review.

The bulletin would continue the movement toward better rulemaking that was started by the Information Quality Act and the Information Quality Guidelines that all federal agencies adopted last year. We commend OMB for taking this direction toward improving the quality of information that is used in rulemaking. We provided comments on the proposed bulletin on Peer Review and Information Quality.

As in our previous comments, we suggest the bulletin be an amendment to the Information Quality Guidelines, and individual agencies be required to amend their own information quality guidelines to comply with this bulletin.

Peer review of a study or report at the pre-decisional stage of the regulatory process, as set forth in the proposed bulletin, is especially important. It is much easier to fix a rule before it is proposed or at the proposal stage than to undo a regulatory decision that has already occurred. The information quality guidelines provide a data correction mechanism to address situations where flawed information has already been disseminated. The peer review requirement provides a complement to this requirement at the pre-dissemination stage.

In addition to rules becoming more costly and more complex, they are also becoming more controversial. More regulatory decisions are being challenged now than ever before. The U.S. Fish & Wildlife Service (FWS) stopped making decisions relating to critical habitat designations in July of 2003 because it ran out of funding, due to court challenges to their decisions. The FWS's work plans on listing and critical habitat decisions are being dictated by the courts instead of by the priorities of the agency.

Peer review of the science used in agency decision-making should provide greater public confidence in agency rulemakings. Science that is peer-reviewed is less likely to be appealed or challenged in court because it has already undergone an additional screening for accuracy and

reliability. Controversial or cutting-edge science used in proposed rulemaking would receive greater credibility if it receives a “second opinion” in the peer review process.

Agency rulemaking is also more likely to be upheld if the science behind it has been peer reviewed. Courts are more likely to respect rulemaking science if it has undergone independent scrutiny.

The revised bulletin is quite different than the first draft in many significant respects. The revised bulletin grants complete discretion to the agencies in determining what type of peer review to use in individual cases, whereas the first draft provided minimum requirements for peer review. In addition, the revised bulletin provides certain exemptions for time sensitive information, and provides a more transparent process for public input into the type of peer review applied in each instance.

In some cases, the changes made improve the bulletin, in other cases we believe the changes weaken it. We support the exemptions made for time-sensitive medical, safety and other sensitive information. We also support agency flexibility in peer review. We believe, however, that the revised bulletin provides so much agency discretion and flexibility that it eliminates agency accountability for compliance with the bulletin. Minimum agency peer review requirements must be retained and enforced. Under the revised bulletin, there is no enforcement mechanism to ensure that agencies are compliant with peer review requirements.

1. **Agency Discretion of Peer Review Methods Should Not be Unfettered.** The revised bulletin gives the agencies complete discretion in the type of peer review to employ in each individual case. We support the concept of providing agencies with discretion in these cases, so that each agency can address its own needs and determine how to conduct the peer review according to its resources.

One of the problems identified in the first draft, however, is that there is no consistency in the way agencies approach or conduct peer review of its products. Some agencies have extensive peer review processes in place, while others have little or none at all. The quality of peer review will be markedly different between such agencies. Unlike the first draft, the revised bulletin does not address this issue.

There is no incentive for these agencies to improve their peer review process, or to establish one. Agencies are free under the revised bulletin to choose whatever type of peer review process it wants for each individual project. An agency might choose one process for one project, and then choose a completely different process for an identical or similar project.

The bulletin should either: (1) establish a minimum peer review requirement to establish a consistent baseline for all agencies, with the recognition that agencies have discretion to choose the type of peer review process appropriate for them in any particular circumstance; or, (2) require agencies to establish peer review guidelines which indicate the type of peer review that an agency will undertake for a particular type of product. This would ensure that an agency would use the same peer review process for all listing decisions under the Endangered Species Act, for example. Agencies would still have complete discretion, but there would be some assurance that the discretion would be consistently applied.

2. **There Must be Greater Agency Accountability for Compliance with Peer Review Requirements.** The revised bulletin requires little or no accountability by the agencies for compliance with the bulletin. While agencies are required to take certain actions, there is no enforcement mechanism to ensure that agencies in fact comply with the bulletin. One of the problems identified in the first draft is that agencies with peer review procedures in place often do not follow them. The revised bulletin would not address this problem, and would in fact allow it to continue. Peer review requirements mean little if there is no enforcement or oversight mechanism.

a. There is no accountability of an agency to ensure that it complies with its peer review agenda. For example, the revised bulletin requires agencies to publish an agenda of scheduled peer reviews along with a description on how peer review will be done for each project. It allows for public comment on the agenda. But there is no mechanism to ensure that public comment is considered, or even that the process described in the agenda is followed. Without that, the public comment requirement is virtually meaningless. The revised bulletin requires a certification for the administrative record that the bulletin has been followed in cases where influential information is considered in a rulemaking. Such a requirement does little to ensure compliance with the peer review requirement.

The bulletin should allow public scrutiny of the process used in the peer review. This might take the form of allowing the full peer review process to be open to scrutiny in the course of an Information Quality Act challenge to the scientific document or by opening the peer review process in the course of a challenge to the regulation or rule at issue. The bulletin also might provide for periodic OMB scrutiny of agency peer review processes that are used in certain cases.

b. There is no way to ensure that peer review is effectively considered. The revised bulletin requires a detailed summary or copy of peer reviewer comments be made available to the public for influential scientific information, and also requires the agency to consider the peer review report. But the agency is free to reject the peer review report with no further action required and no questions asked. That raises issues about the utility of the peer review process and whether it is providing meaningful input. If peer review is going to be required, there must be a transparent process whereby the report is taken into account by the agency.

The revised bulletin requires agencies to respond to the peer review report in cases of highly influential scientific information. The bulletin should extend the requirement that the agency respond to the peer review report to all cases where peer review is required. This would also be consistent with the requirements of the Administrative Procedures Act, which requires that agencies respond to comments made in the course of a rulemaking.

c. There is no way to determine whether peer review requirements are met. The revised bulletin does an excellent job in describing the qualifications of peer reviewers, the balance necessary in order to prevent bias and the need to avoid conflicts of interest for peer reviews involving highly influential scientific

information. All of these are necessary factors for effective peer review. However, there is no mechanism to ensure that these essential elements are met. Also, there is no similar requirement for cases involving influential scientific information, which will form the bulk of the peer reviews under this bulletin. For such situations, there is no requirement of balance or avoidance of conflict of interest, and there is no way to determine whether any of those requirements are met.

The bias and conflict of interest requirements should extend to all situations where peer review is required. The bulletin should also require agencies to submit the same peer review reports required for highly influential scientific information to OMB for all peer reviews conducted under the bulletin. The bulletin should require that these complete reports be made part of the administrative record for any judicial or Information Quality Act challenge to the information.

Farm Bureau understands and supports the need for agency flexibility and agency discretion in application of peer review requirements. But with increased discretion should come increased accountability. While the revised bulletin allows increased discretion, it does not provide for the increased accountability.

We urge you to consider the suggestions that we have made to address our concerns. We understand the needs for reviewer confidentiality, agency flexibility and discretion being balanced with the need for agencies to be accountable for their actions. Our suggestions would make certain information accessible only in cases where an Information Quality Act challenge or judicial challenge has been filed, thus avoiding the release of peer review information to promote “fishing expeditions” by entities seeking a basis to attack a study or a rule.

Thank you for the opportunity to provide comments, and we look forward to working with you in finalizing the bulletin.

Sincerely,

A handwritten signature in black ink, appearing to read 'Bob Stallman', with a long horizontal flourish extending to the right.

Bob Stallman
President