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12/17/2003 09:44:47 AM

Record Type: Record

To: Mabel E. Echols OMB_Peer_Review/OMB/EOP@EOP
cc:
Subject: FW: PEER REVIEW COMMENTS

To whom it may concern:

We were told that you could not open the Word document that we sent. We have pasted the letter to this e-mail.

Rick Krause

December 15, 2003

Office of Information and Regulatory Affairs (OIRA)
Office of Management and Budget (OMB)
725 17th Street, NW
New Executive Office Building, Room 10201
Washington, D.C. 20503

RE: Proposed Bulletin on Peer Review and Information Quality

To Whom It May Concern:

The American Farm Bureau Federation (AFBF) is pleased to submit our comments and strong support of the proposed Bulletin on Peer Review and Information Quality.

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. The requirements set forth in the bulletin provide a welcome supplement to the Information Quality Guidelines and continues the trend toward ensuring that sound information is used in rulemaking activities. We suggest that the bulletin be an amendment to the Information Quality Guidelines, and that individual agencies be required to amend their own information quality guidelines to comply with this bulletin.

Farm Bureau has long advocated that sound science must be a cornerstone of any regulatory policy. Regulations affect people's lives and livelihoods, and government must assure the public that these regulations have a sound basis.

Scientific peer review is a tool that is widely accepted in both the scientific and regulatory community. Peer review of the science used in regulations helps to ensure that the scientific analysis used in regulatory actions and decisions is reliable. With regulations becoming more costly and more complex, peer review of the science used in reaching decisions is especially important.

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.

For example, in 2001, the U.S. Fish & Wildlife Service made a decision to shut off irrigation water to over 1400 farmers and ranchers in the Klamath Basin in California and Oregon based on the conclusions of a biological opinion that irrigation use of scarce water supplies would likely jeopardize the continued existence of two endangered fish that inhabit streams in the area. The decision caused considerable hardship and economic loss to the entire Basin, and especially to the farmers and ranchers who were denied a crop for the 2001 growing season.

Because of the anguish and the controversy that this situation caused, Interior Secretary Norton sent the biological opinion to the National Academy of Sciences for peer review of the scientific underpinnings. The Academy report concluded that the bases for the decision to shut off water were flawed, and the farmers and ranchers should have received their promised water. But by then it was too late. The damage had been done.

Had the bulletin been in effect at that time, the situation would have been avoided. While vindication might be satisfying for those who were affected, it cannot undo what they suffered.

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 had to stop making decisions relating to critical habitat designations in July of this year because it ran out of funding, due to court challenges to the decisions it had made in the past. The service's work plans on listing and critical habitat decisions are dictated by the courts instead of by the agency's priorities.

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 screen 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. Peer review will better ensure that agency rules are predicated on sound science rather than on court decisions.

Many federal agencies already have their own peer review programs for various types of rulemaking. There is, however, no consistency between agencies on the standards or procedures for the various peer review programs, and possibly no consistency between different programs within the same agency. The bulletin would provide minimum standard criteria for all agencies to incorporate in peer review programs. These minimum criteria are necessary to improve the quality of rulemaking for all agencies. Agency peer review programs that already meet or exceed the criteria in the bulletin should not change.

Agency peer review programs prove the point that peer review of agency science does not have to unduly delay the regulatory process. An efficient peer review process can occur in a timely manner without causing regulatory gridlock. We believe that as agencies implement and refine their peer review processes, they will become more efficient so that delay can no longer be

considered an issue. Any minimal additional expenses would be built into the rulemaking system so that they will no longer be an issue as well.

We have some specific comments relating to the proposed Bulletin and to questions posed by OMB.

1. Competence of Peer Review Panels Should be the Overriding Consideration Rather than Independence of Peer Reviewers.

A major thrust of the proposed bulletin seems to be to establish a peer review system that is independent of the agency whose science is being reviewed. We believe that to the extent possible, independent, outside peer review should be employed for all agency rulemaking.

We recognize, however, that there will be circumstances where peer review expertise cannot be achieved if strict independence must be maintained. The most knowledgeable experts often have certain ties to an agency or opinions on the subject matter that could otherwise disqualify them from completely independent peer review.

We believe that a distinction can and must be drawn between conflict of interest and bias. Conflict of interest situations must be subject to strict scrutiny and avoided. Standards used by the Office of Ethics can and should be applied to conflicts of interest in peer review situations.

Bias is a more difficult issue to overcome. It may be difficult to find experts who do not have an opinion on the subject matter of their expertise. If true unbiased experts can be found, they should be used. Rather than striving for unbiased peer review panels at the cost of expertise, it might be more effective to look for balanced peer review panels where bias on one side is balanced by bias on the other.

Farm Bureau believes that the guidelines should be strengthened to include uniform standards for conflict of interest and for defining and addressing bias in the peer review process.

2. Agencies Should Develop Their Own Peer Review Procedures, with OMB Oversight.

We support the approach taken in the Bulletin that provides that agencies shall develop their own peer review procedures for significant rulemaking. Each agency has different procedures and operating statutes, and each agency must be allowed to develop a procedure that works best for it.

We also support more OMB oversight in the development of these procedures than proposed Bulletin currently contains. Just as OMB reviewed the original individual data quality guidelines, OMB should also review the peer review procedures that will amend these guidelines. Those agencies that already have a peer review procedure must have a means of validating them to ensure compliance with the Bulletin. OMB oversight will also provide a greater degree of consistency between agencies.

3. Peer Reviewers Should Be Selected by the Agencies and Not by a Central Organization.

OMB requests comments on whether peer reviewers should be selected by the agencies or whether a central agency or organization should select them. It is our position that the peer reviewers should be selected by the agencies themselves.

We believe that there is little to be gained by having a central agency such as the National Academy of Sciences select peer reviewers for the agencies. The measure of independence that might be gained by a central agency selecting

the reviewers will be outweighed by the added bureaucracy that such a process would entail. We believe that OMB should have oversight of an agency's peer review process, but not necessarily the peer reviewers.

Agency peer review will work better and be more accepted by the agencies if they are permitted to select their own peer reviewers. In many cases, the people actually working on an issue will be more familiar with who the experts are. Agency selection of peer reviewers will also allow peer review to proceed more quickly and efficiently.

We do believe, however, that OMB should prescribe minimum agency guidelines for selection of peer reviewers. Conflict of interest standards and bias considerations spelled out above are a start. But additional guidelines should be included.

For example, peer reviewers should not be selected from the action agency if at all possible. Sometimes agency personnel are the most expert on a particular subject and could in some circumstances be eligible peer reviewers. If agency personnel must be selected, they should be from outside the program area or department that is promulgating the rules. Agency personnel should not be reviewing science used in rules promulgated by their program area.

We also believe that any peer review project should have more than one peer reviewer. There should be at least two and maybe three peer reviewers for each project to ensure balance.

4. Peer Review Requirements Should Explicitly Extend to Proceedings that have the Force and Effect of Agency Rules.

OMB has asked for comment on the scope of the proposed Bulletin. We strongly support the Bulletin as a good first step in improving and maintaining the quality of agency rulemaking.

We also recognize, however, that agency policy is set in other ways than formal or informal rulemaking. Scientific information often plays an important role in these types of policy statements and peer review requirements should be extended to them.

Many agencies, such as the Environmental Protection Agency, essentially regulate through the issuance of guidance documents that have the force and effect of regulation but which circumvent the requirements of the Administrative Procedures Act. The Peer Review Bulletin should expressly apply to these situations.

Science also plays a major role in other decisional actions that greatly impact people's lives. Under section 7 of the Endangered Species Act, for example, federal agencies are required to consult with either the Fish & Wildlife Service or the National Marine Fisheries Service regarding proposed activities with a federal nexus that "may affect" a listed species. Scientific information plays a critical and determining role in these consultations through preparation by the action agency of a "biological assessment" and by the Service of a "biological opinion." It is critical that the scientific information used in making decisions based on the consultation undergoes the same level of peer review as science used in proposed rulemakings. The situation in the Klamath Basin in 2001 cited above is an example of a situation where peer review of the science used in the consultation process could have avoided a catastrophic situation.

Science is used by agencies in many different ways. We strongly believe that any science used in policy, regulation or decisions that impact people's lives and livelihoods should be peer reviewed.

We strongly support the efforts of OMB to ensure that the science used in agency rulemaking is sound. Peer review is a necessary element in making that

happen. Peer review of agency science will also serve to instill a level of public confidence in agency rulemaking that could have the effect of decreasing appeals and legal challenges to agency rules.

We believe that agencies will find that any perceived problems of added costs or delay resulting from a peer review process will not in fact occur once a process is in place. Many agencies already have peer review procedures for different types of programs and they have not caused the regulatory upheaval that some predicted. We believe that the same result will occur for the rest of the federal agencies.

We hope you will consider our comments as you fashion the final bulletin. We look forward to working with you to accomplish that.

Sincerely,

Richard W. Newpher
Executive Director
Public Policy

-----Original Message-----

From: Nancy_Beck@omb.eop.gov [mailto:Nancy_Beck@omb.eop.gov]
Sent: Tuesday, December 16, 2003 6:32 PM
To: Marissa Woodhull-Weiser
Cc: Rick Krause
Subject: PEER REVIEW COMMENTS

we can not open the word document.
please advise.
thanks,
Nancy
202-395-3258

----- Forwarded by Nancy Beck/OMB/EOP on 12/16/2003 06:30 PM -----

(Embedded
image moved Marissa Woodhull-Weiser <MarissaW@fb.org>
to file: 12/15/2003 01:40:19 PM
pic24683.pcx)

Record Type: Record

To: Mabel E. Echols OMB_Peer_Review/OMB/EOP@EOP
cc: Rick Krause <rickk@fb.org>
Subject: PEER REVIEW COMMENTS

Attached please find AFBF's comments on the Proposed bulletin on Peer Review and Information Quality. Should you have any problem opening the attachment please contact Marissa at 202/406/3681.

Thank you.

Marissa Woodhull-Weiser
American Farm Bureau Federation
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