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To: Mabel E. Echols OMB_Peer_Review/OMB/EOP

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Subject: Comments of the California Farm Bureau Federation regarding the Office of Management and Budget Peer

Review and Information Quality Bulletin

<<CFBF Final Comments 10-28-03 Electronic PDF.pdf>> Pursuant to the instructions contained in the above-referenced bulletin, the comments of the California Farm Bureau Federation are submitted as a PDF attachment, as well as in the body of this message. The comments have are being submitted under the signature of Mr. Bill Pauli, President of the California Farm Bureau Federation; 2300 River Plaza Drive; Sacramento, CA 95833; (916) 561-5520; rlucas@cfbf.com

October 28, 2003

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SENT VIA ELECTRONIC MAIL AND FASCIMILE (202) 395-7245

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

RE: Office of Management and Budget Peer Review and Information Quality Proposed Bulletin (August 29, 2003)

Dear Dr. Schwab:

The California Farm Bureau Federation ("Farm Bureau"), is the state's largest private sector general agricultural organization. Farm Bureau is a voluntary membership, nonprofit corporation organized under the laws of California to work for the solution of the problems of the farm, farmers and ranchers, the farm home, and the rural community. Its membership consists of 53 county Farm Bureaus in 56 counties, through which it represents more than 90,000 members who are not commercial agricultural producers, but support Farm Bureau's principles and its dedication to ensuring the continuance of a rural environment in this increasingly urbanized state. Farm Bureau shares the Administration's desire to make regulatory science more competent and credible, creating a more consistent regulatory environment and, ideally, fewer lawsuits.

As discussed in greater detail below, the Farm Bureau supports the Office of Management and Budget's ("OMB") Peer Review and Information Quality Proposed Bulletin ("Bulletin"). The Farm Bureau requests that certain aspects of the Bulletin be expanded in order to foster scientific principles in the regulatory decision-making process and to further reduce the amount of litigation surrounding agencies' regulatory decisions.

I. GENERAL COMMENTS

1. Science Plays a Prominent Role in Environmental Decision-Making

Utilizing science to guide agency decisions is a cornerstone of environmental statutes. Congress has expressed repeatedly a belief that science should be the major factor affecting environmental policy decisions. In fact, in some agency decision-making processes, science should be the "sole basis" for a determination. In spite of the heavy reliance on science, many environmental statutes, and their associated regulations, policy manuals, and guidance or handbooks available to agencies' staff and the general public do not define "science." The absence of a uniform approach to utilizing science in agency decision-making can be remedied, at least partially, by expanding and implementing OMB's Bulletin.

2. <u>Meaningful Peer Review is Essential to Making Sound Regulatory Science</u> Determinations

Peer review is an essential part of the scientific process in the United States. Scientific journals will not publish scientific findings until a scientifically rigorous review and critique of the study's methods, results, and findings by others in the field with requisite training and expertise occurs. This process is known simply as "peer review." As noted in OMB's Bulletin, "[i]ndependent, objective peer review has long been regarded as a critical element in ensuring the reliability of scientific analyses." According to the General Accounting Office, "[p]eer review is critical for improving the quality of scientific and technical products. . . ." However, government agencies do not have a uniform approach to conducting peer review, just as they do not have a uniform definition of the term "science." This has led to situations where the public's confidence in regulatory decisions, whether formal rulemakings, listing determinations under the ESA, processing of individual permits, or issuance of guidance documents, is lacking and activist groups appear to be in a race to the courthouse. Under this scenario, everyone loses and the environmental protections implemented by the agencies are questionable. ⁵

¹ See generally the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. §§ 136, et seq. ("FIFRA"); the Federal Endangered Species Act, 16 U.S.C. §§ 1531, et seq. ("ESA"); the Federal Water Pollution Control Act, 33 U.S.C. §§ 1251, et seq. ("Clean Water Act" or "CWA"); the Federal Air Pollution Control Act, 42 U.S.C. §§ 7401, et seq. ("Clean Air Act" or "CAA").

² 16 U.S.C. § 1533(b); 50 C.F.R. § 424.13 (When determining whether a species should be listed under the ESA, the Secretary of the Interior and/or the Secretary of Commerce must make the determination "solely on the basis of the best scientific and commercial data available"). *Id*.

³ Office of Management and Budget, <u>Peer Review and Information Quality Proposed Bulletin</u>, at 2. (Aug. 29, 2003) (Hereinafter "<u>Bulletin</u>").

⁴ *Id*.

⁵ See Natural Research Council Committee on Endangered and Threatened Fishes in the Klamath River Basin, Endangered and Threatened Fishes in the Klamath River Basin: Causes of Decline and Strategies for Recovery, (2003) (Prepublication Copy) at 4-5, 29-30. (Hereinafter "Klamath Report"). ("There is no evidence of a causal connection between water level and water quality or fish mortality ... [in] Upper Klamath Lake." The U.S. Fish and Wildlife Service's "recommendations on maintenance of higher water

Expanding and implementing OMB's Bulletin will result in agencies utilizing improved science when making decisions. This has the potential of creating greater environmental protections and less litigation.

II. SPECIFIC COMMENTS

1. <u>Agency Decisions Under Court Imposed Deadlines Should Not Be Excluded from</u> the Bulletin

As currently written, certain categories of regulatory decision-making are excluded from the peer review requirements. These include "individual adjudications and permit applications" and "when court-imposed deadlines or other exigencies make full compliance with this Bulletin impractical." Agency decisions made under court-imposed deadlines should have more safeguards in place rather than fewer. Many of the decisions that fall under this category are related to environmental statutes that require the use of science in decision-making. Peer review is a key component of the scientific process. It is improper to exclude these decisions from a complete scientific process, yet the Bulletin, as currently written, will result in decisions being made in a short-circuited process that may not meet scientific standards. This should not be the case.

Further, if a court-order is imposed, the decision at issue is clearly important and controversial, as evidenced by the fact that some group or individual expended their time and resources to exhaust their administrative remedies, hire legal staff, and file and complete legal action. One purpose of this Bulletin is to ensure that important science utilized by the federal government regarding regulatory topics is subject to "meaningful peer review." Further, Dr. John Graham, Office of Information and Regulatory Affairs Administrator, stated the goal of this Bulletin "is fewer lawsuits. . . ." Exempting decisions for which a court-ordered deadline is imposed is contrary to the purpose of this Bulletin and will undermine one of its goals.

The recent events in Northern California/Southern Oregon's Klamath Basin highlight problems that will occur if OMB does not require agency decisions under court order to follow this Bulletin. Prior to 1997, the Klamath Project ("Project") was operated to ensure water deliveries to irrigators. Since then, the U.S. Bureau of Reclamation ("Bureau") has been under increasing pressure from the U.S. Fish and Wildlife Service ("FWS") and the National Marine Fisheries Service ("NMFS"), collectively referred to as "Services," to operate the Project to increase Klamath River flows and maintain high water levels at Upper Klamath Reservoir for the purported benefit of the federally listed Lost River Sucker, Shortnose Sucker, and coho salmon. On June 30, 2000, the Bureau

levels in Upper Klamath Lake" and the National Marine Fisheries Service's recommendation "calling for higher flows in the Klamath River main stem ... have little scientific support.") *Id*.

⁶ Bulletin at 6.

⁷ See supra Footnote 1.

⁸ Bulletin at 2-3.

⁹ Bulletin at 1.

¹⁰ Executive Office Of the President Office of Management and Budget, <u>OMB Proposes Draft Peer Review Standards for Regulatory Science</u>, Press Release (Aug. 29, 2003).

was sued by a variety of environmental organizations¹¹ for alleged violations of the ESA.¹² The environmental organizations sought an injunction ordering the Bureau to restore instream flows to the levels that the Services determined were necessary for the listed species. A flurry of additional litigation ensued. In short, a biological opinion was prepared in 2001 that shut-off water to the agricultural communities served by the Project. This created a political firestorm, garnered national media attention, and forced several farmers and ranchers to sell land their families had cultivated for generations and to endure the rigors of bankruptcy.

After the 2001 biological opinion was completed, under a court-imposed deadline, after the water had been shut-off, and after the crisis had been created, the National Academy of Sciences ("NAS") was asked to evaluate the science behind the Services' 2001 biological opinions that resulted in farmers and ranchers throughout the Klamath Basin receiving little or no water during the 2001 irrigation season. NAS released its final report on this situation this month. NAS found there was "no empirical support" for the Services' required increases in Klamath River flows and maintaining high water levels at Upper Klamath Reservoir.¹³

If a situation similar to the Klamath situation arises again, agencies' regulatory decisions will **not** be subject to this Bulletin because of the presence of a court-imposed deadline. This is problematic. The Bulletin must be expanded to help ensure a situation similar to the Klamath situation never happens again. The scientific process, including a rigorous, independent peer review must be followed, especially in situations where courts have gotten involved. Frequently, court-imposed deadlines are the result of settlement agreements wherein the agencies have an opportunity to negotiate the deadlines. If the Bulletin is expanded, agencies can negotiate for longer deadlines in light of the peer review process that will be required.

2. <u>Clarification is Needed in the "Charge to Peer Reviewers" Section of the Bulletin</u>

The Bulletin currently directs that agencies "shall be careful not to divulge internal deliberative information to the peer reviewers." This is appropriate **unless** the agency is utilizing "best professional judgment" in lieu of science or when the agency has decided to utilize the "precautionary principle" in making regulatory decisions. In these two circumstances, the agency should inform the peer reviewers of these decisions and ask the reviewers to discuss scientific uncertainties and ways to reduce or eliminate those uncertainties.

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¹¹ The Pacific Coast Federation of Fishermen's Association, Golden Gate Audubon Society, Klamath Forest Alliance, North Coast Environmental Center, Oregon Natural Resources Council, Institute for Fisheries Resources, The Wilderness Society and the Sierra Club (with legal counsel from the EarthJustice Legal Defense Fund).

¹² Pacific Coast Fed'n of Fishermen's Assoc., et al., v. U.S. Bureau of Reclamation, et al., No. 00-01955 (N. D. Calif.) (June 30, 2000) (First Amended Complaint for Declaratory and Injunctive Relief); (The complaint alleged violations of numerous other federal statutes as well).

¹³ Klamath Report at 29.

Bulletin at 10.

A. Utilizing "Best Professional Judgment"

As discussed above, many environmental statutes direct agencies to make regulatory decisions based on the best science available. This creates situations where agencies have to make decisions when very little scientific evidence exists. In such circumstances, agencies frequently utilize their best professional judgment. Utilizing best professional judgment may be appropriate in such circumstances. But the public should not be led to believe that a decision is based on science when, in fact, it is merely the professional opinion of agency staff. NAS recently discussed the use of best professional judgment when agencies make ESA determinations:

Professional judgment can be used in three ways, and the distinctions among them are quite important. . . . First, for an issue about which there is no information whatsoever, an agency that is charged with protecting a threatened or endangered species can justify the use of professional judgment. Although such an approach is weak in that the transferability of ecological knowledge from one set of circumstances to another is problematic, there is **some** scientific basis for it, and barring the feasibility of other approaches, it can be said to have **weak but not negligible scientific strength**.

Second, a resource agency might use professional judgment to endorse various proposals for action when valid scientific information contradicts it. This use of professional judgment is **difficult to justify**. Scientifically, ... sound and relevant empirical information always trumps speculation or generalization; an agency could argue the reverse only on the basis of a very conservative approach to risk.

Third, an agency might choose to use professional judgment that is consistent with a small amount of direct evidence. In this case, the use of professional judgment is reinforced rather than contradicted, and scientific support for it can be deemed moderate rather than negligible. ¹⁵

It is important for the public to know when an agency is making a regulatory decision using best professional judgment and under which scenario. Such knowledge, particularly when the public knows that a panel of independent peer reviewers also evaluated the propriety of the agency's decision to use best professional judgment, may help reduce litigation and accusations that the decision was based on political science rather than sound science—thus fulfilling the purpose of this Bulletin. A candid discussion and analysis of the use of best professional judgment will help build trust in the agency's decision. Because the peer reviewers' reports will be included in the administrative record under this Bulletin, the public will have greater confidence in the decision and may be more accepting of it. As currently written, however, the peer reviewers will not be afforded the opportunity to evaluate the agency's decision to utilize best professional judgment because of the lack of scientific information. Section 3 of the bulletin must be expanded to ensure that peer reviewers are informed of and asked to

¹⁵ Klamath Report at 30.

analyze an agency's decision to utilize best professional judgment rather than relying on science to make a regulatory decision.

B. <u>The Precautionary Principle</u>

An agency's internal decision to utilize the "precautionary principle". When making regulatory decisions should also be subjected to peer review. Under the precautionary principle, a higher burden of proof lies with those who wish to utilize resources or undertake an activity that may result in environmental degradation. Frequently, agencies utilize the precautionary principle when making decisions that should be based on science and never inform the public that they are proceeding under this policy instrument. Under these circumstances, agencies should acknowledge that the precautionary principle is a decision-making policy instrument, **not** a scientific standard of proof required by the statute under which the agency is acting. The decision to utilize the precautionary principle, like the decision to utilize best professional judgment should be subject to the peer review requirements of this Bulletin.

"[E]ven when a policy decision is made to apply the precautionary principle, the question of whether the decision is consistent with the available scientific information is important." Frequently, in the decision-making context, regulatory agencies have the discretion to utilize the precautionary principle when they are confronted with substantial, but inconclusive or conflicting data. "At some point, however, erring on the side of protection in decision-making ceases to be precautionary and becomes arbitrary." It is difficult for the public to determine whether agencies are acting appropriately or arbitrarily when utilizing the precautionary principle if there is no acknowledgment by agencies that they have decided to utilize that approach. This often leaves the public with doubt about agencies' regulatory decision. The public then seeks a neutral arbitrator – the courts – to ascertain whether agencies acted appropriately.

Subjecting agencies' decisions to implement the precautionary principle to peer review under this Bulletin will help avoid this situation and reduce the amount of litigation. It is also appropriate to have peer reviewers evaluate the agencies' decision to implement the precautionary principle because "[o]ne indication that policy-based precaution has given way to bias or political forces is a major inconsistency of a presumed precautionary action with the available scientific information." Section 3 of the Bulletin must be expanded to ensure that peer reviewers are informed of and asked to analyze agencies' decision to utilize the precautionary principle to make regulatory decisions.

¹⁹ *Id.* at 267-68.

¹⁶ Several versions of the precautionary principle exist. The prototype is found in Principle 15 of the 1992 Rio Declaration of the United Nations Conference on Environment and Development, 31 I.L.M. 874 (1992): "In order to protect the environment, the precautionary approach shall be widely applied by the States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation."

¹⁷ Klamath Report, at 267.

¹⁸ *Id*

III. CONCLUSIONS

Farm Bureau appreciates the opportunity to provide comments and looks forward to working with the Administration to ensure scientific principles guide all agency actions. Farm Bureau applauds OMB for attempting to create a uniform approach to peer review in regulatory decision-making processes. The need for this Bulletin is amply demonstrated by the number of regulatory decisions that are being challenged in courtrooms throughout the nation. Further, this Bulletin will strengthen the quality of science used in regulatory decisions, resulting in greater environmental protections and less litigation. Farm Bureau recommends that OMB expand this Bulletin to apply to agency decisions being made under court-imposed deadlines. The Bulletin also needs to clearly apply so that an agency's decision to utilize best professional judgment or the precautionary principle is also subject to independent peer review.

Sincerely,

BILL PAULI President

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