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Please respond to Joel Nelsen <joeln@cacitrusmutual.com>

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To: Mabel E. Echols OMB_Peer_Review/OMB/EOP

cc:

Subject: Peer Review comments

Attached are comments from Joel Nelsen, President, California Citrus Mutual. Our mailing address is 512.N. Kaweah Ave., Exter California - 93221. CCM's phone number is 559/592 - 3790. My email address is joeln@cacitrusmutual.com.
- per review stmt.doc

Dr. Margo Schwab
Office of Information & Reg Affairs
OMB
725 17th St, NW
Room 10201
Washington, D.C. 20503

Dear Dr. Schwab

California Citrus Mutual (CCM), a citrus producers' voluntary membership trade association, appreciates the opportunity to comment on the Office of Management & Budget proposal regarding *peer review* issued August 29, 2003. CCM's producer members constitute well over half of this family farmer based industry which produces a billion dollars in citrus product and employs over 14,000 workers who earn in excess of \$465 million in wages. In addition, according to a study conducted by Arizona State University, another 11,000 employees are directly dependant upon our industry for jobs and this aligned sector accounts for another \$1.5b in economic activity.

We believe OMB's proposal to initiate a policy and guidelines implementing peer review for the most important science disseminated by the federal government regarding regulatory topics *is positive* and we support this effort.

In the course of doing business at the federal level CCM has participated in more than one peer review. We have advocated that a similar step be included at USDA. The state of California has also implemented the use of the peer review process. CCM's views on peer review continue to strengthen, peer review achieves its intended goals.

As Dr. John Graham, OIRA Administrator stated "fewer lawsuits and a more consistent regulatory environment" is the end result. As a stakeholder it is difficult to initiate political or legal activity when a non-partisan peer review process validates the science supporting a regulatory proposal. The end result is a *more streamlined and less controversial* regulatory process.

Federal rules "based on science" are being challenged to a greater degree thus a process should be adopted that is impervious to challenge from stakeholders, U.S. Government and trading partners. What will result is a process that will be a model for other countries thereby creating a rule

making process on several fronts that creates confidence, stability and ultimately less controversy. As the Carnegie Commission on Science, Technology and Government, Risk and the Environment has identified: “*A key element in setting risk-based priorities is science advice, both internal (within the agency) and external (science advisory boards and other mechanisms). External science advisory boards serve a critically important function in providing regulatory agencies with expert advice on a wide range of issues.*”

We speak from a foundation of experience for we have challenged USDA, and won, as the science supporting a proposed rule was flawed. We have participated in peer reviews at EPA and witnessed a sound methodology that in one instance totally disagreed with the Agency and in another agreed.

A principled disagreement with USDA led us to participate in a lengthy rule making, an active political process and eventually a legal path. Ultimately we were victorious. The proposal lacked a solid scientific foundation and had a peer review made that determination the Agency could have fixed the problem and moved the rule forward with minimal opposition. Considerable expense and several years of productivity were lost.

We concur with OMB in that genuine independence must be obtained to avoid any conflict of interest charges. For that reason *we do not believe* that a member of the Agency from which the proposal is issued should be part of the peer review panel. We believe an ample number of scientists presently engaged in state government, academia, other federal agencies and the private sector could be the universal pool from which a review panel is drawn.

Concomitantly we believe a five-year historical separation from the Agency in question should be mandated on potential reviewers. We would also suggest a one-year interval from review to future employment be imposed.

Transparency and inclusiveness are two pillars of the process we envision. For example an agency issues a rule that is challenged by stakeholders and a peer review panel is formed. The scientific underpinnings of the rule plus the challenges issued by stakeholders would be subject to review. Papers and statements would be circulated and a public “hearing” specifically reviewing the documents would be held.

The Agency and all interested parties would be invited to participate. All would be subject to clarifying questions by the peer review panel. At the conclusion of stakeholder involvement a public discussion among the panel would follow. Determinations for areas of concern would start to form and a general conclusion reached. The panel would subsequently issue a formal statement within 60 days of the public discussion.

The panel itself could be selected by the Agency, in our view, with advice from affected stakeholders. The administrative process to form the pool of potential panel members could be cumbersome and the library of candidates must be housed in a central location. Thus the Agency is best suited to coordinate this activity.

CCM is concerned with two statements made in OMB's proposal. There must be clarification as to what constitutes a respected scientific journal that could be substituted for a peer review panel. This could be a major loophole for avoiding the transparent, neutral and inclusive process OMB envisions.

OMB must clearly articulate the principal that while a study is published this does not necessarily constitute satisfying the mandate of peer review.

Secondly, OMB proposes that agencies "conduct peer reviews of the most important scientific and technical information relevant to regulatory policies that they disseminate to the public,..." We're not convinced *most important* is an appropriate term in this endeavor. Discord is not going to surface over areas of agreement. The effected community by their level of and areas of participation will make the determination as to what is *most important*.

This leads us to another suggestion. Government has become more transparent in its deliberations and development of regulations. As such if debate is not flowing around a proposal then why require a peer review? Therefore we suggest that not *all* important documents or rules be subject to peer review. Those that are contentious yes, those in which all parties are of the same mind, no.

We agree that the scientific panel must engage in scientific determinations only, not establish policy. Nevertheless should an Agency establish a policy that seemingly deviates from the peer review conclusion that **must** be articulated and broadly circulated.

We ask that OMB clarify its intent by suggesting that agencies collaborate with the Office of Science & Technology Policy as to their peer review plans. We do concur that a roster or calendar of rules and peer review status be forwarded to the Agency but collaboration is an encumbrance that has not been proven to be necessary. OMB itself cites several agencies that already engage in adequate peer review processes therefore the need to add another step is seemingly unnecessary. Those agencies not presently utilizing this tool may consult as necessary to establish a viable peer review process but in the final analysis we believe the scientific community and staff within a specific agency will develop the appropriate vehicle to accomplish the objective.

In closing there is no doubt that some elements of government will protest this proposal. They will argue about additional administrative requirements, expense, encumbrances and OMB's technical ability to provide guidance. They will be sensitive to "turf" issues and the "morale" of their scientists. CCM believes that all these arguments are misdirection.

A sound peer review process can reduce expense, shrink the time necessary for a rule making, eliminate political pressure, eliminate or reduce litigation and be a viable tool in a myriad of government settings. CCM therefore urges continued pursuit of this objective.

Cordially,

Joel Nelsen

Joel Nelsen, President