



Phil Wakelyn <PWAKELYN@cotton.org>

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To: OMB_peer_review@omb.eop.gov

cc: Andy Jordan <AJordan@cotton.org>, Gerret Van Duyn <GVanDuyn@cotton.org>

Subject: Comments on Revised Peer Review Notice

Thank you for your cooperation.

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1521 New Hampshire Avenue, NW • Washington, DC 20036
(202) 745-7805 • FAX (202) 483-4040

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May 28, 2004

Dr. Margo Schwab
Office of Information and Regulatory Affairs
Office of Management and Budget
725 17th St. NW.
New Executive Office Building, Room 10201
Washington, DC 20503
OMB_peer_review@omb.eop.gov

RE: Revised Information Quality Bulletin on Peer Review (69 FR 23230; Apr. 28, 2004)

Dear Dr. Schwab:

The National Cotton Council (NCC) is submitting these comments in response to the Office of Management & Budget (OMB) Federal Register notice (69 FR 23230; 4/28/04) regarding the revised information quality bulletin on peer review of data. Since the cotton industry uses many products that are subject to strict regulatory review, and is subject to regulations promulgated by many regulatory agencies (EPA, OSHA, CPSC, FDA, and others), this guidance is very important to help insure that any regulations promulgated are based on sound-science.

The NCC is the central organization of the United States cotton industry. Its members include producers, ginnors, oilseed crushers, merchants, cooperatives, warehousemen and textile manufacturers. While a majority of the industry is concentrated in 17 cotton-producing states, stretching from the Carolinas to California, the downstream manufacturers of cotton apparel and home furnishings are located in virtually every state.

The industry and its suppliers, together with the cotton product manufacturers, account for more than 440,000 jobs in the U.S. Annual cotton production is valued at more than \$5.5 billion at the farm gate, the point at which the producer sells. In addition to the cotton fiber, cottonseed products are used for livestock feed, and for food products ranging from margarine to salad dressing. Taken collectively, the annual business revenue generated by cotton and its products in the U.S. economy is estimated to be in excess of \$100 billion.

The NCC is concerned about the revised peer review guidelines that OMB has proposed. Specific phrases and explanations in the proposed guidelines need to be clarified. Specifically, NCC is concerned with:

Determination of “highly influential” or “important” information

In the proposal OMB uses the terms “highly influential” or “important” to describe information that should be peer reviewed. In Section III: *Peer Review of Highly Influential Scientific Assessments* p. 23236 of the FR notice, “highly influential” information is defined as information that “could have clear and substantial impact on important public policies (including regulatory actions) or private sector decisions with a potential impact of more than \$500 million in any one year ...”. OMB should clarify the origin of the \$500 million figure, why it was adopted instead of \$100 million for a major regulation, and how it is to be calculated. Different agencies may calculate damage or risk by different means. This would lead to inconsistencies across the various regulatory agencies in how peer review would be applied.

Public Participation in the Peer Review Process

OMB suggests that public participation could take the form of written comment to the peer review panel. NCC agrees with OMB’s original assessment that open-ended comment periods should be avoided, and that peer reviewing should take place before public participation to give the public the best available information. Any scientific disagreements with the information presented in the proposed regulation could be addressed by the public during the normal notice and comment period, and reviewed by the regulating agency.

OMB also states that reviewer comments should be given reasonable consideration and be incorporated where relevant and valid. OMB should clarify their definitions of “reasonable consideration” and what is deemed as “relevant” or “valid”.

Panel Selection Excludes Qualified Reviewers and Could Introduce Bias

In the panel selection process, OMB mentions that potential peer review candidates should have expertise, be balanced, and be independent of outside influences. NCC agrees that all peer reviewers should be highly qualified to review the data. However, we would caution OMB against setting ethics rules that automatically disqualify many experienced scientists based on their collaboration with industry, government, or other potential conflicting source. Private sector involvement in research and development of data is critical to discovering new technologies and methods that may be subject to regulatory action. Such researchers are usually the individuals that are most qualified to review work in their particular field. These individuals would be the most appropriate from an expertise point of view and most appropriate to make judgments on the data in question.

Furthermore, OMB's definition of "balance" in the peer review process needs to be clarified. OMB describes researcher's "scientific perspectives" and "competing views" in regards to peer review as potentially healthy for the peer review process. OMB should clarify that such "perspectives" reflect legitimate differences between scientific disciplines and interpretations of the available data.

In summary, NCC urges OMB to revise the proposal to make these clarifications. NCC appreciates the opportunity to comment on this proposal and if there are questions please contact us at 202-745-7805.

Sincerely,



Gerret Van Duyn,
Manager Environmental and Biotechnology Policy
and

Phillip J. Wakelyn, Ph.D.
Senior Scientist Environmental Health and Safety
National Cotton Council