

Ray McAllister <rmcallister@croplifeamerica.org>
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To: Mabel E. Echols OMB_Peer_Review/OMB/EOP@EOP

cc:

Subject: Comments of CropLife America on Proposed Peer Review Bulletin

- CLA-peer review.pdf



December 15, 2003

[Submitted by e-mail only: OMB_peer_review@omb.eop.gov]

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: "Proposed Bulletin on Peer Review and Information Quality;" 68 FR 54023;
September 15, 2003**

Dear Dr. Schwab:

CropLife America (CLA) concurs with thorough comments submitted by the American Chemistry Council on the subject "Proposed Bulletin Peer Review and Information Quality." We see development of the proposed Bulletin as a very positive step in improving the integrity and credibility of the regulatory processes by the federal government, and as a significant enhancement of the Information Quality Guidelines promulgated by OMB in 2002.

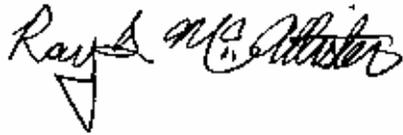
CropLife America is the national trade association that represents the developers, manufacturers, formulators, and distributors of plant science solutions for agriculture and pest management in the United States. CropLife America member companies produce, sell and distribute virtually all the crop protection and biotechnology products used by American farmers.

We also wish to emphasize the following concerns:

1. OMB should create an electronically accessible public docket for the comments submitted on the proposed Bulletin.
2. OMB and individual agencies should clarify, subject to public comment, the breadth of actions encompassed by the "permit applications" that are excluded from the requirements for peer review by Section 2 of the proposed Bulletin.
3. The proposed Bulletin can do more to recognize formally the existing mechanisms within agencies that provide peer review of information used in regulatory actions. For example, the crop protection industry provides large volumes of data at great expense to the Environmental Protection Agency (EPA)

in support of crop protection product registrations. This information is produced under strict Good Laboratory Practice Standards (GLPS; 40 CFR Part 160). (The Food and Drug Administration (FDA) administers very similar GLPS to assure the quality of data submitted by industry to support the approval of pharmaceutical products.) Nevertheless, the GLPS are often ignored by activist groups who oppose use of industry-generated data to support pesticide registrations.

Sincerely,

A handwritten signature in black ink that reads "Ray S. McAllister". The signature is written in a cursive style with a large, stylized initial "R".

Ray S. McAllister, Ph.D.
Regulatory Policy Leader