

Janis.E.Hulla@usace.army.mil
12/19/2003 04:34:53 PM

Record Type: Record

To: Mabel E. Echols OMB_Peer_Review/OMB/EOP@EOP

cc:

Subject: Revised to indicate submission as individual, not agency

- Rev 12_18 Response to Request for Comments OMB peer review data quality.doc

Subject Document Title: Proposed Bulletin on Peer Review and Information Quality
Originating Agency: Office of Management and Budget
Action: Review of Subject Document
Reviewer: Janis E. Hulla, Ph.D., Diplomat of the American Board of Toxicology
Date: December 4, 2003, Revised December 19, 2003

The United States regulatory process is without rival. No other country or coalition approaches the effectiveness of our federal regulatory process in reaching the best possible balance between risk and fiscal responsibility. The process must evolve however. Protections against the allures of financial gain and political influence must be dynamic. In this regard, supplemental guidance that will effectively ensures the ideals of independent and expert peer-review should be embraced.

General Recommendations

1. **Peer-review of regulatory information must not be centralization.** The introduction to OMB's request for comments cites bipartisan support for independent review¹. Will coalescence or centralization of federal review and advisory panel authority under the OMB have bipartisan support? Not likely. Scientific review and advisory service must be independent of political influences.
2. **New guidance should encourage inter-agency review.** Regulatory harmony is achievable if there is strong support for interagency subject-matter-expert review and advisory service.
3. **New guidance should foster overlapping reviews of scientific and economic assessments.** Cross-talk between economists and scientists is needed to better demark margins of sound science and ensure that important scientific advances survive the uncertainties of cost benefit analyses.
4. **New guidance should encourage the use of independent assessment services.** Useful tools include the Web-of-Science and independent journal impact raters should be used to judge the adequacy of expertise and prior peer review. See paragraph 1 of section 2.

¹ S.343, the "Comprehensive Regulatory Reform Act of 1995", S. 1001, the "Regulatory Procedures Reform Act of 1995", s. 291 the "Regulatory Reform Act of 1995", H.R. 1022, the "Risk Assessment and Cost-Benefit Act of 1995, S. 746 the "regulatory Improvement Act of 1999".

Specific Recommendations

1. **Scope- Regulatory information related to national defense and foreign affairs must be peer-reviewed with conforming quality standards.** Section 2, paragraph 1 excludes from peer review regulatory information that relates to national defense or foreign affairs. Unless the unavailability of experts with appropriate security clearances is demonstrated on an-issue specific level, these exclusions are not justifiable.
2. **Guidance should clearly state that researchers *directly* funded by the issuing-agency are not eligible to peer review *especially significant* regulatory information.** Section 3, “Selection of Peer Reviewers”, (iii) states that direct research funding by the issuing-agency is a factor to be *considered* during the selection of reviewers. This clause is under the heading of “... Requirements for Especially Significant Regulatory Information”. Issuing agency employees should be excluded from review of especially significant regulatory information.
3. **Individuals who receive research funding from the issuing agency should not be excluded from acting as peer reviewers if funding is received via a competitive process (such as NIH study section) and expertise is based on peer-reviewed publication.**
4. **The concept of balancing biases should not be incorporate into guidance.** Section 3, “If it is necessary to select a reviewer who is or appears to be biased..., the agency shall ensure that another reviewer with a contrary bias is appointed to balance the panel.” Balanced bias lacks creditability and is not equivalent/substitute for independent expert peer-review.
5. **Broad participation in federal peer review should be encouraged but subject to term limits.** Peer reviewers should be compensated. It is suggested that two reviews in five years will assure independence is retained. Yet, 2 in 5 is not too stringent to assure availability of the limited number of independent experts.