

"Brooks, Laura" <LBrooks@USChamber.com>
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cc: "Environment, Technology & Regulatory Affairs" <Environment&RegulatoryAffairs@USChamber.com>, "Marcoe, Jeff" <JMarcoe@USChamber.com>, "Wohlschlegel, Eric" <EWohlschlegel@USChamber.com>
Subject: Comments with Regard to Proposed Bulletin on Peer Review and Information Quality

<<COMMENTS - Proposed Bulletin on Peer Review and Information Quality_OMB (108th).pdf>>

Laura Brooks
Manager, Production & Databases
Environment, Technology & Regulatory Affairs
U.S. Chamber of Commerce
1615 H Street, N.W.
Washington, D.C. 20062
202.463.5431 (P)
202.887.3445 (F)
lbrooks@uschamber.com

- COMMENTS - Proposed Bulletin on Peer Review and Information Quality_OMB (108th).pdf

CHAMBER OF COMMERCE
OF THE
UNITED STATES OF AMERICA

WILLIAM L. KOVACS
VICE PRESIDENT
ENVIRONMENT, TECHNOLOGY &
REGULATORY AFFAIRS

1615 H STREET, N.W.
WASHINGTON, D.C. 20062
(202) 463-5457

December 15, 2003

Dr. Margo Schwab
Office of Information and Regulatory Affairs
Office of Management and Budget
725 17th Street, N.W.
New Executive Office Building
Room 10201
Washington, D.C. 20503

Re: Proposed Bulletin on Peer Review and Information Quality

Dear Dr. Schwab:

The U.S. Chamber of Commerce (Chamber), the world's largest business federation, representing more than three million businesses of every size, sector, and region, is pleased to provide the following comments concerning the Office of Management and Budget (OMB) "Proposed Bulletin on Peer Review and Information Quality" (Bulletin).¹

The Chamber strongly supports OMB's efforts to improve the quality, objectivity, utility, and integrity of information disseminated by the federal government to the public, and in particular, this Bulletin, which aims to realize the benefits of meaningful peer review of the most important science used by the government to make regulatory decisions. OMB's focus on ensuring greater transparency should improve agency accountability and help to further ensure the soundness of the science that underpins federal policies encompassed in regulations, guidance documents, and risk assessments.

Although the Chamber believes OMB has provided a Bulletin of high quality and sound judgment, we do have several comments that we believe will enhance your work product.

¹ OMB, "Proposed Bulletin on Peer Review and Information Quality," *Federal Register*, 68:54023-54029, September 15, 2003, <http://www.sysconn.com/harbor/SEG/General%20Info/OMB%20Proposed%20Draft%20Peer%20review.pdf>.

I. Overview of Peer Review

In the early part of the 20th century, prior to use of electronic media such as the Internet, journal publishers employed peer review both to assure the quality of information published in hard-copy journals and in response to the space limitations imposed by having to publish paper copies of journals. Then and now, there has been no consistent peer review format.

A resulting example of concern about the quality of peer review in scientific journals is encompassed in the observation of university professor Andrew Odlyzko, who notes:

The peer review system is really a collection of many different systems, of uneven effectiveness. They guarantee neither correctness nor novelty of the published results, even among the most selective and prestigious journals [emphasis added].²

OMB should be congratulated for attempting to build a more consistent peer review process for integrating sound science into the regulatory process. We recognize that many in the scientific community may be uncomfortable with the transparency of process proposed by OMB, but these scientists have to clearly understand that once science enters the public policy arena, it must be made as transparent as possible, warts and all, to both policymakers and stakeholders, inclusive of all affected parties and the public generally.

II. Clear Statement of Authority

As an initial matter, we recommend that OMB more clearly state that its authority to promulgate these peer review requirements emanates from its authority under the federal Information Quality Act (IQA) and Executive Order 12866. The IQA required OMB to issue government-wide guidelines to federal agencies to ensure and maximize the quality, objectivity, utility, and integrity of the information they disseminate. Requiring thorough and consistent peer review of important scientific and technical information early in the information development process is critical to ensuring information quality, and is fundamental to OMB's obligation to ensure that information that underpins federal regulatory actions is based on sound science and rigorous technical analysis. Accordingly, OMB should make clear that the Bulletin is an amendment of OMB's Information Quality Guidelines³ and will become part of them.

² A. Odlyzko, "Peer and non-peer review," Digital Technology Center, University of Minnesota, <http://www.dtc.umn.edu/~odlyzko/doc/peer.review.txt>.

³ OMB, "Guidelines for and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies; Republication," *Federal Register*, 67:8,452, 8,460, February 20, 2002.

OMB also has clear authority under Executive Order 12866 to establish procedures for federal agencies to follow in developing regulations. OMB is obligated to review and approve only regulations that are cost effective, maximize the utility to the public, and are based on sound technical information. Requiring peer review of underlying science will ensure that OMB can meet its obligations for centralized regulatory oversight.

III. Definitional Consistency between IQA Guidelines and the Peer Review Bulletin

On examining the Information Quality Guidelines (IQG) and the proposed Bulletin, the Chamber notes that there appear to be ambiguities in the comparative meaning of various terms of art used in the two documents. In other words, and as one example, we are uncertain about the nature of the similarities and differences that exist when we try to compare the term of art, “influential information” (as used in the IQG) with the term of art, “significant regulatory information” (as used in the Bulletin). “Influential information” in the IQG is tied to “scientific, financial, and statistical” information and to “information concerning risks to human health, safety, and the environment” whereas “significant regulatory information” references “any scientific and technical study.” Is one of these intended to be broader (or narrower) than the other, and what types of information are (and are not) intended to be covered? If “significant regulatory information” (as used in the Bulletin) is intended to mean the same thing as “influential information” (as used in the IQG), then perhaps the term of art “influential information” should be used in both instances. We suggest that OMB examine both documents, identify all the term of art ambiguities, and then harmonize, clarify, and where possible, simplify the language to remove any apparent confusion.

IV. Transparency Throughout the Process

We call your attention to the following language, which appears in Section 2 of the Bulletin:

For purposes of this Bulletin, peer review undertaken by a scientific journal may generally be presumed to be adequate. This presumption is rebuttable based on a persuasive showing in a particular instance.

This statement is contrary to the objective of assuring complete transparency of process. There should be no presumption (rebuttable or otherwise) as to the adequacy of the peer review of articles published in scientific journals. Peer reviewed scientific information appearing in journal literature should be required to meet the same levels of transparency required by OMB of all other materials used by the government for regulatory purposes, otherwise such information will be subject to vastly different standards. A recent example of the doubtfulness of the rebuttable presumption is the retraction of two peer

reviewed papers published in *Science*, and as discussed in *The Scientist*.⁴ In that instance, procedural errors in assessing the effects of the recreational drug, ecstasy, led to seriously incorrect conclusions about the problems that can arise as a result of its use.

The retraction occurred after the lead author of the research effort discovered that some of the chemicals used in the study had been mislabeled and that additional experiments failed to reproduce the results. The retractions did not occur, however, until lengthy criticisms of the published results forced a re-examination of the research effort.

In another example, the U.S. Geological Survey⁵ (USGS) investigated hundreds of peer reviewed, literature-reported numerical values for the octanol-water partition coefficient and solubility constant for the pesticide, DDT, and DDE (a DDT breakdown product).

USGS found that: there is an enormous range of errors in reporting data and references; there is poor data quality and inadequate documentation of procedures; and the accuracy and reliability of the vast majority of reported data are unknown. USGS concluded that data used for model development and validation may consequently be of unknown reliability; that estimation of critical environmental parameters such as bioconcentration factors on the basis of such uncertain data is inadvisable because it will likely lead to incorrect environmental risk assessments; and the predictive and interpretive value of environmental studies can be seriously compromised if the physico-chemical data upon which they rely are of questionable or unknown quality. This observation is for just two chemicals. Almost certainly such observations pertain to many others.

Even when federal policy decisions do not have “major” (in the context of how OMB discusses this concept) economic impacts, government product development by policymakers can be highly controversial, can have a far-reaching impact on public perceptions of risk, and can profoundly affect the normal course of business in the marketplace.

For example, although significant amounts of the scientific information contained in the U.S. Environmental Protection Agency (EPA) Integrated Risk Information System (IRIS) database is obtained from peer reviewed science journal literature, this information is nonetheless considered by many stakeholders to be highly controversial. In fact, even EPA acknowledges that there are problems—the agency recently noted that about 37% of the 460 entries in the IRIS database might need to be revised in light of new data.⁶ The deficiencies affect agency decisions about how to regulate many chemicals and also affect public and industry perceptions of the soundness of the regulatory decisions that depend on this database. In the aggregate, however some such decisions may not rise to the scale of “major” impact. Yet, because EPA's expert judgments regarding how much exposure to a

⁴ As discussed in the following articles: R. Walgate, “Retracted Ecstasy paper ‘an outrageous scandal,’” *The Scientist*, September 16, 2003, <http://www.biomedcentral.com/news/20030916/04>; R. Walgate, “Second Ecstasy paper to be retracted,” *The Scientist*, September 17, 2003, <http://www.biomedcentral.com/news/20030917/02>; and G. A. Ricaurte et al., “Retraction,” *Science*, 301:1479, September 12, 2003, <http://www.sciencemag.org>.

chemical is “safe” are reliant on the IRIS database, in instances where individual companies have limited product lines, the possibility exists that scientifically unsound regulation, based on flawed IRIS data, could conceivably cause financial devastation.

V. Transparency of Peer Reviewers Opens the Door for Broader Participation in the Review Process

In the public policy making arena, a transparent review of this nature might resolve some of the concerns voiced about “balancing” the make-up of peer review panels in an attempt to eliminate pro and anti-industry biases. If this observation proves true, then open peer review could be a constructive advancement in policy making practices, as it may instill greater public confidence in science-driven outcomes. While the practice may be a departure from the current practice in academia and elsewhere, it should be a significant improvement. When the identity, financial interest, and potential bias of peer reviewers are disclosed, the public can evaluate for itself whether there may be some reason to question the validity of the review. Transparency will facilitate public oversight of agency practices, and help safeguard the integrity of the regulatory process.

With open peer review and creative use of the Internet, far more comprehensive participation by the scientific community in scrutinizing scientific work products becomes possible. Contrast this with the classical peer review process in which typically two peer reviewers will examine a research paper—this means that many other capable peer reviewers did not examine the paper, as they were not invited to participate.

VI. Confidential Information and Secret Models Should Not be Used to Impose Regulations

The Chamber supports the rights of individuals and business, in legitimate instances, to maintain the integrity of confidential information. However, special confidentiality circumstances do not mitigate the need for maximizing transparency in all other instances in which science information (including both data **and** models) is disseminated or used for policy making purposes of a regulatory nature. Where this information cannot be made transparent and subject to public scrutiny, it should not be used as the basis of a regulatory action. This practice is already followed in many scientific journals. It is, for example, the policy of the journal, *Environmental Science & Technology*, not to accept articles if authors refuse to make the models they used in performing their analyses available for peer review. Such a reasonable standard of acceptance should similarly be applied to all science-based models used in support of government regulatory policy making activities.

⁵ “How Reliable are Chemical Property Data in the Literature?”, U.S. Geological Survey, <http://toxics.usgs.gov/highlights/kow.html>.

⁶ C. Hogue, “Chemical Databases in Budget Crunch,” *Chemical & Engineering News*, 81:9, September 22, 2003.

The cost of the modern regulatory process already exceeds \$850 billion annually, and it is not uncommon for a regulation to impose billions of dollars in costs on society, as well as to restrict the rights of citizens to engage in various activities they would otherwise choose. These costs cannot be justified in any circumstances where secret models and private information serve as the foundation for a regulatory action. Accordingly, if the information cannot be disclosed and subjected to public scrutiny, it should not be used to support a regulatory action.

VII. Waiver Provisions Are Too Broad

Note the following language, which appears in Section 4c:

The Administrator may waive some or all of the peer review requirements of Sections 2 and/or 3 of this Bulletin if an agency makes a compelling case that waiver is necessitated for specific information by an emergency, imminent health hazard, homeland security threat, or some other compelling rationale. As appropriate, the Administrator shall consult with the Director of OSTP before deciding to grant a waiver.

The Supplementary information of OMB's Bulletin notes further that:

The Bulletin also recognizes that waivers of these [peer review] requirements may be required in some instances, such as when court-imposed deadlines or other exigencies make full compliance with this Bulletin impractical.

These waiver provisions are too broad and should be further qualified. For example the Chamber believes that OMB should clarify, and in particular, explicitly *qualify*, this waiver provision in order to avoid the creation of regulation by judicial fiat. Such an outcome denies the public and other stakeholders the equity to which they are entitled. Without qualifying this provision of the Bulletin, the requirement to regulate based on sound science information could be ignored simply by deliberately entering into a consent decree that, by its design, makes impossible the prospect of conducting a transparent peer review and that deliberately ignores any reasonable alternative consent decree constructions that could have allowed for a reasonable peer review to occur. Simply put, the absence of a qualifier has the effect of allowing for politicization and disenfranchisement of the regulatory process.

Consent decrees are another area where additional guidance from OMB is required. Specifically, the Chamber believes that OMB should require that in all future instances in which agencies negotiate schedules for consent decrees, such negotiations must include due consideration of the adequacy of, and/or need for peer review of any science-based information underpinning the contemplated agency action to be driven by the consent decree. OMB should require that if there are any unmitigated peer review deficiencies that cannot be addressed within the timeframe of the established consent decree schedule, then such a consent decree must include a discussion of why the delaying event occurred.

Moreover, to minimize the possible occurrence of such an event, OMB should require that, to the maximal extent possible, and with as much advance notice as is possible, all agencies inform OMB of any anticipated negotiations of schedules for consent decrees, in particular highlighting the possibility that peer review deficiency issues may arise.

Where peer review is not undertaken, either because of a waiver or because it is part of a consent decree, OMB should require that after the delaying event is removed, the participating agency post, on a publicly accessible website, a full account of the circumstances for such deficiencies, detailing why the peer review requirement cannot be met, what aspects of the peer review will not be satisfied, and the possible consequences that may, or will in fact, arise because the peer review requirement will not be satisfied. In addition, once the delaying event is removed, the agency should conduct the appropriate peer review after the fact and change any temporary regulatory decisions accordingly.

VIII. Procedural Uncertainties Must be Resolved

It is unclear whether OMB's instructions, in the aggregate, mean that dissemination shall be considered to have occurred only after (at a minimum) the required peer review process (where applicable) is completed. Moreover, if the peer review process is not yet complete, it is unclear whether an agency can nonetheless proceed to regulate or establish regulations on the basis of yet to be peer reviewed information. For example, one can envisage a situation in which an agency chooses to regulate on the basis of information that has not yet been peer reviewed, while at the same time, the right of third parties to challenge the quality of the information underpinning the regulation is denied by the agency because, as the peer review has not yet been completed, the information is not yet considered disseminated and is therefore not yet challengeable. Such a situation, should it arise, would unfairly impair public and other stakeholder efforts to petition for correction of defective information in a timely manner.

The Chamber believes that OMB should: (1) establish unambiguous criteria about how to determine if (and when) a peer review is complete; (2) clarify whether (and under what circumstances) an agency can proceed to establish regulatory policy on the basis of information that has not yet been peer reviewed; and (3) ensure a reasonable and timely opportunity for affected parties to challenge such information prior to its use for regulatory purposes in instances where such parties believe the information is defective.

IX. OMB Should Conduct a Pilot Test of Open Peer Review

By open peer review we mean that, to the maximum extent practicable, all science used in formulating regulatory policy (such as regulations and guidance documents) must be fully transparent to the public, business, and industry, and to policymakers inclusive of all the peer reviews of such science. In all instances where science drives policy making, this can

only be accomplished through, and in so much as it is possible, a completely open peer review process in which the public has full access to the underlying science information, the peer reviews of the science information, and knowledge of the identities, associations, and qualifications of the peer reviewers.

While the traditionally used closed peer review process in which peer reviewer identities and peer reviews are withheld from public scrutiny may serve the science community well, it is not in the greater public interest. Certainly, in the long-term (often, the very long-term), science is self-correcting. However, policymakers must make their decisions in the here and now, and given this circumstance, to the greatest extent practicable, maximal access to all available information is imperative.

As an initial step, we recommend that OMB require pilot testing of open peer review – perhaps through use of the Internet. While the wholesale adoption of open peer review may not be feasible at this time, initial exploration of its utility and practicality would be extremely helpful and beneficial.

Advocacy for such an improvement in transparency is not just solely the position of business and industry. The call for, and adoption of, open peer review are strong and growing movements among many within the academic community itself.⁷ In large measure, due to the rapidly occurring growth and reliance upon the Internet and its manifold capabilities (especially the pace of information transmission and its accessibility), open peer review is increasingly becoming the norm as a standard for generation of scientific information, and the Chamber therefore believes that OMB must consider this development in refining its Bulletin.

In fact, enormous efficiencies of process are already being realized, especially within the disciplines of physics and mathematics. This emerging happenstance is a societal development of broad dimension in its ramifications that should not, over time, be ignored by policymakers. By way of an example of what is possible through an overhaul of the peer review system, combined with use of the capabilities of electronic media, consider this discussion excerpted from a recent article written by Professor Odlyzko:⁸

An example of how evolving forms of peer review function, is provided by the recent proof that testing whether a natural number is prime can be done quickly. This had been an old and famous open problem of mathematics and computer science. On Sunday, August 4, 2002, Maninda Agrawal, Neeraj Kayal, and Nitin Saxena of the Indian Institute of Technology in Kanpur sent out a paper with their astounding proof of this result to several of the recognized experts on primality testing. (Their proof was astounding because of its unexpected simplicity). Some of these experts responded almost

⁷ F. Godlee, "Making Reviewers Visible—Openness, Accountability, and Credit," *Journal of American Medical Association*, 287:2762-2765, June 5, 2002.

⁸ A. Odlyzko, "Peer and non-peer review," Digital Technology Center, University of Minnesota, <http://www.drc.umn.edu/~odlyzko/doc/peer.review.txt>.

right away, confirming the validity of the proof. On Tuesday, August 6, the authors then posted the paper on their Web site and sent out email announcements. This prompted many additional mathematicians and computer scientists to read the paper, and led to extensive discussions on online mailing lists. On Thursday, August 8, the New York Times carried a story announcing the result and quoting some of the experts who had verified the correctness of the result.”

Review by peers played a central role in this story. First, the authors privately consulted known experts on the subject. Then, after getting assurance they had not overlooked anything substantial, they made their work available worldwide, where it attracted scrutiny by other experts. Coverage of this development in the New York Times was based on the positive evaluations of correctness and significance by those experts. Eventually the authors will submit their paper to a conventional journal, where it will undoubtedly undergo conventional peer review, and be published. The journal version will probably be the main one cited in the future, but will likely have little influence on the development of the subject. Within weeks of the distribution of the Agrawal-Kayal-Saxena article, improvements on their results had been obtained by other researchers, and future work will be based mainly on those. Agrawal, Kayal, and Saxena will get proper credit for their breakthrough. However, although, their paper will go through the conventional journal peer review and publication system, that will be almost irrelevant for the intellectual development of their area.

The Chamber appreciates the opportunity to submit these comments and thanks the Office of Management and Budget, and the Office of Information and Regulatory Affairs for considering the views of the U.S. business community on this important subject.

Sincerely,



William L. Kovacs