

Glen Kedzie <GKedzie@trucking.org>
12/15/2003 05:08:53 PM

Record Type: Record

To: Mabel E. Echols OMB_Peer_Review/OMB/EOP@EOP
cc: Richard Holcomb <RHolcomb@trucking.org>, Robert Digges <RDigges@trucking.org>
Subject: Comments of the American Trucking Associations on OMB's Proposed Bulletin on Peer Review and Information Quality

To Whom It May Concern:

The American Trucking Associations, Inc. (“ATA”) submits the following comments in response to the United States Office of Management and Budget’s “Proposed Bulletin on Peer Review and Information Quality” published in the *Federal Register* on September 15, 2003, 68 Fed. Reg. 54023 (2003). Per your instructions for electronic submittal, the full text of ATA’s comments are attached below and as an attachment to this e-mail.

- Comments.PeerScience.doc

Before the:

United States Office of Management and Budget,
Executive Office of the President

Comments of the:
AMERICAN TRUCKING ASSOCIATIONS, INC.



**AMERICAN
TRUCKING
ASSOCIATIONS**

Driving Trucking's Success

On the:

Notice and Request for Comments on the Office
of Management and Budget's Proposed Bulletin
on Peer Review and Information Quality
68 Federal Register 54023 (September 15, 2003)

December 15, 2003

INTRODUCTION

The American Trucking Associations, Inc. (“ATA”) submits the following comments in response to the United States Office of Management and Budget’s (“OMB”) “Proposed Bulletin on Peer Review and Information Quality” (“Bulletin”) published in the *Federal Register* on September 15, 2003, 68 Fed. Reg. 54023 (2003).

ATA is the trade association of the American trucking industry. As the national representative of the trucking industry, ATA is vitally interested in matters affecting the nation’s trucking fleets, including OMB's proposal to establish a standardized process by which all significant regulatory science documents will be subject to peer review by qualified specialists in appropriate technical disciplines.

ATA strongly supports OMB’s goal of making regulatory science more competent and credible. Our members also strongly support the use of sound science in creating a more consistent regulatory environment, thereby decreasing the likelihood of protracted and costly litigation.

BACKGROUND

A. ATA’s Representation of the National Trucking Industry

ATA is a united federation of motor carriers, state trucking associations, and national trucking conferences created to promote and protect the interests of the trucking industry. Its membership includes more than 2,000 trucking companies and industry suppliers of equipment and services. Directly and through its affiliated organizations, ATA encompasses over 34,000 companies and every type and class of motor carrier operation. As such, ATA effectively represents the interests of the trucking industry in the United States.

The trucking industry is composed of both large national enterprises as well as a host of small businesses. Over 81% of all interstate motor carriers operate six or fewer trucks and 93% of motor carriers (nearly 539,000 in number) have 20 or fewer trucks.¹ The trucking industry is a major force in the United States economy, employing 10.1 million people in jobs that directly relate to trucking.² Trucking accounts for 87 cents of every dollar collected for freight transportation in the U.S., and trucking hauls practically every type and kind of product and raw material used in the manufacturing and retail sectors of the economy.

Moreover, as the predominant mode by which U.S. consumers receive virtually all of their goods, the trucking industry ensures the availability and cost-effective distribution of finished goods and raw materials throughout all segments of the economy. In this regard, over 80 percent of all communities in the United States rely *exclusively* on trucks to deliver all of their fuel, clothing, medicine, and other consumer goods. In sum, the nation's trucking industry provides the essential transportation resources, infrastructure and services that are necessary to sustain the growing economy that benefits all Americans.

COMMENTS

A. OMB Should Consider Adjusting the \$100 Million Annual Impact Threshold

The Bulletin “requires” peer review of especially significant regulatory information having a possible annual economic impact of more than \$100 million. Many regulatory actions are “phased-in” and result in economic impacts being spread out over

¹ *American Trucking Trends*, American Trucking Associations, Inc., pp. 2-3 (2003).

² *American Trucking Trends*, American Trucking Associations, Inc., pp. iv-v (2003).

time. Economic impacts that may not satisfy the annualized \$100 million threshold may, however, have lifetime costs of a staggering proportion. Consideration should be given to using a “lifetime” expense threshold as opposed to an annualized cost threshold when determining what regulatory information must be peer reviewed. In addition, agencies must thoroughly account for third party and downstream economic “ripple” effects when equating monetary threshold cutoffs.

B. OMB Should Develop Guidelines to Clarify Standards and Procedures to Secure a Peer Review of Regulatory Information not Meeting the Economic Threshold

Agencies make their best efforts in developing cost projections. Cost estimates oftentimes cannot be verified until real-time information is evaluated after the implementation date of the regulatory action. In instances where this situation may arise and the \$100 million annual cost threshold is not met, discretion is given to the Administrator of OMB’s Office of Information and Regulatory Affairs (“OIRA”) to determine if a significant interagency interest or a relevant Administration policy priority requires the need for a peer review. It is assumed that an “appeal” to OIRA to conduct a peer review on regulatory information that does not meet the \$100 million threshold will be onerous and difficult for stakeholders. OMB should consider developing guidelines to clarify the standards and procedures industry must meet to secure a peer review of regulatory information not meeting the financial economic threshold requirement.

C. The Annual Economic Threshold Should Account for Disproportionate Impacts on Small Businesses

The \$100 million annual impact cutoff does not account for the disproportionate economic impacts of regulatory actions on the operations of small businesses. As stated above, 93% of motor carriers have 20 or fewer trucks and are generally defined as being

small businesses. Insofar as the trucking industry is concerned, most regulatory measures have a disproportionate impact on trucking operations and their ability to conduct business. The composition of our industry is not unlike many other business sectors whereby the number of small businesses far outweigh the number of large businesses. Since the \$100 million annual impact threshold does not take into account the associated economic impacts born by small businesses, OMB should consider requiring peer reviews in instances where a Small Business Regulatory Enforcement Fairness Act (“SBREFA”) panel finds that a regulatory activity will result in a disproportionate economic impact on small businesses.

D. Federal Agencies Must Allocate Appropriate Resources to Adequately Fund Annual Peer Reviews

It is uncertain how the directive to conduct peer reviews may be impeded by an agency’s funding limitations to do so. It is unclear what agencies currently expend on peer reviews, both internally and externally. Though OMB has no input in the appropriation process, the Bulletin should reference the need for agencies to appropriately budget for such resources in each fiscal year.

E. Agency Peer Review Must Occur at the Earliest Stages of the Regulatory Process and Include Stakeholder Input

Currently, peer reviews that are undertaken oftentimes occur unbeknownst to interested stakeholders. The first knowledge stakeholders typically receive follows publication of the proposed regulation and supporting documentation. OMB should be commended in requiring the issuance of peer review final reports detailing the nature of their reviews, findings, and conclusions. It is critical that the peer review reports disclose the reviewers’ qualifications and affiliations in order to make public any perceived bias

or conflict of interest. Agencies, in being required to provide written comments to the peer review reports explaining both points of agreement and disagreement, will provide stakeholders greater insights into the agency's regulatory review process. Both the peer review reports and the agency responses should be required to be included in the administrative record of the rulemaking.

ATA suggests that final peer review reports be noticed in the *Federal Register* and be made available for public comment. Stakeholder comments on the peer review reports should be given the same amount of deference as that afforded to the lead agency.

F. Scientific Journals Should Only be Used to Supplement the Peer Review Process

The Bulletin sets forth a rebuttable presumption that peer review undertaken by a scientific journal will satisfy the requirements of the peer review mandate. The Bulletin goes further to state that the presumption is rebuttable based upon a persuasive showing in the particular instance. The Bulletin needs to establish appropriate procedures outlining how the presumption can be rebutted and which stakeholders have standing to raise the challenge.

The Bulletin states that professional journals may generally be presumed to be adequate in satisfying peer review requirements. The questions that beg to be asked are who will be the judge and jury regarding which scientific journals are credible, which authors are reputable, how transparent are the relationships of the editorial board and the author to special interest influences, and who is peer reviewing the peer reviewers? Articles appearing in scientific journals are typically fodder for promoting further academia debate. Positions taken by individual authors are not the end-all in establishing definitive conclusions. Given the wide use of variable inputs, methodologies, statistical

margins of error, models, presumptions, and assumptions, reliance upon an individual's (or a limited number of individuals) findings do not sit well with the regulated community when reliance upon such conclusion(s) will dictate the path of a regulatory process that will impact a large sector of the business community.

In some very limited instances, scientific journals may be the best information available to satisfy the peer review requirements set out under the Bulletin. For example, some areas of expertise are so unique due to the nature of the subject matter that there may only be a handful of experts worldwide. In these situations, it may be justified to rely upon the professional journal findings. Aside from this unique instance, ATA recommends that reliance on scientific journal publications not be used exclusively as a means to satisfy peer review requirements. ATA encourages the use of scientific journals to "supplement" the peer review process, not "supplant" the process.

G. Federal Agencies Must not Rely Upon Third Party Studies Conducted Prior to the Effective Date of the Bulletin's Requirements Unless Properly Peer Reviewed

The rulemaking process is dynamic in nature. Regulations rely and build upon prior scientific studies and analyses. Given the timing of the finalization of the Bulletin, many forthcoming federal regulations will be issued that rely upon prior publications, peer reviews, or other scientific findings. OMB should be clear in stating that any federal agency disseminating information subsequent to the effective date of the Bulletin's requirements that supports a new regulation or policy must fully comply with the peer review requirements established under the Bulletin. ATA agrees that third-party data only needs to be peer reviewed when relied upon and disseminated by a federal agency during its deliberative process. Non-peer reviewed, third-party data should continue to

serve a critical role by serving as a guide for federal agencies in conducting their literature reviews and in developing their regulatory scoping plans.

H. The Process of Selecting Peer Reviewers Must be Conducted in a Way to Minimize the Appearance of Bias or Conflicts of Interest

The appearance of bias in the peer review process should be avoided at all costs. Academia and professionals cannot make a living by volunteering to do peer reviews. The quest for knowledge and challenge peak the interests of peer reviewers, not the pursuit of riches. With this being said, compensating individuals via stipends and travel should not rise to the level of inferring bias in an individual's peer review. On the other hand, peer reviews by individuals employed by federal contractors having contracts with the agency conducting the peer review raises the perception of bias. ATA recommends that all efforts should be taken to avoid the use of peer reviewers having current federal contracts with the agency undertaking the peer review.

Insofar as using individuals from the federal agency conducting the peer review, such employees should only be used in instances where the subject matter of the review is so highly technical or unique that the international pool of experts is extremely limited. An agency should be afforded greater deference in permitting employees possessing unique qualifications from other federal agencies to be considered as peer reviewers.

OMB has requested input on the question relating to who should select the peer reviewers. Short of creating a further level of bureaucracy, and given the discussion and suggestions on the issue of peer reviewer transparency below, agencies should be free to select peer reviewers that do not have, or infer, a conflict of interest and/or bias in the area of the subject matter in question. Failure of agencies to exercise caution in selecting unbiased peer reviewers will increase the likelihood of the agency's peer review being

challenged both administratively and legally. It remains in the best interest of all federal agencies to avoid this scenario from occurring.

I. A Certain Level of “Transparency” Must be Required of All Peer Reviewers to Avoid Conflicts of Interest or the Appearance of Bias

The role of peer reviews is to ensure the soundness of the underlying science supporting the basis of a rule or other associated regulatory activity. All peer reviewers, due to human nature and experiences, possess a certain element of bias. However, peer review panels create an environment of checks and balances whereby biases will be disclosed in the form of comments and/or input in the review process. Positions taken by individual peer reviewers, however varied they may be, must be able to withstand the scrutiny of other peer reviewers, the federal agency required to undertake the peer review, and interested stakeholders.

In order to further avoid the appearance of bias, peer reviewers should be required to disclose potential conflicts prior to participating in a specific review. Such documents should include, among other matters: (1) all financial disclosures or compensation (if any) between the reviewer and the agency; (2) any employment history with the agency or other individuals involved in the peer review process; and (3) any potential for monetary gain on behalf of the peer reviewer associated with the outcome of the review in question (including opportunities for financial gain associated with investments either directly or indirectly linked to the regulatory activity under review). Conflict of interest forms, if not already developed and on file at each federal agency, should be consistent and made available as part of the supporting administrative record on the regulatory activity. The Office of Government Ethics (“OGE”) should ensure that each federal agency is consistent in the development and use of such forms for all peer

reviewers. OGE should establish consistent standards respecting years of separation from a federal agency prior to a peer reviewer being selected to conduct peer reviews for his/her prior employer (with the exception to the rule being the reviewer possesses unique qualifications in an area where international expertise is extremely limited).

J. OMB Must Address Reviews Involving Developing Regulatory Science

Some federal agencies, in particular the U.S. Environmental Protection Agency (“EPA”), conduct protracted studies on health effects issues. One specific example involves EPA’s *Health Assessment Document for Diesel Exhaust* which has been under review since 1990. Since that time, there have been five panel reviews and comment periods and an extensive number of drafts and redrafts. The literature review involved in the development of this document is extensive. As the state of science has progressed over the past 13 years, so has the direction of the findings and the preliminary conclusions. The peer review requirements under the Bulletin should apply to all protracted scientific analyses, especially in light of the use of potentially outdated science relied upon during the earliest stages of the document. What was once current in the way of science becomes outdated at a rapid pace. In our opinion, the role of peer review plays a more pivotal role in instances where regulatory policy is based upon protracted findings and science.

K. OMB Should Consider Expanding the Guidelines to Include Consent Decrees Negotiated with Federal Agencies

Studies and/or analyses undertaken pursuant to, or in preparation for, Consent Decrees negotiated between the U.S. Department of Justice (acting on behalf of federal agencies) and third parties should be required to comply with the peer review provisions

set out in the Bulletin. Independent impact analyses or other studies relied upon by both the courts and federal agencies must not be conducted in a vacuum. Parties and/or stakeholders potentially subject to the terms of negotiated Consent Decrees should have an equitable right and adequate lead time to assess and refute findings being relied upon by federal agencies and the courts. Given the fact that the economic threshold will rarely be met, OMB should consider a special exception insofar as Consent Decrees are concerned. Peer reviews, conducted in a timely manner so as to not delay judicial efficiency and expediency, would bolster the findings in Consent Decrees and make federal agencies' more accountable in matters involving their enforcement discretion.

L. A Need Exists to Audit Federal Agencies' Compliance with the Bulletin

It is assumed that federal agencies' will be periodically audited to evaluate their compliance with the Bulletin. This function should be carried out by either OMB or respective Inspector Generals' of each federal agency.

CONCLUSION

In closing, ATA once again thanks OMB for the opportunity to comment on the draft Bulletin. We applauds OMB's efforts to ensure agencies conduct reliable, independent, and transparent "peer reviews" of scientific and technical information relied upon in writing regulations and making federal policy.

The draft Bulletin reflects OMB's thorough knowledge of the need for such guidelines. Implementation of the Bulletin will afford stakeholders a better opportunity to get involved in the regulatory process at earlier stages than in the past. In ensuring that

the basis of science being relied upon by federal agencies is sound, the regulatory process will be vastly improved and hopefully less litigious.

Respectfully submitted,

Glen P. Kedzie
Assistant General Counsel & Environmental Counsel
American Trucking Associations, Inc.
2200 Mill Road
Alexandria, VA 22314-4677
Phone: 703-838-1879
E-Mail: gkedzie@trucking.org

