

"Parson, Marolyn" <mparson@nahb.com>
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To: Mabel E. Echols OMB_Peer_Review/OMB/EOP@EOP
cc: "Asmus, Susan" <sasmus@nahb.com>, "Crowe, Dave" <dcrowe@nahb.com>, "Holliday, Andrew" <aholliday@nahb.com>
Subject: Comments on Proposed Bulletin on Peer Review & Information Quality from the National Association of Home Builders

Dear Dr. Schwab: as per the Federal Register announcement , I am including the text of our comments within this email and am also attaching a file in pdf format with our comments. If you have problems with this email, please contact me via email (mparson@nahb.com) or by telephone at 202-266-8157.
Marolyn J. Parson, Ph.D.
Director, Environmental Policy
National Association of Home Builders
1201 15th St NW
Washington, DC 20005
800-368-5242, x8157 or 202-266-8157
mparson@nahb.com

- NAHB's Peer Review Bulletin comments 12-15-03.pdf



ADVOCACY GROUP

Federal Regulatory & Housing Policy

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
Submitted via email to OMB_peer_review@omb.eop.gov

December 15, 2003

Re: Proposed Bulletin on Peer Review and Information Quality

Dear Dr. Schwab:

The National Association of Home Builders (NAHB) appreciates this opportunity to comment on the "Proposed Bulletin on Peer Review and Information Quality" (68 Fed. Reg. 54023 *et seq.*, September 15, 2003). NAHB represents 215,000 builders and associate members organized in more than 800 affiliated state and local associations in all fifty states, the District of Columbia, and Puerto Rico. NAHB's membership not only includes firms that construct and supply single-family homes, but also apartment, condominium, and commercial and industrial builders, as well as land developers and remodelers. NAHB members are responsible for the construction of approximately 80% of all new homes built in the U.S. and are regularly required to comply with a plethora of federal regulations promulgated by the Department of Labor, Department of Housing and Urban Development, Department of Transportation, Department of Energy, Veterans' Administration, Environmental Protection Agency, Army Corps of Engineers, Forest Service, Bureau of Land Management, Fish and Wildlife Service, National Marine Fisheries Service, U.S. Trade Representative, Bureau of the Census, and others.

NAHB is very supportive of recent initiatives by Congress and the Office of Management and Budget to assure that the science used to support regulatory actions and policy are of the highest quality and generally supports the requirements presented in the Bulletin. NAHB regards the proposals in the Bulletin as important steps toward achieving the goals of data quality, utility, objectivity, and integrity. However, NAHB has some suggestions and recommendations that would strengthen the peer review process that OMB has proposed. NAHB's comments generally follow the order of the questions posed in the Bulletin.

The NAHB staff who prepared these comments have published papers in peer-reviewed journals, conducted peer review for journals, and have reviewed the comments of peer reviewers relevant to important regulatory decisions. These staff has observed the problem expressed in the Bulletin that "while agencies have policies that require or

encourage peer review, they do not always conduct peer review according to their own policies—even for major rulemakings. . . . Consequently, the quality of some science remains unknown.” 68 Fed. Reg. 54027, September 15, 2003. For example, when EPA was developing the documents to support its proposed Effluent Limitation Guidelines for the Construction and Development Category, NAHB staff had the opportunity to read peer reviewers’ comments on a draft version of the “Environmental Assessment for Proposed Effluent Guidelines and Standards for the Construction and Development Category.” This opportunity was arose when small business representatives were providing input to the Small Business Advocacy Review Panel, which was convened to review the impact of the proposed ELGs on the industry’s small businesses. However, there was no reference or mention of peer review when EPA published the ELG proposal, and most important, the peer reviewers identified a variety of concerns that do not appear to have been addressed in the final version of the document. This appears to be contrary to EPA’s peer review policy, particularly when the document forms the basis of EPA’s Environmental Assessment – a key document that supports EPA’s regulatory options. Therefore, it is clear the agencies need increased pressure to follow acceptable research review policies, and we are hopeful that the Bulletin will provide this needed impetus.

Overview

Federal regulation affects far too many people and far too much of our economy to allow new rules to be promulgated without objective and independent review of the validity of the underlying research. However well intentioned, NAHB believes that agency employees cannot provide the fresh look and critical scrutiny that outside reviewers bring to the research process. Equally important for public policy, external independent review brings a transparency to the regulatory process that is crucial in order for regulations to be seen and accepted as fair. Both sound science and sound policy demand external review that is independent, external, and objective, and it must be seen as such.

Transparency also requires that the reviewers’ comments be public, and they must be public when or before the public comment period begins. NAHB believes the qualifications and opinions of the reviewers are proper material for public comment to the agency, and the agency’s response to the reviewers is also an appropriate subject for public comment. Input from the public is needed on all of these matters to ensure regulation is fair and reasonable, rather than capricious. Importantly, the external review is needed to evaluate the scientific and technological information the agency is using to reach a policy decision, as reviewers must not be retained to recommend policy. Including policy issues in the review clouds the reviewers’ assignment. A temptation arises to scrutinize research less closely when the research would support a policy the agency or the reviewers themselves are perceived to favor. Even if the review is meticulous, the public perception may be one of indulgence.

Experience cited by OMB (68 Fed. Reg. 54023, at 54025) and witnessed by NAHB suggests that external review policies cannot be left to the discretion of the agencies themselves. NAHB is pleased that OMB has developed and proposed these review regulations that bind all agencies and offices of the executive branch. Further,

NAHB believes that the review regulations must be mandatory, so failure to comply results in the invalidation of a regulation based on any research that is not reviewed properly. Our specific comments on the Bulletin are as follows.

Scope

NAHB believes the scope of the Bulletin is not too broad, and it should not be narrowed any further. The exceptions for foreign affairs and national defense are appropriate, yet raise some concern that they may be used to shield any action taken by an agency that deals with national defense or foreign affairs in any way. For a most prominent example, the Corps of Engineers is part of the U.S. Army, within the Department of Defense. Yet the Corps is charged with management of the nation's navigable waterways, and it is the enforcer of a substantial amount of environmental regulation, especially wetlands regulation. But surely there is no intention to exclude the Corps from seeking peer review of research supporting wetlands regulation. Even within military operations, some of those operations may be sufficiently non-strategic and carry enough domestic impact that external review is called for, such as the building and maintenance of military housing, the preservation or disposition of old facilities, and the effect of flight paths on neighborhoods.

In the arena of foreign affairs, research relating to international trade and the domestic pursuit of treaty obligations surely call for external review, if the regulatory action is significant. Treaties such as NAFTA and the Migratory Bird Treaty have substantial implications for the operation of the domestic economy, as would prospective treaties like the Kyoto protocols on global warming (even if that particular treaty is now moribund). Though agencies have no charge to make treaties, they are charged with writing regulations to implement treaties. The agencies need independent, objective review of research supporting these regulations as much as any agency needs such review for its research. The Bulletin must recognize the distinction between conducting foreign affairs and the process of implementing domestically the nation's international obligations and require review of the latter.

The exception for scientific journal articles is useful, but it could use additional clarification. NAHB supports the rebuttability of the presumption of adequacy, but the necessary "persuasive showing" is vague. It sounds something like "preponderance of evidence" and it appears to be weaker than "clear and convincing evidence," but is it weaker than a "preponderance" standard? To maintain public trust, requiring a preponderance of evidence to rebut the presumption is too high a hurdle. Any amount of evidence that casts reasonable suspicion on objectivity, independence, or expertise of the authors or reviewers should be sufficient to rebut the presumption of adequacy and compel additional external review, even if the additional review is less than would have been done in the absence of the refereed article. The authors and referees should be subject to the same scrutiny as any other peer reviewers, particularly the conflict of interest rules listed in the second paragraph of Section 3 of the proposed Bulletin. Otherwise, the journal article could be used as bootstrap for unwise regulation, allowing undue influence to interested parties. To avoid this, NAHB recommends that the

presumption of adequacy be inapplicable unless the identities of the referees and editor are disclosed by the time the public comment period begins.

While it is true that many agency adjudications and permit applications will not even amount to major regulatory actions, some permit applications may have broad ramifications. Building a large dam, dredging a harbor, issuing a NPDES permit to a new sewage system, and opening or preserving public lands may all be cases where the agency's decision may require specific and extensive scientific or technical research, and the consequences of the agencies decision may be large. In those cases, even the issuance of a permit is an action that calls for the high safeguards of external review of the underlying new research. There, NAHB urges that the blanket exception for permits and adjudications be amended to allow for possibility of external review when the consequences of the regulation are large, and the agency requires new research to make its decision.

Conflicts of Interests

OMB seeks comment on whether some provisions of the proposal should be strengthened, modified or removed, especially directing attention to the selection of peer reviewers. Since OMB discusses the issues of finding expertise after its mention of conflict-of-interest requirements, NAHB will comment on the conflict rules first, addressing the expertise issue in a subsequent section of these remarks.

Though Part I of the "Notice and request for comments" contains extensive discussion of the necessity of real and perceived independence of the reviewers, the actual proposed rules are found in Part II, which is the proposed bulletin, specifically in Section 3, second paragraph. NAHB believes the proposed rules make perfect sense and believes they would be a step forward in ensuring the quality of information received by agencies. Rule (i) is obvious—anyone with a financial interest in the outcome has a clear conflict, and Rule (ii) is equally obvious—those have previously taken a stand on the scientific or technical issue carry a known risk of bias. Rules (iii) and (iv) would help prevent situations where an agency continues to use a reviewer who seems to be rewarded with agency grants, as well cases where a reviewer is retained because he or she has given favorable reviews earlier. As most individuals act not on their own but as employees of firms, agencies, associations, foundations, universities or other institutions, NAHB urges OMB to make clear in the Bulletin that these rules apply where the individual **or his or her employer** meets any of the listed criteria.

Agency employees present a special difficulty. While they are quite likely to have expertise on the subject, it stretches credulity to imagine they are independent. Even if they are so independent of mind that they will ignore the agency's implicit pre-approval of the research, employees are bound to be seen as servile, giving automatic approval to agency research and restricting any review to a justification of the agency's methods. Agency employees are not external, and do not give an external review. To the extent that one of the purposes of external review is to avoid the appearance of bias, the use of agency employees to review that same agency's research fails to accomplish that purpose of external review. This critique would hold even if the employee were in

another department, office or area of the same agency. The review would be written under same aegis as the research, under the direction of the same agency head. On its face, it is not independent.

The use of employees of other agencies is more complicated. Employees in other agencies may be well credentialed, and as long as they work in different Cabinet departments or independent agencies, they may be independent of each other. However, they still work in the same Executive branch, and they are still bound to pursue the Administration's policies. If agencies co-operate with each other rather than compete with each other, then there is less than an arm's length relationship between them. This danger of a close relationship, or the danger of such an appearance, also argues against the use of employees of other agencies or the employees of state or local governments who could be subject to agency reprisal.

Therefore, NAHB recommends that conflicts criteria be developed and that they be extended to employers of reviewers in addition to the reviewers themselves. Agency employees should not be used as reviewers under any circumstances, and the use of other government employees is discouraged strongly.

Disclosure

NAHB believes it is essential to disclose any reviewer's identity, background, and all factors that make him or her a qualified expert. It is equally essential to disclose any factors that could create a bias or an appearance of one. Disclosure requirements should be easy to satisfy, so this requirement should not create a new burden. Any expert is likely to keep a current resume or curriculum vitae (CV) on file. Such a CV will have the reviewer's employment history within the area of expertise. It also will tend to list grants received, articles published, papers delivered, and work done for any agency or firm.

Possible conflicts may be harder to explore, but they are as important as the underlying expertise. In addition to the factors of expertise, including employment and publication history, the reviewer should disclose dates and subjects of testimony in litigation, before Congress, or in other hearings. While it may take some investigation on the part of the peer reviewer to discover past associations between his/her employer and an agency, that information must be revealed if the public is to evaluate the independence of the reviewer and employer. Past dealings with the agency will be in agency files, so the agency has some disclosure duties here, as well. The agency disclosures may be particularly important in dealing with long-lived institutions with high employee turnover, such as consulting firms and universities, where an employee may not know the history, yet the history may imply a special relationship with the agency.

Disclosure should not be viewed as a substitute for finding qualified and independent reviewers. Full disclosure should be made in all cases, not just those where the agency thinks there may be a problem. In cases where a reviewer must be used despite an appearance of risk of bias, special attention must be taken to see that disclosure requirements are met, including a discussion of the putative conflict of interest, but the disclosure requirements here should be no greater than in the case of other reviewers.

Agencies should not be free to choose whomever they like, then disclose the biases. Bias and its appearance must be avoided at all costs, and reliance on disclosure to cleanse the record must be considered arbitrary and unfair conduct by the agency and not tolerated.

Reviewers can retain some small degree of anonymity by presenting their individual reports as one panel report, rather than singular reports by each individual member. That way, no particular remark is traced to any one individual, and the risk of reprisal is reduced. The collaborative process of preparing a panel report could also help the reviewers understand the research more richly through the use of differing perspectives, resulting in a more thorough analysis. In fact, NAHB believes that the panel approach provides the opportunity for a more thorough and impartial review, because it provides a format for those with opposing views to discuss their differences in the open, which removes the temptation of reviewers to stick to a particular viewpoint without justification.

Thus, NAHB recommends panels as the preferred form of review and doesn't believe that cost can be used as a legitimate reason for avoiding the panel approach. Agencies can reduce expensive travel and per diem costs associated with face-to-face meetings by using innovative technologies such as Internet conferencing. Using existing virtual technologies, a face-to-face meeting can be mimicked, leaving little need for the reviewers to be present simultaneously in the same room.

Availability of Experts

These rules will expand the usage of peer reviewers greatly. As noted in a conference at the National Academies of the Sciences, the people who are doing reviews currently are already booked up. They can't do much more reviewing. Though some may treat that fact as evidence that the rules are untenable, the better view is that the rules will expand the pool of people doing reviews, bringing more diversity of viewpoint and experience to the reviewing process. Indeed, one of the benefits of these rules, whether intended or accidental, is that reviewing and evaluation can no longer be contained within a relatively small clique of professional comrades, people who continually attend the same meetings, serve on the same panels, review the same articles, and develop a culture among themselves. This is the culture so ruefully described by Thomas Kuhn in *The Structure of Scientific Revolutions*, and which led him to conclude "Science progresses one funeral at a time."

The nation possesses a wealth of talent capable of reviewing scientific and technical research. Often, the most knowledgeable people in a field are the people who have received their PhDs very recently. They have had to study all the current literature in the field, and they will know more than anyone else in the world about their dissertation topic. If they have academic appointments, they will be eager for reviewing opportunities in order to put more scholarly activity on their resumes. Tenured faculty may be qualified reviewers, even if they are not at the most prestigious research universities. It is important to recall that the quest is for reviewers who can tell if the agency's research is sound; it is not a quest for people to do the research. It is much easier to analyze the work of others than to conduct a research program of one's own.

The reviewers need intelligence and knowledge; they do not need to be the most prominent people in their fields.

In addition to currently untapped college and university professors in general, the people who serve as referees for scholarly journals should be qualified, in general. Issues of conflicts may arise in particular cases, but at least this is another pool of easily recognizable, acknowledged experts. If articles in peer-reviewed journals are presumed to have adequate review, then the referees for those articles should be presumed to possess sufficient expertise to act as agency peer reviewers, though the conflicts of interests may still need to be resolved.

NAHB also urges the agencies to consider members of the regulated community as reviewers. They are unlikely to be any more biased than agency employees, and they have equivalent experience, at the very least. Many times, the most highly expert members of a profession will be in the regulated community, rather than in government or academe. Some believe that so much expertise is found in agency employees that they should be the only ones used as reviewers, despite a perceived reduction in objectivity. Some members of the regulated community may be at least as expert, however, and NAHB believes it is equally unwise to discard their knowledge because of a fear they will not be objective. If exigencies can force the use of agency employees as reviewers, the same or analogous exigencies could call for the use of reviewers from the regulated community.

In short, expanding peer review from its current levels will likely require that more people act as peer reviewers. That would be a good result, because there is an abundance of talent able to act as reviewers, and they are light to bring fresh light to the debates. A broad pool of reviewers would tend to prevent the development of a “received wisdom” among the reviewers and discourage the development of opinions that are based on custom and friendships, rather than on science. NAHB applauds this outcome and believes that it would improve the overall peer review process.

Burden on Peer Reviewers

These rules should impose no substantial additional burden on reviewers. The heart of the rules is the disclosure requirements, and they contain nothing that would not be contained in any current CV. Essentially, the rules require reviewers to submit an up-to-date CV, and make it available for public scrutiny. EPA already follows this practice for its Science Advisory Board and its panels, and the agency regularly receives more than enough qualified applicants.

There seems little utility to limiting the number of years covered by the disclosures, as an expert’s entire professional life can be relevant. Only a long history will reveal whether a reviewer has a habit of supporting the agency or employer, regardless of the issue. The expert’s education is relevant, and many reviewers will be years past their student days. On the other hand, matters not related to the reviewer’s expertise or objectivity have little bearing on credentials. Service on administrative university committees, for example, is something that could be omitted, though service

on scholarly review committees, like grants administration, may be relevant in certain cases.

Finding experts will require a more proactive approach by the agencies. Posting opportunities on websites or publishing them in the Federal Register will reach those who watch those sources regularly. A more proactive approach could include publication in general interest publications in the scholarly community, particularly the *Chronicle of Higher Education*. More specifically targeted announcements could be sent to university departments, trade associations, other non-profit organizations, and scholarly or professional groups in the relevant disciplines. Agencies may encourage the formation of a continuing pool of qualified reviewers by regularly reminding university departments and deans that reviewing opportunities are frequently available, and faculty may wish to have their resumes on file with the agencies likely to seek guidance in their disciplines. Participation may also be raised through regular announcements in journals of professional organizations like the American Association for the Advancement of Science or the American Medical Association, as well as journals for more specialized journals. To find experts, the agencies will have to seek them, but that is not a daunting procedure as the foregoing examples illustrate.

Outside Consultants

NAHB supports and urges special note of the instruction in the last sentence of subsection a of Section 4 of the proposed Bulletin, on page 54028: “Although [an outside consultant] can be engaged to oversee multiple peer review processes for an agency, the agency shall ensure that the firm itself possesses independence (and the appearance of independence) from the agency.” One of the implications of this instruction is that agencies must spread any such management work over a variety of firms, so no firm becomes dependent on a particular agency, and no agency develops a less-than-arms-length relationship with a consultant. Even the use of these consultants as peer review process managers should be discouraged, to be used only when substantial savings can be made for the taxpayer without sacrificing expertise and objectivity.

Clarifications

The proposed Bulletin is commendably comprehensive, yet some confusion remains. NAHB urges OMB to clarify the ambiguities discussed below.

a. Review Standards and Applicability Under Bulletin Sections 2 and 3

Section 2 seems to allow for less stringent review than Section 3 demands. It is unclear why OMB has taken a tiered approach to peer review standards whereby there are different levels of rigor to the peer review standards. Specifically, the Bulletin distinguishes between “significant” and “especially significant” regulatory information in the following manner:

1. “Significant regulatory information” is information that an agency believes “will have or does have a clear and substantial impact on important public policies or important private sector decisions.” 68 Fed. Reg. 54024, September 15, 2003. (*This definition is from OMB’s Information Quality Guidelines.*)

2. “Especially significant regulatory information” is significant regulatory information that is subject to peer review and “(i) the agency intends to disseminate the information in support of a major regulatory action, (ii) the dissemination of the information could otherwise have a clear and substantial impact on important public policies or important private sector decisions with a possible impact of more than \$100 million in any year, or (iii) the Administrator determines that the information is of significant interagency interest or is relevant to an Administration policy priority.” 67 Fed. Reg. 8460, February 22, 2002.

The Bulletin then describes a peer review process for “significant regulatory information” using “should” and “can” directives, which gives an agency wide latitude for peer review procedures; allows peer reviewers from the same agency, if from a different program area; and allows either the agency or an outside group to select the peer reviewers. NAHB strongly disagrees with this approach.

NAHB believes that it is imperative for agencies to have and to adhere strictly to peer review policies that assure reliable, independent, and transparent peer review for **both** “significant” and “especially significant” regulatory information and believes that it is impossible to justify a lesser standard for “significant” regulatory information. The members of the public that must comply with any regulation expect the agencies to use scientifically sound information in the development process regardless of the breadth of the impact of the agency’s decisions. OMB fails to justify this distinction in the background information to the Bulletin or in the Bulletin itself, so the public is left wondering why this distinction is made. Thus, NAHB recommends that the Bulletin be revised so that the same guidelines apply to both types of information. At the very least, NAHB urges OMB to modify the Bulletin to make the conflict-of-interest rules of Section 3 apply to reviewers operating under Section 2. If the research is significant enough to call for external review, then the issues of reviewers’ expertise, objectivity, and the appearance of independence are relevant.

The Section 3 rules entitled “Peer Review Reports” are also crucial to the review process. It is not enough that the agency conducts a review, but the public needs a chance to see the agency’s response. In the interest of transparency, objectivity, and the appearance of fairness, the report and the agency’s response must be available to the public before the public comment period can begin. This is as important for the less significant rules of Section 2 as it for the major regulatory actions of Section 3. The rules on peer review report should apply to all reviews of significant regulatory information.

b. Public Comment on the Review

Under the heading “Opportunity for Public Comment” in Section 3 on page 54028, OMB has inadvertently created substantial confusion. It is possible to read this paragraph to imply that the comments given to the reviewers are the comments made during the comment period after the Notice of Proposed Rulemaking. If that were the case, it would imply that the reviewers’ final report would not be complete until some time after the public comment period had been concluded. If this is indeed the intent of the paragraph, NAHB strongly opposes this policy.

A fundamental purpose of the review process is to provide a check on arbitrary agency action, which agencies can cloak under the guise of agency discretion. A public review and a report of the agency's response to that review comprise a strategy for keeping the agency from straying from the science. The public cannot determine the agency's objectivity or the rule's utility if the reviewers' report is still mutable. Therefore, the final reviewers' report on any reviewed significant regulatory information must be finalized and available before the public comment on a rulemaking can begin, for any rule on which that information could be influential.

If, on the other hand, OMB means to create a separate comment period for the review process itself, NAHB welcomes this chance for the public to participate in the review process. Upon seeing the draft review report, the public may be able to provide substantial information that reviewers may find useful, and they may pose questions the reviewers would deem useful to answer. It can only improve the research to allow the reviewers to receive comments and weigh them, as long as the process is open, transparent, and fair.

It is essential that the public have an opportunity to comment on the finished report, including comments on the qualifications and apparent objectivity of the reviewers. The agency's responses must also be available for public comment. All of this implies the public will have a chance to comment on the finalized report or final proposal.

In conclusion, NAHB welcomes the development and implementation of a meaningful peer review process and urges OMB to seriously consider our comments and to finalize the Bulletin in a timely manner. If you have questions or wish to discuss our comments further, please contact us at 202-266-8200 or via email at aholliday@nahb.com or mparson@nahb.com.

Sincerely,



Andrew J. Holliday, J.D., Ph.D.
Housing Policy Economist



Marolyn J. Parson, Ph.D.
Director of Environmental Policy