Spiller <spiller@erols.com>
12/08/2003 04:07:10 PM

Record Type: Record

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

cc:
Subject: re-send, with required attachment

A few moments ago, I sent a comment to the peer review docuement, including the text of my comment and referring to it as attached. But I failed to attach it. This message is an attempt to attach the document. I incorporate another copy of the comment as text below. I apologize for the multiple messages.

Robert M. Spiller, Jr.

==========

- OmbComment8DEC03.wpd

OmbComment8DEC03
To:
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

Comments on OMB "Peer Review" requirements 68 FR 54023 published 15 SEP 03
Comments submitted by email and by mail 8 DEC 03.

Information about the commentor as required by the proposal:

Name	Robert M. Spiller, Jr.
Title	Mr.
organization	self
postal address	1404 Homeric Court, McLean, Virginia 22101-5610
telephone number	703 356 4501
email address	spiller@erols.com

Summary:

I oppose the proposed Bulletin because it would unnecessarily increase the cost and delay of agency actions, including regulatory actions; because it incorporates a surreptitious veto power for OMB over supposedly independent scientific or technical decisions, and because it imposes the costs of these deficiencies on the agency budgets without explicit and public attribution of these costs to OMB. I believe the net effect of the proposal would be to reduce the effectiveness of each of the agencies affected by the bulletin, and to delay and to increase the cost of their work for the public. The proposal's scope is immense: its definition of "Regulatory information" at 68 FR 54027, second column; includes anything an agency might be thinking about saying: "any scientific or technical study that is relevant to regulatory policy. Information is relevant to regulatory policy if it might be used by local, state, regional, federal and/or/international regulatory bodies".

The "Additional Peer Review Requirements for Especially Significant Regulatory Information" may be obliged by the Administrator, OIRA, if the "Administrator determines that the information...is relevant to an Administration policy priority"[68 FR 54027, third column]. Presuming that an agency is doing the Administration's work, this would enable the imposition of these requirements on anything the agency is doing.

Specifically:

1. The proposal does not reveal the estimated costs in time or money of the proposal, but a reading of the proposed bulletin reveals that each affected agency would be required to:

a. In its annual report (described at page 54029, first column, about two tenths of the way down the column) [for convenience, citations to the proposal in this comment will provide the last two digits of the Federal Register page number; then the column number on that page, 1, 2 or 3; followed by a decimal and a number approximating how many tenths down the column to look for the referenced text: in this case: 29/1.2], each agency must describe "any existing, ongoing, or contemplated scientific or technical studies that might (in whole or in part) constitute or support significant regulatory information the agency intends to disseminate within the next year". But the proposal would apply to [29/2.5] " information disseminated on or after January 1, 2004". So, in order to comply with the proposed bulletin's requirements, the affected agencies would have to delay any pending information dissemination until the requisite one-year advance notice had been provided. Strictly applied, this would effectively freeze information dissemination for one year (plus the time necessary for the descriptions to be prepared) to afford OMB the one year period of advance notice. Absent any OMB estimate, I guess this would require each agency 30 to 60 days at a minimum to prepare, in addition to the year's lead time.

b. Each affected agency would have to supplement or amend its Information Quality guidelines, [28/3.2] including specification of "entanglements" which could disqualify potential peer reviewers [28/3.4]. Absent any OMB estimate, I guess this would require each agency 90 to 120 days at a minimum to prepare.

c. Each affected agency would have to supplement or amend its Information Quality guidelines [27/3.4] to address confidential business information and privacy issues. Absent any OMB estimate, I guess this would require each agency 30 to 60 days at a minimum to prepare.

d. Each agency will have to provide an opportunity for outside comments for each information dissemination prior to providing the information and those comments to the peer reviewers. [28/1.9] (Note that this pre-agency-speech comment requirement is much more extensive than the occasional requirement for such comment before taking certain regulatory actions.) Absent any OMB estimate, I guess this would require each agency 30 days to invite comment, and 60 days to receive it, at a minimum, as these comments would have to be made in, or reduced to writing, in order to distribute them as required, to the peer reviewers.

e. The Agency would have to prepare an "explicit, written charge statement" to the peer reviewers [28/1.1] with specific questions "about information quality, assumptions, hypotheses, methods, analytic results, and conclusions in the agency's work product". But this charge would be delayed by the proposed bulletin's requirement that the charge be accompanied by the necessary information, which would first have to be redacted [28/1.5] of certain deliberative

process information. Absent any OMB estimate, I guess this would require each agency 30 to 60 days at a minimum to assemble, review, redact and to prepare a charge to the peer reviewers.

f. Each disseminating agency would have to brief its peer-reviewers on OMB guidance, presumably updated with the latest guidance from the latest bulletin. Absent any OMB estimate, I guess this could be accomplished with the charge.

g. Although nowhere explicit in the proposal, each disseminating agency would have to pay the peer reviewers for their work in reviewing the proposed dissemination, the charge and the briefing on OMB requirements, and for preparing their reports. This cost would be increased by the overhead of any outside peer-review-coordinating contractors [28/2.9-3.1]. The cost of this program would inevitably come out of the disseminating agency's budget, not out of OMB's budget. The effect of this "unfunded mandate" would be to increase the cost of agency work, to increase the appearance of "agency inefficiency" because of the increased intra-federal government costs imposed by this bulletin and to suppress agency dissemination of scientific r technical studies by imposing high transactional costs on the information release. Absent any OMB estimate of the cost of such consultation, I cannot guess the total cost of such review, and any such costing could only be fairly estimated by the paying agencies. But their dissemination of such estimates will be subject to OMB consultation [28/2.5], and one might fairly worry that the agencies will be urged to minimize any such estimates now, and pay for them in full, later.

h. The paid peer reviewers would need to be given time for their study and evaluation of the material to be disseminated. This time would necessarily be dependant upon the bulk of the material to be reviewed, but the proposal does not even acknowledge or estimate the minimum time required by (presumably busy) expert peer reviewers to receive, review, evaluate and respond to the charge and the material to be evaluated. Absent any OMB estimate, I guess this would require the peer reviewers two weeks for even small packages, and over 30 days for typical review packages of technical or scientific material.

i. More time will be required if group reports are to be constructed, after the individual reports are made and exchanged among the peer reviewers [28/2.2].

j. Then, the proposed bulletin would require the agency to prepare written reaction to each written response from the peer reviewers, including the basis of the agency's response, and a description of any agency action taken in response to the peer reviewers' comments. [28/2.2]. Absent any OMB estimate, I guess this would require each agency 30 to 60 days at a minimum to prepare. (This would be in addition to any statutory or regulatory notice-and-comment procedure undertaken by the disseminating agency.) If the peer reviewers' comments deserved substantial revision, the agency might have to re-propose its intended action to afford fair notice to those desiring to comment on the changed proposal.

k. The agency that had hoped to disseminate the technical or scientific information would then have to disseminate the final peer review, with the agency's reaction, and include the peer reviews in the administrative record of any formal decision. [28/2.4] The time for this would be included in step j, above.

l. But the dissemination of the agency's reaction to the peer review(s) would be subject "upon request" (without limitation of who might impose such a request) [28/2.5] to a required consultation with OIRA, which could consult in turn with OSTP. Although the agency would be obliged to submit such a draft "at least seven days prior to its intended issuance" [29/1.9], there is no obligation on OIRA to review the draft within that seven-day period, or within any time limit.

m. The required "consultation" with OIRA and OSTP is not limited in duration, but the proposal provides a veto power: "The agency shall not issue its response until OIRA has concluded consultation with the agency." [29/2.1]. If OIRA wishes to prolong the consultation, the agency will never be permitted to issue its response to the peer review, and the dissemination will never be permitted. If a particularly concerned industry was able to convince OIRA that a particular dissemination should not be made, OIRA could continue the consultation indefinitely, and the agency would never be able to disseminate the information.

2. Quite apart from the time and dollar costs that are not specified or even estimated in the proposal, the proposal would enable OIRA input to affect dissemination decisions without leaving appropriate attribution and traceability information on the public record of OIRA's effect on the decision. The proposal states that "OIRA <u>may</u> make such comment public, or direct that it be included in the Administrative Record for any related rulemakings." [emphasis added]. Any such input into any matter that is a rulemaking or for which an Administrative Record is required should be required by the bulletin to be documented and included in the Administrative Record, so that the public can tell who made which changes to the dissemination, the action or the rulemaking.

3. The proposal is systematically and asymmetrically concerned more about the possibility that peer reviewers would be unduly influenced by agency views, than by other (like industry) views. [24/3.9-25/1.1; 26/2.7; 26/3.7; 27/3.6; 27/3.8; 28/2.1; 28/3.2]. Undue influence should be avoided, from any source. Conflicts should be surfaced and reported, from any source.

4. The inclusion of "any controversy regarding the science" [27/2.9] as one of the factors for consideration of appropriate review is particularly unfortunate, given the ability of zealots and toxic industries to create "controversy" over even trivial or already-scientifically-concluded issues. The ability of the tobacco industry to pretend, for 50 years, that there was a "controversy" about the addictive and toxic effects of smoking tobacco is but one tragic example of the ability to manufacture a "controversy" about anything.

5. I would comment that each administration is entitled to declare and to impose its policy stamp on its actions through its OMB, but Congress has created and empowered the scientific and technical expert agencies in order to separate science from partisan control, which can oscillate with elections. If an Administration and a Congress should conclude that they cannot trust the regulatory agencies to protect the public according to the existing statutes, they may propose and pass legislation to limit the exercise of regulatory authority (or information dissemination) by the agencies (or to abolish the offending agency). But it would be misleading to leave the illusory facade of regulatory expertise and independence before the public, and then to impose an information filter, as this proposal would, to enable OMB and OIRA, to veto any proposed scientific or technical information release by the government agencies, leaving the public without the agency voice of scientific or technical expertise it pays its taxes to hear. Any agency confronted with this bulletin will have another reason to hold important scientific or technical information out of the public's view. If that is the intended effect of the proposed Bulletin, it should be withdrawn.

Sincerely,

Robert M. Spiller, Jr.
Citizen, voter, taxpayer.