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

cc:
Subject: OMB Bulletin Comments

Enclosed and attached are our comments on the draft Bulletin.

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We have provided the comments in two formats: PDF and Word document. They follow. The complete text of the comments also appears below, after the two attached documents. It is likely that there will be formatting problems with the email text. We therefore urge you to use the Word version with "launch."

(See attached file: OMB_Bull.pdf) (See attached file: OMB Bulletin Comments.doc)

- OMB_Bull.pdf
- OMB Bulletin Comments.doc

Comments

on

Office of Management and Budget

Peer Review and Information Quality

68 Fed. Reg. 54023 (September 15, 2003)

by

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December 15, 2003

Summary of Specific Recommendations

- OMB should expand the scope of peer review applicable to "especially significant" information or drop the category in favor of a uniform requirement that all significant information be subject to formal external peer review. Specifically, we propose that the first paragraph of section 3 be reworded as follows:

> If significant regulatory information is subject to the peer review requirements of section 2 of this Bulletin and the agency intends to disseminate the information in support of a major regulatory action, or
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> i. the dissemination of the information could otherwise have a clear and substantial impact on important public policies or important private sector decisions with the possible impact of more than $100 million in any year, or
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> ii. the Administrator determines that the information is of significant interagency interest or is relevant to an Administration policy priority, or
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> iii. the information addresses novel issues or applies analytic techniques at the frontiers of science and technology of likely long-term precedential value regardless of perceived regulatory, economic, interagency, or policy significance,
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> then, to the extent permitted by law, the agency shall have a formal, independent, external peer review conducted on the information.

- OIRA should require agencies to report quarterly in the *Federal Register* on important information products that the agencies intend to disseminate. At a minimum, agencies should report on a bi-annual basis in the *Federal Register*.

- OMB should adopt the following alternative language for substitution in section 2 of the Bulletin to assure exemption from peer review of information:

> disseminated in the course of agency adjudications or similarly formal proceedings in which the rights and duties of individual parties are formally determined, but subject to case-by-case exceptions to this exclusion, where such information may have precedential or science policy importance beyond the parties to the proceeding.

- OMB should withdraw the rebuttable presumption of adequacy of peer reviews undertaken by scientific journals pending further refinement by OMB.

- OMB should include a provision in the Bulletin cautioning agencies against premature submission of documents for Bulletin review and encouraging expanded use of confidential peer review prior to any public release for review under the Bulletin.

- In keeping with its policy on transparency, OMB should direct agencies to allow for public comment on their draft revised guidelines under the Bulletin.

- The Bulletin should make clear that where emergency or other time-pressured waivers are granted, OIRA expects the agencies to conduct a post-hoc peer review of the information disseminated.

- The Bulletin should encourage agencies to utilize committees of the National Academies for the peer review of especially significant regulatory information.

- OMB should serve as a gatekeeper to ensure that only the most scientifically or technically important documents receive maximum levels of peer review.

- OMB should use its proposed Interagency Work Group on Peer Review Policies to develop ways to expedite and improve science-oriented peer reviews, if their number becomes unwieldy.

I. Introduction

We endorse OMB's effort to re-enforce the practice of systematic, independent review by the scientific community of technical information relevant to regulation and policy. The Bulletin is an appropriate part of OMB's wider effort to ensure that important and publicly influential agency disseminations meet high standards for quality, objectivity, accuracy, and transparency. We believe that in time federal agencies and regulatory stakeholders, and in particular the scientific and technical community in and out of federal government, will come to value OMB's new emphasis on early and transparent peer review.[1]

Several of our recommendations involve expansions of the scope of the Bulletin, with the potential to increase the agency and OMB workload of peer-reviewable documents. Yet we believe OMB intends to implement the Bulletin in the same incremental, evolutionary, and flexible manner as it is implementing the Information Quality Act. If demand actually produces an unmanageable docket of full formal peer reviews, the Bulletin process can be revised accordingly so that agencies do not become overburdened.[2]

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> [T]he bulletin may help ensure that basic scientific and technical conclusions are formulated more objectively, with an early and complete record of what a broader range of independent scientists think about the science behind new federal initiatives. If the science can be made stronger at the inception, then regulatory disputes could be less contentious, more science-based, less subject to last-minute political intervention and more quickly resolved because they are less shrouded in mystery about how the agencies reach technical conclusions that underpin the costliest regulations and most important policies.

Frederick R. Anderson, "Peer Review of Data," National Law Journal, September 29, 2003 at p. 22.

[2] See "Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies," 67 Fed. Reg. 8452 (Feb. 22, 2002) at 8453 (cols. 1-2) and p. 8458 ("beginning of an evolutionary process").

Predictions of unmanageable burdens and costs, or a deluge of adversarial proceedings, have been notoriously inaccurate for earlier federal proposals. Some predicted a deluge of information requests under the Shelby Act; almost none have occurred. Predictions that Information Quality Act correction requests would mushroom have not materialized. In earlier years analysts over-estimated certain compliance costs for environmental regulation, underestimated others (e.g., black lung disease compensation), and failed entirely to anticipate any of the hundreds of suits filed under the National Environmental Policy Act. The burden of peer review will be determined in part by the specifics of the agency peer review guideline updates to be undertaken after the Bulletin is finalized.

We also think that the successful implementation of the Bulletin hinges crucially upon the detailed case-by-case peer reviews that the Bulletin requires agencies to propose for each document on the agency's public roster of "existing, ongoing, or contemplated" scientific or technical studies. Listing more documents, but tailoring peer review down to the right size, is preferable to extended discussions over which pigeonhole to assign a document to – "especially significant," "significant," "influential," etc. The important point is to place any document that may have importance on the agency's "roster" of proposed information products and then decide on the appropriate course of action. Finally, OMB has proposed a standing Interagency Work Group on Peer Review Policies (section 5) specifically charged to make recommendations "to expedite and improve" agency implementation of the Bulletin, should the burden prove unacceptably large.

All of our recommended changes address either scope of coverage ("especially significant," exclusions, presumption of adequacy of peer review of journal articles, and waivers) or process (pre-disclosure review, public roster of documents, interagency comment and peer

review, FACA, and National Academy of Sciences review). We have only praise for the Bulletin's requirements regarding the selection of peer reviewers to enhance their independence and objectivity and the OMB's pathbreaking efforts to define a formal, independent, and external peer review process that we hope will become a new type of "common rule" for significant federal regulatory and policy science documents. The comments others have submitted to OMB delve more deeply into the issues of bias, conflict, and intra-agency sourcing of peer review. While we would endorse many of these comments (particularly those of the American Chemistry Council (ACC)), we have nothing to add to the OMB's excellent analysis of the issues in its Preamble and the draft requirements of the Bulletin.[3]

OMB specifically asked for comment on whether this proposal would unnecessarily burden participating scientists or discourage qualified scientists from participating in agency peer reviews, how participation of such scientists could be encouraged, and whether disclosure of potentially disqualifying "entanglements" should be time-limited. Other than to observe that a 5-10 year limitation on such written disclosure might excuse highly relevant but somewhat aged information of crucial relevance to a party's fitness to serve, we observe only that (1) the Bulletin would achieve what many scientists have long sought and presumably will support, i.e., an early and more meaningful role in the application of science and technology to federal regulation and policy making, and (2) OMB should adopt a wait-and-see approach to the willingness of the scientific community to serve in what is admittedly a more time-consuming and transparent peer review process.

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[3] But see Frederick R. Anderson, "Improving Scientific Advice to Government, in *Issues in Science and Technology*, Spring, 2003.

II. Scope of Coverage

The heart of OMB's effort lies in the Bulletin's provisions for peer review of "especially significant" information. Yet the exemplary requirements of section 3 apply only to a small collection of the most important and controversial information products. We urge OMB to expand the scope of peer review applicable to "especially significant" information, as outlined below, or to drop the category entirely in favor of a uniform and requirement that all significant information be subject to formal external peer review as currently described in section 3.

Some far-reaching scientific and technical studies may not initially meet the "especially significant" standard but then later reappear as established science or technology in a more costly and controversial context. Seminal science may not initially have a clear and substantial impact on public policies or private sector decisions with $100 million annual impacts, or excite significant interagency interest, or address an Administration policy priority. Yet it is precisely these documents that may benefit substantially from the Bulletin's most valuable standards (i.e. section 3). OMB-mandated external peer review could become the vehicle through which the nation's scientists are afforded an early role in the development of credible regulatory science. Specifically, we propose that the first paragraph of section 3 be reworded as follows:

> If significant regulatory information is subject to the peer review requirements of section 2 of this Bulletin and the agency intends to disseminate the information in support of a major regulatory action, or:
>
> iv. the dissemination of the information could otherwise have a clear and substantial impact on important public policies or important private sector decisions with the possible impact of more than $100 million in any year, or
>
> v. the Administrator determines that the information is of significant interagency interest or is relevant to an Administration policy priority, or

vi. the information addresses novel issues or applies analytic techniques at the frontiers of science and technology of likely long-term precedential value regardless of its perceived regulatory, economic, interagency, or policy significance,

then, to the extent permitted by law, the agency shall have a formal, independent external peer review conducted on the information.

New section (iii) may apply to development or first use of such things as:

- new modeling or projection techniques;
- unusual data collection and processing;
- innovative research protocols;
- meta-analysis;
- internationally derived analytic approaches, technical conclusions, or data; and
- use of additional safety and scientific uncertainty factors for particular sub-populations or types of exposure to risk.

Some examples of federal information that may especially benefit from section 3 peer review under proposed new (iii) are:

- new statistical, modeling, or other analytic techniques used in environmental, health, and safety trends and other status reports, and economic sector projections, trends, and conditions reports (whether statutorily mandated or not);
- various health and ecological risk assessment guidelines and technical memoranda;
- environmental impact statements (EISes) under the National Environmental Policy Act (NEPA);
- entries or revisions in the federal Integrated Risk Information System (IRIS) for toxic substances;
- critical habitat and endangered species designations under the Endangered Species or Marine Mammal Protection Acts;

- natural resources shortages, supply, cost, and extraction impact studies (energy, minerals, metals, etc.);
- Remedial Investigation and Feasibility Studies (RI/FS) and technical guidance documents under the federal Superfund; and
- workplace risk determination methods.

To anticipate the objection that such an amendment would expand the agencies' section 6 public list of documents subject to full section 3 peer review, we observe, first, that in section 6 OMB explicitly instructs agencies to propose peer reviews of appropriate scope. Agencies thus have the initial opportunity to streamline and focus peer review. Second, OMB can be an important gatekeeper to ensure that only the most scientifically or technically important documents receive maximum levels of peer review. Third, OMB can use its proposed Interagency Work Group on Peer Review Policies (section 5) to develop ways to expedite and improve science-oriented peer reviews, should their number become unwieldy.

To understand the potential importance of proposed new provision (iii), it may help to imagine that the Bulletin was in effect a few decades ago when the nation's regulatory policies for chemical human carcinogens were being developed. At that time, through a variety of specific regulatory actions and federal science policy documents that did not uniformly undergo extramural peer review, the relevant federal agencies (e.g., the Food and Drug Administration) came to the conclusion that post-World War II chemicals released into the environment created a human cancer hazard that was different in kind from the hazards to human health already presented by the many other human toxicants known to be in the environment. Somewhat oversimplified, a single hit on a human cell by a single carcinogenic chemical molecule could cause cancer; thus, no safe level of human exposure existed. Thus no protective "threshold" of human resistance sheltered us from even the smallest amounts of such chemicals in our systems.

Today, federal approaches to cancer and other human toxic risks tend to converge. Yet, even at the time, a respectable body of scientific opinion doubted that potential chemical carcinogens created hazards different in kind from those created by other known toxic agents. To produce the current federal approach to human cancer risk—and it is still evolving—took many years of effort to correct the misconceptions embedded in federal cancer risk policy, including the nation's experience in enacting and then repealing the Delaney Clause.

Similarly, many years ago two FDA scientists reviewed the scarce contemporaneous literature on the relative sensitivities of humans and experimental animals and the degree of variable sensitivity within the human population and concluded in a brief paper that a safety factor of 100 would be adequately protective in extrapolating results from animal experiments to human cancer risk regulations.[4] Other federal agencies soon followed the FDA's original, thinly justified approach. To our knowledge, the FDA paper was not peer reviewed, but its basic approach – add tenfold safety factors whenever additional biologic variability is encountered – has had profound impacts. Safety factors too have been revised over time. Similar federal studies were done to explain the use of animal data to develop human cancer risks regulations.

What if the Bulletin's requirements for peer review had applied to the federal regulatory science information products disseminated at the time to establish the no threshold-no safe dose federal cancer risk policy? To the first federally disseminated FDA analysis proposing that a 100-fold safety factor be used in cancer risk regulation? To the federal documents that established the policy that any chemical that causes cancer in animals presumptively does so in humans?

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[4] See Joseph Rodricks, *Calculated Risks* (1992), at pp. 193-196.

Of course, much has changed, and few if any could see that an enormous body of federal environmental, health, and safety regulation was in formation. The drafting of these science policies was, by current standards, somewhat casual and ad hoc, although peer review and scientific consultation were sometimes used and are not particularly modern concepts. Then, federal science policy was preoccupied with prevention of infectious disease (especially polio), laboratory research on cancer, and Cold War nuclear technology. Yet it would be hard to deny that these contemporaneous science policy documents were "especially significant regulatory information." But the relevant agency documents would not likely have met the Bulletin's high threshold $100 million impact or other importance requirements. Nevertheless, more formal, independent, external peer review at the time might have made a pivotal difference in the evolution of federal cancer risk policy. Transparent and independent external review might have more nearly succeeded in separating out intertwined scientific and value-based policy choice issues.

Two types of uncertainty arise under proposed new (iii). First, it is uncertain that a document containing "novel" or "precedential" science and technology will eventually have major impacts. But agencies and OMB can make reasonable inferences, confer, and if unsure err on the side of inclusion, since such a document is especially suited for peer review. Second, such documents are likely to involve scientific uncertainty, and techniques to analyze and characterize it. Indeed, the treatment of scientific uncertainty will be at the heart of most controversies that arise under Bulletin peer review. The more uncertain the science, the grater the need for consensus-based peer review. The more the opportunity for political and social values to affect the treatment of scientific uncertainty and selection of safety factors, the greater the need for external, independent, analytically rigorous peer review.

The need for thorough external peer review of emerging regulatory science is so great that it calls into question OMB's proposed two-tier peer review scheme. All information that already can reasonably be said to be "significant" or "influential" should be subjected to formal, independent, external review. We think the comments of the American Chemistry Council (ACC) are persuasive in this regard. As we indicated in the Introduction, it would be far simpler if the OMB applied a standard "common rule" to all significant/influential federal information, focusing on case-specific descriptions of needed peer review to streamline the process.

III. Pre-disclosure Peer Review

The Bulletin's peer review requirements appropriately apply only to information that agencies intend to disseminate. Yet agencies may conduct confidential "pre-dissemination" peer reviews in order to assess the validity or quality of work in progress – the goal being to produce the best possible document for more formal peer review and dissemination. Sometimes agencies have asked peer reviewers, who may well include reviewers from academic or other institutions, to pledge to carry out their work under a "cone of silence" and not to disclose their reviews, which can be viewed as a part of the agency's internal deliberative process. Thus not even the fact that a peer review is under way, much less the identity of the reviewers or the nature of the reviews, is disclosed.

Confidential peer review ensures a better initial extramural product, less risk of premature publicity for still-evolving agency analyses, reduced risk of avoidable economic impacts and reputational harm, and less opportunity for distorted use of agency scientific and technical conclusions in judicial proceedings, especially tort actions.

The Bulletin is silent regarding such confidential review, but we recommend that it not be. The reason quite simply is that in the Information Era, even the mere mention that an agency document is under development – especially listing in the Bulletin's public roster of "contemplated" information products – may have significant consequences. Introducing a draft document into the Bulletin review process with its thoroughgoing transparency requirement, well prior to the official release of a finally approved product, is nevertheless a *de facto* dissemination to the public, with potential reliance on its draft contents by the media, stakeholders, and other federal, state, and local units of government. The OMB consequently should include a provision in the Bulletin cautioning agencies against premature submission of documents for Bulletin review and indeed encouraging the continued or expanded use of confidential peer review that has served agencies and academic science well over time.

When federal information is released – even with the qualification that the information is in draft form, is not meant for general circulation, and does not constitute a final agency product – such information is often legitimized and interpreted as official government information. Indeed, the predicate of the Information Quality Act is that federal information carries a measure of extra authority, and caveats about its use tend to fall by the wayside.

Consequently, the OMB should also instruct agencies to include provisions in their revised peer review guidance, and in other agency guidance to the extent necessary, that prior to peer review and final dissemination, reliance on or use of the document for regulatory or policy-making purposes is not allowed. Any such use would undermine the purposes which the Bulletin serves. De facto versus de jure dissemination of important environmental studies in particular presents a growing challenge to federal regulatory policy.

IV. The Federal Agenda for Developing Scientific and Technical Studies – The Section 6 "Roster"

Section 6 of the Bulletin directs agencies to identify in advance the studies and other information products that will be subject to peer review, together with the agencies' specific plans for peer review of the identified information products. The Bulletin would create a public list, i.e., a "roster" of each agency's "existing, ongoing, or contemplated" technical information products. The current draft requires each agency to update its roster on an annual basis. Elsewhere in its draft (Section 3, "Opportunity for Public Comment") OMB instructs agencies to provide an opportunity for "interested agencies and persons" to submit comments, and to ensure that those comments are provided in ample time for use by the peer reviewers. Thus, stakeholders will have an opportunity to critique regulatory science documents before they are peer reviewed, including comment on the appropriateness and extent of the peer review proposed by the agency for the relevant document.

The roster, proposed peer review, and opportunity for public comment initiate a thoroughly transparent information quality process that is carried forward throughout the proposed Bulletin. The successful operation of the Bulletin's peer review process hinges on these critical initial steps. Yet the Bulletin falls short in specifying how, and how frequently, this roster will be provided. OMB's proposal merely states that agencies should report to OMB "at least" annually, either in their annual reports required by the Information Quality Law, or under existing reports required by Executive Order 12866. None of these choices would be as effective at achieving the Bulletin's goals as separate periodic publication in the *Federal Register*.

We recommend, therefore, that OIRA require agencies to report quarterly, rather than annually, on regulatory information that the agencies intend to disseminate. The roster of

important "existing, ongoing, or contemplated" information is almost certain to change rapidly, especially since OMB requires notice at a very early point in the information development process. Agency studies and documents will change in numerous ways, from the time they are first contemplated until they are actually completed. A contemplated document may never be initiated; ongoing document development may be abandoned. If agencies report on an annual basis only, neither OMB nor the public can reliably monitor and participate in the federal regulatory science development process. Agencies and other stakeholders may spend a great deal of time and effort preparing comments, only to learn months later that the agency has dropped or modified the document.

Quarterly reporting would exceed the twice-annual requirements of the Regulatory Flexibility Act and Executive Order 12866, which require agencies to release in April and October of each year an agenda of all regulations under development or review. But this is in fact quite appropriate. Proposed regulatory policy is more evolved and certain, less diverse, and less fluid than information development. Consequently, updates on information products under development should be more frequent than for regulations. At a minimum, agencies should report on a bi-annual basis.

We believe that, in time, the agency roster will become an important focal point of Bulletin peer review. As suggested above, the emphasis should be on making the roster as inclusive as possible of the range of an agency's important information products. The overall burden of compliance with the Bulletin will be determined, not by placing items on the roster (especially if the criteria for listing are simplified and widened) (see also section II, above), but by the way in which agencies develop individualized, document-by-document peer review protocols.

An important aid to the Bulletin process will be the role stakeholders play in surveilling the rosters and commenting to agencies on entries therein. Stakeholders have the opportunity to comment, not only on the substance of items appearing on an agencies roster, but also on the scope of a "contemplated" study (e.g., a proposed research protocol or use of particular models) and on the charge for the proposed peer review and on the composition and candidates. The comments of scientists and stakeholders on "contemplated" documents may be particularly helpful. Peer review of research protocols, study designs, and proposed types and means of data collection *before* a study or report is begun is well-established. An example is the modus operandi of the Health Effects Institute (co-sponsored by EPA and the auto industry), whose standing Research Committee, composed primarily of prominent academic scientists, vigorously critiques and approves the health effects research protocols submitted by HEI's outside principal investigators before HEI can authorize the project to go forward. HEI's similar Report Review Committee peer reviews the finished research. Thus two demanding consensus peer reviews occur.

V. Exclusions From Peer Review

The Bulletin exempts from its peer review requirements information that is disseminated in the "course of an individual agency adjudication or proceeding on a permit application."[5] We think OMB is correct that such an exclusion from the Bulletin's peer review requirements is warranted; however, the meaning of the phrase "individual agency adjudication or proceeding" is unclear and may be too broadly construed by agencies seeking to narrow the scope of the

[5] Bulletin § 2.

Bulletin.[6] Our recommended alternative language for substitution in section 2 of the Bulletin assures exemption for information:

> "disseminated in the course of agency adjudications or similarly formal proceedings in which the rights and duties of individual parties are formally determined, but subject to case-by-case exceptions to this exclusion, where such information may have precedential or science policy importance beyond the parties to the proceeding."

The OMB's proposed language may be read to exempt a significant amount of regulatory information disseminated by agencies that would otherwise benefit from peer review. We do not believe this was OMB's intent. We believe that OMB intended to exclude from the Bulletin's peer review requirements information disseminated through agency proceedings that affects only the rights of *individual* persons or entities. (Perhaps OMB intended this result with its reference to "individual adjudication or proceeding," but if so its adjective is misplaced.) Further, we believe that OMB had in mind relatively formal individual adjudications (not the broad range of agency actions sometimes called "informal adjudication") and similarly formal statutorily-required permit approvals. Examples of excluded materials, subject to the caveat below, may include documents prepared by the agency in the course of:

- granting or denying a specific individual permit application (e.g., a permit to fill wetlands or to discharge pollutants into US waters);

[6] Under the Administrative Procedure Act, an "adjudication" is defined as the "agency process for the formulation of an order." 5 U.S.C. § 551(7). An "order" is defined as a "final disposition, whether affirmative, negative, injunctive, or declaratory in form, of an agency in a matter other than rule making but including licensing." *Id.* § 551(6). Thus, the Bulletin could arguably exclude all agency actions other than rule makings.

- granting federal approvals (e.g., new drug or medical device approvals, pesticide registrations, and letters of authorization for incidental takings under the Endangered Species Act or Marine Mammal Protection Act);

- granting federal licenses (e.g., those issued by the FCC);

- issuing orders mandating compliance with the law or that certain actions be taken; and

- adjudicating personal entitlements or rights (e.g., social security benefits or proceedings held pursuant to section 554 of the Administrative Procedure Act).

Still, OMB and the agencies should not lose sight of the fact that individual proceedings have been a seedbed of much federal science policy, as they also have been of evolving federal regulatory policy. In some instances, best identified on a case-by-case basis, federal technical information prepared for use in an otherwise exempted individual proceeding may have precedential or general scientific and technical significance that would benefit from Bulletin review. The OMB should encourage agencies to develop more specific peer review policies under which some information products destined for use in individual proceedings are added to its public roster under section 6, lest agencies be tempted to develop influential technical information incrementally to evade Bulletin review.

To fulfill the Bulletin's broad goal of improving federal regulatory science, all other documents intended for dissemination in conjunction with agency decisions or policy making should be subject to peer review. For example, the National Contingency Plan requires the Environmental Protection Agency to base a hazardous waste site remedial action on a remedial

investigation and feasibility study (RI/FS) that is prepared either by the agency itself or by private parties subject to EPA oversight and approval.[7] The RI/FS could be peer reviewed. It is a science and technology-based document that is used to support actions EPA specifies to protect human health and the environment. Moreover, the RI/FS is an excellent example of the type of document that may raise novel issues or contain new analytic modeling or other applications that are precisely the kind of information of precedential value that would benefit from early wide independent external peer review, despite not meeting the importance criteria in OMB's current draft Bulletin.

VI. Rebuttable Presumption for Journal Peer Review

We recommend that the rebuttable presumption of adequacy of peer reviews undertaken by scientific journals be withdrawn for further development by OMB. As it is currently written, the presumption of adequacy is confusing and incomplete. To whom is it directed? To peer reviewers? Stakeholders? Who can exercise the right to rebut, and when and how is a challenge to be initiated? Where is a challenge to be adjudicated? And finally, did OMB intend to create a private *right* to participate in triggering application of the Bulletin and in defining the scope of peer review?[8]

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[7] 40 C.F.R. § 300. Based on this analysis, the EPA prepares a record of decision (ROD) that specifies the remedial action required for a Superfund site. The ROD is a regulatory decision document that presumably would not be subject to peer review despite the fact that it does not adjudicate the rights of any individual or entity. It no longer is "regulatory information" under the Bulletin's definition and would not benefit from specialized technical peer review. Public stakeholder comment, however, may be provided. Under a subsequent consent decree or EPA administrative order, individual persons or entities may be required to implement the remedial action selected in the ROD. *A fortiori* neither of these would be subject to the Bulletin.

[8] Although also not clearly worded, the OMB apparently intends for the presumption to apply to the peer review of both significant regulatory information (section 2) and especially significant regulatory information (section 3) because section 2 states "*for purposes of this Bulletin,* peer review undertaken by a scientific journal may generally be presumed adequate" (italics added).

We doubt that the concept ultimately can be redesigned to serve OMB's basic objectives in promulgating the Bulletin. Deference to secret peer review seems out of step with OMB's rigorous insistence on transparency in most other parts of the new Bulletin and in the OMB Information Quality Act guidelines on which the Bulletin would in part be based. More profoundly, while it draws upon the model of academic peer review, Bulletin review moves well beyond its antecedents in scope, depth, intensity, and purpose. But for the present it is enough to observe that the function of the rebuttable presumption in the overall plan for Bulletin review has not yet been carefully enough been developed. The concept of the rebuttable presumption should at the least be withdrawn pending further refinement.

The agency information most likely to involve full formal review under the Bulletin contains a mixture of published peer-review journal articles and a variety of other material and data, all of which is used to support agency analyses and factual conclusions. Numerous examples are available, but the list in II, above, is illustrative, i.e., IRIS entries, EISes, endangered species and critical habitat designations or delistings, health and ecological risk assessment guidelines, workplace risk documents, and various trends and status assessments. Clean Air Act criteria documents for updating national ambient air quality standards (NAAQS) are also an excellent example, and have precipitated the most focused and at times heated debate about the preferred status afforded peer-reviewed journal literature and the importance of meeting high data quality, reproducibility, and transparency standards in tightening the NAAQS for particulate matter and ozone.

If the agency has proposed the particulars of peer review on such documents in its public notice of existing, ongoing, or contemplated studies (section 6), then presumably a party seeking to rebut the presumption of adequacy of journal peer review may at that time seek to have the

agency charge the peer reviewers to disregard the fact an article has received journal review and proceed to review the article as if it had never been published, possibly directing that Bulletin-type reviewers consider underlying data, laboratory practices, and other matters not usually within the scope of academic peer review.

But such early challenge before peer review has actually been completed under the Bulletin may be premature. The reviewers may exercise appropriate and considerable discretion themselves to weigh, discount, and critique journal articles – unless OMB intends that agencies must instruct peer reviewers not to "look beyond" peer-reviewed articles, which we think is unlikely. Thus, an early challenge lacks ripeness. It would also directly involve stakeholders in advocating the contents and scope of the charge to be given to the reviewers, but in an adversarial and mandatory context, subject to a quasi-judicial "rebutability" standard.

To delay challenge until the results of the peer review are known raises other problems. A challenge after the peer review is made public is in fact a challenge, not just to the adequacy of peer review of journal articles, but also to the Bulletin-governed peer review itself. Should the challengers prevail, the only adequate remedy would be to start the process over, with instructions to peer reviewers to dig more deeply into the journal literature, giving no weight to journal publication. Leaving aside the issue of what sort of forum will be made available to contest reliance on journal literature (no small issue itself), we doubt that OMB intended to raise so many questions and to open so many opportunities for adversarial proceedings in the Bulletin's peer review process. The only explicitly-identified stakeholder role under the draft Bulletin is an opportunity to comment on information identified in agency rosters of pending disseminations; agencies are to receive and pass such comments on to the peer reviewers. (See IV, above).

There are a few instances where agencies disseminate information based entirely on or containing only peer-reviewed articles. In such cases agencies need not propose to conduct any peer review at all, in accordance with the Bulletin. Such instances are infrequent, but they do occur, and they may be "especially significant" if a single large study gives rise to one or more journal articles and the agency decides, e.g., to tighten a major regulation, discontinue a large drug use or trial, or issue a health warning based entirely on the journal literature. A successful challenge then would precipitate Bulletin review that would not otherwise occur, of a scope presumably determined in light of the issues raised in the challenge.

As we indicated, the Bulletin patterns its requirements on the familiar concept of peer review. But Bulletin requirements are more demanding, and serve more demanding regulatory and policy goals, than journal review. Journal peer review and peer review for major regulatory policy are fundamentally different activities with fundamentally different objectives. Journal peer review provides a "gatekeeper" function to the scientific literature. A science editor wants confidential, candid appraisals to ensure a valuable addition to the scientific literature. Publication merely puts research results into the scientific public domain, to be improved or disproved in time, which is the essence of scientific progress. Science is tentative and iterative and, in a sense, the best possible outcome will be that as a result of journal publication, an article's results will be extended or disproved, thereby extending the horizons of science and expanding our technical knowledge base. But a federally disseminated study, report, or collection of data may be the predicate for major regulation, a policy priority, or an attempt to alter public opinion, all of which may have enormous economic costs or other social impacts. Major federal disseminations may be highly consequential, journal publication much less so. Regulatory policy making momentarily "freezes" scientific and technical analysis, assuming it to

be correct, goes on to impose what may be onerous and costly regulatory burdens. Science itself has the luxury of being more tentative and cautious; its consequence is insight and understanding.

Journal peer reviews are also not transparent. Journals rarely agree to disclose the identifies of its peer reviewers and virtually never make the reviews public. In most cases, journal peer review is blind review, where the author of the study does not know the identities of the reviewers. Such secrecy is far out of step with the Bulletin's emphasis on transparency, which helps ensure the accuracy and public acceptability of high-impact federal technical information.

In sum, peer review for regulatory policy is aimed at ensuring the quality, reliability, and integrity of research upon which regulations that may have profound cost implications are based. Journal articles, without more, are not ready for policy making. Agency reliance on studies for major regulations or public pronouncements requires a different order of review to ensure reliability.

VII. Interagency Comment

We commend OMB for providing for comments from other agencies on a peer review, information quality request, or major regulatory action (Section 8). This section will address a tension that has existed for years between environmentally "regulated" agencies, i.e., departments with energy, defense, agriculture, transportation, social services, and commerce portfolios, and "regulatory" agencies (environment, health, safety, workplace, product, etc.) – a tension that has grown particularly intense as the regulatory agencies, especially EPA and its state counterparts, have begun to tighten the emissions and effluent standards for such

contaminants as perchlorate, dioxin, PCBs, and trichloroethylene (TCE) with a consequent budgetary impact on "regulated" agencies' budgets that may grow to billions of dollars. Indeed, some regulated agencies have begun to demand an earlier role in the development of the science upon which EPA regulations are based.

Regulated agencies, as well as similar regulatory agencies, may now have a role in the early development of the science upon which EPA regulations are based. The OMB's inclusion of the regulated agencies in the peer review process correctly attempts to bring within a principled framework the peer review that has been the purpose of recently-created ad hoc inter-agency groups on perchlorate, dioxin, and TCE risk assessment led by the OSTP with OMB involvement, usually pointing toward the creation of National Academy of Sciences' committees (in effect, peer review committees), to critique EPA risk assessments on these "big ticket" contaminants, cleanup of which may cumulatively become quite costly.

We also applaud the Bulletin's creation of an interagency group, led by OIRA, and made up of peer review specialists and program managers, that will make recommendations regarding best peer review practices and improving agency processes.

VIII. The Tasking of the Agencies: Individual Agency Guidelines, Selection Processes, Review of Implementation

Section 4(b) of the Bulletin directs agencies to revise its information quality guidelines to incorporate peer review requirements. In addition, agencies are directed to fill in many of the details not covered in the Bulletin, including what may constitute a conflict of interest or bias precluding participation of a peer reviewer and what information about the peer reviewers will be publicly disclosed. In keeping with OMB's policy of transparency, OMB should direct agencies to allow for public comment on draft guidelines.

IX. The Federal Advisory Committee Act (FACA)

In section 4(a) of the Bulletin, OMB advises agencies that when selecting an outside panel of peer reviewers, agencies should assess the treatment of such a panel under the Federal Advisory Committee Act (FACA). In addition, OMB suggests that in light of the D.C. Circuit's opinion in *Byrd v. EPA*,[9] agencies consider retaining a firm to oversee the peer review process. While we believe that there may be times when FACA is implicated in a peer review process, such as when the Science Advisory Board reviews EPA projects and advises the Administrator on the currency and technical merit of agency positions, in the normal course, peer review should not constitute "advice to government" as contemplated by FACA.

Section 3(2) of FACA defines an advisory committee as "any committee, board, commission, council, conference, panel, task force, or other similar group" which is "established or utilized" by an agency for the purpose of obtaining advice or recommendations for the President or the agency. The General Services Administration (GSA) regulations governing implementation of FACA, defines "advisory committee" by echoing the statutory definition but limiting "advice or recommendations" to only "issues or policies within the scope of an agency official's responsibilities."[10] A peer review does not provide advice or recommendations on agency issues or policies. Peer review is an analytical function to determine the accuracy of scientific and technical information. It is, as the Bulletin states, a "critique of a study's methods, results, and findings." The analysis merely points out to the agency the technical attributes or inaccuracies of a particular study – it does not advise the agency on whether the study should or should not be relied upon for regulatory purposes.

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[9] 1714 F.3d 239 (D.C.Cir. 1999).

[10] 41 C.F.R. § 102-3.25.

If FACA were to apply to all per review panels, agencies will most certainly seek to avoid using consensus panels and instead rely on serial reviews from individual peer reviewers.[11] This would be an unfortunate result because consensus peer reviews add much to the quality of the peer review. Indeed, without explicitly stating, the Bulletin seems to encourage the use of peer review panels. FACA should not become a disincentive for agencies to use peer review panels.

X. Waiver Provision

The Bulletin provides that OIRA may waive some or all of the peer review requirements if an agency makes a compelling case that is necessitated by an emergency, imminent health hazard, or some other compelling rationale. Waivers in such extraordinary circumstances are appropriate and we recommend that these "emergency needs" be liberally construed to allow agencies to properly act to protect public health and welfare. A flexible approach and rule of reasonableness are imperative to allow the public health and perhaps other agencies to act expeditiously in the face of imminent health hazard.[12] However, in situations where time allows, we believe it is reasonable for OIRA to request that even an informal peer review be conducted before an agency pronouncement to ensure that the information disseminated is of the highest quality. We also recommend that the Bulletin make clear that where waivers are granted, OIRA expects the agencies to conduct a post-hoc peer review of the information disseminated.

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[11] GSA exempts from FACA groups assembled to provide individual advice. 41 C.F.R. § 102-3.40(e) (Any group that meets with a Federal official(s), including a public meeting, where advice is sought from the attendees on an individual basis and not from the group as a whole.)

[12] See Comment on this Bulletin of the American Association of Medical Colleges and Federal of American Societies for Experimental Biology (December 4, 2003).

XI. National Academy of Science Reviews

For years, committees formed by the National Academy of Sciences have provided peer reviews for agencies. The Bulletin, however, is silent on Academy reviews. We recommend that the Bulletin, either in the text of the guidelines or in the Preamble, encourage agencies to utilize Academy committees for the peer review of especially significant regulatory information. The Academy's selection process for committee members satisfies the Bulletin's independence and transparency requirements.

Academy committee members are vetted for bias, conflict of interest, and balance, and their bios are posted before appointment for public review and comment, which satisfies the Bulletin's requirements for independence--although the Academy may need to add information on the prior and existing involvement of the member with the agency whose information is being reviewed. The committee's final report would be a group peer review as contemplated by the Bulletin, and the agency can respond in writing to the committee report, as required by the Bulletin. Both the committee report and the agency's response can be placed in the administrative record of any agency regulation or policy, as also contemplated by the Bulletin. Public comments to the agency on the materials under peer review can be provided to the committee and also placed in the administrative record, again as the Bulletin provides. Other measures, such as public presentations to the committee, and the confidential peer review conducted by the Report Review Committee of the Academy, are extra measures provided by the Academy to ensure that the committee report is of first quality and deserves the Academy's imprimatur, but these extra measures are not required by the Bulletin.

XII. Requirements for Peer Reviewers

Because the reliability of especially significant regulatory information is "paramount," the Bulletin requires that external peer reviewers be independent of the agency, not possess real or perceived conflicts of interest, and be open-minded and unbiased towards the subject matter. Criteria for assessing independence and objectivity include whether candidates receive or seek substantial funding from the agency, have conducted multiple peer reviews for the same agency, have conducted reviews on the specific subject matter at issue, have a financial interest in the matter, or have advocated a position on the specific matter at issue.

We can only applaud these requirements, and the OMB's discussion of them in the Preamble to the notice requesting comment on the Bulletin. On minor point: OMB's discussion should explicitly reaffirm that its proposed requirements for peer-reviewer independence and freedom from bias and conflict apply equally to *all* candidates, including candidates from industry, as we believe OMB intended. Some critics have noted a failure to specifically affirm the uniformly broad application of the Bulletin's requirements in this regard. We add that the OMB was wise not to provide examples or catalogue the occasions on which agencies have fallen short of meeting high standards for objectivity and independence from bias and conflicts of interest, as suggested by some participants in the National Academies' workshop on the Bulletin held on November 18, 2003. Suggestions that OMB prove that the benefits of the Bulletin would exceed its costs, or to otherwise identify with particularity the problems the Bulletin is designed to correct, are misplaced. Such an effort would quickly lead to discussion of

the merits of selecting individual named agency and external peer reviewers and *ad personam* remarks about their biases and conflicts for long-since concluded reviews.[13]

[13] See Frederick R. Anderson, "Improving Scientific Advice to Government, in *Issues in Science and Technology*, Spring, 2003.