
ADMINISTRATIVE LAW & REGULATION

INDEPENDENT PEER REVIEW: THE *SINE QUA NON* OF INFORMATION QUALITY

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Introduction

In September 2003, the Office of Management and Budget's (OMB) Office of Information and Regulatory Affairs (OIRA) published a notice in the *Federal Register* that proposed new guidance regarding independent peer review of federal agency scientific and technical information, and also asked for comments.¹ The OMB notice states that existing agency peer review mechanisms have not always been sufficient to ensure the reliability of regulatory information disseminated or relied upon by federal agencies.² OMB is entirely correct in its assessment of the challenges agencies face in developing high-quality and objective information that is used in regulatory decision making. Independent peer review, if properly conducted, would add integrity and transparency to the regulatory process. Equally important, Congress requires OMB to issue peer review guidelines.

OMB should be complimented for recognizing the importance of independent peer review of agency scientific and technical information. Regulatory decision making requires high-quality and credible information. Information cannot be considered to be objective until it has received impartial and erudite scrutiny. Furthermore, independent peer review also allows OMB to comply with its statutory directives to ensure and maximize the quality, objectivity, utility and integrity of information disseminated by federal agencies.³

As noted in the *Federal Register* notice, the guidance is a work in progress. This article does not attempt to cover the many nuances of peer review, but it will show why peer review is required by law, outline a few aspects of the Bulletin as currently written, and discuss some additional questions that arise.

The Information Quality Act Requires OMB to Issue Peer Review Guidelines

In order to fulfill its obligations under the Information Quality Act,⁴ OMB must issue peer review guidance. OMB's current information quality guidance encourages but does not require peer reviews.⁵ Section 515 of the Treasury, Postal Service, and General Government Appropriations Act for Fiscal Year 2001 required OMB to replace its existing informal guidance with more formal guidance.⁶ OMB's present information quality guidance identifies general criteria that agencies should consider when they conduct such reviews, but consistency could only be achieved through strengthening these recommendations into more formal guidelines. In section 515(a), Congress directed OMB to issue government-wide guidelines that "provide *policy and procedural guidance* to Federal agencies for ensuring and maximizing the quality,

objectivity, utility, and integrity of information (including statistical information) disseminated by Federal agencies..."⁷ Section 515(b) goes on to state that the OMB guidelines shall:

- (1) apply to the sharing by Federal agencies of, and access to, information disseminated by Federal agencies; and
- (2) require that each Federal agency to which the guidelines apply —

(A) issue guidelines ensuring and maximizing the quality, objectivity, utility, and integrity of information (including statistical information) disseminated by the agency, by not later than 1 year after the date of issuance of the guidelines under subsection (a);

(B) establish administrative mechanisms allowing affected persons to seek and obtain correction of information maintained and disseminated by the agency that does not comply with the guidelines issued under subsection (a); and

(C) report periodically to the Director —

- (i) the number and nature of complaints received by the agency regarding the accuracy of information disseminated by the agency; and
- (ii) how such complaints were handled by the agency.

OMB in coordination with the Office of Science and Technology Policy (OSTP)⁸ issued its guidelines under sections 3504(d)(1) and 3516 of the Paperwork Reduction Act.⁹ OMB designed the guidelines so agencies will meet basic information quality standards. Given the administrative mechanisms required by section 515 as well as the standards set forth in the Paperwork Reduction Act, agencies should not disseminate substantive information that does not meet a basic level of quality.¹⁰

Independent peer review is perhaps the only way to ensure and maximize the objectivity of scientific or technical information prior to dissemination. For instance, if an agency promulgates conclusions based upon inadequate information, expert peer review can help to detect when data is flawed or when the science is unsound. The "objectivity"¹¹ and "quality"¹² of information can only be achieved through extensive, impartial analysis. Independent peer review is by no means a given that information will be perfect, but it would add transparency and consistency to the regulatory process which would enhance the "integrity"¹³ of information that is used and

disseminated by agencies. As OMB notes: “The focus of Section 515 is on the Federal Government’s information dissemination activities. In recent years...Federal information dissemination has grown due to the advent of the Internet, which has ushered in a revolution in communications. The Internet has enabled Federal agencies to disseminate an ever-increasing amount of information.”¹⁴ Given OMB’s statutory directives, the quality of information cannot be ensured prior to dissemination without independent expert critique. Hence, peer review provides a mechanism for OMB to fulfill its legal responsibilities.

The Importance of Independent Peer Review

Regulatory decision making must use accepted notions of science and technology; otherwise, costly burdens are unjustly imposed upon the economy.¹⁵ Independent peer review can promote better information quality because it would allow for greater scrutiny from the scientific and technical communities and input from affected stakeholders. In fact, independent peer review is not a novel concept; it is established protocol. Of course, peer review is not a panacea.¹⁶ Nevertheless, the lack of consistency in current peer review guidance necessitates some form of interagency standards. As one commenter stated, “requiring thorough and consistent peer review of important scientific and technical information *early* in the information development process is critical to ensuring information quality, and is fundamental to OMB’s obligation to ensure that information that underpins federal regulatory actions is based on sound science and rigorous technical analysis.”¹⁷

Opponents of OMB’s proposed guidelines make several points in order to defeat the addition of any peer review guidance for agencies.¹⁸ Critics argue that OMB does not have the legal authority to establish peer review guidelines; peer review guidance would permit politics to interfere with the regulatory process to the benefit of industry; and, currently there is no problem with the regulatory process that would necessitate peer review guidelines. All of these points are without merit.

First, OMB has the legal authority to issue peer review guidance for agencies. The specific requirements of the IQA (which applies to all federal information disseminated regardless of a regulatory application) mandate that information be of the highest quality, be objective, and have integrity and utility. In addition, the IQA explicitly gives OMB/OIRA the authority to “provide policy and procedural guidance” to agencies in order to ensure that the aforementioned criteria have been maximized. Therefore, because OMB has the authority to promulgate policy and procedural guidance for information quality, peer review guidelines are well within OMB’s legal authority. Furthermore, the PRA *inter alia* exists to “improve the quality and use of Federal information,”¹⁹ which taken together with the benefit-cost requirements of Executive Order 12866, grants OMB the authority and discretion to implement its directives.

In arguing that OMB does not have the legal authority under the IQA to issue peer review guidelines, opponents seem to be preoccupied with the act’s length²⁰ and the subjective intent of prior Congressional inaction on the issue of peer review.²¹ Regardless of its nominal length, the IQA outlines clear information quality standards for agencies and gives OMB the authority to ensure and maximize those standards. Similarly, one should not attach much significance to Congressional silence on the topic, especially from nearly a decade ago.

Opponents also claim that the regulatory process does not require improvements because “no fundamental or overarching problem exists in peer review as it is used by federal agencies...” and because “the majority of agency programs are working effectively.”²² To this end, critics argue that the IQA is a nefarious tool used by regulated industries to defeat or delay necessary regulations that protect the public welfare. Additionally, opponents object to the notion that agencies’ conclusions should be impartially scrutinized out of fear that industry-funded scientists would capture the regulatory process. The flaw in this line of reasoning is simple: the IQA makes the regulatory process *more* transparent, not less. The IQA applies to information disseminated by the federal government for a reason: if regulations are to be imposed, then the underlying data must be sound. If concern exists that backroom deals could be made, peer review guidelines would prevent such an occurrence, not facilitate it. Again, if information is subject to peer review, this fact in itself makes the regulatory process more open.

Some critics argue that the cost of having peer reviews would be too expensive and burdensome. But the negligible cost of paying for expert personnel would be well offset by the savings to the national economy by preventing flawed technical and scientific data from being used in regulatory decision making.

Finally, opponents argue that peer review guidelines would expand the authority of the OIRA Administrator, thereby politicizing the regulatory process. However, as required by Executive Order 12866, OIRA must review proposed “major” regulations to ensure that benefit-cost standards are met.²³ OIRA would neglect its duties if it were to ignore the veracity of scientific and technical data that underpins the bases of proposed regulations.

Irrespective of the wholesale criticism put forth by interest groups, OMB’s proposed guidance does raise some questions as to how the peer review guidelines will be specifically implemented. A handful of the more pertinent questions deserve extra attention.

Some Aspects of OMB’s Proposed Bulletin

The proposed OMB Bulletin would supplement (but not replace) OMB’s information quality guidelines pursuant to the Information Quality Act, and would also serve as guidance pursuant to the Paperwork Reduction Act,

and Executive Order 12866. If an agency already has peer review requirements, OMB's guidance would supplement those requirements for the peer review of "*significant regulatory information*," which is scientific or technical information that (i) qualifies as "influential" under OMB's information quality guidelines and (ii) is relevant to regulatory policies.²⁴ This category does not include most routine statistical and financial information, such as that distributed by the Census Bureau, the Bureau of Labor Statistics and the Federal Reserve.²⁵ Nor does it include science that is not directed toward regulatory issues.²⁶ It is also limited to the peer review of *studies* to be disseminated, as opposed to applications for grants.²⁷ OMB has also excluded national security information.²⁸

OMB's Bulletin also establishes a second category of information that would be subject to peer review, which is called "especially significant regulatory information."²⁹ It is unclear why OMB made this distinction, because any information disseminated would have a potentially "significant" or "especially significant" impact depending upon what entity it was applicable to. OMB, therefore, ought to clarify what exactly the difference is, how agencies should determine the difference, and how to manage their peer reviews based upon the difference. The distinction, for peer review purposes, between "significant" or "especially significant" information seems irrelevant to the impact that any information disseminated by agencies can have on society generally and, in particular the private sector.

Also ambiguous is the distinction between the terms "influential information"³⁰ in the information quality guidelines, and "significant regulatory information" as it appears in the Bulletin. "Influential information" in the information quality guidelines is tied to "scientific, financial, and statistical" information and to "information concerning risks to human health, safety, and the environment" whereas "significant regulatory information" references "any scientific and technical study." Is one of the terms intended to be broader or narrower than the other, and what types of information are (and are not) intended to be covered?³¹ OMB needs to address this point in its final guidance.

Irrespective of the types of information that would be subject to peer review, it is important to note that the data quality guidelines (of the IQA) apply to all and any information that federal agencies make public.³² Among its other provisions, the IQA provides that OMB's interagency data quality guidelines require all federal agencies subject to the PRA to establish administrative processes allowing "affected persons to seek and obtain correction of information maintained and disseminated by the agency that does not comply with" OMB's interagency guidelines.³³ In practice, OMB's peer review guidance would be reserved only for what it had deemed "significant regulatory information" or "especially significant regulatory information." The IQA, however, applies to all

information disseminated regardless of a regulatory application.³⁴ Peer review guidance should not alter that scheme; it should supplement existing information quality guidelines to ensure the quality of significant regulatory information. Consequently, any peer review guidance must adhere to the requirements of the IQA, and OMB should explicitly mandate that agencies amend their information quality guidelines to conform to the final OMB peer review guidance. If, for example, a particular peer review failed to meet dissemination standards, challenges to the veracity of that data could be brought under the IQA's data quality guidelines. Although helpful to ensure the consistency and integrity of information, problems might arise between the IQA and prospective peer review guidelines. For instance, "if the peer review is not yet complete, it is unclear whether an agency can nonetheless proceed to regulate or establish regulations on the basis of yet to be peer reviewed information. One can envisage a situation in which an agency chooses to regulate on the basis of information that has not yet been peer reviewed, while at the same time, the right of third parties to challenge the quality of the information underpinning the regulation is denied by the agency because, as the peer review has not yet been completed, the information is not yet considered disseminated and is therefore not yet challengeable."³⁵

OMB's Bulletin raises additional questions as to how the peer review guidance will be specifically implemented. Most notably, what does "adequate" peer review look like? It is foreseeable that an agency could comply with the peer review guidance in form but not in substance. For instance, would there be a difference between *peer input* and peer review?³⁶ And, what institution and who would ultimately select the reviewers? If the same agency selects the peer reviewers, problems might arise because the reviewers may simply serve to rubber stamp an agency's views.³⁷ Alternatively, peer reviews must be independent, but to what degree? For "significant regulatory information," whose reliability is paramount, the OMB Bulletin requires that agencies must take care to select external peer reviewers who possess the requisite experience and independence from the agency.³⁸ But, because virtually all reviewers will have some potential conflicts, should more weight be given to actual expertise in a field than perceived conflicts of interest?³⁹ In other words, objectivity in a vacuum might lead to less than "adequate" peer reviews.

The OMB Bulletin states that agencies must provide the peer reviewers with sufficient information and an appropriately broad charge.⁴⁰ Taken alone, however, this provides no guarantee that the final work product will be of the highest quality. One suggestion was that the reviewers, if qualified, should be financially compensated for their time in order to provide incentives for high quality regulatory analysis.⁴¹ Experts will have to spend a degree of time reviewing agency information, and financial incentive can promote better quality work.

The OMB Bulletin also presumes that journal peer review is adequate. This poses a substantive problem because “journal peer review often does not attempt to address the supportability of a manuscript’s conclusions, and focuses more on whether the material is worthy of dissemination to the scientific community where it can be subjected to further scrutiny and attempts to replicate and validate its findings and conclusions. Thus, journals often publish material because it is believed to contain significant observations, suggest a new hypothesis for further examination, or describe potentially useful new test methods or materials.”⁴²

Perhaps the most important requirement is transparency. Transparency must apply to all information, data, and economic models. Such a policy would allow stakeholders to fully participate in the regulatory process and would further ensure that benefits and costs are appropriately quantified. Without transparency, peer review requirements are unlikely to have any real impact because there is no way for OMB and others to verify that the peer review is, or was, indeed independent, rigorous, and objective.⁴³ Thus, total transparency adds “objectivity” and “integrity” to the peer review process by improving agency accountability and helping to further ensure the soundness of the science that underpins federal policies encompassed in regulations, guidance documents, and risk assessments.⁴⁴

Conclusion

Inevitably, tradeoffs will have to be made at some point in the guidance, but that should not discourage OMB and the public from moving forward on this initiative. Those who have criticized OMB’s Bulletin in its entirety view regulation as an absolute necessity, albeit without any regard to the costs and inefficiencies imposed by wanton regulatory policies. If hastily imposed without transparency, careful consideration to the benefits and costs and the underlying science and technical data, regulations do not serve to protect health and safety or market inefficiencies, they exist only to create unnecessary economic costs and damage the very entities they ostensibly seek to protect. If properly drafted, OMB peer review guidance can balance independence with expertise, insist upon accepted scientific conclusions, and mandate total transparency in the process. Federal information has enormous impacts on the business and economic climate; therefore, it must pass benefit-cost tests and be based upon objective scientific and technical information. Peer review is the manner in which to achieve high-quality information that is used and disseminated by the federal government. OMB is on the right track; the finer points and details of its guidance, however, are yet to be determined.

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Footnotes

¹ See Proposed OMB Bulletin on Peer Review and Information Quality, 68 Fed. Reg. 54023 (September 15, 2003). A list of all the comments submitted is available at http://www.whitehouse.gov/omb/inforeg/2003iq/iq_list.html.

² *Id.* at 54024

³ See Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies (“data quality guidelines”), 67 Fed. Reg. 8452 (February 22, 2002) available at <http://www.whitehouse.gov/omb/fedreg/reproducible.html>.

⁴⁴ U.S.C. § 3516.

⁵ 68 Fed. Reg. 54023 at 54026; see also John D. Graham, Administrator, Office of Information and Regulatory Affairs, Office of Management and Budget, Memorandum for the President’s Management Council (September 20, 2001) “For economically significant and major rulemakings, OMB recommends that agencies subject RIAs [Regulatory Impact Analyses] and supporting technical documents to independent, external peer review by qualified specialists. Given the growing public interest in peer review at agencies, OMB recommends that (a) peer reviewers be selected primarily on the basis of necessary technical expertise, (b) peer reviewers be expected to disclose to agencies prior technical/policy positions they may have taken on the issues at hand, (c) peer reviewers be expected to disclose to agencies their sources of personal and institutional funding (private or public sector), and (d) peer reviews be conducted in an open and rigorous manner. OIRA will be giving a measure of deference to agency analysis that has been developed in conjunction with such peer review procedures.”

Available at http://www.whitehouse.gov/omb/inforeg/oira_review-process.html.

⁶ Consolidated Appropriations FY 2001 of 2000, Pub. L. No. 106-554, 114 Stat. 2763A-153 to 2763A-154.

⁷ *Id.* (emphasis added).

⁸ The Office of Science and Technology Policy (OSTP), like OMB, is an office within the Executive Office of the President of the United States (EXOP).

⁹ *Id.*; see also note 3, *supra*.

¹⁰ 67 Fed. Reg. 8452.

¹¹ 67 Fed. Reg. 8452 at 8460. “Objectivity” involves two distinct elements, presentation and substance. “Objectivity” includes whether disseminated information is being presented in an accurate, clear, complete, and unbiased manner. This involves whether the information is presented within a proper context. Sometimes, in disseminating certain types of information to the public, other information must also be disseminated in order to ensure an accurate, clear, complete, and unbiased presentation. Also, the agency needs to identify the sources of the disseminated information (to the extent possible, consistent with confidentiality protections) and, in a scientific or statistical context, the supporting data and models, so that the public can assess for itself whether there may be some reason to question the objectivity of the sources. Where appropriate, supporting data should have full, accurate, transparent documentation, and error sources affecting data quality should be identified and disclosed to users.

¹² “Quality” is an encompassing term comprising utility, objectivity, and integrity. It contains concepts based upon the PRA. 67 Fed. Reg. 8452 at 8459; *cf.* 44 U.S.C. § 3504(e)(1)(B)(2000).

¹³ *Id.* at 8459. “Integrity” refers to the security of information – protection of the information from unauthorized access or revision, to ensure that the information is not compromised through corruption or falsification.

¹⁴ See note 3, *supra*, also available at http://www.whitehouse.gov/omb/fedreg/final_information_quality_guidelines.html

¹⁵ See *e.g.* Thomas J. Bray, “Garbage In, Regulation Out,” *OpinionJournal.com*, July 9, 2002 (The thought that policy should be based on objective, reproducible information, as the Data Quality Act requires, appalls regulatory zealots. “It ultimately could lead to less government action,” Sean Moulton, senior policy analyst for OMB Watch, a left-wing watchdog group, fretted to *The Wall Street Journal*... “If human health is potentially at risk, you can’t wait for all the facts to come in.” [sic]) available at <http://www.opinionjournal.com/columnists/tbray/?id=110001962>.

¹⁶ See Robert W. Hahn and Robert E. Litan, Comment on Peer Review and Information Quality, Regulatory Analysis 03-11 at 2 (December 2003) available at

<http://aei-brookings.org/admin/pdffiles/phpjZ.pdf>

¹⁷ See William L. Kovacs, Chamber of Commerce of the United States of America Comments on Proposed OMB Bulletin on Peer Review and Information Quality at 2 (December 15, 2003) (emphasis added) available at <http://www.whitehouse.gov/omb/inforeg/2003iq/170.pdf>.

¹⁸ See OMB Watch Comments on OMB’s Proposed Bulletin on Peer Review and Information Quality (December 15, 2003) available at <http://www.ombwatch.org/info/dataquality/PRbulletinOMBWcomments.pdf>; see also Public Citizen Comments on OMB’s Proposed Bulletin on Peer Review and Information Quality (December 15, 2003) available at <http://www.publiccitizen.org/documents/OMB%20Comments.pdf>; see also Center for Progressive Regulation (CPR) Comments on OMB’s Proposed Bulletin on Peer Review and Information Quality (December 7, 2003) available at <http://www.whitehouse.gov/omb/inforeg/2003iq/24.pdf>.

¹⁹ 44 U.S.C. § 3501(4)

²⁰ See *e.g.* OMB Watch, *supra* note, at 2, referring to the IQA as “a slim 15 line rider on an appropriations bill; see also CPR, *supra* note, at 3, “After all, the IQA was a rider hidden in an appropriations bill.”

²¹ CPR, *supra* note, at 2, citing H.R. 9 (1995) that failed to be enacted in the 104th Congress. This legislation, which would have required agency peer review, passed the House, but did not come to a vote in the Senate.

²² OMB Watch, *supra* note, at 3.

²³ Executive Order 12866, 3 C.F.R. 638 (1993). OIRA oversees agency activity in three areas: regulation, collection of information, and information resources management. OIRA is headed by a Presidential appointed, Senate confirmed, Administrator. Pursuant to Executive Order 12866, OIRA reviews major regulations, i.e. Federal regulations that would have an impact on the economy of \$100 million or more, to insure that the benefits of the regulation “justify” the costs.

²⁴ 68 Fed. Reg. 54023 at 54026. The Bulletin requires peer review of “significant regulatory information” and has specific requirements for this type of information that an agency intends to disseminate in support of a major regulatory action, that could 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 that the Administrator of OIRA determines to be of significant interagency interest or relevant to an Administration policy priority. As OIRA notes, such an impact can occur whether or not a federal rulemaking is envi-

sioned or considered likely to occur, in part because information might influence local, state, regional, or international decisions.

²⁵ *Id.*

²⁶ *Id.*

²⁷ *Id.*

²⁸ *Id.*

²⁹ *Id.* at 54027.

³⁰ 67 Fed. Reg. 8452 at 8460. “Influential” when used in the phrase “influential scientific or statistical information” means the agency expects that information in the form of analytical results will likely have an important effect on the development of domestic or international government or private sector policies or will likely have important consequences for specific technologies, substances, products or firms.

³¹ Kovacs, *supra* note, at 3.

³² 44 U.S.C. § 3516.

³³ *Id.*

³⁴ See *e.g.* U.S. Environmental Protection Agency, Information Quality FY03 Annual Report (January 1, 2004) available at http://www.epa.gov/oei/qualityguidelines/pdf/EPA_IQG_FY03_Annual_Report.pdf.

³⁵ Kovacs, *supra* note, at 7.

³⁶ See William G. Kelly, Jr., Center for Regulatory Effectiveness Comments on Proposed OMB Bulletin on Peer Review and Information Quality at 10 (December 15, 2003) available at <http://www.thecre.com/quality/120.pdf>.

³⁷ Hahn and Litan, *supra* note, at 1.

³⁸ 68 Fed. Reg. 54023 at 54026.

³⁹ Hahn and Litan, *supra* note, at 4.

⁴⁰ 68 Fed. Reg. 54023 at 54026.

⁴¹ Hahn and Litan, *supra* note, at 4.

⁴² Kelly, *supra* note, at 5.

⁴³ *Id.* at 6.

⁴⁴ Kovacs, *supra* note, at 1.