

Center for Regulatory Effectiveness

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NMFS Acoustic Guidance Violates the Peer Review Requirements of the Information Quality Act

NMFS Acoustic Guidance is a “highly influential scientific assessment” (“HISA”) under the definition of a HISA in the 2005 OMB information quality peer review guidance.¹

The OMB guidance contains “requirements” for the conduct of impartial outside peer reviews of such assessments. The U.S. Court of Appeals for the D.C. Circuit determined in *Prime Time Int’l, Inc. v. Vilsack*² in 2010 that OMB guidance issued pursuant to the Information Quality Act is binding. Other legal precedents from the U.S. Supreme Court and the D.C. Circuit confirm that the peer review guidance is a binding and enforceable “legislative rule.”

At this time, NMFS has already failed to comply with multiple requirements of the OMB guidance. Those deficiencies must be corrected and the Acoustic Guidance be subjected to independent external peer review, with public participation in the peer review planning and conduct, before the “guidance” can go forward, and certainly before it could be sent to OMB for review under the Paperwork Reduction Act.

I. The Acoustic Guidance Contains and Relies on Scientific Assessment of Models That is a HISA Under the OMB Peer Review Guidance.

The OMB peer review guidance sets out requirements for peer review of all “influential scientific information” (“ISI”) and for “highly influential scientific

¹ 70 Fed. Reg. 2664-77 (Jan. 14, 2005).

² 599 F.3d 678, 685 (D.C. Cir. 2010).

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assessments” (“HISA”s). The provisions for ISI allow for exercise of considerable discretion, while the provisions for HISAs, which are layered on top of the requirements for ISI, are more numerous and mainly mandatory.

The OMB guidance is careful to distinguish between ISI and HISAs. A key term in the HISA definition concerns the meaning of the term “assessments.” The OMB guidance also exhibits a careful distinction between what is discretionary and what is mandatory, based on use of the terms “requirements,” “shall,” and “must,” as opposed to arguably non-mandatory terms such as “should,” “may,” and “encouraged.”

The term “scientific assessment” is defined in the OMB guidance as requiring a synthesis of various inputs. The OMB guidance definition states that it means “an evaluation of a body of scientific or technical knowledge, which typically synthesizes multiple factual inputs, data, models, assumptions, and/or applies best professional judgment to bridge uncertainties in the available information.” The definition expressly includes “technology assessments.” 70 Fed. Reg. at 2675.

The OMB guidance definition of a HISA states that a “scientific assessment” is “highly influential” if it “(i) could have a potential impact of more than \$500 million in any year, or (ii) Is novel, controversial, or precedent-setting or has significant interagency interest.” 70 Fed. Reg. at 2675. It is highly likely that the cost would exceed \$500 million in a given year.

II. The OMB Peer Review Guidance is Binding.

That OMB guidance issued under the Information Quality Act (“IQA”) is legally binding, having the “force of law,” has already been determined by *Prime Time Int’l, Inc. v. Vilsack*, 599 F.3d 678, 685 (D.C. Cir. 2010). In *Prime Time*, the D.C. Circuit stated that a provision in OMB guidance issued under the IQA was “binding,” and referenced a

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statement from the Supreme Court’s opinion in *United States v. Mead Corp.*, 533 U.S. 218, 226-27, in which the Court held that “administrative implementation of a particular statutory provision qualifies for *Chevron* deference when it appears that Congress delegated authority to the agency generally to make rules carrying the force of law, and that the agency interpretation claiming deference was promulgated in the exercise of that authority.” (Emphasis added) Subsequent to the issuance of the decision, the Department of Justice was very concerned that CRE opined that the *Prime Time* decision concluded that the IQA is judicially reviewable. This concern on the part of the Department of Justice led them to request that the court make clear that IQA is not judicially reviewable; the court refused to honor that request.³

The IQA (also known as the “Data Quality Act”), 44 U.S.C. § 3516 note, was enacted as a supplement to the requirements of the Paperwork Reduction Act (“PRA”) provisions authorizing and directing OMB to issue “Rules and regulations” to ensure and maximize the quality of information disseminated by federal agencies. 44 U.S.C. §§ 3516 and 3504(d)(1). The IQA expressly incorporated those PRA provisions and others. The OMB peer review guidance states that it is promulgated under the legal authority of the IQA and other OMB authorities. 70 Fed. Reg. at 2666, 2667.

The *Prime Time* holding is in line with U.S. Supreme Court precedent and other D.C. Circuit caselaw. In *Chrysler Corp. v. Brown*, the Supreme Court held that regulations have the “force and effect of law” when they are issued pursuant to legislative authority to implement a statute and are promulgated pursuant to any procedural requirements imposed by Congress, such as the notice-and-comment requirements of the APA. 441 U.S. 281, 302-03 (1979). The D.C. Circuit has elaborated on those basic principles by holding that a regulation has the force and effect of law if it appears on its face to be binding, as indicated by its use of mandatory language. *Cement Kiln Recycling Coalition v. U.S. EPA*, 493 F.3d 207, 216 (D.C. Cir. 2007); *Elec. Privacy Info. Ctr. v. U.S. Dept. of Homeland Security*, 653 F.3d 1, 7 (D.C. Cir. 2011). The OMB peer review guidance was issued following extensive formal notice and comment⁴ and uses mandatory language for those provisions it describes as “requirements.”

³ The Dept. of Justice motion is available at http://thecre.com/pdf/20100603_Government_DQA_Appeal_to_Court.abrev.pdf. In denying the motion, the court did not issue an opinion.

⁴ OMB issued an initial draft in the *Federal Register* for public comment, then a revised draft for public comment. The National Academies commented extensively. When the revised draft was issued, the three

Although the OMB guidance contains a disclaimer regarding judicial reviewability (70 Fed. Reg. at 2677), such a disclaimer cannot transform the guidance from a binding legislative rule into a non-binding advisory. A similar disclaimer in EPA “guidance” was expressly given no effect by the D.C. Circuit in *Appalachian Power Co. v. U.S. EPA*, 208 F.3d 1015, 1022-23 (D.C. Cir. 1015). The court characterized such a disclaimer as “boilerplate,” and held that the guidance imposed binding obligations subject to judicial review because it required, ordered, and dictated what must be done. Likewise, the disclaimer in the OMB peer review guidance does not have any effect because the guidance contains numerous mandatory “requirements” for what must be done. An agency cannot, by fiat, immunize itself or other agencies from judicial review of non-compliance with legislative rules.

III. NMFS Is Violating the Requirements of the OMB Guidance for HISAs.

1. Peer Review Agenda and Plans

NMFS is required to post notice of an upcoming peer review on its peer review agenda, and to set out a peer review plan containing ten specific items of information. The agency must establish a mechanism for allowing the public to comment on the adequacy of the peer review plan, and it must consider any such public comments. 70 Fed. Reg. at 2675-76.

2. Requirement for Independent Peer Review by Diverse Experts

All HISA’s must be peer reviewed. The only exception is official reports of the National Academy of Sciences [sic – should probably be National Academies].⁵ The group

Presidents of the National Academies (National Academy of Sciences, National Academy of Engineering, and National Institute of Medicine) praised the revised guidance as “point[ing] to a new and constructive era of scientific engagement in public policy-making.”

<http://www8.nationalacademies.org/onpinews/newsitem.aspx?recordid=s04152004>.

⁵ 70 Fed. Reg. at 2671.

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of peer reviewers must be “sufficiently broad and diverse to fairly represent the relevant scientific and technical perspectives and fields of knowledge.” Agencies shall consider nominations from the public and professional societies. 70 Fed. Reg. 2675-76. The peer reviewers must be independent of the sponsoring agency. *Id.* Public comment on a guidance proposal is not a substitute for peer review. *Id.* at 2665.

3. Public Participation

“Whenever feasible and appropriate,” the agency “shall” sponsor a public meeting where oral presentations on scientific issues can be made to the peer reviewers by interested parties, and “whenever practical” the agency “shall” “provide the peer reviewers with access to public comments that address significant scientific or technical issues.”

CRE could find no indication that NMFS sponsored the kind of peer review required for HISAs, much less that it sponsored a public meeting with the peer reviewers and provided them with significant public comments.

4. Peer Reviewers’ Report and Agency Response

The agency must instruct the peer reviewers to prepare a peer review report that will be made public. 70 Fed. Reg. at 2675, 2676. In the case of HISAs, the agency must prepare a written response to the report. For example, the EPA HANDBOOK reflects this requirement as a “responsibility” of agency personnel at 25-26.

5. Certification of Compliance

If an agency relies on either ISI or a HISA to support regulatory action, it “shall include in the administrative record for that action a certification explaining how the agency has complied with the requirements of this Bulletin and the applicable information quality guidelines.” 70 Fed. Reg. at 2677. Absent such a certification, it is clear that OMB could not, as a matter of law, approve an ICRE incorporating ISI or a HISA.

IV. In Particular, Prior Outside Peer Review of Materials Referenced and Discussed in the Acoustic Guidance Does not Satisfy the Requirements of the OMB Guidance for a HISA Unless the HISA is Relying on an Official NAS report.

The OMB guidance requires independent group peer review of highly influential technology assessments. The technology assessment contained in the Acoustic Guidance clearly meets the definition of a “highly influential scientific assessment.” There is nothing in the peer review agenda section of the agency’s Science Inventory to explain why this is not so.

For HISAs, the only exception to a new independent peer review of the technology assessment in the Acoustic Guidance, as stated in the OMB guidance, would be an official report of the National Academy of Sciences. 70 Fed. Reg. 2675-76. OMB explanation in the preamble to its guidance makes this even clearer, stating:

Section III(2) clarifies that the principal findings, conclusions and recommendations in official reports of the National Academy of Sciences that fall under this section [on requirements for HISAs] are generally presumed not to require additional peer review. All other highly influential scientific assessments require a review that meets the requirements of Section III of this Bulletin. 70 Fed. Reg. at 2671 (emphasis added).

Since there is no such NAS report being relied on, any prior peer review, including those sponsored by NMFS, is not sufficient to comply with the OMB requirements. Moreover, there is no explanation in the peer review agenda portion of the Science Inventory explaining why the agency has concluded that the type of independent peer review required by the OMB guidance is not necessary.

V. Compliance with the Peer Review Requirements Should Be Achieved at the Earliest Possible Time, and Certainly before any Draft ICR is Sent to OMB for Review pursuant to the Information Quality Act.

Although timing of a HISA peer review is not expressly addressed in the substantive portion of the OMB guidance, the discussion in the preamble strongly recommends that

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peer review be completed prior to issuance of the Draft Acoustic Guidance. The OMB guidance preamble states:

When an information product is a critical component of rule-making, it is important to obtain peer review before the agency announces its regulatory options so that any technical corrections can be made before the agency becomes invested in a particular approach or the positions of interest groups have hardened. If review occurs too late, it is unlikely to contribute to the course of a rulemaking. Furthermore, investing in a more rigorous peer review early in the process “may provide net benefits by reducing the prospect of challenges to a regulation that later may trigger time consuming and resource-draining litigation. [Footnote omitted]

70 Fed. Reg. at 2668. Other agencies abide by this mandate; for example The EPA Peer Review HANDBOOK contains a policy statement that “[i]n general, peer review should be completed prior to issuance of the proposed regulation.” At 15.

Since NMFS has not sponsored the necessary independent HISA peer review prior to issuance of the Acoustic Guidance, it appears that it might be necessary for peer review to now focus on the Acoustic Guidance as issued in final form.

VI. NMFS Actions Necessary to Achieve Compliance

NMFS must do the following at a minimum in order to comply with the OMB peer review requirements before it can issue any final rule, and before OMB’s Office of Information and Regulatory Affairs (“OIRA”) can consider approving any final rule pursuant to E.O. 12866:

1. NMFS must post a peer review plan in the peer review Agenda on its Science Inventory and establish a mechanism whereby the public can comment on the plan. It should also consider inviting public and/or professional society nominations for the independent peer review group. Further, although apparently not strictly required, NMFS should post a draft charge to the peer reviewers and request comment on the draft charge.
2. NMFS must select a group of peer reviewers. The selected peer reviewers must be independent from the agency, be impartial experts, and be sufficient in number to

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fairly and impartially represent expertise in the technical, economic, environmental science, geology, and energy areas addressed in all aspects of the evaluation of models. The peer reviewers must be free of any conflict of interest. Selection should be in conformance with National Academy procedures, as indicated in the OMB guidance.

3. NMFS must develop a charge for the peer reviewers that instructs them to address all the assessment issues (including costs) reflected in the Acoustic Guidance, while avoiding allowing any policy considerations that would bias their deliberations and conclusions. The charge must also include instruction on the information quality standards in OMB's 2002 general IQA government-wide guidance. The agency (either in the charge or otherwise) must instruct the peer reviewers to prepare a written report stating their conclusions in response to the charge, and advise them that the report will be made public.
4. NMFS must give the peer reviewers access to all materials relevant to their review.
5. NMFS must sponsor at least one public meeting of the peer review group at which interested members of the public can make oral comments. It must also provide an opportunity for written public comments. NMFS must ensure that the peer reviewers have access to all significant public comments on the scientific/technology evaluation issues.
6. Upon completion of the peer review, NMFS must make available to the public the peer reviewers' report, the charge, and the reviewers' names, affiliations, and areas of expertise.
7. NMFS must provide a written response to the peer review report in which it discusses whether and why it agrees or disagrees with its conclusions.
8. NMFS must include in the administrative record for any final rule that relies on ISI or a HISA a "certification" explaining how the agency has complied with the OMB peer review guidance and the applicable (2002) general information quality guidelines.

VII. OMB's Role

The OMB guidance recognizes that OMB is responsible for overseeing compliance with its rules regarding the quality of disseminated information, which include the peer review guidance. This is a statutory responsibility under 44 U.S.C. § 3504(d)(1), which is incorporated by reference into the IQA. The OMB peer review guidance states that “OIRA [of OMB], in consultation with OSTP, shall be responsible for overseeing implementation of this Bulletin.” 70 Fed. Reg. 2667. OIRA could not approve a final NSPS rule based on CCS without ensuring that its peer review guidance had been complied with. At this time, it would be impossible for OIRA to do so.