

USDA Peer Review Implementation Guidelines

Purpose: The purpose of this document is to implement the Office of Management and Budget's (OMB) *Final Information Quality Bulletin for Peer Review* (hereafter referred to as the Bulletin), which were issued on December 16, 2004, and published in the *Federal Register* on January 14, 2005 (FR 70:2664–2677).

These supplementary peer review guidelines apply to influential scientific information and highly influential scientific assessments that contain findings or conclusions that represent the official position of USDA agencies or offices and are officially disseminated to the public at large. The following peer review guidelines comprise the standards that USDA agencies and offices will follow in peer reviewing influential scientific information and highly influential scientific assessments before disseminating it to the public.

Policy: USDA will strive to ensure and maximize the quality, objectivity, and integrity of influential scientific information and highly influential scientific assessments that its agencies and offices disseminate to the public. Agencies have the discretion to implement the Bulletin and these guidelines as they determine appropriate with general guidance from the Department.

Definition of Scientific Information: The term "scientific information", as defined by the OMB Bulletin, means factual inputs, data, models, analyses, technical information, or scientific assessments related to such disciplines as the behavioral and social sciences, public health and medical sciences, life and earth sciences, engineering, or physical sciences. This includes any communication or representation of knowledge such as facts or data, in any medium or form, including textual, numerical, graphic, cartographic, narrative, or audiovisual forms. This definition includes information that an agency disseminates from a web page, but does not include the provision of hyperlinks on a web page to information that others disseminate. This definition excludes opinions, where the agency's presentation makes clear that an individual's opinion, rather than a statement of fact or of the agency's findings and conclusions, is being offered.

Definition of Influential Scientific Information: The term "influential scientific information", as defined by the OMB Bulletin, means information that the agency reasonably can determine will have or does have a clear and substantial impact on important public policies or important private sector decisions." In the term "influential scientific information," the term "influential" should be interpreted consistently with OMB's government-wide information quality guidelines and USDA's information quality guidelines.

USDA's Information Quality Guidelines define a clear and substantial impact as one that has a high probability of occurring. If it is merely arguable that an impact will occur, or if it is a close judgment call, then the impact is probably not clear and substantial. The impact must be on "important" public policy or private sector decisions. Even if information has a clear and substantial impact, it is not influential if the impact is not on a public or private decision that is important to policy, economic, or other decisions. The definition applies to "information" itself, not to decisions that the information may support. Even if a decision or action by a USDA agency or office is itself very important, a particular piece of information supporting it may or may not be "influential."

In rulemaking, influential scientific information is information that will have a clear and substantial impact on the resolution of one or more key issues in an economically significant rulemaking, as that term is defined in Executive Order 12866. Executive Order 12866 defines an economically significant rulemaking as one that is likely to result in a rule that may have an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities. The reference to key issues on significant rules reflects the "important" public policy language of the guidelines.

In non-rulemaking contexts, USDA agencies and offices will consider two factors—breadth and intensity—in determining whether scientific information is influential. Every decision USDA makes based on disseminated information is important to someone. That does not mean that disseminated scientific information used for each decision is influential, as the term is used in these guidelines. In determining whether scientific information is influential, under the Bulletin, USDA agencies and offices should consider whether the information affects a broad range of parties. Scientific information that affects a broad, rather than a narrow, range of parties (e.g., an entire industry or a significant part of an industry, as opposed to a single company) is more likely to be influential. USDA agencies and offices also will consider whether the scientific information has an intense impact. Scientific information that has a low cost or modest impact on affected parties is less likely to be influential than scientific information that can have a very costly or crucial impact. Information that has an intense impact on a broad range of parties should be regarded as influential. Scientific information that affects a broad range of parties, with a low-intensity impact, or scientific information that affects a narrow range of parties, with a high intensity impact, likely is not influential.

USDA agencies and offices may designate certain classes of scientific information as "influential" or not in the context of their specific programs. Absent such designations, USDA agencies and offices will determine whether scientific information is influential on a case-by-case basis, using the principles articulated in these guidelines.

The "influential" designation is intended to be applied to scientific information only when clearly appropriate. USDA agencies and offices should not designate scientific information as *influential* on a regular or routine basis.

Definition of Scientific Assessment: The term "scientific assessment", as defined by the OMB Bulletin, 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. These assessments include, but are not limited to, state-of-science reports; technology assessments; weight-of-evidence analyses; meta-analyses; health, safety, or ecological risk assessments; toxicological characterizations of substances; integrated assessment models; hazard determinations; or exposure assessments.

Definition of Highly Influential Scientific Assessment: The term "highly influential scientific assessment", as defined by the OMB Bulletin, means information that the agency or the Administrator determines to be a scientific assessment that could have a potential impact of more than \$500 million in any year, or is novel, controversial, or precedent-setting or has significant interagency interest.

Definition of Dissemination: The term "dissemination", as defined by the OMB Bulletin, means agency initiated or sponsored distribution of information to the public (see 5 C.F.R. 1320.3(d) (definition of "Conduct or Sponsor")). Dissemination does not include distribution limited to government employees or agency contractors or grantees; intra- or inter-agency use or sharing of government information; or responses to requests for agency records under the Freedom of Information Act, the Privacy Act, the Federal Advisory Committee Act, the Government Performance and Results Act or similar law. This definition also excludes distribution limited to correspondence with individuals or persons, press releases, archival records, public filings, subpoenas and adjudicative processes. The term "dissemination" also excludes information distributed for peer review in compliance with the Bulletin, provided that the distributing agency includes a clear disclaimer on the information as follows: "This information is distributed solely for the purpose of pre-dissemination peer review under applicable information quality guidelines. It has not been formally

disseminated by [the agency]. It does not represent and should not be construed to represent any agency determination or policy.” For the purposes of the Bulletin, “dissemination” excludes research produced by government-funded scientists (e.g., those supported extramurally or intramurally by federal agencies or those working in state or local governments with federal support) if that information does not represent the views of an agency. To qualify for this exemption, the information should display a clear disclaimer that “the findings and conclusions in this report are those of the author(s) and do not necessarily represent the views of the funding agency”.

Peer Review Agenda: Agencies shall clear peer review agendas for influential scientific information and highly influential scientific assessments through agency heads and inform policy officials within the mission area prior to the agendas being made public. Each agency shall post on its website, and link to the Department’s website, an agenda of peer review plans for influential scientific information and highly influential scientific assessments. In the event that no items fall within the categories of either influential scientific information or highly influential scientific assessments, the agency will post a negative agenda. Entries will initially be posted on June 16, 2005 for highly influential scientific assessments and by December 16, 2005 for influential scientific information. The websites shall be updated a minimum of every six months thereafter.

Peer Review Plan Format: For each entry on the agenda the agency shall describe the peer review plan. Each peer review plan shall be consistent with instructions of Section V(2), Peer Review Plans, of the Bulletin.

Public Participation and Comment: Agencies shall establish a transparent process for public disclosure of peer review planning related to influential scientific information and highly influential scientific assessments, including a web-accessible description of the peer review plan that the agency has developed for each of its forthcoming influential scientific disseminations. Agencies shall establish a mechanism for allowing the public to comment on the adequacy of the peer review plans. Agencies shall consider public comments on peer review plans.

Whenever feasible and appropriate, the agency shall make the draft of a highly influential scientific assessment available to the public for comment at the same time it is submitted for peer review (or during the peer review process) and sponsor a public meeting where oral presentations on scientific issues can be made to the peer reviewers by interested members of the public. When employing a public comment process as part of the peer review, the agency shall, whenever practical, provide peer reviewers with

access to public comments that address significant scientific or technical issues. To ensure that public participation does not unduly delay agency activities, the agency shall clearly specify time limits for public participation throughout the peer review process.

Agencies shall link their peer review agendas to the U.S. Government's official web portal: *firstgov* at <http://www.FirstGov.gov> when the website becomes available.

Adequacy of Peer Reviews for Influential Scientific Information:

Before releasing influential scientific information, USDA agencies and offices will use one or more of the following procedures:

1. Conduct a peer review that meets the standards recommended by the OMB Bulletin.
 - i. Where appropriate, subject the information to formal, independent, external peer review to ensure its objectivity. If data and analytic results have been subjected to such a review, the information may generally be presumed to be of acceptable objectivity. However, in accordance with the OMB standard, this presumption is rebuttable based on a persuasive showing by a petitioner in a particular instance, although the burden of proof is on the complainant.
 - ii. If agency-sponsored peer review is employed to help satisfy the objectivity standard, the review process should meet the general criteria for competent and credible peer review recommended by OMB. 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 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.
2. Confirm that the information to be released has been peer reviewed by a reputable scientific or professional journal, and the journal has agreed to publish the same information.
3. Conduct an internal review, which for the purposes of establishing transparency, ensures that the report or research product clearly

states what the information and data are, how they were obtained, and any reservations or limitations on their use.

Adequacy of Peer Reviews for Highly Influential Scientific

Assessments: In addition to the requirements for influential scientific information, highly influential scientific assessments must meet the more stringent requirements as outlined in Section III of the Bulletin.

Alternative Procedures: The alternative procedure(s) may be applied to a designated report or group of reports as outlined in Section IV of the Bulletin.

Agency Responsibilities for Peer Review Implementation: Agencies will ensure that influential scientific information and highly influential scientific assessments used to support regulatory documents and other decisions, and that is disseminated, meets the requirements of the Bulletin. Agency heads shall also be responsible for establishing an appropriate process for implementation, reporting and clearance of information related to these guidelines. Agencies should designate a peer review coordinator.

Annual Report: Each agency shall provide to the Department by December 1st of each year, the information described in Section VI of the Bulletin. This report will be submitted to the Office of Information and Regulatory Affairs by December 16th of each year.

Regulatory: Each agency that develops regulations that rely on influential scientific information and or highly influential scientific assessments must peer review that information. In addition, agencies must identify at the workplan stage whether scientific information that is influential or highly influential is being used. The Office of Budget and Program Analysis will revise DR1512-1 and workplan forms to be in compliance with the Bulletin.

Exemptions, Deferrals, and Waivers: The agency head may waive or defer some or all of the peer review requirements of the Bulletin where warranted by a compelling rationale. If the agency head defers the peer review requirements prior to dissemination, peer review shall be conducted as soon as practicable.

Agencies need not have peer review conducted on influential scientific information and highly influential scientific assessments if they are exempt as outlined in Section IX of the Bulletin.