The U.S. Experience with Scientific and Evidence-based Rulemaking

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Any views expressed here are solely those of the presenter, and do not necessarily reflect the position of the Office of Management and Budget or the Executive Office of the President.

Key Take-Aways

- Focus on Information Quality and Peer Review
- Why it is important to follow Information Quality guidelines (other than it being a requirement)?
- How to determine if peer review is necessary (vs. simply desirable)?
- The life cycle of the peer review process

Office of Management and Budget

- Support
- Resource Management
- Statutory Offices
  - Financial Management
  - Procurement
  - E-Gov and IT
  - **Information and Regulatory Affairs**

Office of Information and Regulatory Affairs (OIRA)

- The "information policy" function of OIRA includes improving the technical quality of information that agencies disseminate to the public

- Other ‘information policy’ functions include privacy, data security, and e-government initiatives.

OMB's Long Tradition of Ensuring Information Quality

- Federal Reports Act of 1942
- Budget and Accounting Procedures Act of 1950
- Paperwork Reduction Act of 1980 and 1995
  - Requires OMB to "develop and oversee the implementation of policies, principles, standards, and guidelines to…apply to Federal agency dissemination of public information"
  - Expresses the national commitment to minimizing paperwork burdens and improving the quality of information collected while ensuring the greatest possible benefit to the public.
  - Information collections, including surveys are reviewed to assure that information being sought is:
    - Collected via the Least Burdensome approach
    - Not Duplicative of other agency initiatives
    - Has Practical Utility – study design; representativeness and power; privacy; data security.

http://www.whitehouse.gov/omb/inforeg_infocoll#PRA

Information Quality in the Context of Regulatory Planning and Review

- E.O. 12866 and E.O. 13563 govern OMB's oversight of agency rulemaking.
  - OMB reviews whether the information upon which policies are based is consistent with agency IQG's and consistent with principles of scientific integrity.
  - Review includes cross agency coordination; examination of legal authority; technical/scientific underpinnings; evaluation of regulatory impacts.

  http://www.whitehouse.gov/omb/inforeg_regmatters

- Regulatory Impact Analysis
  - Circular A-4 provides guidance on regulatory analysis, including as it relates to risk management decisions

  http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf

Consistent with E.O. 13563

- E.O. 13563, Section *5 Science. Consistent with the President's Memorandum for the Heads of Executive Departments and Agencies, "Scientific Integrity" (March 9, 2009) and its implementing guidance, each agency shall ensure the objectivity of any scientific and technological information and processes used to support the agency's regulatory actions.*

OSTP Director's Guidance to Agencies on Scientific Integrity (December 2010)

- Establish principles for conveying scientific and technological information to the public.
- The accurate presentation of scientific and technological information is critical to informed decision making by the public and policymakers.
- Agencies should communicate scientific findings by including a clear explication of underlying assumptions; accurate contextualization of uncertainties; and a description of the probabilities associated with both optimistic and pessimistic projections, including best-case and worst-case scenarios.

http://www.whitehouse.gov/sites/default/files/microsites/ostp/scientific-integrity-memo-12172010.pdf

Information Quality Act of 2000

- Section 515 of the Treasury and General Government Appropriations Act for FY 2001

- Directed OMB to issue government-wide guidelines that provide policy and procedural guidance to Federal agencies for ensuring and maximizing the quality of information disseminated by Federal agencies.

- OMB issued its government-wide guidelines in interim-final form on September 28, 2001 and in final form on February 22, 2002 (67 FR8452).

Information Quality Act of 2000
Related Initiatives

- Information Quality Guidelines (2002)
  http://www.whitehouse.gov/omb/fedreg/reproducible2.pdf
- Peer Review Bulletin (2004)
  http://www.whitehouse.gov/omb/memoranda/fy2005/m05-03.pdf
- Updated Principles for Risk Assessment (2007)
  http://www.whitehouse.gov/omb/memoranda/fy2007/m07-24.pdf
  - Updates OMB's 1995 guidance. Designed to enhance the scientific quality, objectivity, and utility of Agency risk analyses and will also improve efficiency and consistency among the federal family
- Agency Good Guidance Practices (2007)
  http://www.whitehouse.gov/omb/memoranda/fy2007/m07-07.pdf
  - Goal is to increase the quality, transparency, accountability, and coordination

Government-Wide Information Quality Guidelines

- Agencies must meet basic information quality standards, including pre-dissemination review.
- Applies to financial, statistical, and scientific information.
- Flexibility: The more important the information, the higher the quality standards should be.
  - The Guidelines recognize that high quality comes at a cost and agencies should weigh the costs and benefits of higher information quality.
- Transparency and reproducibility.

To what do the Guidelines apply?

- *Dissemination does include*: "agency initiated or sponsored distribution of information to the public"
  - Includes information which has the appearance of representing agency views *(e.g., justification for a policy position).*

- *Information does not include*: distribution limited to correspondence with individuals or persons, press releases, archival records, public filings, subpoenas or adjudicative processes.

What do the IQ Guidelines Require

- That the quality of information be *appropriate for the context* in which it is used.
  - PRA and IQG emphasize the need to match the quality of the information with its significance for private and public sector policy.
    - There is not a "one size fits all" standard.
- Pre-dissemination review.
  - In the case of scientific information, peer review.
- Opportunity for challenging the quality of information in the context in which it was used.

What we mean by "Information Quality"

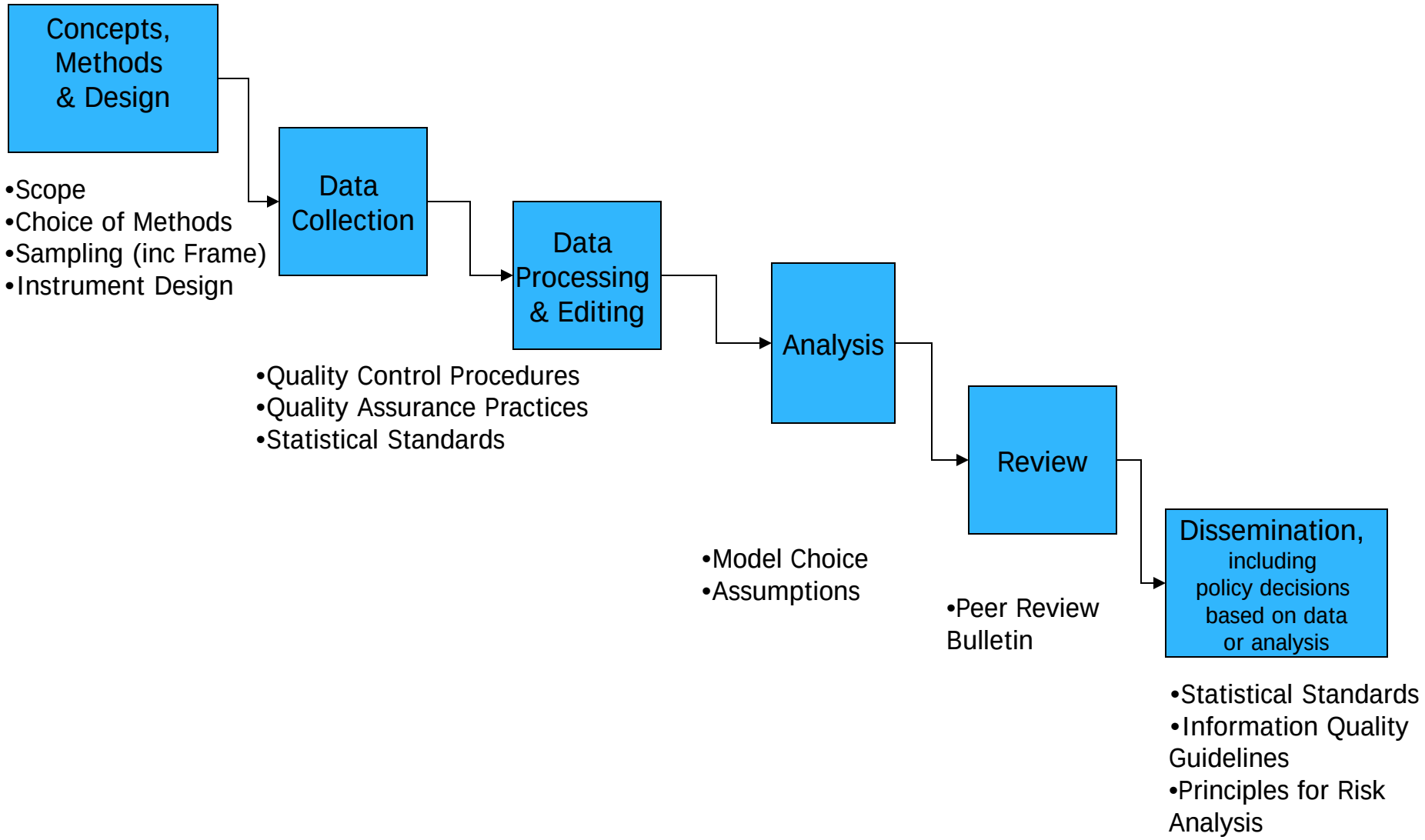
- OMB focuses on objectivity, utility, integrity and reproducibility of information.

- Need to match the quality of the information with its significance for private and public sector policy.
  - There is not a "one size fits all" standard.

Definition of Information Quality

- Utility
  - Usefulness of the information to the intended users.
- Objectivity
  - Whether the disseminated information is presented in an accurate, clear, complete, and unbiased manner.
- Integrity
  - Security and the protection of the information from unauthorized access or revision.

Information Quality Continuum



OMB'S Peer Review Bulletin

- Extension of OMB efforts under Information Quality Act of 2000
  - All gov't information is subject to IQA requirement for pre-dissemantion review
  - Pre-dissemination guidance for influential scientific information

- OMB issued Bulletin on Peer Review December 16, 2004 (FR notice published January 2005).
  - Agencies must peer review certain scientific information before it is disseminated to the public
  - Minimum standards for those reviews
    - More rigorous review required of information that is likely to have the greatest impact on public policy or private sector decisions.
  - General good science/good government guidelines for peer review

2004 Bulletin reinforced by President's Obama's 2009 Memorandum on Scientific Integrity

"When scientific or technological information is considered in policy decisions, the information should be subject to well-established scientific processes, including peer review where appropriate, and each agency should appropriately and accurately reflect that information in complying with and applying relevant statutory standards;"

http://www.whitehouse.gov/the-press-office/memorandum-heads-executive-departments-and-agencies-3-9-09

Coverage of the Bulletin on Peer Review

- "Influential Scientific Information"
  - This is a subset of the information covered by the IQ Guidelines
  - Implementation hinges on the agency's interpretation of how it determines whether "the information will have or does have a clear and substantial impact on important public policies or private sector decisions."
    - Requires thinking about the context in which the information will *likely* be used in the future.
- "Scientific" includes data, analyses, and technical information based on the behavioral and social sciences as well as health and physical sciences.
- Defines a subset of Influential Scientific Information as Highly Influential Scientific Assessments
  - "Scientific Assessment" means an evaluation of a body of scientific or technical knowledge.
  - "Highly Influential Scientific Assessments" are information products that the agency or OMB determines to have a potential impact of more than $500 million in any year, or are novel, controversial, or precedent-setting or have significant interagency interest.

Determining the Level of Pre-dissemination Review

- Is it subject to IQ Guidelines?
  - Is the agency disseminating it?
- Is it also subject to Bulletin?
  - Is it influential scientific information?
    - Is it also highly influential scientific assessment
- Is it also subject to the Principles of Risk Assessment?
- Is it also subject to Circular A-4?

Dissemination

- "agency **initiated** or **sponsored** distribution of information to the public"
  - Includes information which has the appearance of representing agency views *(e.g., justification for a policy position).*
  - Does not include information that a federally employed scientist or Federal grantee or contractor publishes and communicates in the same manner as his/her academic colleagues.
    - Researchers should use appropriate disclaimers such as "these views those of the author and do not necessarily reflect the view" of the agency.
  - "Agency **sponsored** refers to situations where an agency has directed a third party to disseminate information or where the agency has the authority to review and approve the information before release.
    - Agencies can provide funding to researchers without 'sponsoring' the dissemination."
  - Dissemination does not include distribution limited to correspondence with individuals or persons, press releases, archival records, public filings, subpoenas or adjudicative processes.

OMB Definition of Influential: How do we achieve appropriate for the context?

- Influential Information:
  - "Influential" means that the agency can reasonably determine that dissemination of the information "**will have or does have a clear and substantial impact on important public policies or important private sector decisions.**"
  - Influential information needs to meet additional quality standards including reproducibility (capable of)
  - Agencies define criteria for influential within context of their mission.

USDA's
Definition of Influential

- Additional detail on OMB definition:
- In regulatory context, influential if the information will have a clear and substantial impact on resolution of one or more key issues in an economically significant rulemaking
- In non-rulemaking: consider breadth and intensity of impact. More likely to be influential if affects a broad range of parties and has costly or crucial impacts.

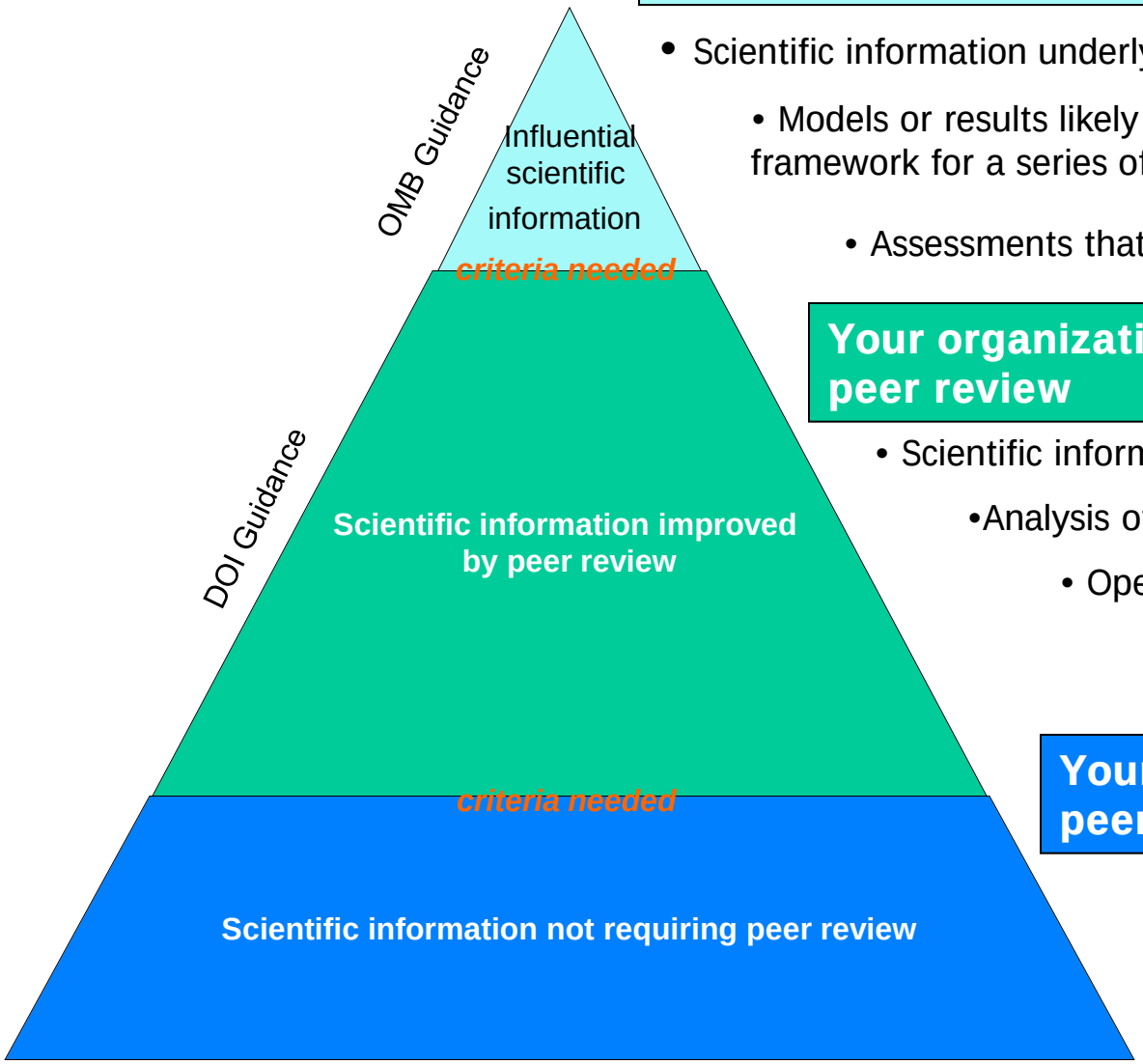
Further Granularity based on Mission Statement and Products: example from FWS

- As a general rule, FWS considers an impact clear and substantial when a specific piece of information or body of information is a principal basis for a FWS position .
  - Information is influential if the same decision would be difficult to arrive at if that information was absent.
  - If a FWS position would lose its fundamental scientific, financial or statistical underpinnings if the information was absent, then this information is the principal basis for the position, and its presence has a clear and substantial impact.

- FWS interprets the phrase "can reasonably determine" to mean that the agency is convinced that the impact has a high probability (certainty) of occurring.

- It should also be noted that the definition applies to "information" itself, not to decisions that the information may support. Even if a decision or action by FWS is itself very important, a particular piece of information supporting it may or may not be "influential."

- http://www.fws.gov/informationquality/topics/IQAguidelines-final82307.pdf



Information is subject to OMB Bulletin

- Scientific information underlying significant policies/decisions
- Models or results likely to set precedents or form a framework for a series of smaller decisions.
- Assessments that impact regional economies

Your organization may require peer review

- Scientific information to support local
- Analysis of monitoring data
- Open File Reports
- Research manuscripts

Your organization may not require peer review

- Routine monitoring data
- Testimony
- Press releases
- Fact Sheets

What gets Reviewed when Science and Policy are Integrated?

- Does not apply to the policy or management decision, but governs review of the underlying scientific information that, along with other factors, informs a decision maker.
  - For example, proposed management options associated with parts of the NEPA process would not be subject to peer review.
- However, this peer review policy does apply to the components of an EIS that present a scientific evaluation or are otherwise based upon scientific information or analytical models.

Scope of the Review: Importance of Charge Questions

- The goal of each peer review is to ensure that:
  - assumptions, findings, and conclusions of the scientific information are clearly stated and supported;
  - identify oversights, omissions, and inconsistencies; and
  - encourage authors to more fully acknowledge limitations and uncertainties.

Peer Review Requirements for "Influential Scientific Information"

- Flexible guidelines for the choice of a peer review mechanism (e.g., individual letter reviews or panels). Consider/weigh
  - complexity of the information, importance of the information to decision making, and benefits and costs of additional review.
- Select peer reviewers based on expertise, experience and skills, and consider possible conflicts of interest.
  - Peer reviewers must representative the relevant scientific and technical perspectives (balance).
  - Peer reviewers must not have participated in the development of the work product (independence).
- Agencies must instruct peer reviewers to prepare a report with their findings, must disclose the names and organizational affiliations of the reviewers in the final report, and must place the report on the agency's website.

Additional Requirements for Highly Influential Scientific Assessments

- Scientists employed by the sponsoring agency may not be reviewers (with rare exceptions).
- Avoid repeated use of the same reviewer.
- Provide reviewers with sufficient information to understand the data, analytical procedures, and assumptions in the draft assessment.
- Where feasible and appropriate, make the draft scientific assessment available to the public and sponsor a public meeting for presentations to the peer reviewers by members of the public.
- Prepare a written response to the report and place the response on the website.

Exemptions

- Information disseminated in adjudications.
- Regulatory Impact Analyses or Regulatory Flexibility Analyses subject to OMB review, *except for underlying data and analytical models.*
- Routine statistical information released by federal statistical agencies.
- Accounting, budget information, entitlements
- Agency head may waive or defer some or all of the peer review requirements on in compelling circumstances
  - Interfere w/ time-sensitive health and safety or national security

Peer Review Planning

- Website
  - Update as needed, but at least every six months
  - All planned information subject to the Bulletin
  - Link to relevant documents
  - Mechanism to alter interested members of updates
  - Mechanism for public comment
- Plan
  - Description
  - Level of influence
  - Mechanism (e.g., panel vs individual letter)
  - Number of reviewers
  - Expertise needed
  - Opportunities for public comment and nomination of reviewers

Summary of Agency Responsibilities (the full life cycle)

- Categorize the types of information disseminated and develop criteria for regarding which information products are covered by the Bulletin - to streamline implementation
- Develop plan for peer reviewing those items – to encourage early planning
- Develop a Peer Review Agenda describing the peer review plan for each item – for transparency
- Place the agenda on website and update *at least* every six months – for timeliness
- Provide for public comment on the peer review plans – for early input
- Develop a charge – to focus reviewers and ensure review provides appropriate level of guidance
- Respond to peer reviewer comments – to actually improve the quality of the document
- Disseminate peer review report on web site – for transparency
- Provide an annual report to OMB summarizing the previous fiscal year's peer reviews – goes to Congress.

Other Executive Office Initiatives Related to Scientific Research

- Scientific Integrity
- Public Access to Federally Funded Research
  - Peer-reviewed publications
  - Managing data for public access
- Open Data
  - Inventory of agency datasets
  - Making “public access” the expectation