Revised Draft Information Quality Guidance on Human Health, Safety, and Environmental Risk Information

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SUMMARY: There has long been controversy over the role of policy or "science policy" assumptions or defaults embedded in health, safety, and environmental risk information disseminated to the public by federal agencies and used to develop regulations. In the Information Quality Act, which became law in 2000, and which supplemented the Paperwork Reduction Act of 1995, Congress required OMB to develop and issue guidance to federal agencies on ensuring and maximizing the quality of all types of information disseminated to the public, including its "objectivity" and "utility". In its government-wide information quality guidelines issued in February 2002, OMB defined the terms "objectivity" and "utility" and also specifically addressed scientific information containing analysis of risks to human health, safety and the environment. Since then, it is clear that there still remain issues with regard to the requirements of "objectivity" and "utility" as applied to health, safety, and environmental risk information disseminated to the public. The purpose of this guidance is to clarify the meaning of the terms "objectivity" and "utility" as applied to such information, as those terms are used in the IQA and the existing OMB IQA guidelines. The National Research Council of the National Academies recently recommended that a previous OMB guidance proposal on this topic be withdrawn and replaced by more general goals and principles. This guidance follows that NRC recommendation. It supplements, and does not supersede or modify, the OMB government-wide guidance of February 22, 2002 (67 FR 8452).

SUPPLEMENTARY INFORMATION

Legal Authority

These guidelines are promulgated pursuant to section 515 of Public Law 106-554, 114 Stat. 2763, 2763A-153, Dec. 21, 2000, 44 U.S.C. § 3516, note, commonly referred to as the Information Quality Act or IQA (or also as the Data Quality Act or DQA). The IQA supplemented the information dissemination and quality provisions of the Paperwork Reduction Act of 1995 (the "PRA") by requiring OMB to issue, no later than one year after its enactment, guidance to Federal agencies "for ensuring and maximizing the quality, objectivity, utility, and integrity of information (including statistical information) disseminated by Federal agencies." The IQA and PRA also required Federal agencies to issue their own guidelines in compliance with the OMB guidance.

Background

OMB has already addressed how the requirements of the IQA and PRA apply to scientific information generally, and to human health, safety, and environmental risk information specifically, in two previous sets of guidelines.

On September 28, 2001, and again on February 22, 2002, OMB issued its initial government-wide guidelines on information quality. Those guidelines addressed all types of information disseminated to the public by Federal agencies, and therefore covered human health,

safety, and environmental risk information. They provided specific definitions of "objectivity" and "utility", and they required that agency information products meet minimum standards for objectivity and utility. They also established a higher standard of transparency and reproducibility for "influential" scientific information, as defined, and they specifically addressed human health, safety, and environmental risk information. Those original guideline provisions that encompass scientific information that are most pertinent to this current proposal are summarized below.

"Objectivity" is defined as requiring that information be presented "in an accurate, clear, complete, and unbiased manner." In a "scientific context", the information must supply "the supporting data and models." The substance of the information must be "accurate, reliable, and unbiased"; and "in a scientific context", "the original and supporting data shall be generated, and the analytic results shall be developed, using sound statistical and research methods." "Competent and credible" peer review establishes a rebuttable presumption of "acceptable objectivity". 67 FR at 8459 3d col.

"Influential" scientific information must include "a high degree of transparency about data and methods to facilitate the reproducibility of such information by qualified third parties." 67 FR at 8460 1st col.

"Utility" is defined as "usefulness of the information to its intended users, including the public." In the case of scientific risk information, the audiences would include agency risk managers, peer reviewers, the scientific community, and the public.

With regard specifically to information on human health, safety, and environmental risk, agencies were required to either adopt or adapt the requirements of the Safe Drinking Water Act Amendments of 1996.

The agencies are to interpret the reproducibility and peer-review standards in a manner "appropriate to assuring the timely flow of vital information from agencies to medical providers, patients, health agencies, and the public," and the requirements may be waived temporarily under urgent situations "in accordance with the latitude specified in agency-specific guidelines." *Id*. 2d col.

On December 16, 2004, OMB issued guidelines setting out requirements for peer review of "influential" scientific information and "highly influential" "scientific assessments". 70 FR 2664, Jan. 14, 2005. Of particular pertinence to these current draft guidelines is the requirement that peer reviewers "shall be charged with reviewing scientific and technical matters, leaving policy determinations for the agency. Reviewers shall be informed of applicable access, objectivity, reproducibility and other quality standards under the Federal laws governing information access and quality." *Id*. at 2675 1st & 2d cols. The preamble of the peer review guidance further explains: "[W[here appropriate, reviewers should be asked to provide advice on the reasonableness of the scientific judgments made from the scientific evidence. However, the charge should make clear that the reviewers are not to provide advice on the policy (*i.e*., the amount of uncertainty that is acceptable or the amount of precaution that should be embedded in

an analysis). Such considerations are the purview of the government." *Id*. at 2669 (footnote omitted).

On January 9, 2006, OMB released for public comment proposed guidance "to enhance the technical quality and objectivity" of human health, safety, and environmental risk assessments. In line with the original government-wide quality and peer review guidelines, this proposed guidance set higher standards for "influential" risk assessments. OMB received 79 public comments on the proposed guidance. (The public comments are available at http://www.whitehouse.gov/omb/inforeg/comments_rab/list_rab2006.html.)

After the guidance was proposed, seven Federal agencies co-sponsored a review of the proposed guidance by the National Research Council ("NRC") of the National Academies. The NRC committee held one public meeting and requested comments from the Federal agencies on a number of topics. The NRC questions and agency responses are in Appendix E of the report issued by NRC.

On January 11, 2007, the NRC issued a report on its review of the proposed guidance.[1] The report viewed the January 9 draft as inadequate in many respects, and recommended that it be withdrawn, and that instead OMB issue guidance that outlines goals and principles for risk assessment rather than rigid technical requirements, and direct agencies to issue their own technical guidelines consistent with those goals and principles.

OMB has decided to follow the NRC report's recommendation to issue goals and principles (also termed standards herein) instead of detailed technical guidance. Agency technical guidance will be reviewed by OMB for consistency with those goals and principles

In developing these goals and principles, OMB believes it is essential that it address the issue of how to make risk assessments scientifically "objective", in compliance with the IQA and its previous quality and peer review guidance, and how, at the same time, to ensure and maximize the utility of risk information. The NRC report viewed the OMB January 9 draft as largely failing to address the role of policy and default assumptions in risk assessment as currently practiced; however, the NRC report omitted any discussion of the "objectivity" requirement in the IQA and the existing OMB guidelines.[2]

Objectivity is the bedrock of scientific information. Yet for many years risk information, including assessments, disseminated by some Federal agencies has intermingled scientific data and judgment with "default options" or "assumptions" that are based substantially on policy considerations. Those default options or assumptions have been used to bridge limitations, gaps, and uncertainties in the science and produce a firm estimate of risk that can be utilized by risk

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[1] SCIENTIFIC REVIEW OF THE PROPOSED RISK ASSESSMENT BULLETIN FROM THE OFFICE OF MANAGEMENT AND BUDGET (The National Academies Press 2007) .

[2] The Statement of Task for the NRC committee that was negotiated with the sponsoring agencies contained no mention of the IQA or previous OMB IQA guidance.

managers and others.[3] Although such defaults or assumptions are usually identified as such, their commingling with the scientific evidence in producing risk information can introduce substantial policy bias into the summary risk information disseminated to the public. A characterization of risk, whether quantitative or qualitative, that is based on a combination of science and policy cannot be viewed as "objective", or unbiased and accurate, and, to the extent it is perceived as an assessment of the science, it is misleading and lacking in utility as scientific information. Commingling of policy and science also makes more difficult, if not impossible, the job of peer reviewers, who are prohibited under the OMB guidelines from addressing policy issues in reviewing scientific information and assessments. While it is understood that total objectivity and absence of bias is usually not possible due to many human factors, it is possible to avoid recognizable policy bias in an assessment of the scientific data regarding risk. Once the state of the science has been evaluated and articulated, it is then possible, in a separate analysis, to decide whether and how to fill gaps and uncertainties in the science with policy-driven default options or assumptions in order to establish regulatory standards required by statute.

Some agency-specific guidelines issued following the OMB government-wide guidance have failed to address clearly the issue of objectivity and bias in risk information. For example, the EPA guidance states that, on the one hand, it will disseminate risk information that is objective, yet it also states that it will continue to follow its current Risk Characterization Handbook (see fn. 1, below), and that its presentations of information on risk will be "comprehensive, informative, and understandable", but not that such presentations will be unbiased. Sec. 6.4. The CPSC guidelines make the same statement.[4]

In view of the inconsistencies among agencies on presentation of risk information, conflicts between agency risk assessment and characterization practice, and the requirement in the IQA and OMB guidelines for objectivity, OMB finds it necessary to clarify through goals and principles how the objectivity and utility requirements apply to risk information.

The term "risk information" is used herein to ensure that all forms of scientific information disseminated to the public that are likely to be perceived by the public as risk information are covered, while avoiding the definitional problems associated with use of the term "risk assessment" that were explained in the NRC report. "Risk information" therefore includes hazard characterizations or identifications that are not clearly identified as screening tools, such as the hazard characterizations disseminated in the Report on Carcinogens program, reference doses or action levels, and qualitative risk summaries in agency fact sheets and similar documents.

As with the original OMB guidelines of February 22, 2002, agencies are to interpret this guidance in a manner appropriate to assuring the timely flow of vital information from agencies to medical providers, patients, health agencies, and the public, and the requirements may be

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[3] See, for example, the EPA Risk Characterization Handbook, which states: "There is an understood, inherent, EPA bias that in the light of uncertainty and default choices the Agency will decide in the direction of more public health protection than in the direction of less protection. However, it is not always clear where such bias enters into EPA risk assessments." Sec. 3.2.9 at 41.

[4] On the other hand, see the HHS guidelines, which state that risk assessment information must be "unbiased" in order to be objective. Sec. 4.d.

waived temporarily under urgent situations "in accordance with the latitude specified in agency-specific guidelines."

GUIDANCE ON ENSURING AND MAXIMIZING THE QUALITY OF RISK INFORMATION

Goals

1. To ensure and maximize the scientific objectivity, accuracy, and absence of significant policy bias in risk information disseminated to the public and thereby enhance its credibility and reduce controversy.

2. To maximize the utility of risk information disseminated to the public, the scientific community, and government regulatory officials ("risk managers") by informing them of significant limitations in the scientific evidence, significant uncertainties in the state of the science, and both realistic and realistic worst-case risk scenarios based on professional assessment and judgment so that they are aware of the state of the science and the degree to which any exercise of policy discretion affects a decision regarding regulatory or design decisions or standards and any gaps in the science that could be addressed by new research.

3. To provide for a means by which agency scientists/risk assessors can participate in discussions with risk managers on policy matters such as appropriate margin of safety and degree of conservatism.

4. To facilitate peer review of risk information by clearly separating science from policy.

5. To ensure that risk information addresses unusually vulnerable, sensitive, or highly exposed populations consistent with the requirement for objectivity.

6. To provide sufficient flexibility for agencies to accommodate the objectivity and utility requirements to their specific programs and different types of documentation, or to waive requirements in urgent situations.

Principles and Standards for Risk Information

The following principles and standards shall apply unless inconsistent with statutory mandates. These principles and standards supplement, and do not supersede or modify, the requirements for scientific information and assessments in the previous IQA guidance issued by OMB.

Risk information in support of a significant regulatory action, as defined in Executive Order 12866, is presumed to be influential scientific risk information.

1. All presentations of risk information shall represent realistic appraisals based on the best available scientific evidence and professional scientific judgment concerning that evidence.

2. Risk information that is not being used as the basis for a regulatory decision shall be presented and summarized in an objective scientific manner. This means that the information shall accurately convey the state of the science without any infusion of significant policy views -- in particular, without use of policy-influenced defaults or assumptions, or views regarding appropriate margins of safety or conservatism (*i.e.*, bias in the direction of indicating more risk than is supported by the science and professional scientific judgment based on the science). Such risk information shall include, where the data warrant, an expression of professional scientific judgment concerning the level of confidence that can be placed in the underlying data, the scientific understanding of the data, and the overall conclusions in the information presented. Single expressions or point estimates of risk shall not be presented when not supported by the scientific evidence and professional scientific judgment concerning that evidence. Expression of risk as a range must also be based on scientific evidence and professional scientific judgment concerning the scientific evidence. If the scientific data and understanding do not support either a single estimate or a range, neither shall be used; rather, the extent of uncertainty that prevents such an expression of risk shall be explained.

3. Risk information that is to be used as the basis for a regulatory decision shall be presented to the risk manager and decisionmaker in an objective scientific manner, as described above. A separate analysis, in which agency scientists/risk assessors may participate, may explore the options for arriving at a regulatory decision in the face of limitations and uncertainties in the scientific risk information, and the specifics of a particular statutory mandate. This separate analysis shall address the extent to which any of the options are based on policy rather than scientific evidence, the basis for preferring any particular option, and any differences in perceptions of risk and impacts on regulatory actions that are likely to result from choice of a particular option.

4. The above requirements for scientific objectivity in describing the state of the science do not preclude the exercise and presentation of views based on professional scientific judgment based on the evidence; however, such views shall be distinguished from scientific knowledge, and the basis for any such judgments in the scientific evidence shall be clearly explained, as well as the level of confidence.

5. When risk information is disseminated to the public in a relatively brief and summary manner, such information shall include identification of any key determinants of risk that will help interested persons to discriminate between levels of risk based on different circumstances. Hazard characterizations shall not be disseminated without such additional information when there is a significant potential that interested persons will perceive the characterization as an expression of risk. Even when risk information is disseminated in a more comprehensive manner, as in a full risk assessment, any presentation of a hazard characterization in the course of the assessment shall be clearly explained to not be an expression of risk.

6. All presentations of risk information shall include information on any individuals, populations, resources, or other entities that scientific evidence indicates are likely to be more vulnerable, sensitive, or more highly exposed and therefore likely to be at significantly higher risk, and any other unusual but reasonably foreseeable circumstances that would be likely to increase risk significantly.

7. Risk information shall include information on the adversity and severity of the effects at risk. If the risk information is based on precursor effects or events, or other effects or events the significance of which is uncertain, the relationship of any such effect to a recognized adverse effect and any significant uncertainty regarding the significance of the effect shall be described.

8. A model or simulation used in the generation of risk information shall not be based to any significant extent on policy-influenced defaults or assumptions. When modeling or simulation plays a significant role in assessing the science, the assessment shall describe any significant scientific data, particularly empirical data, that do not fit the model or simulation, the extent to which the model or simulation has or has not been validated, and the overall level of confidence that can be placed in the model based on professional scientific judgment. If alternative models or simulations are potentially applicable, the alternatives and their effect on the assessment shall be described, and the choice of any model or simulation over alternatives shall be explained and justified in an objective scientific manner.

9. If available scientific evidence indicates that mitigation of one risk that is presented in the risk information would result in increase in another risk, this shall be explained. If there is a significant possibility that, based on the risk information, members of the public or risk managers will face choices between or among different risks, those risks shall be compared based on an assessment that complies with this guidance.

Agency-specific guidance

Any agency-specific guidance developed or modified to implement or conform to this guidance shall be submitted to OMB for review for consistency with these goals and principles and standards. Any such guidance shall be proposed for public comment and submitted to OMB for review within one year of publication of this guidance. Until any such agency-specific guidance is approved by OMB, this guidance shall apply.

Effective date and updating of existing risk information

(a) This guidance shall be effective immediately unless prevented by the need to comply with other legal requirements.

(b) Risk information disseminated prior to the effective date of this guidance that does not comply with the guidance shall be brought into compliance as soon as agency resources permit, or as necessitated by the need to respond to a petition for correction.