CRE GENERIC COMMENTS TO ALL FEDERAL AGENCIES RELATED TO DATA QUALITY GUIDELINES

Introduction

OMB's Data Quality guidelines have provided a strong foundation for improvement in the overall quality of information which the federal government disseminates to the public. However, as acknowledged by Congress in passage of the Data Quality Act, individual agencies must promulgate their own conforming Data Quality guidelines that address the unique characteristics and information products of their programs. It is imperative that these agency guidelines be drafted in such a way as to ensure that they are workable, effective, and in keeping with the government-wide standards set by OMB.

To assist in this process, the Center for Regulatory Effectiveness (CRE) has compiled a list of key issues related to the Data Quality guidelines and reviewed a large number of agency guidelines issued to date to see if and how these important topics have been addressed. CRE sees these as "cross-cutting" issues, in that they would apply to most if not all federal agencies. The balance of the paper will provide:

- Statement of the cross-cutting issue.
- Explanation of the issue, its importance, and CRE's recommended approach.
- Examples of current agency proposals on the issue which are satisfactory (if any) and the reasoning for that conclusion.
- Examples of current agency proposals on the issue which are unsatisfactory (if any) and the reasoning for that conclusion.

CROSS-CUTTING ISSUES RELATED TO AGENCY DATA QUALITY GUIDELINES

(1) Exemptions from Applicability of the Data Quality Guidelines

OMB's interagency Data Quality guidelines exempt some types and categories of information the Data Quality guidelines. Many other agencies have proposed additional exemptions. *As demonstrated in the accompanying Legal Memorandum, the OMB and additional agency exemptions from the Data Quality guidelines contradict clear congressional intent to the extent that they exempt any information that an agency has in fact made public. Neither OMB nor any other federal agency has authority to make such exemptions.*

OMB's interagency Data Quality guidelines exempt from their coverage certain publicly disclosed federal agency information:

> "Dissemination" means agency initiated or sponsored distribution of information to the public (see 5 CFR 1320.3(d) (definition of "Conduct or Sponsor")). Dissemination does not include distribution limited to government employees or agency contractors or grantees; intra- or interagency use or sharing of government information; and responses to requests for agency records under the Freedom of Information Act, the Privacy Act, the Federal Advisory Committee Act or other similar law. This definition also does not include distribution limited to correspondence with individuals or persons, press releases, archival records, public filings, subpoenas or adjudicative processes.

67 FR 8452, 8460 (Feb. 22, 2002).

This definition of "dissemination" is considerably narrower than OMB's previous definitions of this term in a PRA context. For example, in OMB Circular A-130, at page 3 OMB defined "dissemination" to mean:

> ... the government initiated distribution of information to the public. Not considered dissemination within the meaning of this Circular is distribution limited to government employees or agency contractors or grantees, intra-or-inter-agency use or sharing of government information, and responses to requests for agency records under the Freedom of Information Act (5 U.S.C. 552) or Privacy Act."

Other agencies have included the OMB exemptions in their proposed Data Quality guidelines. Some agencies have proposed to expand the OMB exemptions, or to add new exemptions. For example:

Retroactivity Exemption (See Issue #2)

Several agencies, such as NIH at page 4 of its guidelines, make statements indicating that their guidelines, and the OMB guidelines, will apply only to information that is initially disseminated initially after October 1, 2002. This proposed exemption contradicts OMB's interagency guidelines which specify that they apply to information created or originally disseminated prior to October 1, 2002, if an agency continues to disseminate the information after that date.

Case-by-Case Exemption (See Issue #3)

Several agencies, including EPA at pages 22-23 of its proposed guidelines, propose application of the PRA's Data Quality guidelines on a case-by-case basis, rather than application of them to all information disseminated by the agency.

Rulemaking Exemption (See Issue #4)

A number of agencies, including EPA at page 22-23 and the Department of the Treasury at page 6 of their proposed guidelines, have stated that the Data Quality error correction process required by OMB's interagency Data Quality guidelines will not apply to information in proposed rulemakings, and that any alleged errors will be addressed only through the rulemaking notice and comment process. It is not clear from these proposed exemptions whether the agencies believe that any of the PRA's Data Quality standards apply to information disseminated during rulemakings.

Adjudicative Processes Exemption

EPA's proposed data quality guidelines, at page 17, substantially expand OMB's adjudicative processes exception by broadening it to include, *inter alia*:

> Distribution of information in documents relating to any formal or informal administrative action determining the rights and liabilities of specific parties, including documents that provide the findings, determinations or basis for such actions. Examples include the processing or adjudication or applications for a permit, license, registration, waiver, exemption, or claim; actions to determine the liability of parties under applicable statutes and regulations; and

determination and implementation of remedies to address such liability.

The OMB interagency and individual agency Data Quality guidelines are promulgated under and implement the Information Dissemination requirements of the Paperwork Reduction Act ("PRA"). 44 U.S.C. §§ 3504(d)(1), 3516 note. The Multinational Legal Services (MLS) Legal Memorandum accompanying CRE's Generic Data Quality Comments explains that the relevant statutory text and legislative history demonstrate clear congressional intent that these Data Quality guidelines, like the PRA's other Information Dissemination requirements, apply to any and all information that federal agencies have in fact made public. By contrast to the PRA's separate Collection of Information requirements, there are no statutory exemptions from any of the PRA's Information Dissemination requirements. OMB's attempt to create exemptions by restricting the definition of "dissemination" in its interagency Data Quality guidelines contradicts Congress' own pervasive and all encompassing use of this term. OMB's "dissemination" exemptions in its interagency Data Quality guidelines are also inconsistent with OMB's prior, much broader definition of "dissemination" in implementing the PRA's Information Dissemination requirements. The additional exemptions proposed by other federal agencies also violate clear congressional intent because OMB cannot provide any exemptions from its interagency Data Quality guidelines, and the other agencies have to comply with OMB"s interagency guidelines. 44 U.S.C. §§ 3504(d)(1); 3506(a)(1)(B); 3516 note.

(2) Retroactive Application of the Data Quality Guidelines

In compliance with the statute, each agency's Data Quality guidelines must become effective on October 1, 2002. The guidelines must apply to information being disseminated on or after October 1, regardless of when the information was first disseminated. This retroactivity principle is explicitly enunciated in OMB's February 22, 2002 guidelines, at III.4. All agency guidelines are required to comply with the requirements set forth by OMB in their interagency February 22nd Final Guidelines. 44 U.S.C. §§ 3504(d)(1); 3506(a)(1)(B); 3516 note.

Example(s) of Satisfactory Agency Proposals

Department of Justice

DOJ's draft guidelines state at page 2, "These guidelines will cover information disseminated on or after October 1, 2002, regardless of when the information was first disseminated...."

These guidelines are in full compliance with the retroactivity provision in OMB's February 22nd guidelines.

Example(s) of Unsatisfactory Agency Proposals

National Institutes of Health

The NIH guidelines state at p.4, "The OMB guidelines apply to official information (with the NIH imprimatur) that is released on or after October 1, 2002."

NIH's statement about OMB's guidelines directly contradicts the text of OMB's guidelines which clearly state that they "shall apply to information that the agency disseminates on or after October 1, 2002, regardless of when the agency first disseminated the information." [Emphasis added]

(3) Individual Agency Guidelines Must Comply with OMB's Interagency Guidelines; and There Are No Case-By-Case Exemptions From Applicability Of The Guidelines

OMB's interagency Data Quality guidelines implement section 3504(d)(1) of the PRA. 44 U.S.C. § 3516 note. Section 3504 \(d)(1) requires that "with respect to information dissemination, the [OMB] director shall develop and oversee the implementation of policies, principles, standards, and guidelines to apply to Federal agency dissemination of public information, regardless of the form or format in which such information is disseminated...." 44 U.S.C. § 3504(d)(1). All federal agencies subject to the PRA must comply with OMB's interagency Data Quality guidelines when they issue their own Data Quality guidelines. 44 U.S.C. §§ 3504(d)(1); 3506(a)(1)(B); 3516 note. The MLS Legal Memorandum accompanying CRE's Generic Data Quality Guidelines explains that Congress clearly intended OMB's Data Quality guidelines to apply to all information agencies subject to the PRA in fact make public

Example(s) of Satisfactory Agency Proposals

None

All agency guidelines reviewed appear to try to reduce significantly the binding nature indicated in the OMB guidelines.

Example(s) of Unsatisfactory Agency Proposals

Multiple Agencies

None of the agency proposals reviewed make any reference to the directives of the PRA; they refer only to section 515 of the FY 2001 Consolidated Appropriations Act, the Data Quality Act itself, and ignore the fact that the Data Quality Act expressly states that the Data Quality guidelines are promulgated under and implement the PRA.

EPA's proposal states that its guidelines do not impose any "legally binding requirements or obligations.... The guidelines may not apply to a particular situation based on the circumstances, and EPA retains discretion to adopt approaches on a case-by-case basis that differ from the guidelines, where appropriate." Sec. 1.1. "Factors such as imminent threats to public health or homeland security, statutory or court-ordered deadlines, or other time constraints, may limit or preclude applicability of these guidelines." Sec. 1.2. Information that generally would not be covered by the guidelines includes "information in press releases and similar announcements: These guidelines do not apply to press releases, fact sheets, press conferences or similar communications in any medium that announce, support the announcement or give pubic

notice of information EPA has disseminated elsewhere." Sec. 1.3, Ins. 482-85.

The CDC/ATSDR proposal has lists of information products to which the guidelines do and do not apply. It also includes press releases and interviews, but does not include "similar announcements," as does EPA. The umbrella HHS guidelines state that the quality standards do not apply to press releases. Sec. D.3.

The NIH proposal also lists with considerable specificity types of information covered and not covered. Press releases are listed as not covered. There is no qualification as to whether a press release simply announces, supports an announcement, or gives public notice of information the agency has disseminated elsewhere, as in EPA's proposal. Sec. II, 2. The NIH proposal states that its information dissemination products must conform to the OMB guidelines. Sec. V, 1.

DOT's proposal states that it contains only "suggestions, recommendations, and policy views of DOT. They are not intended to be, and should not be construed as, legally binding requirements or mandates. These guidelines are intended only to improve the internal management of DOT . . . ." Sec. III, b. The DOT proposal is very specific in excluding certain types of information. Information presented to Congress is excluded if it is "not simultaneously disseminated to the public". III, j. Also excluded are "[p]ress releases and other information of an ephemeral nature, advising the public of an event or activity of a finite duration - regardless of medium". III, k.

The DOL proposal begins with a Preface which states that the document provides an "overview" of the agency's "efforts" to ensure and maximize information quality. DOL states that the guidelines are only intended to improve the internal management of the government and "are not intended to impose any binding requirements or obligations on the Department . . . A Departmental agency may vary the application of information quality guidelines in particular situations where it believes that other approaches will more appropriately carry out the purpose of these guidelines or will help an agency to meet its statutory or program obligations." DOL also specifies certain types of information to which the guidelines do not apply, including press releases, adjudicative processes, policy guidance, and statements of legal policy or interpretation. Sec. on "Scope and Applicability".

The CPSC proposal states that information is not subject to the guidelines if it states explicitly that it was not subjected to them. P.5.

Finally, all of the above agency proposals exempt material relating or adjudicatory proceedings or processes, including briefs and other information submitted to courts. *See e.g.*, DOT at IV, g.

(4) Inclusion of Rulemaking Information in the Data Quality Act Petition Process

Information present in rulemaking records, both completed and ongoing, comprises much of the information disseminated by federal agencies. Neither the Data Quality Act itself nor OMB's February 22nd agency-wide guidelines exclude rulemaking records from coverage.

Example(s) of Satisfactory Agency Proposals

None

Example(s) of Unsatisfactory Agency Proposals

EPA; Treasury

EPA's proposed guidelines, at pages 22-23, appear to exclude most rulemaking records from the Data Quality Act petition and correction process:

> ... where a mechanism by which to submit comments to the Agency is already provided. For example, EPA rulemakings include a comprehensive public comment process and impose a legal obligation on EPA to respond to comments on all aspects of the action. These procedural safeguards assure a thorough response to comments on quality of information. EPA believes that the thorough consideration required by this process meets the needs for the correction of information process. A separate process for information that is already subject to such a public comment process would be duplicative, burdensome, and disruptive to the orderly conduct of the action.
>
> If EPA cannot respond to a complaint in the response to comments for the action (for example, because the complaint is submitted too late to be considered along with other comments or because the complaint is not germane to the action), EPA will consider whether a separate response to the complaint is appropriate. EPA may consider frivolous any complaint which could have been submitted as a timely comment in the rulemaking or other action but was submitted after the comment period.

The Treasury Department's proposed guidelines (page 5) also have a rulemaking

exclusion.

These proposed exclusions could, as a practical matter, remove all EPA and Treasury rulemaking records from coverage under the Data Quality Act. This exclusion is contrary to the letter and intent of the Act, as explained in the MLS Legal memorandum accompanying CRE's Generic Data Quality Guideline comments.

Moreover, many rulemakings are very lengthy proceedings. Information in a rulemaking public docket may be publicly available for years before the agency takes any action on comments on the information in its promulgation of final rules. Not allowing a Data Quality guidelines petition to correct this information before promulgation of final rules would violate OMB's interagency Data Quality guidelines, which require a timely correction process for correcting errors in all agency information made publicly available, including "preliminary information" used in agency rulemakings:

> ... agencies shall establish administrative mechanisms allowing affected persons to seek and obtain, where appropriate, *timely correction of information* maintained and disseminated by the agency that does not comply with OMB or agency guidelines. These administrative mechanisms shall be flexible, *appropriate to the nature and timeliness of the disseminated information*, and incorporated into agency information resources management and administrative practices.
>
> i. *Agencies shall specify appropriate time periods* for agency decisions on whether and how to correct the information, and agencies shall notify the affected persons of the corrections made.
>
> ii. If the person who requested the correction does not agree with the agency's decision (including the corrective action, if any), the person may file for reconsideration within the agency. The agency shall establish an administrative appeal process to review the agency's initial decision, *and specify appropriate time limits* in which to resolve such requests for reconsideration.

67 FR 8452, 8459 (Feb. 22, 2002)(emphasis added).

> OMB does not believe that an exclusion for preliminary information is necessary and appropriate. It is still important that the quality of preliminary information be ensured and that preliminary information be subject to the administrative complaint-and-correction process.

66 FR 49718, 49720 (Sept. 28, 2001).

(5) Third-Party Submissions of Data to An Agency

Much of the information disseminated by federal agencies is originally submitted by states or private entities. In addition, federal agencies often disseminate research from outside parties, some of which is funded by the agency.

The MLS Legal Memorandum accompanying CRE's Generic Data Quality Comments explains that Congress clearly intended the Data Quality guidelines to apply to all information that agencies in fact make public. Consequently, all third-party information that an agency makes public is subject to the Data Quality guidelines.

Where an agency does not use, rely on, or endorse third-party information, but instead just makes it public, then the agency itself should have not have the initial burden of ensuring that the information meets the quality, objectivity, utility and integrity standards required by the Data Quality guidelines. The information should, however, be subject to the Data Quality correction process through administrative petitions by third parties.

When, however, an agency uses, relies on, or endorses third-party information, then the agency itself should have the burden of ensuring that the information meets the quality, objectivity, utility, and integrity standards required by the Data Quality guidelines.

Example(s) of Satisfactory Agency Proposals

Department of Transportation

While not entirely consistent with the PRA's Data Quality requirements, the Department of Transportation at page 8 of its proposal guidelines comes close to meeting these requirements:

> The standards of these guidelines apply not only to information that DOT generates, but also to information that other parties provide to DOT, if the other parties seek to have the Department rely on or disseminate this information or the Department decides to do so.

Example(s) of Unsatisfactory Agency Proposals

CPSC; EPA

The Consumer Product Safety Commission on page 3 of its proposed guidelines stated that "the standards and policies applied to the information generated by CPSC cannot be applied to external information sources

EPA at pages 14-17 of its proposed guidelines exempts from the Data Quality guidelines

most third-party information submitted to the agency.

(6) Definition of "Affected Persons"/Definition of a "Person"

The definition of an "affected person" is fundamental to the operation of the Data Quality Act because it determines who is eligible to file an administrative petition for correction of agency-disseminated information.

OMB's interagency Data Quality guidelines concluded that "affected persons are people who may benefit or be harmed by the disseminated information. This includes persons who are seeking to address information about themselves as well as persons who use information." 66 FR 49718, 49721 (Sept 28, 2001). Individual agencies should use OMB's broad definition, which is consistent with the intent of these guidelines: to provide the public with a right to agency disseminated information that meets high Data Quality standards; and with a right to correct any publicly disseminated information that does not meet these standards.

Example(s) of Satisfactory Agency Proposals

OMB

OMB's definition of "affected persons" encompasses anyone who benefits or is harmed by the information including, "both:(a) persons seeking to address information about themselves or about other persons to which they are related are associated; and (b) persons who use the information." OMB's definition is further detailed by their comprehensive definition of "person" which includes individuals, organized groups, corporations, international organization, and governments and government agencies.

Example(s) of Unsatisfactory Agency Proposals

Department of Commerce

Commerce, at 67 FR 22398, 22401, (May 3, 2002), proposes to define "affected person" in an extremely narrow manner:

(1) *Affected person* means a person who meets each of the following three criteria:

(i) The person must have suffered an injury "harm to an identifiable legally-protected interest [sic];

(ii) There must be a causal connection between the injury and the disseminated information-the injury has to be fairly traceable to the disseminated information or decision

based on such information, and not the result of independent or unrelated action; and

(iii) It must be likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision.

Department of Labor

The Department of Labor provides no definition of “affected persons.”

(7) Deadline for Deciding a Petition

Setting an appropriate, specific timeframe for agency decisions on information correction petitions is necessary to fulfil one of the key purposes of the Data Quality Act amendments of the PRA – enabling parties to obtain correction of information. It is also required by OMB's guidelines.

Example(s) of Satisfactory Agency Proposals

Multiple Agencies

Agencies including HHS, the Social Security Administration, and the Nuclear Regulatory Commission have proposed a 45-working-day time limit for the responsible agency to respond to the petition with either: (1) a decision; or (2) an explanation of why more time is needed, along with an estimated decision date.

The HHS and similar proposals are cognizant of: (1) agency responsibility to respond in a timely and informative manner to all petitioners; and (2) that some petitions may require a longer timeframe for a response. These proposals provide agencies with flexibility without allowing open-ended delays in deciding a petition. It should be noted that these proposed guidelines do not include provisions allowing additional response extensions.

Example(s) of Unsatisfactory Agency Proposals

Department of Labor

DOL's proposed guidelines state that the agency should "try to respond to complaints and appeals within ninety (90) days of their receipt, unless they deem a response within this time period to be impracticable, in light of the nature of the complaint and the agency priorities."

DOL's proposal does not require any communication to the petitioner and allows for open-ended delays in responding to requests for correction of information.

(8) Who Decides the Initial Petition?

The selection of the party responsible for acting on information correction petitions is important because this person will have a substantial responsibility for ensuring that one of the primary intents of the PRA is realized – allowing affected persons to obtain necessary correction of federally disseminated information.

Example(s) of Satisfactory Agency Proposals

The Federal Housing Finance Board

The FHFB's proposed guidelines state that the Board's "Chief Information Officer and other personnel responsible for the information will review the underlying data and analytical process used to develop the disputed information to determine whether the information complies with OMB and agency Guidelines and whether and how to correct the information, if appropriate." P. 6.

The FHFB's short correction process statement has several important strong points including: (1) designation of an official with primary responsibility for the correction who did not originate the information; (2) examination of the data in question and the process used to produce it; and (3) determination of whether the information complies with the Data Quality requirements of both the agency and OMB.

Example(s) of Unsatisfactory Agency Proposals

National Science Foundation

NSF does not provide any indication as to the official or organization within the agency responsible for acting on information correction petitions. Other agencies, including the Department of Labor and CFTC provide little or no information on who is responsible for evaluating information correction petitions.

Without knowing who has responsibility for the information correction process, it is difficult to evaluate that process. Furthermore, by failing to indicate the official/organization responsible evaluating information correction petitions, the agencies raise questions as to the extent to which they have thought through their process.

(9) Who Decides Appeals?

The appeal is the last administrative process open to an affected person seeking correction of information. Thus, to fulfill congressional and OMB intent with regard to ensuring the quality of disseminated information, it is important that agencies have a meaningful appeals process that is able to catch any errors which may have made it through both the initial dissemination quality review and the initial information correction process.

Example(s) of Satisfactory Agency Proposals

Securities and Exchange Commission

The SEC's proposed appeals process (referred to as a "request for staff reconsideration") routes the appeal to an official (usually in the Office of General Counsel) who was not involved in either producing the original data in question or in making the decision on the original request. The SEC's proposal also allow the appeal official to seek the advice of other officials.

The SEC's proposal ensures that the decision on any appeal is made by an objective official.

Example(s) of Unsatisfactory Agency Proposals

Department of Treasury

The Department of Treasury has proposed that any administrative appeal of an information correction petition be conducted "... within the Bureau (or Departmental Office), which disseminated the information." P.6.

By failing to provide for independent review of administrative appeals, Treasury's proposal: (1) reduces the likelihood of any errors being recognized on appeal because the appeal would be performed by the same organization which handled both the initial dissemination and the original complaint; and (2) creates a potential conflict of interest.

(10) Must the Agency Correct Information When It Agrees with a Petition?

The Data Quality Act amendments to the PRA explicitly gives the public the right to seek and obtain correction of federally disseminated information. Thus, to comply with the law, agencies should be required to correct information disseminations covered by the guidelines.

Example(s) of Satisfactory Agency Proposals

Department of Defense

DOD's proposed guidelines state, "If the PAA [Public Affairs Activity of the relevant DOD Component] agrees with any portion or all of a complainant's request, he will notify the disseminator of the information that the correction must be made, and shall explain the substance of the requested correction. The PAA shall inform the requester, in writing, of the decision and the action taken." Sec. 3.3.5.1.

DOD's proposed guidelines recognize that when a request for an information correction is valid, the information "must" be correct. The DOD procedures would also ensure that the petitioner is informed of the action.

Example(s) of Unsatisfactory Agency Proposals

Department of Labor

DOL's proposed guidelines indicate that, when there is a valid request for information correction, the Department's response will be based on a number of loosely-defined factors including "the agency's more pressing priorities and obligations." P.7.

DOL's proposed guidelines would not implement the Act's legal requirement that affected parties be able to obtain correction of erroneous information. Although under OMB's guidelines agencies "are required to undertake only the degree of correction that they conclude is appropriate for the nature and timeliness of the information involved....," the OMB guidelines do not create exemptions from the correction requirements due to "more pressing issues." 67 F.R. 8452, 8458.

(11) What is the Standard for Rebutting the Presumption of Objectivity Resulting from Peer Review?

The OMB guidelines state that information will generally be presumed to be objective if data and analytic results have been subjected to formal, independent peer review; however, this presumption is rebuttable "based on a persuasive showing by a petitioner in a particular instance." 67 F.R. 8452, 8454. The OMB guidelines also specify certain standards for agency-sponsored peer reviews. The issue is what will be considered a "persuasive showing" that will overcome the presumption of objectivity under the proposed agency guidelines. For example, if the agency does not comply with majority peer review criticism, views, or recommendations, does a presumption objectivity apply?

Example(s) of Satisfactory Agency Proposals

None

The closest satisfactory example, perhaps, is the DOL proposal, which simply adopts the exact language of the OMB guidelines: "rebuttabal based on a persuasive showing by the petitioner in a particular instance". App. II sec. 3, b, i.

Example(s) of Unsatisfactory Agency Proposals

Multiple Agencies

EPA's proposed does not address this issue.

The HHS proposal, the CDC/ATSDR proposal, and the NIH proposal do not address this issue.

The DOT proposal does not address this issue.

The CPSC proposal does not even mention peer review.

(12) How is "Influential Information" Defined?

The OMB guidelines define the term "influential;" however, they also provide agencies with some flexibility in adopting their own definition. The OMB guidelines state that "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." 67 F.R. 8452, 8455. The guidelines then state that "[e]ach agency is authorized to define "influential" in ways appropriate for it given the nature and multiplicity of issues for which the agency is responsible." *Id.* The issue is whether, and how, agencies have deviated from the OMB definition in proposing their own definition of "influential scientific, financial, or statistical information.

Example(s) of Satisfactory Agency Proposals

EPA

The closest to a satisfactory approach might be considered to be EPA's although it could be considered overly restrictive.

EPA adopts the OMB language, and then specifies several types of information that will generally be considered "influential," such as those that appear to meet the definition of a significant regulatory action, including an economically significant action, under E.O. 12866, and major scientific and technical work products undergoing peer review.

Example(s) of Unsatisfactory Agency Proposals

Multiple Agencies

The HHS proposal simply defines "influential" in the same way as OMB, adding, like OMB, that each of its subsidiary agencies is free to define "influential" in way appropriate for it given the nature and multiplicity of issues for which the agency is responsible. Secs 2), I and 4), d.

The CDC/ATSDR proposal does not contain an definition of "influential."

The NIH proposal defines "influential" in close conformity with the OMB interim final and final guidelines. Sec. VII.

The DOT proposal contains a very extensive discussion of the meaning of "influential," extending for almost two pages. In general, the discussion appears to be intended to restrict the

situations in which the "influential" requirements will be applied. For example, broad impact is required, so that substantial impact on individual companies would not be included, and the economic impact benchmark is the $100 million per year from the "economically significant" regulatory action portion of E.O. 12866. Other aspects of the definition of "significant regulatory action" from E.O. 12866 are also incorporated. Sec. XI, a.

DOL has an interesting qualification to "influential": "Whether information is influential is to be determined on an item-by-item basis rather than by aggregating multiple studies, documents, or other informational items that may influence a single policy or decision." DOL then defines "influential" using the OMB language, but also provides examples of what meets the definition and what does not. Among the examples of non-influential information products are "fact sheets", "technical information issuances", "accident prevention bulletins", and "studies". Sec. titled "Information Categories".

The CPSC guidelines do not define "influential." They simply refer to the OMB guidelines.

(13) What is "Objective" and "Unbiased" Information on Risks to Human Health, Safety and the Environment?

The Data Quality Act requires agencies to issue guidelines ensuring and maximizing the "objectivity" of all information they disseminate. The OMB guidelines implementing the legislation define "objectivity," and that definition includes a requirement that information be "unbiased" in presentation and substance. "Objectivity," along with "unbiased," is correctly considered to be, under the OMB guidelines, an "overall" standard of quality. 67 Fed. Reg. 8452, 8458. However, the OMB guidelines do not provide any explanation of how to eliminate bias from risk assessment.

For many years, risk assessments conducted by EPA and other federal environmental agencies have been criticized for being biased by the use of "conservative," policy-driven, "default assumptions", inferences, and "uncertainty factors" in order to general numerical estimates of risk when the scientific data do not support such quantitation as accurate. When such numerical assumptions are presented in any agency risk characterization, it is likely that members of the public who are unfamiliar with how the agency arrived at such numbers believe that the numbers are based on "sound science." In actuality, the risk numbers are a result of co-mingling science with policy bias in a manner such that they cannot be disentangled. The question is whether the proposed agency guidelines have attempted to address this issue and how.

Example(s) of Satisfactory Agency Proposals

None

None of the agencies have attempted to address this issue directly. The least objectionable proposal guidelines are those of agencies such as DOT and CPSC, which simply state that the information they disseminate must be "objective" and "unbiased," in accordance with the OMB guidelines.

Example(s) of Unsatisfactory Agency Proposals

A number of agencies appear to have attempted to effectively avoid this issue in order to continue the practice of employing default assumptions, inferences, and uncertainty factors to generate speculative risk numbers which they believe are necessary to ensure protection of public health. It appears they believe it is necessary to exaggerate risks in order to protect the public, rather than accomplishing that goal through the risk management decisionmaking process by making explicit policy decisions that are clearly separated from the presentation of scientific data and analysis.

Three agencies' proposed guidelines are examples: EPA, DOL/OSHA, and HHS/CDC/ATSDR. The three proposals bear a strong resemblance to each other. First, in discussing the requirements for risk assessments, they do not refer to the requirement for "objectivity" and "unbiased" data and presentation. Instead, they imply that OMB's requirement to adopt or adapt the quality standards from the Safe Drinking Water Act Amendments substitutes for that requirement. Accordingly, all three agencies state that presentations of risk information must be "comprehensive, informative, and understandable," rather than "objective" and "unbiased."

EPA goes a little further, referring to the use of "assumptions" and incorporating by reference its Science Policy Council Handbook on Risk Characterization. This Handbook was published in December 2000 but is based on its 1995 internal guidance.[1] This EPA risk characterization guidance makes clear that the agency will use policy-driven default assumptions, inferences, and uncertainty factors to generate risk characterizations (*e.g.*, pp. 15, 18, 21, 41, and C-24 of the Handbook and pp. 2 and 3 of the Administrator's Mar. 21, 1995 Memorandum), while at the same time stating that risk characterizations should be "separate from any risk management considerations" (Mar. 1995 Policy Memorandum, p.2) and that numerical risk estimates should be "objective and balanced" (*id*. at p. 4). One passage from the EPA risk characterization Handbook, incorporated into its proposed Data Quality guidelines, is particularly illuminating:

> **3.2.9 How Do I Address Bias and Perspective?**
>
> 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 [sic] in the direction of less protection. However, it is not always clear where such bias enters into EPA risk assessments. To the extent it may make a difference in the outcome of your assessment, highlight the relevant areas so that impact will not be overlooked or misinterpreted by the risk manager.

Handbook, p. 41. Nothing is said about such agency "bias" being overlooked or misinterpreted by the public. In addition, the statement confuses risk management ("protection") with risk "assessment," contrary to other statements of agency policy as indicated above. Inclusion of such readily acknowledged "bias" in agency risk assessments and characterizations disseminated to

[1] This risk characterization guidance was never subjected to public notice and comment, and the EPA proposed Data Quality guidelines do not inform the public regarding how to obtain it online. The document can be found at www.epa.gov/osp/spc/2riskchr.htm along with two related policy memoranda from 1995.

the public is directly contrary to both the Data Quality legislation and the OMB guidelines. The SDWA amendment quality standards do not take the place of the legislative requirements, interpreted and implemented by OMB, that risk assessments, along with all other agency information disseminated to the public, must be "objective" and "unbiased" as an "overall" quality standard.

(14) Application of the SDWA Health Risk Assessment Standards

OMB's February 22nd agency-wide guidelines stated that the science quality and risk assessment standards contained in the 1996 amendments to the Safe Drinking Water Act (SDWA), 42 U.S.C. § 300g-1(b)(3)(B), should be adopted or adapted by federal agencies. Agencies should adopt both the SDWA science quality and risk assessment standards unless they conflict with the other federal statutory requirements. If such conflicts do arise, agencies should make every efforts to reconcile the SDWA standards with the conflicting statutory requirements.

There are only two valid reasons why a federal agency should not adopt these standards:

- The agency does not conduct health risk assessment; or
- The SDWA risk assessment standards conflict with the specific risk assessment standards of another federal statute governing the agency.

In the latter case, the agency should identify the conflicting specific risk assessment standards; make every effort to reconcile the conflicting standards with the SDWA standards; and request public comment on both the conflict and the attempt at reconciliation.

Example(s) of Satisfactory Agency Proposals

None

Example(s) of Unsatisfactory Agency Proposals

EPA

EPA's proposed guidelines state that EPA will only adapt the SDWA risk assessment standards, without explaining how or why.

(15) Robustness Checks for CBI

OMB's February 22nd interagency Data Quality guidelines require robustness checks for data, models, or other information that the agency cannot disclose, but which are material to information that the agency does disclose. These robustness checks are critical for ensuring compliance with the Data Quality Act because the public will not be afforded any other mechanism for determining the objectivity, utility, and reproducibility of this non-disclosed information, which underlies disclosed information. OMB explained in its February 22nd agency-wide guidelines that the "general standard" for these robustness checks is "that the information is capable of being substantially reproduced, subject to an acceptable degree of imprecision." 67 FR 8452, 8457. Moreover, agencies must disclose "the specific data sources that have been used and the specific quantitative methods and assumptions that have been employed." *Id.*

Moreover, agency robustness checks for confidential business information (CBI) or proprietary models should be subject to the Data Quality Act petition process.

Consequently, agency guidelines should state:

- Agencies will perform robustness checks meeting OMB's general standard set forth above.
- Agencies will provide sufficient information to the general public to determine whether that standard has been met.
- The agency's compliance with these requirements is enforceable through the Data Quality Act petition process.

Example(s) of Satisfactory Agency Proposals

None

Example(s) of Unsatisfactory Agency Proposals

Multiple Agencies

Most agencies' proposed guidelines are very vague on the robustness check issue, and none specifically state that the agency's robustness checks, or lack thereof, are subject to the Data Quality Act petition process.

(16) Use of Third-Party Proprietary Models

Federal agencies often use various models developed by third parties (often government contractors) to formulate policies based upon influential scientific information. The third-party models are sometimes asserted to be confidential and proprietary.

This issue does not involve the concerns that arise when regulated entities are required to submit confidential or proprietary data to an agency pursuant to a regulatory program. Instead, this issue is limited to situations where any agency and a contractor agree to use a model on a proprietary basis to develop influential scientific information.

OMB's interagency Data Quality guidelines require that influential scientific information be reproducible. This reproducibility standard generally requires that the models used to develop such information be publicly available. The OMB guidelines further explain that when public access to models is impossible for "privacy, trade secrets, intellectual property, and other confidentiality protections,: an agency "shall apply especially rigorous robustness checks to analytic results and documents what checks were undertaken." 67 F.R. 8452, 8457.

RECOMMENDED SOLUTION

General Policy

- Federal agencies should adopt a general prohibition against use of third-party proprietary models in their Data Quality Act guidelines.

- Use of third-party proprietary models conflicts with the goals and intent of the Data Quality Act.

- Public disclosure of third-party models should be required in all but the most unusual circumstances.

- If federal agencies believe they must use third-party proprietary models in order to carry out their regulatory duties and functions, then they should have the burden of demonstrating to OMB, before entering into a contract to use the model, that no other option is available.

- Federal agencies' Data Quality guidelines should explain in detail what "especially rigorous robustness checks" will be applied to third-party proprietary models that the agencies and OMB agree must be used and explain how the public will be informed of these "robustness check." The public should be allowed to review and comment on these robustness checks.

Implementation of the General Policy

Prospective Implementation:

Federal agencies should propose and promulgate Data Quality guidelines declaring the general policy on this issue as described above. These guidelines should further state that, before the agencies agree to use a third-party, non-public, proprietary model, they will provide OMB a written justification as to why the agencies have no other option, and await OMB's views before entering into a contract that utilizes an allegedly proprietary model. The written justification to OMB should describe why the agencies cannot:

· Use an existing public model;

· Enter into a contact to develop a new public model;

· Reimburse a contractor so as to convert a proprietary model into a public model.

Agencies should provide public notice of and an opportunity to comment on the above justification.

Retroactive Implementation:

If a federal agencies has already agreed to use a third-party proprietary model before it proposes Data Quality guidelines, then the agency should undertake the following actions within 45 days of the date it sends its proposed Data Quality guidelines to OMB for review.

· Provide OMB with a written identification of what third-party proprietary models are being sued by the agency;

· Provide OMB with a written explanation of why the agency cannot reimburse the contractors so as to convert third-party proprietary models into public models, or enter into a contract to develop a public model.

Agencies should provide public notice of and an opportunity to comment on the above justification.