Center for Progressive Regulation

May 31, 2002

[address]

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Re: Draft 2002 Data Quality Guidelines

Dear [ ]:

These comments are submitted by the Center for Progressive Regulation (CPR), a newly created organization of academics specializing in the legal, economic, and scientific issues that surround health, safety, and environmental regulation. CPR's mission is to advance the public's understanding of the issues addressed by the country's health, safety and environmental laws and to make the nation's response to health, safety, and environmental threats as effective as possible.

The Center is committed to developing and sharing knowledge and information, with the ultimate aim of preserving the fundamental value of the life and health of human beings and the natural environment. One component of the Center's mission is to circulate academic papers, studies, and other analyses that promote public policy based on the multiple social values that motivated the enactment of our nation's health, safety and environmental laws. The Center seeks to inform the public about scholarship that envisions government as an arena where members of society choose and preserve their collective values. We reject the idea that government's only function is to increase the economic efficiency of private markets.

The Center also seeks to provoke debate on how the government's authority and resources may best be used to preserve collective values and to hold accountable those who ignore or trivialize them. The Center seeks to inform the public about ideas to expand and strengthen public decision-making by facilitating the participation of groups representing the public interest that must struggle with limited information and access to technical expertise.

Summary

Unlike the Office of Management and Budget (OMB), which has no statutory responsibility (or authority) to implement the nation's laws regarding health, safety, the environment and many other objects of public concern, regulatory agencies, including [**name of agency**], must balance their statutory obligations under the Data Quality Act (DQA) with their statutory obligations to implement their substantive mandates. Nothing in the language, structure, or history of the DQA evidences any considered congressional judgment to alter any agency's substantive mandates.

The Center supports the efforts of this agency and of OMB to ensure that data disseminated to the public are of high quality. This objective, however, must take into account the impact of data quality activities on the agency's substantive mission and the role of disseminated data in the implementation of that mission. The potential benefits of administrative procedures, including accuracy and objectivity, must be balanced against the efficient disposition of agency business.

A balanced approach to implementation of OMB Data Quality Guidelines would include the following elements:

- Where an agency has existing procedures that address the quality of data it disseminates, the agency should use that process for purposes of the OMB guidelines. An agency should not establish new procedures for information that is used in agency rulemaking. It is doubtful that use or disclosure of information through notice-and-comment procedures constitutes the type of dissemination contemplated by the DQA, and the rulemaking process itself provides the opportunity to challenge the quality of the information being relied upon by the agency.

- If, despite the fact that the DQA's substantive requirements are limited to the "dissemination" of information, an agency nevertheless chooses (wrongly, in our view) to follow these requirements in promulgating agency rules through informal rulemaking, the agency should reserve the most rigorous data quality review for information disseminated in support of agency actions that are "major" regulations under Executive Order 12866, provide a "significant" opportunity to advance the agency's mandate by other means, or involve precedent-setting or reasonably controverted issues.

- An agency should restrict the use of peer review to disseminated data that is "influential," and it should use peer review in that context only if it is necessary to establish the objectivity of scientific, financial or statistical information. Agencies should charter peer review committees under the Federal Advisory Committee Act (FACA).

- An agency should have procedures to notify the public about pending requests to modify data and to dismiss data correction requests that are frivolous, duplicative of other requests, refer to issues that have been the subject of prior complaints that have been resolved, or that occur after reasonable time deadlines set for the submission of such claims.

- An agency is not legally obligated to use the risk assessment procedures prescribed by the Safe Water Drinking Amendments, and if an agency does use those procedures, it should adapt them to suit the particular data quality activities in which it engages.

- Agencies should seek, and OMB should support, additional funding to carry out responsibilities under the OMB Guidelines.

Background

CPR supports the use of the best available data and analysis by the federal government, including when the government is disseminating information to the public. It must noted that a considerable source of the absence of quality data has been the unwillingness of business firms, which are in the best position to produce reliable data, to do so. Despite years of chemical regulation, for instance, we still lack basic toxicological testing information on a majority of even high production volume chemicals. Ensuring the quality of data disseminated by the government is no substitute for vigorous efforts to produce quality data in the first place.

The disclosure of information to the public has a vital role in the government's efforts to implement the nation's health, safety and environmental laws and to make these laws as effective as possible in reducing harm to public health and the environment. The dissemination of information has the potential to fulfill regulatory goals in two general ways. First, armed with additional information, individuals may be able to alter their behavior in a manner that reduces their risk or risk to the environment. Second, an agency may be able to prompt firms to reduce risks to individuals or to the environment by releasing information about business behavior.

The disclosure of health and safety risks serves an additional goal. Information disclosure about potential health and safety risks satisfies the public's right to know about potential hazards. Thus, information disclosure respects and serves the principle of individual autonomy, an important political value in our country.

The use of information for these purposes can be an effective, low-cost way of supplementing traditional regulatory activities. This possibility has been enhanced by the advent of the Internet and the ubiquity of computers. Although information disclosure may not be an adequate substitute for regulation in many contexts, the scholarly literature indicates that it can be effective in promoting public health and safety and environmental protection in other contexts.

Information disclosure can have several advantages over traditional regulation as means of promoting regulatory goals. First, until now, it has been a solution to the much-maligned "ossification" of administrative processes. While a rulemaking may take most of a decade from initiation to conclusion of judicial review, agencies have been able to assemble and disseminate a database or other information product in considerably less time. Information dissemination activities have generally been less expensive than rulemaking, especially if an agency already possesses the information or can gather it cheaply. Rulemaking, by contrast, requires substantial contractor support and the creation of numerous ancillary documents for compliance with executive orders and statutes. As discussed in the next section, however, implementation of OMB's Data Quality Guidelines is likely to increase the time and cost of such activities.

Information disclosure can also have benefits from the perspective of regulated entities because it creates no enforceable obligations to take preventative action. Thus, to the extent it has the practical effect of stimulating action, it does not require any particular action, and hence is flexible and performance-based. For example, industrial interests have praised EPA's Toxic Release Inventory (TRI) program precisely because it only requires facilities to report; what further steps they take, and when they take them, are up to the facilities.

There are also advantages from the public's point of view. A fully informed consumer is one of the necessary preconditions to a properly functioning market. Information disclosure obviously has broad public appeal from a right-to-know perspective, and the efficiencies discussed above should cumulate into societal savings. In addition, information disclosure by federal agencies can provide valuable support for state and local governments in their efforts to administer their regulatory authorities

While information disclosure by government has undeniable virtues, it can also harm regulated entities, the public, and an agency. From the perspective of individuals, information that is inaccurate or misleading can lead to inappropriate economic and political actions on their part. From the perspective of business, such information can damage a corporation's reputation. Ultimately, inaccurate or misleading information is also damaging to the issuing agency's reputation.

Death by Data Quality

The Center believes that information disseminated to the public should be of high quality. This objective, however, must take into account the impact of data quality activities on the agency's substantive mission and the role of disseminated data in the implementation of that mission. As Roger Cramton reminded us years ago, the potential benefits of administrative procedure – fairness and accuracy – must be balanced against the "efficient disposition of agency business." Roger C. Cramton, *A Comment on Trial-Type Hearings in Nuclear Power Plant Siting*, 58 VA. L. REV. 585, 591 (1972).

Striking the appropriate balance between fairness, accuracy and the efficient implementation of an agency's statutory mission in the context of data quality is a complex matter. Refusing to act until data quality improves can result in substantial harm to vital public purposes. The danger is that data quality will become a goal in and of itself, rather than a way of ensuring the most effective regulation possible under existing circumstances. This danger is real. It is widely recognized that the rulemaking process has become ossified because of the various procedural obligations of agencies to analyze the potential impacts of a rule before it is issued. *See, e.g.,* Celia Campbell-Mohn & John S. Applegate, *Learning from NEPA: Guidelines for Responsible Risk Regulation*, 28 HARV. ENVTL. L. REV. 93, 121-23 (1999); John Applegate, *A Beginning and Not An End in Itself: The Role of Risk Assessment in Environmental Decisionmaking*, 63 U. CIN. L. REV. 1643, 1648-51 (1995); Sidney A. Shapiro, *Political Oversight and the Deterioration of Regulatory Policy*, 46 AD. L. REV. 1 (1994); Thomas O. McGarity,

Some Thoughts on "Deossifying" The Rulemaking Process, 41 DUKE L. REV. 1385 (1992). Overly strict OMB supervision of these requirements has contributed to these delays. While reasonable efforts to anticipate regulatory consequences is a good idea, "paralysis by analysis" defeats agencies efforts to protect health, safety and the environment. OMB's data quality initiative, if not properly administered, will create "death by data quality."

The potential for "death by data quality" arises from several sources. The burden of complying with data quality procedures is an unfunded mandate for an agency. Agency efforts to disseminate data will undoubtedly be slowed by procedural requirements to ensure the quality of data. The more elaborate the procedures the greater the likely delay. Similarly, to the extent that procedures invite industry or other interest groups to use them in a strategic manner to slow, or even stop, data dissemination, the more likely it is that less information will be available to the public.

A second problem is that the OMB Guidelines attempt to model data quality in the context of agency government based on the development of scientific and other information in the academic community. OMB's insistence on peer review and reproducibility reflect highly important process norms in the development of knowledge by scientists and other researchers. The goal of governing, however, is different than the goal of science. Howard Latin, *Good Science, Bad Regulation, and Toxic Risk Assessment*, 5 YALE J. REG. 89 (1988). Scientific researchers can demand greater assurances of accuracy in their work because the goal is to perfect our knowledge. By comparison, agencies have been charged by Congress to act in a preventative manner to protect the public and the environment from the risk of harm. Since the failure of government to act can have life-threatening consequences, an agency should not routinely await additional information before it acts, as the federal courts have repeatedly recognized. *See, e.g.*, *Industrial Union Dept., AFL-CIO v. Hodgson*, 499 F.2d 467, 474-75 (D.C. Cir. 1974); *Ethyl Corp. v. EPA*, 541 F.2d 1, 19-20 (D.C. Cir.) (en banc), *cert. denied* 426 U.S. 941 (1976); *Environmental Defense Fund v. EPA*, 598 F.2d 62, 79 (D.C. Cir. 1978) (recognizing the "familiar choice" facing EPA between regulating with incomplete evidence and waiting while a hazard goes unabated). Thus, the degree to which agencies insist on higher quality data needs to be a function of the potential consequences of delaying action that might otherwise be taken, including actions that warn the public of possible health, safety and environmental concerns.

Accordingly, if agencies are to perform their missions, regulators will not be able to wait for the perfection of information before they act. Although scientists may continue to study potential risks to the humans or the environment, the issue for an agency is whether information is of sufficient quality that it can be reasonably used to further the agency's mission. As FDA has noted:

> Many of our actions are based on scientific experts' judgments using available data . . . . Such assessments provide useful answers in most instances that are sufficient for regulatory purposes, and much more elaborate quantitative estimates extrapolating beyond the data are unnecessary.

Food and Drug Administration, Draft Guidance on Ensuring the Quality of Information Disseminated to the Public (May 5, 2002), at 19. The Data Quality Act must not impose an obstacle to responsible government action by creating standards that ignore the public health, safety and welfare concerns agencies are charged with addressing. Indeed, as discussed below, Congress has usually defined the level of acceptable evidence for agencies to act in their substantive mandates, and OMB lacks any substantive authority to overrule these statutory mandates.

A third problem is that there is an important distinction between the disclosure of factual information, such as enforcement and inspection statistics, and the dissemination of risk information, which may contain factual information, but which also involves the characterization of risks. The characterization of risk is a difficult and controversial process in part because it involves difficult subjective judgments. The need for such judgments arises because scientific information regarding risks is often incomplete and inconsistent. *See* Thomas O. McGarity, *A Cost-Benefit State*, 50 AD. L. REV. 7, 24 (1998) ("Unfortunately, for most of the risks that regulatory agencies must address, data are sparse and consensus about assumptions is rare.") It is often difficult to say that a risk characterization is clearly "wrong," given the degree to which assumptions, policy choices, and judgments are embedded into every step of the risk assessment process. Industry and interest groups that disagree with these choices can employ data quality procedures to challenge these assumptions and offer their own interpretations. While such a debate is legitimate, there is a real risk that agency efforts to disseminate information will become hopelessly bogged down in procedural challenges, even though there is no realistic way to verify the objectivity of such information.

Death by data quality not only threatens to slow rulemaking, it will discourage agency initiatives to use disseminated data as a supplement, or replacement, for rulemaking. If OMB's data quality initiative has this impact, it will reduce the substantive benefits of information discussed previously.

Data Quality Act

Congress enacted the DQA as a two-paragraph provision buried in an Appropriations Bill. Section 515 of the FY 2001 Appropriations Act, P.L. 106-554. The Act was passed as a rider to an appropriations bill, sponsored by Representative Jo Ann Emerson (R-8th MO), apparently at the behest of Jim Tozzi, a former OMB-official who runs the corporate sponsored Center for Regulatory Effectiveness. It was not the subject of any legislative hearings or committee review or debate.

The Act, amending the Paperwork Reduction Act, provides in full:

> (a) In General.--The Director of the Office of Management and Budget shall, by not later than September 30, 2001, and with public and Federal agency

involvement, issue guidelines under sections 3504(d)(1)and 3516 of title 44, United States Code, that provide policy and procedural guidance to Federal agencies for ensuring and maximizing the quality, objectivity, utility, and integrity of information (including statistical information) disseminated by Federal agencies in fulfillment of the purposes and provisions of chapter 35 of title 44, United States Code, commonly referred to as the Paperwork Reduction Act.

(b) Content of Guidelines.--The guidelines under subsection (a) shall—

(1) apply to the sharing by Federal agencies of, and access to, information disseminated by Federal agencies; and

(2) require that each Federal agency to which the guidelines apply—

(A) issue guidelines ensuring and maximizing the quality, objectivity, utility, and integrity of information (including statistical information) disseminated by the agency, by not later than 1 year after the date of issuance of the guidelines under subsection (a);

(B) establish administrative mechanisms allowing affected persons to seek and obtain correction of information maintained and disseminated by the agency that does not comply with the guidelines issued under subsection (a); and

(C) report periodically to the Director--(i) the number and nature of complaints received by the agency regarding the accuracy of information disseminated by the agency and; (ii) how such complaints were handled by the agency.

The terse and simple statutory language and absence of history reveal several points important to the interpretation and implementation of the Data Quality Act. First, there is no indication that Congress intended to amend legislation protecting individuals and the environment. Congress clearly intended that OMB and agencies should implement the Act in a manner that improves the quality of disseminated data without significantly deflecting an agency from its statutory responsibilities to implement the country's health, safety and environmental laws.

Second, the DQA makes no provision for judicial review of agency compliance with its provisions. Instead, it establishes in OMB the responsibility to ensure agency compliance with these requirements. Agencies are to "report periodically to the Director--(i) the number and nature of complaints received by the agency regarding the accuracy of information disseminated by the agency and; (ii) how such complaints were handled by the agency." DQA, § 515(b)(2)(C).

Third, the guidelines required by the Data Quality Act pertain only to "information *disseminated* by Federal agencies."* DQA, §§ 515(a), 515(b) (emphasis added). In contrast, the Paperwork Reduction Act, which the DQA amends, painstakingly distinguishes between "dissemination" of information and other activities agencies might undertake with respect to information. In delineating the purposes of the Paperwork Reduction Act, for example, Congress referred to information that is "created, collected, maintained, used, shared and disseminated by or for the Federal Government. 42 USCA 3501(2); see also id. at 3501(5) (referring, in addition, to information "disposed of" by agencies); 3501(6) (referring to information "retained" by agencies). Thus, information that is "used" by an agency – such as information relied upon in the course of informal rulemaking – is not subject to the separate requirements of the DQA. Likewise, the Paperwork Reduction Act clearly distinguishes between the "dissemination" of information and "public access to" information. See, e.g., 44 USCA § 3504 (a)(1)(B)(ii); § 3506(d)(1), which indicates that "dissemination" and "public access" are two different things. Because the DQA covers "dissemination," not "public access," the DQA does not apply to agency activities that merely notify the public how to "access" government information, as compared to agency activities that actually provide – i.e., "disseminate" – the information. For example, the DQA would not apply to information that an agency used to formulate a proposed regulation as long as the agency only notified the public of the existence of such information in its Notice of Proposed Rulemaking (NPR). Since the NPR only notifies the public that it can have access to such information, the NPR itself in no way "disseminates" the information. Treating this activity as dissemination would entirely collapse the distinction between dissemination, use, and public access, contrary to the plain wording of the Paperwork Reduction Act.

Fourth, the Paperwork Act, among other goals, is intended to "coordinate, integrate, and to the extent practicable and appropriate, make uniform Federal information resources management policies and practices as a means to improve the productivity, efficiency, and effectiveness of Government programs," and to "minimize the cost to the Federal Government of the creation, collection, maintenance, use, dissemination, and disposition of information." 44 U.S.C. §§ 3501(3), (5). These provisions support the earlier conclusion that Congress clearly intended that OMB and agencies should implement the DQA in a manner that improves the quality of disseminated data without significantly deflecting an agency from its statutory responsibilities to implement the country's health, safety and environmental laws.

OMB Guidelines

On January 3, 2002, OMB published its final data quality guidelines. The guidelines do not acknowledge the tradeoffs, identified earlier, between data quality and the implementation of substantive regulation, except to recognize that some information is more "influential" than other information in the policy process, and may require greater efforts to ensure data quality. In fact, OMB imposed its guidelines without any explicit

* Even section 515(b)(2)(B), which also refers to information "maintained" by federal agencies, applies only when information is both "disseminated and maintained." DQA, § 515(b)(2)(B). No requirement in the DQA applies in the absence of "dissemination" of information by the relevant agency.

explanation or analysis of the costs, although it regularly insists that other agencies carefully balance the benefits and costs of proposed actions. That is, OMB did not attempt to compare the benefits of improved data quality with the cost to the public in terms of lives lost, new injuries, etc. attributable to delayed access to information and delayed implementation of rules.

An agency, however, does not have this luxury. Unlike OMB, which has no statutory responsibility (or authority) to implement the nation's laws regarding health, safety, the environment and many other objects of public concern, an agency must balance its statutory obligations under the Data Quality Act (DQA) with its statutory obligations to implement its substantive mandate or mandates. Moreover, as noted in the previous section, achieving this balance reflects Congress' intent when it passed the Data Quality Act.

Definition of Influential

The OMB Guidelines require that agencies include a "high degree of transparency" for "influential" scientific, financial or statistical information, *Guidelines*, § V3bii. Information is "influential" if it "will have or does have a clear and substantial impact on important public policy decisions or important private sector decisions." *Id.* § 9. OMB authorizes an agency to define "influential" in a manner that is appropriate given the nature and multiplicity of issues for which it is responsible. *Id*.

As explained above, the DQA applies only to information that is "disseminated" by federal agencies. Not all "influential" information is "disseminated" within the meaning of the Paperwork Reduction Act and DQA; as noted, for example, the Paperwork Reduction Act distinguishes information that is "used" or "collected" from information that is "disseminated."

Within the relatively narrow sphere of "disseminated" information, an agency should reserve the designation of "influential" for information disseminated in support of agency actions that are "major" regulations under Executive Order 12866, provide a "significant" opportunity to advance the agency's mandate by other means, or involve precedent-setting or reasonably controverted issues. This designation recognizes that procedures to promote the quality of information have significant costs, and that the most significant (and therefore most costly) of such procedures should be reserved for information that is the most important in terms of the agency's mission.

The use of Executive Order 12866 as a benchmark for defining "influential" information is appropriate because it represents the balance that has been struck between the advantages and disadvantages of ensuring the quality of agency regulatory analysis in the context of OMB review of proposed and final regulations. OMB has relied on this definition since the beginning of the Reagan administration, indicating that it has proven to be a useful way to balance the competing demands of quality analysis and the cost of conducting such analyses.

Health and Safety Testing Data Maintained by Agencies

As we have explained, the DQA applies only to information "disseminated" by federal agencies. Even section 515(b)(2)(B), which refers to administrative mechanisms for correcting information "maintained *and* disseminated" by agencies, requires dissemination as one of its triggers. If, contrary to this clear language, the agency elects to interpret the DQA to apply to information that is only "maintained" but *not* "disseminated," then the agency should be aware of the fact that affected persons may also seek and obtain correction of data submitted by private entities (either voluntarily or pursuant to regulatory requirements). For example, many agencies maintain in their files health and safety testing data that companies have submitted pursuant to legal requirements or in order to obtain licenses permitting the sale, distribution and use of regulated products. History has demonstrated that many of the health and safety testing studies contained in agency files do not measure up to the quality demanded by the OMB Guidelines, and none of those studies have been subjected to external peer review. See generally Thomas O. McGarity and Sidney A. Shapiro, The Trade Secret Status of Health and Safety Testing Information: Reforming Agency Disclosure Policies, 93 Harvard Law Review 837 (1980). If other information maintained in agency files is subject to requests to correct under the Data Quality Act, then information like health and safety testing data and Securities and Exchange Commission disclosure filings should likewise be subject to such requests.

Administrative Mechanism

The OMB Guidelines require an agency to establish an administrative mechanism that allows "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." *Guidelines*, § III3. OMB provides that such "mechanisms shall be flexible, appropriate to the nature and timeliness of the disseminated information, and incorporated into agency information resources management and administrative practices." *Id*.

An agency should not establish new procedures for information that is used in agency rulemaking. The DQA by its own terms does not apply to data that are used in agency rulemaking but not otherwise disseminated. As discussed earlier, the DQA amends the Paperwork Reduction Act, which carefully distinguishes between "agency dissemination of" and "public access to" information. As a result, the DQA does not apply to agency activities that merely notify the public how to "access" government information, as compared to agency activities that actually provide – i.e., "disseminate" – the information. Thus, the DQA does not apply to information that an agency used to formulate a proposed regulation as long as the agency only notifies the public of the existence of such information in its Notice of Proposed Rulemaking (NPR).

Moreover, the rulemaking process itself provides an adequate opportunity to challenge the quality of the data on which an agency is relying. The APA obligates an agency to invite public comments during rulemaking and it is legally obligated to respond

to comments on all aspects of its rule. 5 U.S.C. § 553. Such a process meets the needs of any person who seeks the correction of data that an agency disseminates in a Notice of Proposed Rulemaking (NPR) or an Advanced Notice of Proposed Rulemaking (ANPR).

More generally, whenever the agency has an existing process for vetting data that is disseminated outside of the rulemaking process, the agency should employ that process to meet the requirements of the Data Quality Act. If the process is insufficient to meet this objective, an agency should reform the existing process rather than create duplicative processes. In assessing the adequacy of a process, however, an agency should recognize that the DQA does not require formal procedures, or even any particular type of procedures. According to the DQA, an agency is to "establish administrative mechanisms allowing affected persons to seek and obtain correction of information maintained and disseminated." DQA, § 515(b). Thus, an agency's obligation is to establish procedures that are adequate to review the nature of the complaints it is reviewing.

Reliance on an existing process is important for four reasons. First, a separate process for information that is already subject to a public comment process would be duplicative and burdensome with no additional advantage to the agency. Second, the creation of a second process would be disruptive to the orderly conduct of business at the agency because it would invite interested persons to raise data quality concerns in an action that is collateral to the normal process of an agency in resolving such disputes.

Third, designating rulemaking as the process to vet issues of data quality acknowledges what is clear from the language of the DQA itself: there is no independent judicial review of claims regarding data quality. As discussed earlier, the Act make no provision for such review, and indeed, its language clearly contemplates that OMB - not the courts - will be the entity responsible for reviewing agencies' handling of complaints based on data quality. Moreover, under the Administrative Procedure Act, the dissemination of a scientific report in a Notice of Proposed Rulemaking (NPR) is not a final agency action subject to review because the publication of the study has no mandatory impact on anyone. [*] If corporations or other interested parties could challenges scientific or other studies disseminated as part of the rulemaking process outside of that process, agencies would become embroiled in collateral litigation over the

[*] Since the late 1940s, the D.C. Circuit has taken the view that since governments reports are not rules, sanctions, or any of the other terms that the APA defines as agency "action," they are not subject to review. *See* Hearst Radio v. FCC, 167 F.2d 225 (D.C. Cir. 1948). As recently as 1988, that court refused to review a guide on respirators published by EPA and the National Institute of Occupational Safety & Health, notwithstanding the claim of respirator manufacturers that the report had effectively "decertified" most of the respirators on the market. *See* Industrial Safety Equipment Ass'n v. EPA, 837 F.2d 1115 (D.C. Cir. 1988). The court declined to act in part because the guide did not impose mandatory requirements. *Id*. at 1121. Different results may obtain where dissemination is specifically required by a statutory provision. *See* Flue-Cured Tobacco Cooperative Stabilization Corp. v. U.S. EPA, 857 F. Supp. 1137 (M.D.N.C. 1994), *appeal docketed*, No. 98-2407 (4th Cir. Sept. 15, 1998) (reviewing an EPA report on environmental tobacco smoke); Synthetic Organic Chemical Manufacturers Ass'n (SCOMA) v. Dep't of Health & Human Services, 720 F. Supp. 1244 (W.D. La. 1989) (reviewing EPA's Reports on Carcinogens). These cases, however, should not apply in the context of a rulemaking because the agency is not required to disseminate any report or study as part of its NPR.

data quality of the studies on which the agency is relying in the rulemaking. The need to defend such collateral attacks would siphon agency resources from rulemaking and could indefinitely delay any ongoing rulemaking proceeding.

Finally, designating rulemaking as the process to vet issues of data quality will make it more likely that courts will consider complaints about data quality in the context of all of the information that an agency uses to defend a regulation. An agency at times will take protective action based on the "weight of the evidence"; that is, it will compile a complete picture out of a collective series of individual studies. If industry or other interested parties can challenge individual studies, without regard to their collective meaning, in separate agency and judicial review proceedings, an agency will be stymied in its efforts to adopt rules that reduce safety and health risks and protect the environment.

Peer Review

According to the OMB Guidelines, information is "objective" when it is "accurate, reliable, and unbiased," which requires the use of "sound statistical and research methods regarding scientific, financial, or statistical information. OMB will presume that information is of acceptable objectivity if data and analytic results have been subjected to formal, independent, external peer review. If agency-sponsored peer review is employed to help satisfy the objectivity standard, OMB requires that the process meet the general criteria for competent and credible peer review recommended by OMB-OIRA to the President's Management Council (9/20/01).

Although OMB's Guidelines require that all disseminated data be "objective," agencies should resist OMB's invitation to use peer review routinely to establish the objectivity of such data. This expensive and time-consuming process should be reserved for data that are "influential" as defined early in this comment, if it is used at all. Agencies have the legal authority to restrict peer review to this more limited context. The Data Quality Act does not specifically call for peer review, and Congress has never imposed such a universal peer review requirement on agencies. The reason is simple: if an agency had to engage in peer review as a routine matter, data dissemination would come to a halt. Furthermore, peer review is unnecessary as a general instrument to establish objectivity. If reliance on scientific, financial or statistical information sets a new precedent or is reasonably controverted, the agency should consider such information to be "influential" and subject to enhanced data quality requirements. If it is not, then peer review is unnecessary and wasteful. Finally, peer review is not always a useful exercise. For example, peer reviewers can only review the information provided to them by the agency. In some cases, however, the basis of data submitted by a regulated industry is not available to the agency because of trade secrets or other conditions. And the idea of "peer review" for much of the information routinely disseminated by agencies - such as the peer review of information on agency enforcement actions, violations of statutes, and so forth – is nonsensical. In addition, some influential information utilized by an agency has already been fully vetted by peer review in other

contexts. Although there may be disagreements about the reliability of such data, additional peer review is unlikely to shed any further light on this issue.

When an agency engages in peer review, it should recognize that the procedures recommended in the OMB-OIRA Memorandum omit crucial safeguards.[*] Scientists participating in peer review panels should disclose to the public – and not just to government officials -- all sources of potential conflicts of interest and bias, including financial benefits, specific grants and other forms of institutional support, as well as prior opinions and other pre-dispositions that could potentially affect their objectivity. Scientists are expected to have opinions. However, if scientists with a financial stake in the outcome of a scientific inquiry participate, the objectivity of the review is immediately suspect. Candidates with a conflict of interest should not serve on a panel except under the most unusual circumstances; *i.e.,* they are the only ones who have essential expertise on the subject being reviewed. If persons with such conflicts serve, the existence and nature of the conflict must be publicly acknowledged in the peer review document.

Second, as discussed earlier, an agency should engage peer review only in the circumstance that peer reviewers have access to all data underlying the studies that are subject to peer review. A crucial purpose of peer review is to ensure that research is conducted in an intellectually honest and scientifically appropriate manner and that the results claimed by the researchers are supportable by the data they generate. To permit others to make these judgments, scientists must stand ready to disclose their underlying data, even if the results of a study were not what they – or the sponsors of their studies – had hoped or anticipated. Of course, reasonable accommodations should be made to safeguard patient confidentiality. Trade secrecy and the potential use of information by competitors, however, are not appropriate reasons for nondisclosure of healthy and safety data. See Federal Insecticide, Fungicide, and Rodenticide Act Section 10(b), 7 U.S.C. 136h(b).

Agencies should charter peer review committees under the Federal Advisory Committee Act (FACA). 5 U.S.C. Appendix 2. Since Congress created FACA, in part, to address issues of public disclosure and conflicts-of-interest, such as those identified in the prior paragraphs, agencies should address such problems through the procedures created by FACA. In particular, as required by FACA, an agency should assure that the composition of peer review committees reflect a fair balance and that the committee accomplishes its task with reasonable expedition.

Limitations on Data Review

[*] The Memorandum 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 the 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."

The OMB Guidelines require agencies to 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." *Guidelines*, § III3. Further, OMB provides that "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." *Id*.

Agencies should respond to OMB's call for "flexible" mechanisms "appropriate to the nature and timeliness of disseminated information" by adopting procedures that notify about pending requests to modify data and that permit quick resolution of data quality issues without merit. Specifically, agencies should establish procedural mechanisms to dismiss data correction requests that are frivolous, duplicative of other requests, refer to issues that have been the subject of prior complaints that have been resolved, or that occur after reasonable time deadlines set for the submission of such claims.

Agencies should establish a mechanism to notify the public about pending requests to modify data disseminated by the agency. This step will help establish the legitimacy of such proceedings by permitting the pubic to track the agency's response. This step is unnecessary when requests to modify data are likely to come to the public's attention, such as when they are part of comments filed during a rulemaking.

Any rational system of procedures requires methods to eliminate claims that are not meritorious. Agencies should not devote scarce resources to issues that do not deserve attention.

An agency should also employ reasonable time deadlines to field complaints about ongoing or proposed data disseminations. For example, instead of fielding such complaints, one at a time, over many months, an agency should invite the public to petition the agency once a year for revisions in data that the agency is currently disseminating. Similarly, if the agency is proposing a new information activity that is not subject to rulemaking under the APA, the agency should invite public comments during a fixed period of time. The agency should refuse to hear complaints from persons who failed to comment during the prescribed period and could have reasonably have done so.

Finally, where the challenged information has been published in an electronic medium, such as the World Wide Web, and so access to the information is under the control of the agency, information under challenge should not be removed from the web (or moved to a different site) pending resolution of the challenge. At most, the agency should indicate that the information has been challenged and provide a link to an electronic version of the challenge, so that the reader can evaluate both the original information and the challenge to it.

SDWA Risk Assessment Guidelines

According to the OMB Guidelines, information is "objective" when it is "accurate, reliable, and unbiased," which requires the use of "sound statistical and research methods regarding scientific, financial, or statistical information. *Guidelines*, § V3b. OMB defines "sound statistical and research methods" regarding the analysis of risks to human health, safety and the environment as the use of the quality principles applied by Congress to risk information used and disseminated pursuant to the Safe Drinking Water Act Amendments of 1996 (SDWA) (42 U.S.C. 300g-1(b)(3)(A) & (B)). Agencies shall "either adopt or adapt" these principles. *Guidelines,* § V3biiC.

The SWDA Guidelines are of two types.[*] One provision establishes the minimum quality of the data on which EPA can rely and the other provision indicates how EPA is to describe that data to the public. An agency is not obligated to follow either provision.

An agency is not obligated to follow the first provision – defining the minimum quality of evidence on which EPA can rely -- because the SWDA only applies to EPA's implementation of the Safe Drinking Water Act. There is absolutely no indication that Congress "adopted a basic standard of quality for the use of science in agency decisionmaking" when it enacted the SDWA, as OMB claims. *See* 67 Fed. Reg. 8457 (OMB's claim of universal applicability). To the contrary, Congress has usually indicated the nature of the evidence on which an agency can rely in its own substantive mandate, and these mandates are different, and less prescriptive, than the one Congress used under the SDWA.[**] Even where no such provision exists, an agency is not bound by

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[*] The SWDA provides:

(A) Use of science in decisionmaking
In carrying out this section, and, to the degree that an Agency action is based on science, the Administrator shall use-- (i) the best available, peer-reviewed science and supporting studies conducted in accordance with sound and objective scientific practices; and (ii) data collected by accepted methods or best available methods (if the reliability of the method and the nature of the decision justifies use of the data).

(B) Public information
In carrying out this section, the Administrator shall ensure that the presentation of information on public health effects is comprehensive, informative, and understandable. The Administrator shall, in a document made available to the public in support of a regulation promulgated under this section, specify, to the extent practicable-- (i) each population addressed by any estimate of public health effects; (ii) the expected risk or central estimate of risk for the specific populations; (iii) each appropriate upper-bound or lower-bound estimate of risk; (iv) each significant uncertainty identified in the process of the assessment of public health effects and studies that would assist in resolving the uncertainty; and (v) peer-reviewed studies known to the Administrator that support, are directly relevant to, or fail to support any estimate of public health effects and the methodology used to reconcile inconsistencies in the scientific data.

42 U.S.C. § 300g-1(b)(3)(A)-(B) (emphasis added).

[**] The Occupational Safety and Health Act, for example, only requires the Occupational Safety and Health Administration (OSHA) to use the "best available" scientific evidence in promulgating workplace standards for toxic materials or harmful physical agents. 29 U.S.C. § 655(b)(5). Similarly, the Clean Air Act does not stipulate any specific scientific methodology for estimating risks, but instead simply requires EPA to use the "latest scientific knowledge," as reflected in air quality criteria documents, in setting the

a congressional prescription for the quality of scientific data employed in establishing regulations under the SDWA in determining the quality of information disseminated to the public in entirely different contexts. Furthermore, the SDWA covers "studies" that EPA relies upon when an "action is based on science." 42 U.S.C. 300g-1(b)(3)(A). By comparison, section 515 of the Treasury and General Government Appropriations Act for Fiscal Year 2001 is addressed to "information (including statistical information) disseminated by Federal agencies." The term "information" encompasses far more than "scientific data." The practices and methods that govern the accuracy and reliability of scientific information may or may not be equivalent to the practices and methods that ensure accurate and reliable information that is not strictly scientific in nature.

If an agency considers the data quality requirements of the SDWA at all, it should take care that compliance with these principles does not steer it away from the protective policies of the statutes that the agency is administering. Thus, an agency must weigh the resources needed to gather additional information in terms of its potential to improve the quality of the substance of risk assessments.

When an agency describes the risk data on which it is relying, it should be wary of the difficulties of developing a "central estimate of the human risk for the specific populations affected." 42 U.S.C. § 300g-1(b)(3)(B)(ii). In most cases, the uncertainties that befuddle risk assessment are simply too large to support a "central estimate." Nor is it possible to simply average the predictions of competing risk models in order to derive such an estimate. As one risk assessor notes, calculating a central estimate of risk is like "average[ing] the winning percentage of all Los Angeles sports teams – basketball, football, hockey, and baseball – to derive a 'central estimate' of the likely success for an athlete playing in that city." Thomas O. McGarity, *A Cost-Benefit State*, 50 AD. L. REV. 7, 28 (1998) (quoting Ellen Silbergeld). If different risk assessment models yield different predictions, the predictions should be revealed and the differences explained in a comprehensible fashion.

Additional Funding

National Ambient Air Quality Standards. 42 U.S.C. § 7408(a)(2). In fact, in *Whitman v. American Trucking Assns.*, 121 S.Ct. 901 (2001), industry parties asked the Supreme Court to announce that the Clean Air Act requires a quantitative risk assessment from the Environmental Protection Agency (EPA) when EPA sets National Ambient Air Quality Standards under the Act. The Court declined to impose this requirement under the Clean Air Act. Likewise, science-based decisions under the Clean Water Act, *see, e.g.*, 26 U.S.C. § 1314(a)(1) (requiring EPA recommendations on science-based water quality criteria to be based on "latest scientific knowledge"), and the Toxic Substances Control Act, See 15 U.S.C. § 2626(a) (providing general authority to develop testing protocols for evaluating risks from toxic substances), do not embody the highly prescriptive risk assessment principles announced in the Safe Drinking Water Act Amendments. Moreover, in many cases the requirements for science-based decision-making will track substantive statutory standards; where, for example, a statute requires an agency to set a "margin of safety" in order to protect the public health, it would not be unreasonable for the agency to focus its attention on upper-bound estimates of risk as a policy judgment. *Cf.* Cass R. Sunstein, *The Arithmetic of Arsenic*, at p. 38, Working Paper 01-10, AEI-Brookings Joint Center for Regulatory Studies (August 2001) (available at www.aei-brookings.org) (suggesting congruence of risk assessment protocols and substantive standards).

Finally, agencies should seek, and OMB should support, additional funding to carry out responsibilities under the OMB Guidelines. As noted earlier, since the Guidelines are an unfunded mandate from the agency's perspective, compliance with the Guidelines will siphon off agency resources from other activities, including the promotion of regulatory and information activities that protect the public and the environment. In order that data quality not become a zero-sum game, agencies should request from the administration, if they are subject to OMB budget oversight, or from Congress, if they are not, additional funding to meet these new responsibilities.

Sincerely,

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