Information Quality Act Challenges to Flawed Use of Science

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Consisting of no more than two brief paragraphs inserted into a 2000 general federal government appropriations act, the Information Quality Act (IQA) holds the promise of becoming one of the most significant pieces of legislation affecting the manner in which federal administrative agencies fulfill their statutory responsibilities since enactment of the Administrative Procedure Act. In particular, by requiring both the pre-dissemination review of the "quality" of most forms of information disseminated by federal agencies and a post-dissemination administrative mechanism for challenging and seeking the correction of information deemed to not meet federal quality standards, the IQA provides a heretofore unavailable mechanism for compelling federal agencies to respond formally and in a timely fashion to, among other things, challenges to their disseminated use of science in actions that fall short of formal notice-and-comment proceedings or facility-specific determinations. That said, the ultimate value of the IQA in challenging and correcting what are perceived to be scientifically flawed pronouncements of federal agencies may depend in large measure on whether federal courts determine that administrative agency denials of information correction challenges are subject to judicial review.

This article provides first an overview of the IQA and the manner in which it has been administered by federal agencies through adoption of implementing guidelines. It then addresses certain limitations on use of the IQA to challenge information disseminated by federal agencies, and briefly discusses the issue of whether judicial review of federal agency IQA challenge determinations is available. That discussion is followed by a short analysis of the experience to date under the IQA, including challenges under the Act to federal agencies' use of science. Finally, the article concludes with a discussion of how the IQA can best be employed to challenge scientific pronouncements of federal agencies, with a focus on scientific and technical determinations of the U.S. Environmental Protection Agency (EPA).

We now live in an era in which federal agencies with human health and environmental regulatory responsibilities "regulate" more and more through use of guidance in lieu of formal notice-and-comment regulation. Agencies are also informally disseminating a significant volume of information regarding the potential impacts of various chemicals and products that is then used as a basis for subsequent formal regulation, which can have far-reaching consequences. Those circumstances have increased the stakes with respect to the ability of interested parties to compel agencies to respond both substantively and timely to assertions that those pronouncements are (1) not based on use of the best available science, (2) biased, (3) not sufficiently transparent such that their validity can be tested, (4) not properly peer-reviewed, or (5) otherwise scientifically suspect. Unfortunately, in the absence of formal notice-and-comment rulemakings, agency "adjudications," or other information dissemination amounting to "final agency action" within the meaning of the Administrative Procedure Act (APA), 5 U.S.C. §§ 551 *et seq.*, there has not until now been an effective mechanism to compel an agency to respond directly and timely to such challenges.

The IQA, also known as the Data Quality Act, rather dramatically changes that playing field. Set forth in Section 515 of the Treasury and General Government Appropriations Act for Fiscal Year 2001, Pub. L. No. 106-554 § 1(a)(3) [Title V, § 515], and codified at 44 U.S.C. § 3516 note, the IQA establishes two principal statutory requirements. First, it requires the Office of Management and Budget (OMB) to issue guidelines pursuant to the federal Paperwork Reduction Act (PRA) that provide "policy and procedural guidance" to federal agencies subject to the PRA for "ensuring and maximizing" the "quality, objectivity, utility, and integrity" of information "disseminated" by those agencies. Second, the Act requires every such federal agency to issue its own guidelines, consistent with those of OMB, that (1) ensure that the aforestated "information quality standards" are "*maximized*," and (2) 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 by OMB.

In addition, the IQA requires federal agencies to report periodically to OMB on the number and nature of information quality complaints they receive and how such complaints were handled. As discussed below, federal agencies have now made their initial reports to OMB pursuant to this statutory mandate, and OMB has synthesized

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that information in its first annual report on experience to date under the IQA.

OMB first published its IQA guidelines on an interim final basis on September 28, 2001, 66 Fed. Reg. 49,718, and subsequently published final guidelines on February 22, 2002, 67 Fed. Reg. 8452. OMB has since issued two important refinements to its guidelines, set forth in a June 10, 2002 memorandum (June 2002 Memorandum), which discussed important policy issues and provided guidance on provisions that needed to be adopted uniformly in all agency IQA guidelines, and a September 5, 2002 memorandum (September 2002 Memorandum) furnishing additional guidance on a few fundamental information correction process issues. On April 15, 2004, OMB issued a significant related document, entitled *Revised Information Quality Bulletin for Peer Review*, that requires agencies to undertake a peer review of "influential scientific information" before they disseminate it to the public and sets forth standards for the conduct of those reviews. (OMB's guidelines and interpretative memoranda may be found at www.whitehouse.gov/omb/inforeg/infopoltech.html.)

OMB's guidelines impose three core responsibilities on federal agencies. First, agencies must adopt and pursue a basic standard of "quality" that is to be incorporated into their information dissemination practices. Second, agencies must develop and abide by information quality assurance procedures that are to be applied *before* information is disseminated. Finally, agencies must develop and make available administrative mechanisms that enable parties affected by information not meeting federal quality standards to obtain timely correction of that information.

OMB's guidelines are noteworthy in several respects. First, the pre-dissemination review requirements apply to any covered "information" first disseminated on or after October 1, 2002. An agency's administrative correction mechanisms apply to any information disseminated on or after that same date, regardless of when the agency first disseminated the information (e.g., they apply to information first disseminated prior to October 1, 2002, that an agency continues to post on its Web site after that date).

Second, OMB's guidelines make clear that most types of information disseminated by federal agencies are subject to the IQA. "Information" is defined to include "any communication or representation of knowledge such as facts or data" (but not "opinions" other than an "agency's views") in any medium or form. Because "dissemination" extends to "agency initiated or sponsored distribution of information *to the public*," information supplied to a federal agency by a third party (e.g., a state agency or a member of the public) and cited to and relied on by the agency in support of an action it takes is subject to the IQA. Similarly, information related to research sponsored by a federal agency through contracts, grants or cooperative agreements and disseminated by it (or on its behalf, for example, where the agency directs or approves the dissemination) is subject to the IQA. As such, information submitted by commenters with respect to a proposed agency action that is referenced and relied on by the agency in the action it takes is subject to the IQA, just as if the information had originated from the agency.

Notable exceptions to IQA applicability include: (1) opinions, where the agency's presentation makes clear that someone's opinion, rather than fact or the agency's views, are being offered; (2) information whose distribution is limited to government employees, contractors, or grantees; (3) intra- or inter-agency sharing of government information; (4) responses to requests for agency records under certain federal laws (e.g., the Freedom of Information Act); and (5) distribution limited to "correspondence with individuals or persons, press releases, archival records, public filings, subpoenas or adjudicative processes." The last of these exceptions could be relied upon by agencies, for instance, to refuse to apply the administrative correction mechanisms to information provided to Congress or other entities in response to their request for specific information.

An additional, and highly significant, limitation on the applicability of the IQA relates to information disseminated in connection with rulemaking and other public comment procedures. While this issue was not addressed in the OMB guidelines themselves, the Principles and Model Language appended to the September 2002 Memorandum notes that "[w]here existing public comment procedures—for rulemakings, adjudications, other agency actions, or information products—provide *well-established* procedural safeguards that allow affected persons to contest information quality *on a timely basis*, agencies may use these procedures to respond to information quality complaints. However, agencies should respond sooner *where needed to avoid the potential for actual harm or undue delay*." (emphasis supplied). Accordingly, OMB recommended that agencies include the following language in their IQA guidelines:

> In cases where the agency disseminates a study, analysis, or other information prior to the final agency action or information product, requests for correction will be considered prior to the final agency action or information product [only] in those cases where the agency has determined that an earlier response would not unduly delay issuance of an agency action or information product and the complainant has shown a reasonable likelihood of suffering actual harm from the agency's dissemination if the agency does not resolve the complaint prior to the final agency action or information product.

This OMB "threshold test" for use of the IQA correction mechanisms in situations where sufficiently robust opportunity for public comment exists was largely adopted by various federal agencies that nonetheless provided their own views of the scope of this limitation on the applicability of the IQA. EPA, for example, noted that it generally will avoid use of the IQA administrative mechanisms (absent satisfaction of the OMB threshold test) not only

where a notice of proposed rulemaking is involved, but also in the case of "other processes involving a *structured* opportunity for public comment on a draft or proposed document before a final document is issued, such as a *draft report*, *risk assessment*, or *guidance document*." EPA IQA Guidelines § 8.5 (emphasis supplied) (EPA's IQA guidelines and related information may be found at www.epa.gov/quality/informationguidelines). This language suggests that affected persons wishing to employ the IQA administrative correction mechanisms in the instances cited by EPA (including cases involving proposed remedial action at contaminated sites) may have a difficult burden to overcome in seeking to do so. EPA's pronouncement also raises the issue of when an informal "opportunity to comment" (e.g., on a risk assessment document involving a particular chemical), will be considered sufficiently "structured" such that the IQA should not apply absent a showing that the threshold test is met. Given the thrust of the Act, the IQA guidelines should be found applicable in situations where, despite some opportunity for informal comment, there is (1) no public notice of the availability of an opportunity for comment and/or (2) no requirement that the agency respond to comments received as it would in a formal notice-and-comment setting.

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The OMB guidelines also include definitions of the basic information quality standards. "Quality" itself is employed as an encompassing term comprising objectivity, utility, and integrity. Of these, the definitions in the guidelines of "objectivity" and "utility" are the most important for purposes of challenges to scientific and technical information.

"Objectivity" has both presentation and substantive components. The first refers to whether information is presented in an "accurate, clear, complete, and unbiased" manner, and includes presentation of supporting data, models, and potential error sources affecting data quality so that the public can assess for itself whether there is a basis to question the objectivity of the information. The substantive component focuses on ensuring "accurate, reliable and unbiased information" generated by use of sound statistical and research methods. Notably, although data and analytic results that have been subjected to formal, independent, external peer review enjoy a presumption of objectivity, that presumption can be rebutted. Moreover, to the extent agency-sponsored peer review is used to help satisfy the objectivity standard, the review process is to meet OMB criteria for peer review.

"Utility" refers to the usefulness of the information to its intended users, including not just the agency but the public as well. As is the case with objectivity, utility has a transparency component (i.e., both the information and, in the case of scientific and statistical information, the sources of the information and the data on which it is based must be transparent to the reader).

Importantly, the OMB guidelines also require that agencies conform to heightened quality standards for "influential" scientific and other information. Information is influential if the agency can reasonably determine that its dissemination does have or will have a "clear and substantial impact on important public policies or important private sector decisions." Every agency is to define influential as appropriate for the issues for which it is responsible and to identify categories of information it disseminates that are deemed influential.

In response to this mandate, EPA, for example, has designated as influential, among other things, (1) information disseminated in support of "top Agency actions" that "demand the ongoing involvement of the EPA Administrator and extensive cross-agency involvement;" (2) "issues that have the potential to result in major cross-agency or cross-media policies, are highly controversial, or provide a significant opportunity to advance the Administrator's priorities" (including "precedent-setting or controversial scientific or economic issues"); (3) information disseminated in support of "economically significant" actions defined in Executive Order 12,866, 58 Fed. Reg. 51,735 (Oct. 4, 1993); and (4) major work products undergoing peer review called for under EPA's Peer Review Policy. EPA IQA Guidelines § 6.2. Given both the general definition of influential information and the categories of information EPA has delineated as such, parties should be able to make strong arguments that many disseminated EPA assessments of the risks posed by various chemicals should be subjected to the heightened quality standards for such information.

It should be noted that these heightened standards have both procedural and substantive components. With respect to process, agency guidelines must ensure a high degree of transparency regarding data and methods to facilitate, where it is practicable to do so given ethical, feasibility, and confidentiality constraints, the "reproducibility" of influential information by third parties. In other words, the information must be capable of being substantially reproduced, meaning that a qualified member of the public should be able to undertake an independent reanalysis of the original or supporting data using identical methods to determine whether similar analytic results (subject to an acceptable degree of imprecision) would be

generated. Thus, underlying data and methods must be made publicly available, subject to privacy, trade secret, intellectual property, and other confidentiality protection. Where these protections preclude public access to data and methods, agencies must have in place "especially vigorous robustness checks" to ensure the quality of results and information disseminated, and must document the checks undertaken. In all cases, however, the specific data sources and quantitative methods and assumptions that have been employed must be disclosed.

As for substantive requirements, the OMB guidelines require, with respect to analysis of human health, environment, and safety risks, that agencies "adopt or adapt" the quality principles applied to the use of science for developing risk information disseminated pursuant to the Safe Drinking Water Act (SDWA), 42 U.S.C. § 300g-1(b)(3)(A)&(B). Among other things, these provisions of the SDWA require, to the degree an action is based on science, use of (1) "the best available, peer-reviewed science and supporting studies conducted in accordance with sound and objective scientific practices, and (2) data collected by accepted methods or best available methods (if the reliability of the method and the nature of the decision justifies [sic] use of the data)." 42 U.S.C. § 300g-1(b)(3)(A). In addition to requiring that publicly disseminated information regarding risks of adverse health effects be presented in a comprehensive, informative, and understandable manner, the SDWA directs agencies, in documents made available to support a regulation, to specify, to the extent practicable: the affected population, the expected risks to that population, the upper- and lower-bound risk estimates, the risk uncertainties, and relevant peer-reviewed studies that relate to the risk. 42 U.S.C. § 300g-1(b)(3)(B). Although most agencies, including EPA, have adapted, rather than strictly adopted, these SDWA quality principles to provide themselves flexibility in applying them to various types of risk assessment, the principles clearly provide useful standards by which the quality of influential risk assessment information disseminated by federal agencies can be judged and, if necessary, challenged.

The IQA and OMB implementing guidelines require federal agencies to establish administrative mechanisms allowing affected parties to seek and obtain, where appropriate, timely correction of disseminated information that does not comply with either the OMB or agency's IQA guidelines. Although neither the IQA nor OMB's guidelines define "affected parties," the June 2002 Memorandum evidences OMB's intent that the focus of the complaint process be on the merits of the complaint, not on the possible interests or qualifications of the complainant. As such, OMB encouraged, and most agencies have pursued, an approach that ensures broad public access to the complaint process and eschews a requirement that the complainant demonstrate any injury in fact or some other requisite level of harm or potential harm to avail itself of the correction mechanisms.

The guidelines of OMB, and its subsequent refinements of them, direct agencies to, among other things, (1) specify time periods for agency decisions on whether and how to correct information that is the subject of a request for correction (RFC), and (2) provide for an appeal, or request for reconsideration (RFR), of RFC denials through an objective administrative appeals process that ensures that the office that originally disseminated the information does not have responsibility for both the initial response to an RFC and the response to an RFR. In particular, OMB encouraged agencies to provide for a written response to RFCs and appeals of RFC denials within sixty calendar days, with an extension provided upon notice to the affected party that additional time is needed and of the reasons for the delay and an estimated decision date. At the same time, OMB discouraged setting a time period by which RFCs must be filed after information is originally disseminated, while allowing for reasonable time frames within which administrative appeals must be brought.

Most agencies generally concurred with these requests, while once again seeking to provide themselves flexibility. EPA, for instance, evidenced its intent to respond to RFCs and RFRs within ninety days of receipt of each by providing either (1) a decision on the request *or* (2) notice that more time is required, with the reason why and an estimated decision date. Moreover, RFCs may be filed anytime after covered information is disseminated. Although EPA has requested that appeals be filed within ninety days of the original EPA decision, later appeals are allowed with an explanation of why the RFR should be considered at that time.

There are several other notable elements of the administrative correction mechanisms required by the OMB guidelines and established by federal agencies. First, although the burden of proof is on the complainant to demonstrate that information quality standards have not been met, agencies are required to comply not only with the OMB guidelines and their own guidelines, but also those of any department of which they are a part. For example, the Fish and Wildlife Service (FWS) must comply with the IQA guidelines of the Department of the Interior (DOI), and the Agency for Toxic Substances and Disease Control and the National Institute of Environmental Health Sciences (NIEHS) must comply with IQA guidelines of the U.S. Department of Health and Human Services (HHS).

Second, as a general matter, federal agencies have established very informal procedures for evaluating RFCs and RFRs (and have reached highly divergent decisions as to who should handle such requests within an agency). For example, although typically setting forth the type of information that is to be included in RFCs and RFRs, the agencies have generally established very little in the way of particular processes by which these requests are to be presented and evaluated, and have not provided for hearings, arguments or other formal presentations of evidence regarding these requests (other than what is set forth in

the written requests themselves). For example, RFRs at EPA are typically to be decided (to the credit of EPA) by a high-level appeals panel consisting of the EPA science advisor/assistant administrator (AA) for the Office of Research and Development; the chief information officer/AA for the Office of Environmental Information; and the economics advisor/AA for the Office of Policy, Economics and Innovation. While this approach should help ensure that RFRs are decided by senior officials with a broad perspective of the various issues at stake for the agency, EPA's IQA guidelines merely provide that the written RFR will be sent to the EPA program office or region that has responsibility for the information involved, and that the AA for that program office or the regional administrator will present the issue to the appeals panel. Accordingly, although the EPA office responsible for the information disseminated is allowed to present to the appeals panel, there is no provision for the complainant to do so other than in its written RFR.

Finally, OMB has cautioned agencies that while they are required to undertake only the degree of correction they conclude is appropriate given the nature and timeliness of information found to be noncompliant with applicable information quality standards, they are not free to disregard their own guidelines, nomenclature notwithstanding. As such, and given the statutory mandate that affected parties be able to obtain correction of noncompliant information, agencies should be required to correct virtually all such information in some reasonable time frame. Nonetheless, some agencies have sought to preserve considerable discretion in this regard. EPA, for instance, has stated that considerations relevant to determining appropriate corrective action include not only the nature and timeliness of the information involved, but also the "significance of the error on the use of the information and the magnitude of the error." EPA IQA Guidelines § 8.6. Moreover, given the varying nature of the information that will need to be corrected, agencies have generally avoided time frames for correcting information and have typically failed to require that information found noncompliant be (1) designated as such in the public domain until it is corrected and/or (2) no longer used by the agency until corrected.

Potential Limitations on Use of the IQA

By requiring federal agencies to ensure and maximize the quality of scientific information they disseminate, and to respond in a timely, objective, and substantive fashion to RFCs and RFRs, the IQA and OMB guidelines provide a potentially valuable mechanism to forestall dissemination or continued use of scientifically flawed information. Accordingly, use of the IQA administrative correction mechanisms should be added to the toolkit of instruments to consider in evaluating how best to respond to what is perceived to be an agency's flawed use of science in its pronouncements or decisionmaking.

That said, there are certain limitations that can militate against the effectiveness of the IQA in some cases, and these should be kept in mind in evaluating whether to invoke the Act to address an agency's use of science.

First, as a general matter, federal agencies have failed to adopt any significant new pre-dissemination review procedures, relying largely instead on the very pre-IQA processes that led to the Act's enactment in the first place. Consequently, there often are not meaningfully improved procedures that can be cited in challenges brought on the basis of an agency's failure to comply with them.

Second, with the exception of the substantive SDWA quality standards applicable to influential scientific information involving an analysis of human health, environmental and safety risks, the IQA information quality standards are somewhat subjective. Accordingly, agencies have some flexibility in arguing that they have been met, and RFCs and RFRs must be carefully and persuasively crafted in light of those standards to be successful.

Third, the OMB and agency guidelines exclude from the province of the IQA several important categories of information (e.g., information whose distribution is limited to government employees, contractors, or grantees). Similarly, IQA implementing guidelines typically place considerable constraints on use of the IQA corrective mechanisms where information that is the subject of some meaningful notice and opportunity for comment on a timely basis is involved (e.g., formal rulemakings and decisions involving remediation at contaminated sites). Consequently, absent the requisite showing, a request for correction of information set forth in a proposed rulemaking, for example, is likely to be addressed solely in the final rule, that rule's preamble, or in a "response to comments" document accompanying that rule rather than through the more timely IQA administrative correction mechanisms.

Fourth, although affected parties have the right to information quality determinations, nothing appears to prevent affected agency program offices from engaging in ex parte discussions to argue their cases with agency officials responsible for ruling on correction requests. Moreover, RFCs and RFRs are essentially limited to written submissions. There is no explicit right to a hearing, presentation of witnesses, questioning of agency experts, or any oral argument that might enhance the effectiveness of a challenge.

Finally, although affected parties have the right to recommend the type of information correction they believe is warranted, agencies have considerable discretion with respect to both the timing and substance of correction of noncompliant information. Moreover, there is no requirement that agencies designate information found to be noncompliant as such or terminate use of it until any necessary correction is made.

Given these limitations, and a natural reluctance on the part of agencies to overturn decisions they have already made on the dissemination of information with potentially significant consequences, the availability of

judicial review to challenge agency denials of RFRs has added importance. The IQA is silent on the subject of judicial review of adverse agency decisions. Accordingly, any available review would likely come pursuant to the APA. *See* 5 U.S.C. § 702.

To date, only two courts have opined on the availability of such review. In *In re Operation of the Missouri River System*, ____ F. Supp. 2d ___, 2004 WL 1402563 (D. Minn. June 21, 2004) (*Missouri River System*), the federal district court held that Congress did not intend to provide in the Act a private cause of action for challenges to an agency's denial of an IQA information correction request. Finding that the IQA failed to provide any meaningful standard against which to evaluate an agency's determination of whether the quality of disseminated information was flawed, the court found that agency IQA determinations were committed to agency discretion by law and thus also unreviewable under the APA.

Significantly, however, the IQA challenge before the *Missouri River System* court was a collateral issue that, on the face of the opinion, received relatively little attention by the parties or the court. Moreover, while acknowledging the existence of the OMB guidelines, the court seemingly failed to account for the circumstance that the quality definitions and standards provided in those guidelines, as well those adopted by federal departments and agencies, seemingly provide the requisite minimal level of standards needed for courts under prevailing APA jurisprudence to permit judicial review.

The IQA and OMB guidelines provide a potentially valuable mechanism to forestall dissemination or continued use of scientifically flawed information.

Unlike in *Missouri River System*, the issue of the availability of judicial review of agency IQA determinations was squarely (and solely) before the court in *Salt Institute and the Chamber of Commerce of the USA v. Thompson*, 345 F. Supp. 2d 589 (E.D. Va. 2004) (*Salt Institute*). That case involved an IQA challenge on several fronts to a scientific study prepared by a National Heart, Lung and Blood Institute (NHLBI) grant recipient regarding the risks of salt intake the results of which were disseminated by the NHLBI. The court first held that the plaintiffs failed to satisfy any of the three prongs of the constitutional standing test necessary for them to be able to challenge the NHLBI's action either on their own behalf or on behalf of their members. Although the court did not then need to further address—and arguably should not have addressed—the reviewability of the plaintiffs' challenge under the IQA and APA, it nonetheless did so. The court concluded that there is no private right of action under the IQA, and that review was not available under the APA on the grounds that (1) the NHLBI's "dissemination of advisory information" did not constitute "final agency action" within the meaning of the APA because it was not an action "by which rights or obligations [had] been determined," and (2) consistent with the decision in *Missouri River System*, agency decisions regarding whether information correction requests should be granted are committed to agency discretion by law because "neither the IQA nor the OMB Guidelines provide judicially manageable standards that would allow meaningful judicial review to determine whether an agency properly exercised its discretion in deciding a request to correct a prior communication." *Salt Institute*, 345 F. Supp. 2d at 602.

The *Salt Institute* court's APA decision is notable in at least two respects. First, with respect to the ruling that the NHLBI's action in the matter did not constitute "final agency action," the court failed to consider that the agency's decision that the plaintiffs were not entitled to information correction was one by which their *legal right* under the IQA to "seek and *obtain*" correction of flawed information was finally determined by the agency. *See Salt Institute*, 345 F. Supp. 2d at 602. Second, with respect to its determination that IQA correction decisions are committed to agency discretion by law, the court focused on the measure of latitude agencies seemingly have to decide *how* to correct information of poor quality, and failed to address whether there are standards available to judge an agency's determination not to make *any* correction *at all*. As noted above, under prevailing APA case law, the OMB and departmental and agency IQA guidelines would appear to provide ample standards by which an agency is to, and a reviewing court can, determine whether information is sufficiently flawed to warrant some correction. As such, an agency's erroneous decision not to provide any correction at all under those standards can, at a minimum, be remanded to the agency for a determination of how best to correct the information. These (and other) issues are likely to receive further consideration in an appeal that has been taken of the *Salt Institute* decision and in subsequent judicial challenges that will undoubtedly be brought to other IQA correction decisions.

Implementation of the IQA to Date

From the inception of the OMB guidelines, federal agencies and environmental advocacy groups have remained concerned that the IQA would be employed frequently by the regulated community to seek to delay and

derail agency action, and would constitute an unwarranted burden on limited agency resources. These concerns have led to requests for a Government Accountability Office investigation and congressional oversight hearings on the law's impact on federal agencies, and to such efforts as the unsuccessful attempt in 2004 by the National Oceanic and Atmospheric Administration (NOAA) (the agency with the lead role in managing federal climate change research and a principal federal natural resource damage trustee) to obtain a statutory exemption from the IQA.

The first annual report issued by OMB on implementation of the Act appears to belie those concerns, at least to date. In its Fiscal Year 2003 (FY03) Report to Congress, OMB addressed, among other things, whether agencies have been properly responsive to RFCs and whether changes should be made to the IQA or OMB guidelines "to improve the accuracy and transparency of agency science." Relying in large part on the FY03 Information Quality Reports the agencies provided OMB on RFCs and RFRs they received and on the experience of OMB staff in overseeing implementation of the IQA, OMB reached several conclusions that are instructive to practitioners considering use of the IQA.

First, the number of substantive RFCs received by agencies in FY03 was relatively small. Only approximately thirty-five "distinctively IQA" RFCs that were substantive in nature were received in the first year of the Act's implementation. EPA, HHS, and DOI received the vast majority of these requests. Of those, only eight were characterized by the agencies as related to influential information; twelve additional RFCs were classified as undetermined (due to agency reluctance for various reasons to classify RFCs as influential), and the remainder were classified as noninfluential. Of the twenty RFCs in the first two categories, ten were denied, five were the subject of some sort of correction, and the rest were still under review. The large majority of the fifteen or so noninfluential requests led to some form of correction.

Second, although agencies have been finding that it often takes longer to respond to RFCs and RFRs than the presumptive time frames set forth in their guidelines, none have commented that IQA responsibilities threaten to compromise seriously the regulatory process.

Third, the IQA correction mechanisms have been employed not only by regulated industry but by "virtually all segments of society," including private citizens, liberal and conservative nongovernmental organizations (e.g., the Sierra Club and Public Employees for Environmental Responsibility), government agencies, and four U.S. Senators (in a joint request).

Fourth, to the extent OMB was able to evaluate agency practices in this regard, the IQA has resulted more in efforts to enhance the quality of information disseminated than it has in reduced information dissemination to avoid IQA responsibilities.

Fifth, the RFCs often addressed "interpretations of science or analyses." The majority of nonfrivolous RFCs of this type had been denied, "usually on the basis that a reasonable scientist could interpret the available information in the way that the agency had. Such correction requests might have been better focused if they had addressed the *inadequate treatment of uncertainty* rather than the accuracy of information." (emphasis supplied).

Finally, given this record, OMB concluded that "it is premature to make suggestions for legislative changes at this time." Nonetheless, OMB has recommended a number of administrative improvements to agency implementation of the IQA. Among others, these include (1) increased transparency by putting all RFCs, RFRs, and agency responses thereto on publicly available Web pages; (2) enhanced engagement of agency scientific and technical staff in responding to RFCs and RFRs, and (3) improved timeliness of agency responses to RFCs and RFRs.

In sum, although the limited experience to date with the IQA makes definitive conclusions difficult, the Act appears to be working largely as intended and without the dire repercussions predicted by opponents of the law. Moreover, correction requests have come from a broad cross-section of affected parties representing an extensive array of interests and political viewpoints. Continued OMB oversight of IQA implementation should help ensure that fundamental information quality objectives are achieved without undue compromise of other core agency responsibilities.

Employing the IQA to Challenge Flawed Agency Use of Science

As noted above, federal agencies more frequently disseminate scientific and other technical information as reports, notices, or means of sharing agency findings with the public on Web pages. These disseminations often lead to federal, state, and local rulemakings or other decisions regarding individual chemicals, products or facilities that can significantly impact commercial interests, the public's perception of risk, and agency priorities for commitment of their resources.

Given these circumstances, it is not surprising that initial use of the IQA's administrative correction mechanisms has often been directed to scientific pronouncements of federal agencies, including those of EPA and the federal resource agencies. Challenges to disseminations directed to EPA include those regarding oral reference doses for barium, health risk assessments for certain other chemicals (such as atrazine, perchlorate, and diisononyl phthalate), ozone concentration data collected at an air monitoring site, Superfund site listings, State Implementation Plan reviews, and information in a fact sheet addressing health and environmental risks posed by construction stormwater runoff. Similar challenges have been made to information issued by the federal resource

agencies, including the Fish and Wildlife Service (FWS) and NOAA, including climate change data and genetic data used in a draft Biological Opinion prepared pursuant to the Endangered Species Act to propose conditions on permits for offshore fish pens. These examples are illustrative of the various uses to which IQA RFCs can be put to challenge a federal agency's use of science.

A review of the applicable IQA guideline requirements and the challenges that have been brought to date under the Act to agency use and dissemination of scientific and other technical information reveals a number of considerations in deciding whether—and, if so, how—to employ IQA mechanisms to seek correction of such information perceived to be of poor quality. The following factors bear attention.

First, given its inherent shortcomings, the IQA may not be an optimal tool for challenging dissemination of certain agency information. The pros and cons of employing the IQA in any given situation need to be evaluated on a case-by-case basis. Moreover, the mere threat of filing an IQA RFC (e.g., through presentation of a draft RFC) may be enough to accomplish the desired correction. Agencies have encouraged the use of informal means to correct flawed information in advance of formal IQA challenges.

It is also imperative that the arguments upon which RFCs and RFRs are based track the specific information quality standards set forth in the OMB and relevant department/agency guidelines. For example, challenges to conclusions regarding which reasonable scientific minds could differ are unlikely to prosper. On the other hand, arguments that an agency: has not fairly presented both sides of scientific debate, has failed to address the uncertainty surrounding scientific information, or has neglected to release sufficient information about underlying data and methods such that it can be determined whether the information at issue is capable of being substantially reproduced are more likely (if meritorious) to be successful.

The burden is on the affected party to demonstrate nonconformance with what are somewhat subjective IQA quality standards. Agencies are likely to be reluctant to correct data they have already put in the public domain, and therefore the facts and arguments marshaled in an RFC need to be as robust and persuasive as the challenge is important. Moreover, although agency guidelines are not necessarily clear on this point, the record at the RFC stage will likely be what is reviewed in an RFR proceeding to determine the adequacy of an RFC determination and, to the extent judicial review is available, will constitute the record for review. Accordingly, sufficient upfront thought and resources need to be put into an RFC if the stakes warrant it.

Influential scientific information is subject to heightened quality standards, including those imposed by the SDWA principles as adopted or adapted by agencies. Affected parties (where appropriate) should therefore seek to demonstrate that information they challenge both is influential and fails to meet those higher standards of quality.

Although data and analytic results subject to "formal, independent external peer review" are presumed to be objective, that presumption can be rebutted (e.g., by demonstrating that the peer review process employed failed to meet the criteria for competent and credible peer review in either OMB's Peer Review Bulletin for influential scientific information or any prevailing guidance of the agency involved). Among other things, OMB's Peer Review Bulletin establishes minimum standards for when peer review is required for scientific information and the types of peer review that should be considered by agencies in different circumstances.

If the information being challenged is subject to notice-and-comment procedures, affected parties will need to evaluate whether the limited exception to the exemption from IQA applicability adopted by most agencies for such information applies. That analysis, which parties may wish to include in their RFCs, should extend not only to whether the conditions for the exception have been met, but also to whether the opportunity to comment provided is within the universe of procedures intended to be covered by the exemption. For example, while the procedures afforded for formal rulemakings include widespread notice to the public and a requirement that written responses be provided to substantive comments, those processes may not be evident in less formal comment opportunities provided by agencies with respect to other types of actions.

If the issue in question is sufficiently important that it may well merit a judicial challenge in the event of an unfavorable agency determination on a correction request, consideration should be given to whether the affected party submitting the request would have standing to challenge the agency's action, or if some other sympathetic entity might have better standing arguments and should file the administrative challenge in the first place.

OMB is currently exercising close oversight of implementation of the IQA by federal agencies. To the extent an agency clearly is eschewing its IQA obligations in a fundamental way on a matter of some importance, a conversation with OMB regarding the shortcomings involved may be of some help.

With these and other relevant considerations in mind, the IQA could prove to be a useful tool in individual cases to compel a federal agency to respond in a substantive and timely fashion to challenges to use of scientific information that heretofore could often be largely ignored or given short shrift. The ultimate value of the IQA correction mechanisms, however, will largely depend upon whether and, if so, under what circumstances, the courts see fit to review agency denials of IQA correction requests.