DRAFT #2, Mar. 2018

A CLOSER AND MORE CURRENT LOOK AT THE "INFORMATION QUALITY ACT," ITS LEGISLATIVE HISTORY, CASE LAW, AND JUDICIAL REVIEW ISSUES

William G. Kelly, Jr.*

TABLE OF CONTENTS

---

* The author was General Counsel of the Center for Regulatory Effectiveness (CRE) in Washington, DC from 1996-2015 and worked with CRE and Congressional staff on development of the IQA. The research and views presented in this article are solely his; no outside entity reviewed this work or contributed content or comments. He received no outside funding for this article, except to the extent he was able to use the Westlaw resources of Multinational Legal Services, PLLC, of which he is a member. In addition, he conducted some of the legislative history research between 1998 and 2010 with support from CRE, and his work on the IQA and its implementation was done with the support, and under the name, of CRE. He received his J.D. degree cum laude from Northwestern University School of Law in 1970. He now lives in Idaho and can be contacted at wgkelly@silverstar.com.

INTRODUCTION

It would be difficult to overstate the importance of information disseminated to the public by U.S. federal agencies and used as a basis for regulatory action. Scientific, technical, or financial information often not only provides the basis for proposed and final federal regulations and legislation, it can also operate as a kind of back-door regulation when disseminated outside of a regulatory proceeding, particularly on the Internet/World Wide Web.

For example, agency environmental and health information can induce and form the basis for regulatory or legislative standards for food, water, air, and pharmaceuticals, and influence consumer dietary practices and agricultural production. Technical information can affect vehicle fuel standards and safety equipment requirements. Financial information and statistics (e.g., inflation, employment rates, gross domestic product) can move the equity and bond markets and alter Social Security payouts. Information on perceived hostile actions by another country can even ignite armed conflict.

Federal agency information affects the overall public welfare and our perception of how well officials are doing their jobs. The dissemination of accurate, high-quality information is critical to the proper functioning of our democracy.

While agency officials are generally assumed to be trustworthy and knowledgeable when they develop and disseminate information, they, and processes they rely on, are not infallible, and they can be biased, consciously or unconsciously, by their institutional affiliations and institutional policies and procedures.

When government-disseminated information pertains to controversial or highly important issues, public trust can be enhanced by information quality standards and the availability of judicial review to enforce them. Yet some view the possibility of judicial review as impugning the credibility of agency officials and creating a potential impediment to necessary government action, and a measure not intended by Congress or consistent with legal precedent.

The rapid and pervasive expansion of the Internet since the mid-1990s has amplified these effects and concerns. Virtually every federal government agency now has its own website, on which it posts nearly everything of public interest within its jurisdiction.

So it is not surprising that the subject of quality and accuracy in information disseminated and used by federal agencies should have captured the attention of Congress. and that measures to address the issues it raises should have been the subject of legislation. As will be discussed below, concern over the quality of agency information disseminations was ongoing in Congress for a considerable period before it culminated in 1995 in the revised Paperwork Reduction Act (PRA),[1] and in 2000 in what is now commonly called the Information Quality Act (IQA).[2]

But the passage of the seemingly short and simple IQA legislation, and its implementation through extensive government-wide rulemaking by the Office of Information and Regulatory Affairs (OIRA) in the Office of Management and Budget (OMB),[3] has engendered a remarkable amount of controversy and debate outside Congress. A number of individuals and entities have commented on the legislation in an overtly hostile manner in published materials, often suggesting or asserting that it is a covert scheme implemented by business interests to slow regulations and corrupt information necessary to protect the public. Others have viewed it as beneficial to ensuring that government actions are well-founded and that the public is well-informed.

After OIRA's promulgation of detailed government-wide IQA rules (termed "Guidelines," and later, a "Bulletin") setting substantive and procedural standards for publicly disseminated agency information, controversy turned to the issue of judicial reviewability of allegations that an agency had failed to comply with those standards or procedures. As will be seen here, the battle lines have been drawn in the courts, with the Executive Branch, represented by the Department of Justice, staunchly opposing judicial review. Resolution of that issue, and many others, is yet to be determined decisively at the appellate court level, although a recent circuit decision may have turned the tide in support of judicial review.

1. 44 U.S.C. §§ 3501-3421 (2012).

2. Pub. L. No.106-554, § 1(a)(3) [Appendix C], § 515, 114 Stat. 2763, 2763A-153-154 (2000), 44 U.S.C § 3516 note (2012) (under the heading of "Policy and Procedural Guidelines"). (Although OMB has sometimes referred to the IQA simply as "section 515," there is another section 515 in Appendix A of the Act.) The Information Quality Act or IQA is not an official title of the legislation, and it has also been referred to, especially in earlier years after passage, as the Data Quality Act (DQA) or the Federal Data Quality Act (FDQA). Currently it is almost uniformly referred to as the IQA, presumably because that is the title used by OMB and its Office of Information and Regulatory Affairs (OIRA), as well as the courts, and because the term "information," rather than "data," is the term broadly used in the PRA and IQA and their implementing guidance.

3. Responsibility for implementation of the PRA was legislatively delegated to the Administrator of OIRA, with ultimate responsibility remaining with the Director of OMB. 44 U.S.C. § 3503(a) ("There is established in the Office of Management and Budget an office to be known as the Office of Information and Regulatory Affairs. (b) There shall be at the head of the Office an Administrator who shall be appointed by the President, by and with the advice and consent of the Senate. The Director shall delegate to the Administrator the authority to administer all functions under this chapter, except that any such delegation shall not relieve the Director of responsibility for the administration of such functions. The Administrator shall serve as principal adviser to the Director on Federal information resources management policy.") For simplicity and consistency, and because the PRA and IQA usually refer to OMB, hereafter the acronym OMB will be used instead of OIRA unless accuracy suggests otherwise.

The overall thesis of this article is that so far the issue of IQA judicial review has been treated shabbily by many federal courts, agency litigators, and commentators. Even plaintiffs attempting to utilize the IQA have failed to argue effectively in many cases.

The purpose of this article is to provide considerable additional material and perspective regarding the legislative background of the IQA, its implementation, the legal issues, and the current body of case law,[4] with the hope that it will assist in resolving the judicial review issue, improve the debate over other specific related legal issues, and assist in clarifying or improving some significant aspects of the law's implementation.

I. THE IQA AND ITS LEGISLATIVE HISTORY[5]

The IQA is a legislative directive to OMB and other federal agencies to implement, within a time certain (initially by September 30, 2001), and with certain provisions, Congressional mandates to OMB and agencies contained in the PRA for the issuance of "guidelines" to ensue and maximize the quality of information disseminated to the public by federal agencies. The IQA incorporates and implements all PRA provisions pertaining to the quality of agency information disseminations.

The IQA states in full:

> Sec. 515. (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);

4. The section on IQA litigation refers to many agency and court documents that are not available electronically due to their age or removal from web sites. Those materials were obtained by the author directly from the court or were obtained electronically before being removed. Such materials are on file with the author or available by request from the courts.

5. Although the following discussion of legislative history attempts to present an overall comprehensive picture, it cannot necessarily be regarded as completely comprehensive since the many Congressional bills referred to usually involved many hearings and debate, as detailed in the committee reports cited. In addition, there were related bills that did not receive significant attention. Some of the legislative materials are not currently available through online research sources and were obtained from the Library of Congress, the Government Printing Office, or the National Archives and Records Administration.

> (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.

A. Lack of Consideration of the PRA and Its Legislative History

It should be apparent from the plain text of the IQA that the foundational statutory authority is the PRA, and that the IQA was a directive to OMB to implement the PRA provisions for the quality of disseminated information through "Rules and regulations," referred to as "guidelines," within a certain timeframe. Sections 3504(d)(1) and 3516 of the PRA are specifically cited in the IQA because they are the primary PRA mandates to OMB that were the basis for the IQA mandates. In addition, the first paragraph of the IQA, subsection (a), encompasses all other PRA provisions relating to the quality of federal agency information disseminations, including the PRA statements of purpose. The requirement for individual agency guidelines in the IQA reflects the two-tier structure for information resources management long in place in the PRA--OMB government-wide rules followed by consistent agency-specific rules and compliance with the OMB rules.

Yet, most commentators on the IQA, including some litigants on both sides of the judicial review issue, and judicial opinions dismissing challenges based on the IQA, and even OMB, have often treated the IQA as if it were a standalone statute, barely, if ever, mentioning the PRA provisions that it was expressly intended to implement; nor have they attempted to explore the legislative history of those PRA provisions, or even their plain language.[6] They have asserted that there is no legislative history for the IQA or that it is extremely sparse.[7] This is inaccurate, as will be seen

---

6. *See, e.g.*, Department of Transportation's Information Dissemination Guidelines 2 (2002) https://www.transportation.gov/sites/dot.gov/files/docs/DOT%20Information%20Dissemination%20Quality%20Guidelines.pdf (last visited Dec. 2017) ("Section 515 is a free-standing statutory provision . . . . The only direct connection between Section 515 and the PRA is that Section 515 directs OMB to apply its guidelines to agencies that are subject to the PRA.").

7. *E.g.*, Family Farm Alliance v. Salazar, 749 F.Supp.2d 1083, 1089 (E.D. Cal. 2010) ("The IQA has no legislative history."); Def. Reply Mem. in Supp. of Mot. for Summ. J. 6 in *Family Farm Alliance* (the PRA is "a different statute" and "as FFA admits, the 'IQA is not an amendment to the PRA,' and has no legislative history of its own . . . . Nothing in the earlier enacted PRA or its legislative history shines any light on Congress' intent with respect to the IQA."); Def. Mem. in Supp. of Mot. to Dismiss at 4 n. 2 in *Salt Inst. v Thompson*, 345 F. Supp. 2d 589 (E. D. Va. 2004) ("The only legislative history regarding the IQA is found in a single sentence in the Conference Report and Committee Report accompanying the omnibus appropriations bill." No mention of PRA or full quotation of IQA.); Stephen M. Johnson, *Junking the "Junk Science" Law: Reforming the Information Quality Act*, 58 ADMIN. L. REV. 1 (2006) (addressing the IQA as if it were a standalone law and recommending its modification or repeal); Linda Rosenstock, *Protecting Special Interests in the Name of "Good Science*," 295 J. AMER. MED. ASS'N (JAMA) 2407, 2409-10 (2006) ("All this was achieved by one member of Congress tucking in a few lines of text in the midnight hour of a large appropriations bill. For that alone there should be great concern.") Stephen M. Johnson, *Ruminations on Dissemination Limits on Administrative and Judicial Review Under the Information Quality Act*, 55 CATH. UNIV. L. REV. 58, 64 (2005) ("[T]here is no legislative history for the Act, and the Act does not include a statement of findings or purposes.") (citing McGarity et al., *infra*); Paul Noe, Frederick R. Anderson, Sidney A. Shapiro, Jim Tozzi, David Hawkins, and Wendy E. Wagner (moderator), *Learning to Live with the Data Quality A*ct (edited transcript of ABA

below. These views on lack of legislative history became so prevalent early on that even many of those who supported the law conceded the point.

B. The PRA Provisions Incorporated into the IQA

The IQA states at its beginning that OMB "shall" issue guidelines "under" sections 3504(d)(1) and 3516 of the PRA, as well as in fulfillment of other unspecified relevant provisions and statements of purpose in the PRA. The Office of Law Revision Council has identified section 3516 as the operative Code provision under which to include the IQA as a note. Therefore, that section will be the starting point of this portion of this legislative history review.

Section 3516 states, under the heading "Rules and regulations": "The Director [of OMB] shall promulgate rules, regulations, or procedures necessary to exercise the authority provided by this subchapter."

This provision of the PRA first appeared in the original version of the PRA enacted in 1980,[8] and remained unchanged (except for the word "subchapter") in the PRA of 1995, the PRA version in effect at the time of enactment of, and referenced in, the IQA.

The 1980 Senate PRA bill stated with regard to section 3516 that the Director "may" promulgate "rules, regulations, or procedures,"[9] but the House bill stated that the Director "shall" promulgate

---

panel discussion), 33 ENV. L. REP. 1024 (2003) ("no legislative history," Wagner; "there were no hearings for this law, there was no extensive legislative history," Noe; "[t]he statute's legislative history and background are incredibly brief," Anderson; "no legislative history," Shapiro; and nothing to the contrary by the others present); Derek Araujo et al., *Protecting Scientific Integrity*, CENTER FOR INTEGRITY POSITION PAPER 24 (2007), http://www.centerforinquiry.net/uploads/attachments/scientific-integrity.pdf (last visited Dec. 2017) ("The DQA was enacted without hearings, debate or committee reports as an unnamed rider . . . ," recommending repeal or amendment precluding judicial review); Thomas O. McGarity et al., *Truth and Science Betrayed: The Case Against the Information Quality Act*, CTR. FOR PROGRESSIVE REFORM PUB. NO. 502, (2005), http://www.progressivereform.org/articles/iqa.pdf (last visited Dec. 2017) ("terse statutory language and absence of legislative history"); Thomas O. McGarity et al., *Ossifying Ossification: Why the Information Quality Act Should Not Provide for Judicial Review*, CTR. FOR PROGRESSIVE REFORM WHITE PAPER #601, at 5 (2006) http://www.progressivereform.org/articles/CPR_IQA_601.pdf (last visited Dec. 2017) ("There were no hearings on the Act and no debate in the House or Senate. Nor were there committee reports since the IQA came to life as an appropriations rider."); Rick Weiss, *"Data Quality" Law Is Nemesis of Regulation*, WASH. POST, Aug.16, 2004, at A01 ("[The IQA] was slipped into a giant appropriations bill in 2000 without congressional discussion or debate . . . ."); Dept. of Transportation 's Information Dissemination Quality Guidelines 2 (little if any legislative history") https://www.transportation.gov/sites/dot.gov/files/docs/DOT%20Information%20Dissemination%20Quality%20Guidelines.pdf (last visited Dec. 2017). For a list of some additional commentaries, see JEFFREY S. LUBBERS, A GUIDE TO FEDERAL AGENCY RULEMAKING, 158 n. 177 (5th ed. 2012). Despite limited efforts to correct the record on this matter (*See* William G. Kelly, Jr., *Correcting the Record on the Data Quality Act* (letter), 319 SCIENCE 158-59 (2008)), and despite a more recent decrease in such statements, this inaccuracy regarding lack of legislative history persists, as shown by comments made at the ABA's *State of the Information Quality Act Teleforum*, Feb. 26, 2016 (panel of Nancy Beck, Jamie Conrad, Paul Noe, Sid Shapiro and Connor Raso (moderator); comments by Noe and Shapiro) recording available at http://www.americanbar.org/groups/administrative_law/events_cle/2016.html (last visited Dec. 2017).

8. Paperwork Reduction Act of 1980, Pub. L. No. 96-511, 94 Stat. 2812 (1980).

9. Paperwork Reduction Act of 1980, S. 1411, 96th Cong. § 3516 (1980), 126 CONG. REC. 30171, 30174 (Nov. 19, 1980).

"rules and regulations."[10] The final legislation adopted the House's "shall," and the Senate's "or procedures."[11]

The Senate report explained its version of section 3516 that was rejected in favor of the House version thus: "This section [3516] provides that the Director may promulgate rules, regulations and procedures to exercise the authority provided by this chapter. The word 'may' instead of shall is used to clarify that the Director may exercise the authority contained in this chapter without necessarily resorting to rules and regulations."[12]

It can be inferred, therefore, from adoption of the House language containing "shall" instead of the Senate language containing "may," that Congress intended to require OMB to exercise its PRA authority only by issuing "rules or regulations" rather than through non-binding advisories.[13]

This legislative history of the 1980 provisions of the PRA, including section 3516, was expressly preserved in the conference report on the PRA of 1995.[14]

In several of the cases discussed in the following section of this article, the court or the agency suggested that use of the term "guidelines" in the IQA indicates that all OMB instructions to the agencies (including the peer review "Bulletin") were intended by Congress to be advisory only. This overlooks the IQA language requiring that the guidelines be issued "under section 3516," which means that the intention was that OMB would issue guidance in the form of binding "rules and regulations," although the PRA provisions also refer to OMB "guidelines" and "guidance."

Section 3504(d)(1), the second PRA section specifically cited in the IQA (and presumably including the prefatory subsection 3504(a)(1)), originated in the 1995 PRA, which will be discussed below. It states:

> **§ 3504. Authority and functions of Director**
>
> (a)(1) The Director shall oversee the use of information resources to improve the efficiency and effectiveness of governmental operations to serve agency missions, including burden reduction and service delivery to the public. In performing such oversight, the Director shall—
>
> . . .
>
> (d) With respect to information dissemination, the Director shall develop and oversee the implementation of policies, principles, standards, and guidelines to--
>
> (1) apply to Federal agency dissemination of public information, regardless of the form or format in which such information is disseminated . . . .[15]

---

10. Paperwork Reduction Act of 1980, H.R. 6410, 96th Cong. § 3516 (1980), 126 CONG. REC. 6208, 6211 (Mar. 24, 1980).

11. *Supra* note 8.

12. S. REP. NO. 96-930, at 54 (1980). The House report, which preceded the Senate report, stated only that the section "permits the Director [of OMB] to promulgate rules and regulations necessary to exercise the authority conferred on him by the chapter." H.R. REP. NO. 96-835, at 32 (1980). Apparently there was no conference report.

13. Consistent with the mandate in section 3516, OMB promptly proposed, and then promulgated, "rules and regulations" for information collections from the public, citing section 3516 as legal authority. 48 Fed. Reg. 13,666 (1983), 5 C.F.R. Part 1320.

14. H.R. REP. NO. 104-99, at 27-28 (1995) (Conf. Rep.).

15. The definition of the term "public information" is set out *infra* in the text accompanying note 19.

Prior to 1995, section 3504(d)(1) in the 1980 PRA only required the Director of OMB to develop plans for the improved performance of Federal statistical activities. The wording of this section was only slightly altered in the1986 amendments to the PRA, still requiring development of plans for improved coordination and performance of Federal statistical activities.[16]

After expressly citing these two specific Congressional statements of OMB authority and responsibility, the IQA also includes the more general statement that the exercise of OMB and agency rulemaking authority and responsibility for information dissemination it requires must also be "in fulfillment of the purposes and provisions of chapter 35 of title 44, United States Code, commonly referred to as the Paperwork Reduction Act."

The 1995 PRA was a major revision of the PRA of 1980, as amended it 1986, and it contains multiple provisions that are pertinent to the IQA mandates. As also will be discussed below, the new provisions were added out of recognition of the need for guidance on the accuracy of dissemination of public information and the growing importance of agency information that was becoming more widely disseminated through the Internet and World Wide Web.

The "purposes" stated in the 1995 PRA[17] referred to in the first section of the IQA that are relevant to the quality of agency information disseminations include the following:

Purpose (2) is "to ensure the greatest possible public benefit from and maximize the utility of information *created*, collected, maintained, *used*, shared and *disseminated* by or for the Federal Government."

Purpose (4) is to "improve the quality and use of Federal information to strengthen *decisionmaking, accountability, and openness* in Government *and society*."

Purpose (7) is to "provide for the dissemination of public information on a timely basis, on equitable terms, and *in a manner that promotes the utility of the information to the public* and makes effective use of information technology."

Purpose (9) is to "ensure the integrity, quality, and utility of the Federal statistical system."

Purpose (11) is to "improve the responsibility and *accountability* of the Office of Management and Budget and all other Federal agencies *to Congress and to the public* for implementing the information collection review process, information resources management, and related policies and *guidelines* established under this chapter."

Further provisions of the 1995 PRA that are pertinent to the IQA and its implementation by OIRA, and that were added in 1995, include the following in the "definitions" section:[18] "(7) The term 'information resources management' means the process of managing information resources

16. Paperwork Reduction Reauthorization Act of 1986, Pub. L. No. 99-500, Title VIII, Part A, 100 Stat. 1783-335, sec. 814(b), § 3504(d)(1), Oct. 18, 1986. Section 3504(a), as amended in 1986, was not a preface to section 3504(d)(1), as in the 1995 PRA.

17. 44 U.S.C. § 3501 (2012) (emphasis added).

18. 44 U.S.C. § 3502 (2012).

to accomplish agency missions and to improve agency performance, including through the reduction of information collection burdens on the public;"[19] and "(12) The term 'public information' means any information regardless of form or format, that an agency discloses, disseminates, or makes available to the public . . . ."

Section 3506 of the 1995 PRA sets out other agency, as distinct from OMB, responsibilities, but which OMB must direct and oversee. Two portions of this section are particularly important with regard to the IQA and its guidelines. The first portion, section 3506(a)(1)) states that "[t]he head of each agency shall be responsible for . . . (B) complying with the requirements of this chapter and related policies established by the Director [of OMB]." The next portion, section 3506(b)), provides that "[w]ith respect to general information resources management, each agency shall . . . (C) improve the integrity, quality, and utility of information to all users within and outside the agency . . . ."

The above provisions of the 1995 PRA establish a dual level of responsibilities that is clearly mirrored in the IQA: Individual agencies are responsible for improving the "integrity, quality, and utility" of the information they use or disseminate to the public, and for complying with policies established by OMB, while OMB is responsible for providing oversight and pertinent regulatory guidance with which the agencies must comply to achieve such ends.

C. PRA Legislative History Pertinent to the IQA

There have been three versions of the PRA: 1980, 1986, and 1995. Although the 1995 PRA was the version in effect at the time the IQA incorporated and referenced PRA provisions, the evolution of the law from an emphasis on reducing paperwork burdens to including an emphasis on the quality of information used and disseminated to the public by agencies is revealing in indicating the Congressional concerns that brought about the IQA after 1995.

The 1980 PRA did not specifically address the quality of information disseminated to the public. It did, however, give OMB the primary authority and responsibility for general information policy, stating that "[t]he Director shall develop and implement Federal information policies, principles, standards and guidelines …"[20] and shall have responsibility for "evaluating agency information management practices to determine their adequacy and efficiency, and to determine compliance of such practices with the policies, principles, standards, and guidelines promulgated by the Director . . . ."[21] As discussed above, it also contained section 3516 on OMB promulgation of "rules, regulations, or procedures," the legislative history of which is important.

The House report on its version of the 1980 PRA, which contained the above-quoted provisions, stated that one of the objectives of its bill, H.R. 6410, was "to . . . increase the availability and accuracy of agency data and information . . . ."[22]

---

19. The 1986 PRA included a different definition of "information resources management:" "[T]he planning, budgeting, organizing, direction, training, promoting, controlling, and management activities associated with the burden, collection, *creation, use, and dissemination* of information by agencies . . . ." Pub. L. No. 99-500, sec. 801, § 812(3)(13), 100 Stat. 1783-336 (emphasis added).
20. *Supra* note 7, § 3504(a).
21. *Id*. § 3504(b)(5).
22. H.R. REP. NO. 96-835, at 1 (1980).

The 1986 PRA[23] contained several new provisions directed at agency dissemination of information and its accuracy. It added to the purpose of maximizing the usefulness of information collected by the government the language "maintained and *disseminated*" by the government.[24] It added a definition of "information resources management" as meaning "the planning, budgeting, organizing, directing, training, promoting, controlling, and management activities associated with the burden, collection, *creation, use and dissemination* of information by agencies . . . . [25] It also added the term "dissemination" to 44 U.S.C. § 3504(a) ("Authority and Functions of Director"), mandating that OMB "shall develop and implement Federal information policies, principles, standards, and guidelines and shall provide direction and oversee . . . agency . . . *dissemination* of information . . . ."[26] The amendments also added a new section on agency responsibilities, which stated in part that each agency shall "(6) implement applicable Government-wide and agency information policies, principles, standards, and guidelines with respect to . . . *dissemination* of information . . . (7) periodically evaluate and, as needed, *improve, the accuracy, completeness, and reliability* of data and records contained within Federal information systems . . . . [27]

The conference report on the 1986 legislation reiterated the statement in the House report on the 1980 PRA bill that one objective of the PRA was to "increase the availability and accuracy of agency data and information."[28] It also reaffirmed that OMB had primary responsibility for implementing the information management policies and authority established by the Act.[29]

Efforts to reauthorize and further amend the PRA stalled from 1989 through 1993 due mainly to controversy over OIRA's role in reviewing regulations under Executive Order 12291, which had been issued by President Reagan in 1981.[30] From 1988 to 1995, the Bush Republican Administration faced a Democrat-controlled Congress; however, there was an increasing awareness in Congress of the need to address more thoroughly the matter of the accuracy of "public information" disseminated by the agencies, both in rulemaking and via the Internet and World Wide Web. The controversy over regulatory review by OIRA subsided after President Clinton issued Executive Order 12866 on regulatory review in September 1993.[31] The Democrat-controlled Congress then began work on reauthorization and amendment of the PRA almost immediately after installation of the new Clinton Administration in 1993, and that work continued when the Republicans assumed control of Congress in 1995, resulting in the unanimously-approved, bipartisan, revised PRA of 1995.

In the meantime, Congressional efforts to reauthorize and further amend the PRA had begun on a somewhat limited basis in 1989. For example, in the Senate, S. 1742, the "Federal Information

23. Paperwork Reduction Reauthorization Act of 1986, Pub. L. No. 99-591, Title VIII, 100 Stat. 3341-335, sec. 801 (1986). The PRA of 1986 was one of a number of Acts consolidated into a continuing appropriations Act for fiscal year 1987 by H. J. Res. 738. Due to the consolidation there is another Title VIII that has no relation to the PRA. There is also a previous identical version of the Act, Pub. L. No. 99-500, that was "updated" by Pub. L. No. 99-591.
24. *Id*. at § 811(a), amending § 3501(3) of the 1980 PRA (emphasis added).
25. *Id*. at § 812(3) amending § 3502 of the 1980 PRA (emphasis added).
26. *Id*. at § 814(a), amending § 3504(a) of the 1980 PRA (emphasis added).
27. *Id*. at § 816(4), amending § 3506(c) of the 1980 PRA (emphasis added).
28. H.R. REP. NO. 99-1005, at 771 (1986) (Conf. Rep.).
29. *Id*.
30. 46 Fed. Reg. 13.193 (Feb. 17, 1981), 3 C.F.R., 1981 Compil., at 127.
31. 58 Fed. Reg. 51735 (Oct. 4, 1993).

Resources Management Act" was introduced and referred to the Committee on Government Affairs on Oct. 6, 1989. In the House, H.R. 3695, the "Paperwork Reduction and Federal Information Resources Management Act of 1989," was introduced on Nov. 17, 1989 and referred to the Committee on Government Operations.

Both bills showed an increasing interest in more specifically widening the scope of the PRA beyond information collection to encompass the quality of information disseminated by agencies and the need for OMB to coordinate Federal information policy. The Senate report on its bill explained:

> S. 1742, as amended, seeks to improve the law [the PRA] to address the benefits as well as the burdens of Federal information.
>
> The Committee also sees the need to improve the quality of federal information. In the words of Dr. Michael Boskin, Chairman of the President's Council of Economic Advisors, when he testified at the May 15, 1989 hearing of the Subcommittee on Government Information and Regulation, "While good, better and more accurate information may not assure sound decisions in all cases, surely poor information can only lead to good decision-making by accident." Senator Bingaman, Chairman of the Subcommittee, echoed these sentiments throughout the reauthorization proceedings. The Committee has a clear view that more should be done to improve the quality of Federal information.[32]

The House report explained:

> The fourth finding [of H.R. 3695] states that the unrestricted flow of public information from the Federal Government to citizens of the United States is essential to the proper operation of the United States as a democratic society. The finding also recognizes that public information is a valuable national resource that provides citizens with knowledge of their government, society, and economy, that it is a means to ensure that accountability of government, that it is an essential tool for managing the government's operations, and that it is often a commodity with economic value in the marketplace.
>
> This finding underscores the fundamental importance of government information in the American social, economic, and political structure. The information dissemination policy provisions in H.R. 3695 are premised on this finding. Agency decisions affecting information dissemination should be focused as much on the needs of those outside of government as on the needs of government itself.[33]

The House report, in commenting on the need for OMB to revise its existing guidance to make it consistent with its new information dissemination responsibilities under the bill, also contained an explicit statement of intent regarding the availability of judicial review of agency PRA information dissemination actions:

32. S. REP. NO. 101-487, at 27 (1990).
33. H.R. REP. NO. 101-927, at 27 (1990).

> Given the breadth of dissemination activities throughout the Federal Government, there is a need for a consistent and uniform approach to dissemination policy. OMB's policymaking role is to provide uniform guidance interpreting the [agency] dissemination requirements now moved to section 3506(j).
>
> One consequence of this change is to make it *clearer* that judicial review of agency dissemination decisions is available under the provisions of section 702 of the Administrative Procedure Act.[34]

However, the Senate did not vote on the bill before Congress adjourned, and, as noted above, re-authorization and amendment efforts were temporarily frustrated by the continuing controversy over OIRA regulatory review activities until President Clinton issued the new regulatory review executive order, E.O. 12866, after taking office in 1993.[35]

More significant efforts and progress in reauthorizing and substantially revising the PRA began in earnest in early 1993 with introduction and consideration of S. 560. That bill passed the Senate by unanimous voice vote in October 1994 and was sent to the House in late 1994;[36] but the House failed to act on it prior to expiration of the 103d Congress. That bill contained all the provisions quoted above regarding information quality contained in the 1995 PRA as enacted.

Although Republicans had assumed majority control of the 104th Congress at the start of 1995, there was clear continuing bipartisan support for a new and improved PRA. In the Senate, S. 244, which was substantially identical to the previous S. 560, was introduced with 44 co-sponsors on Jan. 19, 1995. S. 244 was reported by the Senate Committee on Government Affairs on Feb. 14, 1995,[37] and was passed by a 99-0 vote on March 7, 1995 and sent to the House.

The House bill, H.R. 830, which was nearly identical to S. 244, was introduced on Feb. 6, 1995 and referred to the Committee on Government Reform and Oversight. The Committee issued its report on Feb. 15, 1995,[38] and the bill passed with minor amendments by a vote of 418-0.

The two bills went to conference on March 10, 1995. A conference report was adopted 423-0 on April 6,[39] and S. 244 as amended was signed into law by President Clinton on May 22, 1995 as the "Paperwork Reduction Act of 1995."

The 1994 and 1995 Senate committee reports and the 1995 House report consistently describe how the PRA would be amended to establish more clearly that the Information Resource

---

34. *Id*. at 37 (emphasis added). Section 702 of the APA (5 U.S.C. § 702) states in relevant part that "[a] person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action within the meaning of a relevant statute, is entitled to judicial review thereof." Although this statement in the report is not explained further, the word "clearer" indicates that the Committee viewed APA section 702 as already providing judicial review.

35. *See* S. REP. NO. 104-8, at 9-13(1995) and H.R. REP. NO.104-37, at 10-15 (1995) for detailed descriptions and perspective from the Senate Committee on Governmental Affairs and the House Committee on Government Reform and Oversight regarding the controversies between 1987 and 1993 that impeded substantial new action on the PRA.

36. S. REP. NO. 103-392 (1994).

37. S. REP. NO. 104-8 (1995).

38. H.R. REP. NO. 104-37 (1995).

39. H.R. REP. NO. 104-99 (1995) (Conf. Rep.).

Management (IRM) concept of the legislation was intended to encompass the full lifecycle of information management by OMB and the individual agencies, including dissemination of information to the public, ensuring its quality for use in agency decisionmaking, and public accountability.

The 1995 report on S. 244 by the Senate Committee on Governmental Affairs[40] contains the following selection of explanations of changes to the 1980 PRA, as amended in 1986, that are relevant to OMB and individual agency responsibilities for the quality of information disseminated to the public. The statements in the Senate report were mirrored in the House report on H.R. 830 by the Committee on Government Reform and Oversight almost exactly, and citations to the same statements below from both reports are therefore provided in tandem. The reports state:

> A third important issue that requires legislation is the matter of information dissemination. The advent of the electronic information age presents new opportunities and obligations for the Federal Government as it strives to fulfill its continuing responsibility to make government information accessible to the American public. The legislations meets this need by providing for improved dissemination of government information to the public, particularly in electronic formats. The bill establishes basic dissemination policies and principles . . . and integrates dissemination planning into the management of government information.[41]
>
> . . .
>
> Overall, the Committee believes . . . that more needs to be done to improve the management of Federal information resources. Information policymakers must equip themselves with the knowledge necessary to achieve the highest quality, best use, and least burden from government information.[42]
>
> . . .
>
> Through the Paperwork Reduction Act, Congress attempted to articulate the management concept that could drive real world management improvements. Nearly a decade and a half later, the Committee finds that while IRM is a recognized concept in government and the private sector, there is not enough commitment to making IRM work in practice. The Committee is convinced, however, the management concept is not flawed. Rather the need is to develop an improved strategy by which to apply IRM.
>
> Information, as a resource, is not simply a matter of questions answered or systems acquired. Information must be reliable, accurate, complete, accessible, and timely if it is to be used by agency managers to make decisions and take actions in fulfilling agency missions . . . . [43]
>
> . . .
>
> . . . . The bill adds several additional purposes and revises and realigns other purposes to emphasize the need to improve information resources management (IRM) . . . . It promotes the theme of improving the quality and use of information

40. *Supra* note 37.
41. *Id*. at 6; *supra* note 38, at 7.
42. *Id.* at 14; *id*. at 16.
43. *Id.* at 17; *id*. at 19.

> to strengthen decisionmakng and accountability and to maximize the benefits and utility of information created, collected, maintained, used, shared, disseminated, and retained by or for the Federal Government . . . . It also adds the purpose of improving the responsibility and accountability of the Office of Management and Budget and other Federal agencies to the Congress and to the public for effectively implementing the requirements of the Act.[44]
>
> . . .
>
> The goal [of the revised definition of IRM] is to provide reliable, accurate, complete, and timely information needed by top agency and program managers to accomplish the missions of the agency . . . .[45]
>
> . . .
>
> [Subsection 3504(d)] establishes new provisions to provide specific guidance for the management of information dissemination functions. Under existing law, these were only referenced generally (e.g., sec. 3504(a)). While the Act's life cycle approach previously conveyed an expectation of OMB oversight of agency information dissemination function, the developing capabilities of agencies and of information technologies for this purpose necessitates the articulation of specific OMB information policy setting and oversight responsibility. As with other OMB IRM functions detailed in section 3504, the counterpart agency information dissemination responsibilities are spelled out in section 3506.
>
> This new subsection [§ 3504(d)] *requires* OMB to develop government-wide *policies and guidelines* to guide agency dissemination of public information, and promote access to public information. As elsewhere in the legislation, the *mandate* applies to the dissemination of information, regardless of form or format.[46]
>
> . . .
>
> With respect to general information resources management [under subsection 3506(b)], each agency is to undertake several specified actions:
>
> 1. Manage information resources to reduce information collection burdens, increase program efficiency and effectiveness, and improve the integrity, quality, and utility of information to users both within and outside the agency.[47]

A conference report, which addressed mainly how minor differences between the House and Senate bills were resolved, was issued on April 3, 1995.[48] Two significant amendments to the House and Senate bills agreed upon in the conference report were (1) a requirement that agencies make available the "underlying data" if they furnish information to the public in an electronic format,[49] and (2) a requirement that agencies provide adequate public notice when "initiating, substantially modifying, or terminating a significant information dissemination product."[50] On April 6, the Senate agreed to the conference report by unanimous voice vote, and the House agreed by recorded vote of 423-0.

---

44. *Id.* at 35; *id*. at 35 (last sentence beginning "It also adds the purpose . . . ." is not in the House report).
45. *Id.* at 39. The language in the House report, at 37, is similar in substance but not wording.
46. *Id.* at 42; *id*. at 40 (emphasis added to language from both reports).
47. *Id.* at 45; *id*. at 43.
48. H.R. Rep. No. 104-99 (1995) (Conf. Rep.).
49. *Id.* at 34 (§ 3506(d)).
50. *Id.*

The PRA of 1995 was signed into law by President Clinton as Public Law 104-13 on May 22, 1995.

As can be seen, the PRA evolved significantly from 1980 to 1995. In its 1980 version, it appeared to be concerned only with reducing information collection burdens and efficiently managing information resources within the government. In 1986, there was more concern over both public access to information and agency improvement of the accuracy of information, but it was not clear that "accuracy" also applied to disseminated information in addition to information used internally. By 1994 and 1995, with recognition of the emerging importance of electronic dissemination of information via the Internet and World Wide Web, the Act was revised to focus more clearly on the complete life cycle of information, from collection through dissemination, and with a new recognition of the importance of ensuring the quality of disseminated information as the final phase of this "IRM" life cycle.

Throughout this evolution, OMB was charged with the central role of establishing uniform policy, standards, guidance, and procedures in the form of "regulations and rules," with individual agencies being required to comply with OMB guidance in managing their day-to-day operations involving information collection, maintenance, and dissemination, including improving the quality of disseminated information.

D. Post-PRA Legislative History Leading up to the IQA

Over the next five years, from 1995 to 2000, with the rapid spread of Internet use[51] and increasing attention to specific information dissemination quality issues, particularly environmental issues, Congress became increasingly frustrated with a lack of progress by OMB and the agencies in implementing the IRM information dissemination regulatory guidance required by the 1995 PRA.

In January 1995, the House Committee on Commerce began consideration of H.R. 9, the "Jobs Creation and Wage Enhancement Act of 1995," which contained a Title III that addressed principles for risk characterization and communication. Although the Clinton Administration testified that it supported those Title III principles in general (including objectivity and explanation of uncertainties), it opposed enactment on the basis that Title III contained too much detail and inflexible directives.[52] This opposition apparently stymied further action on H.R. 9. Subsequently, however, general principles for risk characterization and communication soon emerged in a revised and more succinct form from the House Committee on Commerce in the Safe Drinking Water Act

51. Susannah Fox & Lee Rainie, *The Web at 25 in the U.S.*, PEW RESEARCH CENTER, Feb. 27, 2014, at 1, www.pewinternet.org/2014/02/27/the-web-at-25-in-the-u-s/ (last visited Dec. 2017) (Internet use by Americans more than tripled during that period, from 14 to 46 percent).

52. *Paperwork Reduction Act and Risk Assessment and Cost/Benefit Analysis for New Regulations: Hearing on H.R. 830 Before the Subcomm. on Nat'l Econ. Growth, Nat. Res. and Regulatory Affairs of the H. Comm. on Gov. Reform and Oversight*, 104th Cong. 15-19 (Feb. 7, 1995) (Statement of Sally Katzen, Administrator of OIRA). H.R. 830 was similar to Title III of H.R. 9.

Amendments of 1996. That legislation passed and became law.[53] The Chairman of the House Committee on Commerce, Rep. Tom Bliley, soon after played a role in supporting the IQA.[54]

Also in 1996, EPA publicized plans to expand the TRI (Toxics Release Inventory) program,[55] and those plans became controversial and came to the attention of Congress and its appropriations committees. Differing views between the Senate and House were resolved with a conference committee directing GAO to conduct a study and prepare a report on issues associated with EPA's plans.[56]

The GAO review was conducted during 1997 and 1998 and likely elevated the importance of the TRI dissemination issues among large segments of the private sector who were involved in furnishing information and commenting to GAO in connection with preparation of its report.[57]

Although the GAO report was not published until September 1998, which was about the same time as the 1998 House report urging OMB to promulgate rules on "Reliability and Dissemination of Information" in fulfillment of the provisions of the PRA (*infra*), it is likely that the interest its investigation generated as a result of numerous interviews and inquiries of interested entities during its research and preparation inquiries resulted in increased Congressional attention to the issues of accuracy in agency information disseminations and measures for obtaining correction of inaccuracies.[58]

The GAO report,[59] which was addressed primarily[60] to the VA, HUD, and Independent Agencies Subcommittees of both the House and Senate appropriations committees and focused mainly on EPA proposals for expansion of TRI reporting and dissemination of TRI information to the public, recommended:

> To help ensure that EPA provides the public with data that are accurate, complete, and relevant to its needs, we recommend that the EPA Administrator supplement the agency's existing policies on information resources management by developing agencywide policies and procedures that specify guidance and standards for

53. Safe Drinking Water Amendments of 1996, Pub. L. No. 104-182, 110 Stat. 1613, § 103 (1996). The risk assessment communication requirements of the Safe Drinking Water Act Amendments of 1996 were later incorporated into OMB's final government-wide IQA guidelines.

54. *See infra* note 67.

55. Under provisions of the Emergency Planning and Community Right-to-Know Act (EPCRA), 42 U.S.C. § §11001 (2016), facilities that produce, handle, or release certain chemicals (numbering in the hundreds) must report this information on potential or actual "toxic" releases annually to EPA if certain thresholds are reached. EPA maintains a public database of this information at https://www.epa.gov/enviro/tri-search. See also https://www.epa.gov/toxics-release-inventory-tri-program/learn-about-toxics-release-inventory (both web pages last visited Dec. 2017).

56. H.R. REP. NO. 104-812, at 70-71 (1996) (Conf. Rep.).

57. See Appendix I of the GAO report, *infra* note 59.

58. GAO procedures for preparation of reports provide for interaction with Congress and affected entities well before the publication date of a report. See GAO, *Request to GAO: Process and Timing*, https://www.gao.gov/assets/690/682523.pdf (last visited Dec. 2017).

59. U.S. GOV'T ACCOUNTABILITY OFF., GAO/RCED-98-245, ENVIRONMENTAL INFORMATION: AGENCYWIDE POLICIES AND PROCEDURES ARE NEEDED FOR EPA'S INFORMATION DISSEMINATION (1998).

60. The report states that it was also provided to "other appropriate congressional committees" and OMB. *Id*. at 21.

> program offices involved in designing, developing and implementing information dissemination projects. Such guidance and standards should address obtaining stakeholder's involvement in the project's design and development, testing for and correcting errors in the data, and communicating contextual information on the data's uses and limitations.[61]

The next year, the House Appropriations Committee (apparently its VA, HUD, and Independent Agencies Subcommittee) requested a more general report from GAO on issues associated with EPA's dissemination of all types of environmental information. The GAO report, issued in September 1999,[62] stated findings on the need for new guidance on agency information dissemination:

> Data accuracy . . . has long been a serious challenge facing EPA. Various reviews that we, EPA, and others have done have revealed persistent concerns about the accuracy of data in many of EPA's information systems.
>
> . . .
>
> Preventing data errors and correcting errors once they have been identified, essential to data accuracy, have proved to be daunting tasks for EPA . . . . [E]fforts to improve the accuracy of EPA's information systems will need the cooperation of . . . EPA employees, staff from state—and in some instances, local-–governments, the regulated community, contractors, and private citizens who use data from these systems.[63]

The report noted that in 1998 EPA's Deputy Administrator had called for a strategic plan to improve agency data quality, and the plan "called for data users to alert the agency to inaccurate data," but the plan had not been adopted.[64]

The report also stated that "EPA does not yet have a common understanding of what data quality means and how the agency and its state Partners can most effectively ensure that the data used for decision-making or disseminated to the public are of high quality."[65]

However, there was a fundamental problem with the Congressional requests to GAO and GAO's recommendations in both 1998 and 1999: They were not consistent with the framework of responsibilities established by the PRA, and they addressed only a single agency. Under the PRA, *OMB* had responsibility for issuing *government-wide* rules and regulations on information dissemination to be complied with by all the agencies. As a result of consideration and enactment of the PRA of 1995, including the criticisms leveled at OMB in the House and Senate reports on the 1995 PRA for failure to fully implement the IRM rulemaking provisions, Congress presumably had a reasonable expectation that OMB would proceed promptly with government-wide rules

---

61. *Id.* at 19.

62. U.S. GOV'T ACCOUNTABILITY OFF., GAO/RCED-99-261, ENVIRONMENTAL INFORMATION: EPA IS TAKING STEPS TO IMPROVE INFORMATION MANAGEMENT, BUT CHALLENGES REMAIN (1999). The report was addressed to the House VA, HUD, and Independent Agencies Appropriations Subcommittee, but stated that it was also being provided to EPA and other interested parties. *Id.* at 23.

63. *Id*. at 10.

64. *Id*. at 12.

65. *Id*. at 13 (citation to another GAO report omitted).

providing guidance on information dissemination quality, which would then be followed by conforming agency-specific regulations.[66]

Although EPA might have proceeded without OMB oversight, that was not the process envisioned by Congress in the PRA. This was apparently overlooked by GAO, but it is clear from subsequent developments that Congress was aware of the discrepancy between the GAO recommendations and the PRA and sought to reconcile GAO's recommendations with the PRA.[67]

In June 1998 the Treasury, Postal Service, and General Government Appropriations Subcommittee of the House Appropriations Committee, which had jurisdiction over OMB appropriations, took over the lead on the information quality issue from the VA, HUD, and Independent Agencies Subcommittee. Its report on FY 1999 appropriations for OMB contained the following statement:

> RELIABILITY AND DISSEMINATION OF INFORMATION
>
> The Committee urges the Office of Management and Budget (OMB) to develop, with public and Federal agency involvement, rules providing 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, and information disseminated by non-Federal entities with financial support from the Federal government, in fulfillment of the purposes and provisions of the Paperwork Reduction Act of 1995 (P.L. 104–13). The Committee expects issuance of these rules by September 30, 1999. The OMB rules shall also cover the sharing of, and access to, the aforementioned data and information, by members of the public. Such OMB rules shall require Federal agencies to develop, within one year and with public participation, their own rules consistent with the OMB rules. The OMB and agency rules shall contain administrative mechanisms allowing affected persons to petition for correction of information which does not comply with such rules; and the OMB rules shall contain provisions requiring the agencies to report to OMB periodically regarding the number and nature of petitions or complaints regarding Federal, or Federally-supported, information dissemination, and how such petitions and complaints were handled. OMB shall report to the Committee on the status of implementation of these directives no later than September 30, 1999. [68]

---

66. As noted in the quoted text accompanying note 46 *supra*, both the House and Senate reports on the bills resulting in the 1995 PRA stated that the newly-added section 3504(d), later incorporated specifically into the IQA, was intended as a "mandate" that "requires OMB develop government-wide policies and guidelines to guide agency dissemination of public information . . . regardless of form or format." However, the 1995 PRA did not specify a timeframe for such OMB action. The author knows first-hand that the TRI issue was a significant factor in generating Congressional interest in ensuring promulgation of PRA guidance on quality in information disseminations and measures for calling attention to quality issues and ensuring agency compliance with such OMB guidance.

67. As discussed below, the Chairman of the House Committee on Commerce, Tom Bliley, subsequently turned his attention from EPA risk communication under the Safe Drinking Water Act to supporting the IQA. *See also supra*, text accompanying notes 53-54.

68. H.R. REP. NO. 105-592, at 49-50 (1998). The Senate Committee on Governmental Affairs (chaired by Senator Fred Thompson) meanwhile reported out legislation (S. 981, The Regulatory Improvement Act of 1998) for improving the quality of risk information disseminated to the public. That legislation would have applied to all risk

The conference report on the appropriations bill incorporated by reference the above language and directives, stating that "[t]he language . . . [in H.R. Rep. No. 105-592 and S. Rep. No. 105-251] should be complied with unless specifically addressed in the accompanying statement of managers."[69] The conference report's statement of managers also stated, in the section on OMB appropriations, under "PERFORMANCE OF STATUTORY RESPONSIBILITIES," that "[t]he conferees have been assured that OMB will strictly adhere to the statutory requirements in the bill on Paperwork Reduction . . . . The conferees will monitor OMB's compliance with these requirements carefully."[70]

When OMB took no visible action to comply with the information dissemination mandates in the 1995 PRA within the timeframe urged in the House report, Members of Congress wrote to OMB to question OMB concerning its progress or inaction. As will be seen, OMB inaction, non-responsiveness, and overt resistance seemed clearly to center mainly on its concern that the IQA provisions outlined in the House report would allow judicial review.

On May 6, 1999, Representative Jo Ann Emerson of the House Appropriations Committee wrote to OMB Director Jacob ("Jack") Lew "to inquire about the status of OMB's efforts to issue rules, as required by the Paperwork Reduction Act of 1995, to govern the quality of data and information that Federal agencies disseminate to the public," noting that the Committee on Appropriations had urged that such rules be issued in final by September 30, 1999 in its conference report on the FY 1999 appropriations bill. Rep. Emerson also referred OMB to a working paper by the Center for Regulatory Effectiveness that concluded that EPA's presentation of scientific information on global warming was unbalanced or selective, and incorrect in several respects, and was likely to mislead the public, and she requested any comments that OMB might have on the CRE paper. She noted that this EPA information dissemination could be considered a good example of why regulations on information quality were needed.[71]

---

assessments (with a few minor exceptions), not just those disseminated by EPA. In addition to establishing requirements for presentation of risk assessment information, the bill would have required independent peer review of all risk assessments supporting major regulations. *See* S. REP. NO. 105-188, at 2-3, 35-43 (1998). Although the bill was never voted on by the full Senate, it indicates that the subject of the quality of agency information dissemination was a matter of widespread concern throughout much of Congress. And, as discussed below, Senator Thompson became involved in consideration of the proposed IQA.

69. H.R. REP. NO. 105-789, at 63 (1998) (Conf. Rep.). The Senate report did not address the reliability of disseminated information as did the House report. The most recently enacted bill on paperwork reduction was the 1995 PRA with its information dissemination requirements.

70. *Id*. at 84-85.

71. This letter is referenced in the May 25, 1999 letter response from OMB Director Jacob J. Lew that is contained in the GPO hearing print cited *infra* note 86, at 512. A copy of the May 6 letter from Rep. Emerson to Director Lew is not reproduced in the full GPO hearing print, but an official copy obtained from the National Archives and Records Administration (NARA) via FOIA is on file with the author. It should be noted that the electronic version of the hearing print, now online at https://www.gpo.gov/fdsys/pkg/CHRG-106hhrg64690/html/CHRG-106hhrg64690.htm (last visited Dec. 2017) does not include the OMB letter responses summarized below, nor is it paginated. Where the letters appear in the hard-copy GPO print, the online version omits them and has inserted "[The information follows:]," although it does not follow, except in the hard-copy print. It should also be noted that copies of the substance (minus letterhead) of all the letters – both to and from OMB – summarized here were posted on the website of the Center for Regulatory Effectiveness (CRE) at http://www.thecre.com/quality/quality_2003_1999.html along with other information on developments relating to the IQA (which CRE refers to as the Data Quality Act). The substance of the May 6 letter from Rep. Emerson to Director Lew is reproduced on the CRE website at http://www.thecre.com/quality/letter-emerson-lew.html (last visited Dec. 2017).

On May 20, 1999, the Chairman of the House Committee on Commerce, Rep. Tom Bliley, also wrote to Director Lew, with copies to Members of the House Committee on Appropriations (Chairman C.W. Bill Young and Subcommittee Chairman Jim Kolbe), in support of the above information quality directives contained in the House report on its FY 1999 appropriations bill. Mr. Bliley emphasized his committee's continuing interest in risk communication quality, the requirement in the PRA for OMB to issue regulations on data quality, and the need for OMB rules to include requirements for administrative mechanisms to allow affected person to petition for correction of information that does not comply with the OMB rules. Finally, he asked for a status report from OMB on what activities OMB had under way to comply with the PRA requirements for regulations on data quality.[72]

On May 25, 1999, Director Lew replied to the Emerson letter of May 6. He assured her that "agencies" (apparently as distinct from OMB) were committed to dissemination of "timely and accurate information . . . as part of their responsibilities under the Paperwork Reduction Act (PRA)." He informed her that OMB was following up on the concerns outlined in the appropriations report by consulting with agency Chief Information Officers for their views on whether changes in existing processes for ensuring the quality and reliability of agency information dissemination were necessary. He did not comment on the assertion in her letter that OMB was required to issue rules ensuring information dissemination quality by the 1995 PRA.[73]

The Senate Committee on Governmental Affairs also indicated its interest in OMB's actions in response to the House appropriations report for FY 1999. Following a Committee hearing on confirmation of John Spotila to be the new Administrator of OIRA, the Committee's Chairman, Senator Fred Thompson, submitted a written question to Mr. Spotila asking what OIRA was doing to develop the data and information quality regulations that the House Committee on Appropriations had urged it to develop promptly. Senator Thompson asked:

> *The Paperwork Reduction Act of 1995 directs OMB to issue rules to improve the quality of data and information that Federal agencies disseminate to the public. In the Conference Report on the FY 1999 OMB Appropriations Act (part of the Omnibus Appropriations Act, Pub. L. 105-277) Congress urged OMB to issue final rules on data quality by September 30, 1999. What is OMB doing to issue regulations to improve the quality of data and information that Federal agencies disseminate to the public?*

Mr. Spotila responded: "Although I have not personally been involved, my understanding is that OMB staff are considering how best to respond to the House Report language. To my knowledge, OMB has not yet made a decision in this regard."[74]

---

72. This letter is referenced in the July 12, 1999 response letter from Director Lew contained in the GPO print of the House hearing on March 28, 2000 on its FY 2001 appropriations bill, *infra* note 86, at 513-15. An official copy of the Bliley letter is on file with the author, obtained from NARA through a FOIA request. A copy of the substance of the letter, with attachments, was posted on the website of the Center for Regulatory Effectiveness near the time of its submission to OMB and can still be found at http://www.thecre.com/quality/letter-bliley-lew.html (last visited Dec. 2017).

73. GPO hard-copy hearing print, *infra* note 86, at 512.

74. *Hearing on the Nomination of John T. Spotila to be Administrator of Office of Information and Regulatory Affairs, Office of Management and Budget Before the Sen. Comm. on Gov. Affairs*, 106th Cong. 43-44 (1999) (italics as in original).

On July 12, 1999, OMB Director Lew also replied to Commerce Committee Chairman Bliley's May 20 letter, with cc's to House Committee on Appropriations Chairman Rep. Young, and Committee Members Kolbe, Hoyer, and Obey. Mr. Lew did not respond directly to Chairman Bliley's request for a report on what activities OMB had under way or planned for issuing data quality regulations, nor did he dispute Rep. Bliley's statement that the 1995 PRA required OMB to issue regulations on information quality; instead, Mr. Lew's response discussed current Administration activities under E.O. 12866 to enhance data quality and the scientific basis for regulatory decisions, and described Administration efforts in working with agency Chief Information Officers to determine what issues regarding data quality might need to be addressed further and what activities agencies already had under way to deal with them.[75]

On Sept. 16, 1999, the Senate Committee on Appropriations and its Subcommittee on VA, HUD, and Independent Agencies issued a report addressing its proposed FY 2000 appropriations for EPA's science and technology programs. The report included views and recommendations on data quality assurance, public participation in making corrections, and the availability of judicial review for those who might be harmed by agency information disseminations.[76]

In its report, the Committee first noted that it was "concerned about the accuracy of information contained in the [EPA's] Integrated Risk Information System [IRIS] database," and it directed the EPA Science Advisory Board to examine a sample of IRIS risk assessments for data quality and report back to the Committee within six months.[77] The Committee also set out a series of "expectations for EPA's information management activities."[78]

The second such "expectation" was that –

> EPA shall establish procedures to engage the public in the development, maintenance and modification of information products it offers to the public . . . . At a minimum, these procedures shall include the process EPA and the states will use to assure prompt correction of data errors in existing EPA Internet resources. These procedures shall also be consistent with EPA's obligations under the Paperwork Reduction Act."[79]

In its sixth "expectation," the report stated:

> [T]he Committee is concerned that the Administration is pursuing legal positions that would have the effect of insulating its information dissemination activities from all forms of judicial review. The Committee believes that the availability of judicial review is an important means to provide redress for those who might be harmed by

75. GPO hard-copy hearing print, *infra* note 86, at 513-15.
76. S. REP. NO. 106-161 (1999).
77. *Id.* at 75-76.
78. *Id.* at 81-82.
79. *Id.* at 81.

> government action and to provide the proper incentives for care in the use of information by government agencies.[80]

The Committee then directed EPA to establish a cooperative agreement with an institution that would consult with legal experts in administrative law to evaluate the judicial review issue, considering, among other statutory authorities, the Administrative Procedure Act and the Paperwork Reduction Act.[81]

The appropriations conference report reiterated concern with the accuracy of IRIS information being disseminated by EPA, but it differed slightly from the Senate report in directing EPA to prepare the report after consultation with the SAB and submit it within one year.[82] The conference report also incorporated by reference the Senate report's language regarding the need for procedures to engage the public in correcting information disseminated to the public, and concern regarding an Administration position against judicial review of agency information disseminations.[83]

On March 20, 2000, Rep. Emerson of the House Committee on Appropriations wrote to John Spotila, Administrator of OIRA, to inquire as to OMB's progress in issuing regulations on data quality as urged in the Committee's conference report for the FY 1999 budget.[84] Rep. Emerson noted that OMB had an obligation under the PRA to oversee agency data quality and that the Committee had urged OMB to draft regulations by September 30, 1999 and report back to Congress, but that date had passed and she would appreciate a progress report.[85] She also announced her intention to bring up this subject with OMB witnesses at the hearing of the

---

80. *Id*. at 82. The reference to the Administration's legal position apparently was not a reference to the Administration's position on judicial review applicable to the IQA, since the IQA had not yet been introduced or enacted and the Administration had not expressed any views on IQA judicial review. It was not until the March 2000 hearing discussed *infra* that any such views were expressed by OMB Director Lew. The legal positions referenced here appear to be the litigation positions taken by the Department of Justice against challenges to alleged inaccuracies in information disseminations prior to enactment of the IQA, such as in *Indus. Safety Equip. Ass'n, Inc. v. EPA*, 837 F.2d 115 (D.C. Cir. 1988), *Tozzi v. HHS*, 271 F.3d 301 (D.C. Cir. 2001), and *Flue-Cured Tobacco Coop. Stabilization Corp. v. EPA*, 313 F.3d 852 (4th Cir. 2002), the latter two of which were before the courts in 1998-1999. This suggests that Congress provided for a petition mechanism in the IQA to ensure that agency rejection of challenges to the accuracy of information disseminations and compliance with OMB rules/guidance on such accuracy would now clearly be reviewable under the APA.

81. *Id*. at 80-82.

82. H.R. REP. NO. 106-379, at 129 (1999) (Conf. Rep.). The EPA report to Congress in response to the directive in the House report was submitted in September 2000. *Characterization of Data Variability and Uncertainty: Health Effects Assessments in the Integrated Risk Information System (IRIS)*, EPA/635/R-00/005F.

83. *Id*. at 82.

84. A copy of this letter is not contained in the hearing prints, *infra* note 86. The substance of the letter is posted on the CRE website at http://www.thecre.com/quality/EmersonLetter20000320.html (last visited Oct. 27, 2017), and is referenced in Mr. Spotila's April 18 response letter in the GPO hard-copy hearing print, *infra* note 86, at 516-17. A copy was requested via FOIA from OMB by the author, but OMB responded that all OMB materials from that period had been accessioned to the National Archives and Records Administration (NARA). A FOIA request was then submitted to NARA, but it responded that it could not find any OMB documents for the period from 1996 to 2000 other than several in Director Lew's personal files, which did not contain the Spotila letter. The author continues to pursue this matter.

85. Although Members of Congress had taken the position that the PRA required OMB to issue regulations on information quality, the PRA did not contain any deadlines or target dates for issuance of the OMB or conforming agency regulations.

Subcommittee on the Treasury, Postal Service, and General Government Appropriations scheduled for March 28, 2000.

At the scheduled March 28 hearing, Rep. Emerson, backed-up by Subcommittee Chairman Kolbe, questioned OMB Director Lew about OMB activity in response to the language in the House and Conference Committee reports.[86] Other members of the Subcommittee present were Representatives Hoyer, Northrup, Goode, and Price.

In response to questions during the hearing by Reps. Emerson and Kolbe about where OMB stood on issuing data quality regulations, Mr. Lew responded that the House report language did not mandate issuance of regulations, but only "urged" that they be promulgated,[87] and OMB had serious concerns with the report language. In commenting on those concerns, it is clear that OMB was concerned that the administrative "petition" mechanism proposed in the House report would provide a right to judicial review.[88] The Director explained:

> Let me, if I may, respond to the substance of the matter [in the House report] and our concern. We have been concerned in the discussion of this policy that right now there are private rights of action in cases where there are consequences. We are concerned about a change of policy *that would create rights of action* where there aren't consequences. That is a tremendous expansion of potential litigation. It is the kind of issue we have worked with the Congress on over the years when we discussed regulatory reform generally, and it is a very, very serious matter.
> . . .
> The problem is – and this is not unique to this particular proposal – there are many proposals where when you change the administrative process *to create rights*. There are [sic] also opportunities *for review* and delay.[89]

86. *Hearings for Fiscal Year 2001 Before the Treasury, Postal Service, and General Government Appropriations Subcommittee of the House Committee on Appropriations, Part 3, Executive Office of the President and Funds Appropriated to the President*, 106th Cong. 477-79 (Mar. 28, 2000) (U.S. GPO print). The hard-copy GPO print contains materials not included in the copy of the hearing report available on GPO's FDsys website at https://www.gpo.gov/fdsys/pkg/CHRG-106hhrg64690/html/CHRG-106hhrg64690.htm (last visited Dec. 2017), which is not a paginated PDF version of the final GPO hearing print (although there is an extensive index with page numbers at the end). The online version of the hearing print omits materials such as the OMB letters responding to the letters from Reps. Bliley and Emerson, the written questions submitted to OMB by the Committee and individual Members following the hearing, and the OMB responses to those written questions. In many instances at the places where those omissions from the hard copy occur, the online version simply inserts the notation "[the information follows]," although the information does not follow. The hard-copy print of the hearing is available through the Library of Congress Law Library or from GPO (GPO 64-690, ISBN 0-16-060759-0, H181-57).

87. No one addressed whether the PRA mandated issuance of regulations, regardless of deadlines. The House language being addressed did not specifically refer to PRA sections 3516 and 3504 and did not assert that it mandated issuance of regulations. But see the House and Senate report language associated *supra* with note 46. The final IQA legislative language did specifically incorporate those PRA sections.

88. Mr. Lew was an experienced attorney and former Congressional policy advisor.

89. GPO hard-copy hearing print, *supra* note 86, at 478 (emphasis added). It appears that the last sentence, beginning with "There are" should have been recorded as part of the previous sentence rather than a new sentence, so that this statement would read "there are many proposals where when you change the administrative process to create rights there are also opportunities for review and delay." In referring to rights without consequences, it appears that Mr. Lew was overlooking the Constitutional requirements for "standing," and that the rules and petition process urged by the House would give rights only to "affected persons." See discussion of this issue *infra* Part V, § F.

Following the hearing, on April 18, 2000, OIRA Administrator Spotila wrote to respond to Rep. Emerson's March 20, 2000 letter.[90] In essence, he explained that, while he conceded that OMB's Circular A-130 on information management might need to be updated or supplemented,[91] there did not currently appear to be significant problems with information quality, and OMB was "not convinced that 'one-size-fits all' rules will add much to existing OMB guidance and oversight activity and the procedures followed by individual agencies. We are also concerned that new regulations might prove counterproductive to the goal of increasing data quality." OMB responded similarly to a written question submitted to it by the full Committee, indicating that it had no plans for developing data quality regulations, and that it opposed a "'petition' process" for "formal 'complaints'" regarding information quality.[92]

The Spotila letter and the written response to the Committee question amounted to a clear Administration rejection of Congressional calls for issuance of OMB and agency information quality regulatory guidelines in conformance with the PRA, including a petition mechanism by which affected persons could raise issues regarding the accuracy of agency information disseminations.

This OMB contrariness, particularly when there were already relevant mandates in the PRA, apparently did not go down well with the Committee on Appropriations and other Congressional supporters of issuance of rules and regulations on the quality of agency information disseminations. On July 18, 2000, the Committee issued its report on its bill for FY 2001 appropriations to OMB, H.R. 4871. That bill contained "section 515," which consisted of what was finally enacted as the IQA.

The report by the House Committee on Appropriations contained the following language describing section 515 in H.R. 4871.

> DATA QUALITY
>
> The Committee has included statutory language (Section 515) which requires the Office of Management and Budget to develop, with public and federal agency involvement, guidelines providing policy and procedural guidance to Federal

90. GPO hard-copy hearing print, *supra* note 86, at 516-17.

91. The OIRA letter referred to a process for submitting to an OMB "ombudsman" complaints regarding non-compliance with data quality guidance contained in the Circular; however, the Circular did not contain any significant guidance, and did not appear to be a legally binding legislative rule. A single sentence in Appendix IV of the Circular stated that "[a]gencies should inform the public as to the limitations inherent in the information dissemination product (e.g., possibility of errors, degree of reliability, and validity) so that users are fully aware of the quality and integrity of the information." 61 Fed. Reg. 6428, 6449 (Feb. 20, 1996). (This language was carried over from the 1993 version of the Circular. 58 Fed. Reg. 36068, 36084.) Circular A-130 was amended on Nov. 28, 2000, and published in the Federal Register on Dec. 12, 2000, with a statement added following the above-quoted language that "[t]he current Analysis of Key Sections in Appendix IV stresses the importance of data quality protections. OMB intends to review data quality policies in 2001 and to issue new guidance as appropriate." (The Appropriations Committee conference report was issued on Dec. 15, 2000, and the appropriations Act with the IQA was signed into law on Dec. 21, 2000.) No reference was made in the OIRA letter to the "Rules and regulations" section of the PRA (section 3516) or the new IQA provisions. *And see* OIRA's Memorandum M-95-22, Sept. 29, 1995, "Implementing the Information Dissemination Provisions of the Paperwork Reduction Act of 1995."

92. GPO hard-copy hearing print, *supra* note 86, at 510-11.

> agencies for ensuring and maximizing the quality, objectivity, utility, and integrity of information disseminated by Federal agencies, and information disseminated by non-Federal entities with financial support from the Federal government, in fulfillment of the purposes and provisions of the Paperwork Reduction Act of 1995 (P.L. 104–13). Committee [sic] reconfirms its instructions with language directing OMB to issue such guidelines no later than the end of the fiscal year 2001, with a copy forwarded to the Committee on Appropriations.[93]

H.R. 4871 was subsequently folded into a consolidated appropriations bill for FY 2001, H.R. 4577. The conference report on H.R. 4577 specifically addressed section 515 of H.R. 4871, stating:

> Section 515. The conferees include a new provision requiring OMB to develop guidelines for ensuring and maximizing the quality, objectivity, utility, and integrity of information disseminated by Federal agencies as proposed by the House. [94]

The conference version of the consolidated appropriations bill containing the IQA passed the Senate and House on Dec. 15, 2000,[95] and was signed into law on Dec. 21, 2000.

II. IMPLEMENTATION OF THE IQA[96]

Since the IQA is a directive to implement the PRA provisions on accuracy of information disseminated by Federal agencies, its agency coverage is the same as for the PRA. This means that virtually all Federal Departments and independent agencies are covered (roughly 100), possibly with a few minor but significant exceptions for Presidential advisors.[97]

---

93. H.R. REP. NO. 106-756, at 54-55 (2000). On July 20, 2000, the White House issued a Statement of Administration Policy with regard to H.R. 4871 "as reported by the House Committee" (H.R. REP. NO. 106-756) http://www.presidency.ucsb.edu/ws/?pid=74856 (last visited Oct. 27, 2017). The Statement did not express any opposition to section 515's "Data Quality" mandates to OMB as quoted above.

94. H.R. REP. NO. 106-1033, at 396 (2000) (Conf. Rep.). In one respect the statutory language was not consistent with the House report: It did not cover "information disseminated by non-Federal entities with financial support from the Federal government." However, as discussed below, the OMB government-wide guidelines did cover information developed by entities outside the disseminating agency if that information was relied on by the agency. Coverage of information disseminated by non-Federal entities with financial support from the Federal government was already covered to a large extent by the "Shelby Amendment" enacted in 1998, as discussed in the Fourth Circuit opinion in *Salt Inst. v. Leavitt*, *infra*.

95. 146 CONG. REC. H12,502, S11,885 (daily ed. Dec. 15, 2000).

96. OMB currently maintains an "Information Policy" webpage with an "Information Quality Government-wide Initiatives" section that includes links to most of the OMB implementation documents referred to in this section. https://obamawhitehouse.archives.gov/omb/inforeg_infopoltech#iq (last visited Dec. 2017).

97. "The term 'agency' means any executive department, military department, Government corporation, Government controlled corporation, or other establishment in the executive branch of the government (including the Executive Office of the President), or any independent regulatory agency, but does not include: (A) The General Accounting Office; (B) Federal Election Commission; (C) The governments of the District of Columbia and the territories and possessions of the United States, and their various subdivisions; or (D) Government-owned contractor-operated facilities, including laboratories engaged in national defense research and production activities." 44 U.S.C. § 3502(1). The definition of "agency" in the OMB rules for the PRA, 5 CFR § 1320.3(a), does not include the language "(including the Executive Office of the President)." *But see* Meyer v. Bush, 981 F.2d 1288 (D.C. Cir. 1993 (discussing case law under which some persons or offices within the Executive Office of the President might be excluded from the similar definition in the Freedom of Information Act).

A. OMB's Government-Wide IQA "Guidelines"

The implementation required by the IQA began on June 28, 2001 with issuance of a Federal Register "notice" of OMB proposed "guidelines" and a request for public comment.[98] The proposed guidelines stated that they would implement "section 515," and made no mention of section 3516 of the PRA, which section 515 expressly states is, along with section 3504(d), the specific legal basis for promulgation of the "guidelines." Instead, it described "section 515" as strongly encouraging and strongly supporting Executive Branch information dissemination efforts and set out "principles" for the agencies to follow that would allow them considerable flexibility in adopting the OMB "guidance" into their existing programs. The proposal notice was written in predominantly non-mandatory language. Although it stated at one point in the preamble that "[i]t is crucial that Federal agencies disseminate information that meets these standards"[99] – referring to the terms "quality, utility, objectivity and integrity" in section 515 – the notice states in the substantive portion only that "[o]verall agencies *should* adopt a high standard of quality (including objectivity, utility, and integrity) as a performance goal . . . ."[100] Similarly, the statement regarding administrative mechanisms for obtaining corrections was that agencies *should* establish such mechanisms and that the agencies *should* respond in written form to correction complaints.[101] Again, there was no mention of the section 3516 mandate in the PRA for OMB to promulgate "Rules and regulations" or the PRA provisions in section 3506 that agencies are responsible for complying with information policies established by OMB.

On September 28, 2001, OMB issued "interim final" government-wide "guidelines" in the Federal Register, again in the notices section.[102] These guidelines were issued over the signature of John D. Graham as the new Administrator of OIRA (confirmed in July 2001).

The preamble to the interim final government-wide guidelines was mainly formatted according to the requirements of the Office of the Federal Register for rules.[103] Like the notice of proposed guidelines, the interim final guidelines cited as their legal authority section 515 (the IQA) but did not mention section 3516 of the PRA, under which the IQA was expressly issued (the "Rules and regulations" section).

The most significant difference between the proposed guidelines and the interim final guidelines is that the latter utilizes clear mandatory language at key points, while at the same time clearly delineating areas where agencies have significant discretion (e.g., regarding the level or type of correction called for in response to a valid petition/complaint, and integrating the guideline

98. 66 Fed. Reg. 34,489 (June 28, 2001). The "Proposed Guidelines" were published in the "notices" section of the Federal Register," with a request for public comment, rather than as a proposed rule in the "Rules and Regulations" section. The issue of whether the "guidelines" are legislative rules is discussed *infra* Part V, sec. C. The "Proposed Guidelines" were issued over the signature of Donald R. Arbuckle as Deputy Administrator of OIRA.

99. *Id.* at 34,490.

100. *Id.* at 34,491 (emphasis added). The reference to "performance goal" appears to be a reference to the "performance goals" required by the Government Performance and Results Act of 1993, Pub. L. No. 103-62, 107 Stat. 285, 31 U.S.C. § 1115 note (2012).

101. *Id.* at 34,492. The IQA states that agencies "shall" establish correction mechanisms.

102. 66 Fed. Reg. 49,718. These guidelines were termed "interim final" because they requested additional public comment on the "capable of being substantially reproduced" standard.

103. 1 C.F.R. § 18.12 (2016).

requirements into their existing programs). The "should" in key provisions of the proposed guidelines noted above was changed to "shall" or "must" in the interim final guidelines -- for example, in stating the requirements for agencies to adopt basic standards of quality as defined by OIRA, including objectivity, utility, and integrity, and establishment of administrative mechanisms for handling "complaints," and to respond to "complaints" in an appropriate manner.[104]

On February 22, 2002, OIRA issued final government-wide guidelines that supplemented and "amended" the interim final guidelines, while stating that they still incorporated the "Underlying Principles" of the interim final guidelines.[105] Again, the amended guidelines were issued as a Federal Register "notice" rather than a "rule," although, like the interim final guidelines, they were formatted much like rules, cited the legislative authority for their issuance, and used mandatory language in many places.[106] They again did not mention the PRA, particularly section 3516 ("Rules and regulations") in addition to section 515 as legal authority for the "guidelines." The amended final guidelines also contained additional discussion of the role of peer review and established the standard of "substantial reproducibility" for "influential scientific, financial, or statistical information."

B. Implementation by Individual Agencies and Additional OMB Interpretive Guidance

Under OIRA's final guidelines, all agencies were required to publish notice of availability of their draft agency-specific guidelines for public comment in the Federal Register (and post the draft on their website) by April 1, 2002. The agencies were then required to submit draft guidelines to OIRA (after consideration of public comments and any revisions) by July 1, 2002, for OIRA review of whether they were consistent with the OIRA guidelines.[107] Final guidelines of individual agencies were required to be issued and noticed in the Federal Register by October 1, 2002.

As stated in both the PRA and the OIRA final government-wide guidelines, and the IQA incorporating the pertinent PRA provisions, the guidelines and policies of other agencies are required to comply with OMB's policies and guidelines. Section 3506(a)(1)(B) states that all agencies are responsible for "complying with the requirements of this chapter and related policies established by the Director." The OIRA final guidelines state that "it is crucial" that an agency's guidelines "meets" and are "consistent with" the OMB guidelines.[108]

OIRA began reviewing drafts of the individual agencies' proposed guidelines prior to July 1, 2002. On June 10, 2002, Administrator Graham issued a Memorandum to the President's

104. 66 Fed. Reg. at 49,723-24.

105. 67 Fed. Reg. 8452.

106. Although mandatory language (e.g., "shall," "must," "requirements," "comply") predominates, there are some inconsistencies. For example, the definition of "objectivity" states at one point that "[w]here appropriate, data *should* have full, accurate, transparent documentation, and error sources affecting data quality *should* be identified and disclosed to users." 67 Fed. Reg. at 8459 (emphasis added). The "where appropriate" might be a reference to the reproducibility standards for "influential" information, but it is not clear.

107. The July 1 date for submission of agency drafts to OIRA was later extended to August 1.

108. 67 Fed. Reg. at 8452-53.

Management Council to address collectively issues appearing in the agency drafts under review at OIRA.[109]

One of the most significant interpretive policy statements in this OIRA memorandum concerned language in some draft agency guidelines stating that their guidelines were not binding and did not establish any right to judicial review. Regarding such language, the OIRA Administrator stated:

> [A] number of agencies emphasize that their guidelines are not intended to provide any right to judicial review. A few agencies even stress that their guidelines may not be applicable based on unspecified circumstances and that the agency may be free to differ from the guidelines where the agency considers such action appropriate.
>
> Regardless of what kinds of litigation-oriented disclaimers the agencies may include, agency guidelines should not suggest that agencies are free to disregard their own guidelines. Therefore, if you believe it is important to make statements that your agency's guidelines are not intended to provide rights of judicial review, we ask that you not include extraneous assertions that appear to suggest that the OMB and agency information quality standards are not statements of government-wide policy, i.e., government-wide quality standards which an agency is free to ignore based on unspecified circumstances. In addition, agencies should be aware that their statements regarding judicial enforceability might not be controlling in the event of litigation.[110]

The PRA and IQA give OMB/OIRA responsibility for promulgating information quality "Rules and regulations" and overseeing information quality policy, and they require other agencies to comply with IQA-related policies established by OMB. The above OMB guidance memorandum is consistent with this, stating clearly that agencies should not suggest that they do not have to comply with the OMB guidelines or their own guidelines. What was new in the above statement was the revelation that a number of agencies were inserting into their proposed guidelines judicial review disclaimers and statements that their guidelines were not binding.

Despite these admonitions from OIRA, many of the major agencies (the Cabinet-level Departments) continued to include judicial review disclaimers in their guidelines. These include DOC, DOD, DOEd, DOE, DHHS (partial), DHS, DOJ, DOL, DOS, DOI, and DOT.[111] In addition, at least two Departments, the Department of Labor, and the Department of Homeland Security, as well as EPA, completely disregarded this policy guidance from OIRA, not only including a judicial review disclaimer in their guidelines, but also stating that the guidelines "are not intended to

---

109. OFF. OF MGMT. AND BUDGET, OFF. OF INF. & REG. AFFAIRS, *Memorandum for President's Management Council from John D. Graham on the Subject of Agency Draft Information Quality Guidelines*, June 10, 2001, https://obamawhitehouse.archives.gov/sites/default/files/omb/assets/omb/inforeg/iqg_comments.pdf (last visited Dec. 2017). This document is listed on the OMB webpage, *supra* note 96. The President's Management Council was established by Presidential Memorandum of July 11, 2001, IMPLEMENTING GOVERNMENT REFORM § 3, 3 C.F.R. 2001 Comp. at 903-05. The Council was designated to consist of the heads of all the principal Departments, and certain other agencies and offices, including EPA, SSA, and FEMA, and such other agencies as OMB might designate.

110. *Id*. at 14-15.

111. All agencies have (or should have) posted their conforming IQA guidelines on their websites, usually under the identifier of "information quality guidelines."

impose any binding requirements or obligations on DOL . . .” (DOL), and “do not impose any legally binding requirements or mandates on the agency or the public.” (DHS).[112] It appears there was a significant amount of conflict between various agencies and OIRA over wording of their guidelines that could influence judicial review, despite section 3506 of the PRA requiring the agencies to comply with OMB policy guidance and the express incorporation of section 3516 of the PRA (“Rules and regulations”) into the IQA.[113]

C. The OMB Peer Review “Bulletin”

Within less than a year after the deadline for publication of individual agency IQA guidelines, OIRA began augmentation of the peer review process for important scientific and technical information disseminated by an agency with publication of a proposed IQA Bulletin for peer review on Sept. 15, 2003.[114] A revised proposal was issued for public comment on April 15, 2004.[115]

This new government-wide guidance, which did not require the subsequent promulgation of conforming agency-specific guidance (although it did require agency compliance pursuant to the PRA), became final on January 14, 2005. Its requirements (with the exception of the agency peer review planning requirements) applied to all "influential scientific information" (ISI, as defined) disseminated on or after Dec. 16, 2005 and to all "highly influential scientific assessments" (HISAs, as defined) disseminated on or after June 16, 2005, unless the peer review had begun prior to then.[116]

The February 2002 government-wide IQA guidelines had addressed the significance of journal and other peer review in meeting the “objectivity” standard of the IQA and the OMB Guidelines. However, those guidelines only established a rebuttable presumption in favor of peer review as a means to meet the objectivity standard; they did not require that peer reviews be conducted. “If” peer review had been performed by a journal or other external source, or the agency had sponsored a peer review, the objectivity standard could be presumed to be satisfied, but the presumption could be rebutted by a “persuasive” showing of non-objectivity.[117] The one portion of the 2002 Guidelines containing requirements for peer review applied only to agency-sponsored peer reviews, which were required to meet certain general criteria in order to establish the presumption of objectivity.[118]

---

112. *See also* EPA, Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity, of Information Disseminated by the Environmental Protection Agency at 4 (2002) https://www.epa.gov/sites/production/files/2017-03/documents/epa-info-quality-guidelines.pdf (last visited Dec. 2017) (“not a regulation,” “provide non-binding policy and procedural guidance,” and are “not intended to create legal rights”). The EPA Guidelines uniformly substitute the term “should” for the “shall” in the OMB government-wide guidelines, and, in response to public comments that its guidelines were legislative rules, stated that the IQA only required issuance of “guidelines” and that “[w]e see no indication in either the language or general structure of Section 515 that Congress intended EPA’s guidelines to be binding rules.” *Id*., Appendix to Guidelines at 39.)

113. The IQA called for "Federal agency involvement" in the issuance of the OMB government-wide guidelines, and an interagency working group provided comments to OMB. 66 Fed. Reg. 49,718 at 49,720 (2001).

114. 68 Fed. Reg. 54,023 (2003).

115. 69 Fed. Reg. 23,230 (2004).

116. 70 Fed. Reg. 2664 (2005).

117. 67 Fed. Reg. 8452 at 8454-55, 8459-60.

118. 67 Fed. Reg. at 8454 (2002).

The peer review "Bulletin" requires that agencies conduct peer reviews for all ISI and HISAs and provide the public with their peer review plans and peer reviewer comments, and, in the case of HISAs, certain opportunities for public participation. The requirements for HISAs are far more stringent than those for ISI, which are minimal. For agency regulatory actions that rely on either ISI or a HISA, the agency is required to certify compliance with the Bulletin and explain how it has complied. At the end of the Bulletin, there is a detailed disclaimer of any right to judicial review.

Labeling the peer review guidance a "Bulletin" (a term not used in the IQA or PRA[119]) and inclusion of a disclaimer of judicial review is not determinative of the judicial review issue, as discussed below. As a matter of Supreme Court and circuit court case law, the label an agency places on a policy document is not a determinative factor in determining whether it is a legally binding legislative rule. The Bulletin contains numerous "requirements" and often uses the terms "shall" and "comply." It cites and quotes as legal authority for its issuance both section 515 of the IQA and section 3504(d) of the PRA, although, as with the original government-wide guidance, it omits any mention of PRA section 3516 ("Rules and regulations") concerning exercise of OMB's authority under the PRA that is expressly a basis for "section 515." Versions of the Bulletin were issued as proposals for public comment (and received extensive comments) twice in the Federal Register before being published there as final.[120]

D. The OMB-OSTP "Updated Principles for Risk Analysis"

On January 17, 2006, OMB issued notice of a "Proposed Risk Assessment Bulletin" with a request for public comment.[121] Eventually, in September 2007, this resulted in issuance of a joint OMB and OSTP "Memorandum" titled "Updated Principles for Risk Analysis," which was not published in the Federal Register.[122] Although the Memorandum does not appear to be an IQA guidance document, it is described briefly here because note 8 in the Memorandum states that it "is intended to complement and support the Information Quality Guidelines." In addition, the Memorandum and related publications are included in OIRA's online list of "Information Quality Government-Wide Initiatives" along with the original government-wide IQA Guidelines and the peer review Bulletin and related materials.[123]

The proposed risk assessment Bulletin of 2006 was issued solely by OIRA and clearly referenced the IQA and PRA as "Legal Authority" for the proposal. It also contained mandatory

---

119. OMB's website states that "OMB Bulletins are generally issued when the nature of the subject matter requires single or one-time action by the departments or establishments or is of a transitory nature." *OMB's System of Circulars and Bulletins*, https://obamawhitehouse.archives.gov/omb/gils_gil-circ (last visited Dec. 2017) (This webpage now contains a notation that "This is historical material 'frozen in time'. The website is no longer updated and links to external websites and some internal pages may not work.").

120. See discussion of legislative rules *infra* Part V, sec. C.

121. 71 Fed. Reg. 2600 (2006).

122. MEMORANDUM M-07-24, to the Heads of Executive Departments and Agencies, from Susan Dudley, Administrator of OIRA & Sharon L. Hays, Associate Director and Deputy Director for Science, Office of Science and Technology Policy, Sept. 19, 2007 https://obamawhitehouse.archives.gov/sites/default/files/omb/assets/omb/memoranda/fy2007/m07-24.pdf (last visited Oct. 2017). The proposed risk analysis Bulletin was signed by OIRA Administrator Graham shortly before leaving OMB in early 2006.

123. *See supra* note 96.

language (e.g., "The Requirements of this Bulletin" and multiple "standards").[124] The final Memorandum, on the other hand, was a joint OMB-OSTP document that did not reference the IQA or PRA as legal authority (other than the problematic statement in note 8, *supra*), was not formatted like a rule, and uniformly used the discretionary term "should."

The Memorandum states that it "reinforces" the 1995 "Principles for Risk Analysis" that "remain valid today."[125] The 1995 Principles were issued in brief memorandum form by OIRA Administrator Sally Katzen, apparently on behalf of a multi-agency Regulatory Working Group. The memorandum states that the principles "are aspirational rather than prescriptive" and that they "are not intended to provide the basis for judicial review or legislation."

One feature of the 2007 Memorandum, the 2006 proposal, and the 1995 Principles, that argues against considering them to be guidance pursuant to the IQA, is that they impliedly condone the use of "assumptions" and "defaults" in risk assessment.[126] This feature is very arguably inconsistent with the requirement of the IQA, the original government-wide guidance, and the peer review Bulletin, for objectivity and elimination of bias in scientific and technical information disseminated by agencies. Assumptions, and particularly "default assumptions," are often intentionally biased to be conservatively health protective (to an unknown degree) in order to bridge uncertainties in the scientific data. Examples are EPA's use of no-threshold and linear dose-response assumptions in cancer risk assessment and its use of multiple "uncertainty factors" (UFs, or "safety factors") as default assumptions to reduce "reference dose" risk numbers in non-cancer risk assessments.[127]

---

124. The proposal also contained a judicial review disclaimer.

125. *Principles for Risk Assessment, Management, and Communication, Memorandum for the Regulatory Working Group* from Sally Katzen, Administrator of OIRA, Jan. 12, 1995. At this time, that 1995 document apparently is no longer available electronically. It was previously accessed electronically in 2016.

126. The 1995 memorandum and the 2007 final Memorandum address both assumptions and defaults. The 2006 proposal referred only to assumptions.

127. *See* INST. OF MED. OF THE NATIONAL ACADEMIES, ENVTL. DECISIONS IN THE FACE OF UNCERTAINTY 156-60 (2013); U.S. EPA, *Guidelines for Carcinogen Risk Assessment* at 1-7 (2005) https://www.epa.gov/sites/production/files/2013-09/documents/cancer_guidelines_final_3-25-05.pdf (last visited Dec. 2017) ("The primary goal of EPA actions is protection of human health; accordingly, as an Agency policy, risk assessment procedures, including default options that are used in the absence of scientific data to the contrary, should be health protective . . . ."); Todd Stedeford et al. *The application of uncertainty factors in the U.S. EPA's Integrated Risk Information System (IRIS). Part 1: UF(L), UF(S), and "other uncertainty factors,"* J. ENVTL SCI. HEALTH, PART C ENVTL CARC. ECOTOX. REV. 245-79 (2007); Robert L. Sielken, Jr. et al., *Challenges to default assumptions stimulate comprehensive realism as a new tier in quantitative cancer risk assessment,* REGUL. TOX. PHARMACOL., 270-80 (1995). It is sometimes stated that it is usually not possible to produce a quantitative risk assessment without the use of defaults. This is not true. If it is necessary to produce a concrete quantitative assessment in the face of uncertainty, risk assessment scientists can describe the uncertainties, and agency risk managers can then apply any policy-driven defaults transparently in the risk management portion of the process. Note also that some agencies and programs, such as the Report on Carcinogens program, administered largely by HHS, produce cancer "hazard" assessments (utilizing labels such as "known," "reasonably anticipated," or "likely" human carcinogen). These are different from "risk" assessments in that they do not take likely levels of human dose/exposure into account. Consequently, such hazard assessments (or identifications) could be regarded as lacking the "utility" for the public required by the IQA and its guidance, unless a hazard identification procedure is required by legislation. The same is true for most cancer hazard assessments produced by the Int'l Agency for Res. on Cancer (IARC), a unit of the World Health Organization, which could therefore prevent U.S. Federal agencies from indicating reliance on IARC determinations. Lack of compliance with the mandated peer review procedures in the OMB Bulletin could also preclude such reliance.

Use of assumptions, default assumptions, uncertainty factors, or safety factors that are not supported by sufficient data (at least not enough to allow application of expert judgment) are often referred to as "science policy" assumptions. Modern peer-reviewed scientific publications would not accept a research or review article that contained unsupported assumptions, as acceptance would be viewed as violation of one of the core values of modern science – objectivity. Rejection of injection of "science policy" in government risk assessments is expressed not only in the definition of "objectivity" in the original government-wide IQA guidelines, but also in the IQA peer review Bulletin, which requires that peer reviewers (of both ISI and a HISA) "shall be charged [by the agency] with reviewing scientific and technical matters, leaving policy determinations for the agency" and "shall be informed of applicable access, objectivity, reproducibility and other quality standards under the Federal laws governing information access and quality."[128] The preamble portion of the Bulletin elaborates on this requirement, stating that "the charge [to the peer reviewers] should make clear that the reviewers are not to provide advice on the policy (e.g., the amount of uncertainty that is acceptable or the amount of precaution that should be embedded in an analysis.)"[129] Government policy officials ("risk managers" as opposed to "risk assessors") can still generally employ precautionary safety/uncertainty factors transparently in their regulatory decisions as a matter of agency policy or statutory mandates, making a clear distinction between objective science and "science policy."

III. IQA LITIGATION TO DATE

This section examines in detail all the cases to date that have involved the issue of judicial reviewability when allegedly affected persons have attempted to utilize the IQA and the OMB government-wide or agency-specific IQA guidelines (including the peer review Bulletin). It addresses the questions: How was the case argued by both sides; how was it decided; and should the court decision be regarded as valid precedent on the issue of judicial review? The section after this will comment on key legal issues that have appeared, often repeatedly, in these cases.

The cases are presented in chronological order, with the earliest first.

A. Competitive Enterprise Inst. v. Bush[130]

This first case brought against a federal agency under the IQA in 2003 was settled and did not result in a court opinion.

The Competitive Enterprise Institute (CEI) sued the White House Office of Science and Technology Policy and President Bush for a 2000 dissemination (on behalf of a federal inter-agency committee[131]), a federal advisory committee report that allegedly violated the IQA and OSTP's IQA guidelines, as well as the U.S. Global Change Research Act of 1990 ("USGCRA").[132]

128. 70 Fed. Reg. 2664 at 2675 (2005).

129. *Id*. at 2669.

130. No. 03-1670 (D.D.C. 2003).

131. The Federal Coordinating Council for Science, Engineering, and Technology and its Committee on Earth and Environmental Science.

132. 15 U.S.C. § 2921, Pub. L. 101-606, 104 Stat. 3101 (1990). CEI claimed in its RFC and in its court Complaint that it was an "affected person" entitled to file an RFC because analysis of climate change and education of the public on the subject were prominent facets of its activities. *See infra* Part V, sec. F.

CEI alleged that the climate modeling in the report violated IQA objectivity and utility requirements because the historical climate data had been modified to effectively delete two significant climate periods, the "Little Ice Age" and the "Medieval Warm Period," making the modeling and assessment unavoidably "inaccurate" under the "FDQA" (the Federal Data Quality Act," another informal name for the IQA). CEI also alleged that the report utilized climate prediction models that were invalid and facially contradictory.[133]

CEI filed a Request for Correction ("RFC") that was denied by OSTP on grounds that the report was not an agency dissemination under the IQA guidelines because it was produced by a FACA committee, not an agency, and because the RFC "did not identify, justify and request correction of particularized errors in the text."

CEI filed an administrative appeal of the RFC denial; and when OSTP did not respond promptly it claimed exhaustion of administrative remedies and filed suit in district court. The relief it requested was a declaratory judgment that the report violated the IQA and the USGCRA and an injunction against dissemination because the deficiencies resulted in errors too pervasive to specify, so that the whole assessment should be withdrawn.

In its court Complaint, CEI alleged that OSTP and the inter-agency committee it headed had statutory responsibility for producing and delivering the report, and therefore its delivery of the FACA report reasonably appeared to constitute "sponsorship" of the report under the IQA guidelines.[134]

The case was settled by stipulation without the filing of an Answer or briefing. A letter from the Department of Justice to CEI to memorialize the settlement stated that OSTP would revise a statement appearing on the disseminated advisory committee report, for as long as the report remained posted on the government's global change research website. The revised statement would read: "The National Assessment Overview and Foundation Reports were produced by the National Assessment Synthesis Team, an advisory committee chartered under the Federal Advisory Committee Act [, and were not subjected to OSTP's Information Quality Act Guidelines] . . . ," with the added settlement language in brackets.[135]

133. Complaint in district court.

134. The preamble to OMB's final government-wide IQA guidelines states that "if an agency, as an institution, disseminates information prepared by an outside party in a manner that reasonably suggests that the agency agrees with the information, this appearance of having the information represent agency views makes agency dissemination of the information subject to these guidelines." 67 Fed. Reg. at 8454.

135. http://www.sejarchive.org/foia/DOJ_note1103.pdf (last visited Dec. 2017). As of Dec. 2017, however, the two FACA reports were being disseminated without the agreed-upon revisions and without any notation that the reports are archival and might no longer represent the views of the advisory committee or the U.S. global change research program. See https://data.globalchange.gov/assets/9a/aa/ec5b4bb3b895bc8369be2ddac377/nca-2000-report-overview.pdf and https://data.globalchange.gov/assets/e9/97/436129058f2107f4925aeec13ed8/nca-2000-foundation-report.pdf. Copies of the report as originally disseminated with the agreed-upon IQA disclaimer language could not be located electronically.

B. Missouri River System Litigation[136]

This was the first case to result in a court opinion on a claim of violations of the IQA. This district court opinion, denying reviewability, has subsequently been relied on extensively by the government.

A number of States and users of the Missouri River for commercial navigation challenged a decision by the Corps of Engineers, based largely on an Endangered Species Act (ESA) biological opinion (BiOp) by the U.S. Fish and Wildlife Service, to alter the flow regime on a portion of the Missouri River in order to comply with the Endangered Species Act.

Most of the issues in the case concerned the ESA, the National Environmental Policy Act, and the Flood Control Act; however, one plaintiff group, Blaske Marine et al., added in an Amended Complaint an IQA and APA cause of action and claim for relief.[137]

The Blaske IQA claim for relief alleged that the information disseminated in the BiOp was "influential" and that it failed to meet IQA objectivity and utility requirements and failed to disclose data necessary to undertake an independent reanalysis of the information. There was no mention of the OMB guideline requirements or Plaintiffs' use of the administrative request for correction (RFC) process.

Blaske filed a motion for summary judgment on the IQA claim for relief that, like its Complaint claim, did not mention the OMB guidelines or use of the administrative correction process.[138] They argued that the Defendants had "failed to comply with the IQA by not justifying and providing the information and science to Plaintiffs and the public" supporting the change in flow regime, and that they had requested disclosure of the data necessary "to undertake an independent reanalysis of the disseminated information" and that the agencies had refused "to correct" the challenged information, in violation of the IQA's objectivity and utility requirements.[139] Again, there was no mention of having filed an administrative RFC pursuant to the OMB and agency IQA guidelines, and no allegations regarding specific requirements of the OMB and agency guidelines that had been violated, particularly regarding the requirements for "objectivity" and "utility," as well as "reproducibility" in the case of "influential" scientific information.

---

136. *In re* Operation of the Missouri River System Litigation**,** 363 F. Supp.2d 1145 (D. Minn. 2004), *aff'd in part, vacated in part*, 421 F.3d 618 (8th Cir.2005). The case in which Blaske Marine (see below) was the lead plaintiff was originally brought in D. Neb. (No. 8:03CV142), and then consolidated with other cases in multidistrict litigation in D. Minn. (No. 03-MD-1555). Blaske's original IQA claim for relief was presented in its Third Amended Complaint in the D. Neb. case as claim number 11.

137. Blaske Marine et al. Third Amend. Compl. For Declar. and Inj. Relief (in D. Minn., No. 03-MD-1555) at 55-57 (11th Claim for Relief), ECF No. 462.

138. Blaske Marine et al. Mem. In Supp. of Mot. for Sum. Judg. for Declar. on Eleventh Claim, Information Quality Act.

139. The controlling OMB government-wide guidelines (mirrored by the agency guidelines) give specific definitions of "utility," "objectivity," and "reproducibility" which require that an agency provide transparency with regard to the data supporting the information; and, with regard to "influential information," sufficiently high transparency about supporting data and methods to allow substantial reproducibility of the information by qualified third parties. 67 Fed. Reg. at 8459-60. Those definitions were not referenced in the Plaintiffs' pleadings and not mentioned by the Government.

The government's opposition to the motion argued that there was no indication in the IQA that Congress intended to establish a private right of action because it only provided an administrative remedy; and the APA did not provide a right of action because the IQA contains no judicially manageable standards to resolve the issues raised by Plaintiffs, not defining what was meant by "objectivity" or "utility." The Government also argued that the OMB guidelines "expressly committed" to the agencies' judgment and discretion "the case-by-case determination of whether certain information meets an agency's information quality standards" because the guidelines left it to the agency's discretion "to make corrections 'where appropriate'."[140] In conclusion, the Government argued that the OMB guidelines "'fairly exudes [sic] deference'" and forecloses application of any meaningful judicial standard of review.[141]

The government also argued that, even if there was a private right of action and judicial review was not precluded, Plaintiffs' motion must still be denied for failure to utilize the administrative mechanism for requesting a correction.[142]

Blaske replied that the Defendant's assertion of failure to employ the IQA request for correction process was faulty because they had filed two ESA notices of intent to sue that explained the lack of rational basis for the change in flow regime, and had asserted the need to supply the basis, and the agencies had not responded to the notices. The notices, and the failure to respond, they asserted, amounted to a "request" for the scientific basis for the change in flow regime, and the agencies failure to respond to the notices amounted to a denial of a request for underlying information. This, they argued, demonstrated that use of the IQA request for correction mechanism would have been futile, and therefore exhaustion of those administrative remedies was not required.[143]

With regard to the APA, Blaske argued that APA section 702 provided for judicial review because no other remedy was available, and that there was law to apply because the IQA requires "meaningful access to information by interested persons." Plaintiffs did not make any reference to the OMB or agency IQA guidelines requiring agencies to provide supporting data for influential information as an aspect of its standards for "objectivity" and "utility" (i.e., the reproducibility requirement of the OMB Guidelines).[144]

The District Court addressed Blaske's IQA claim in a brief final section of its opinion.[145] The Court held that Blaske had failed to state a valid claim because the IQA did not provide a private cause of action and the APA judicial review provisions did not apply because, although OMB was ordered to promulgate guidelines on quality and objectivity, neither the IQA nor its legislative

---

140. Fed. Defs.' Opp. to Blake [sic] Marine, Inc's Mot. for Sum. J. for Decl. on Eleventh Claim, Information Quality Act. The OMB Guidelines state in three of four places that agencies "shall establish administrative mechanisms allowing affected parties to seek and obtain, *where appropriate*, timely correction of information . . . *that does not comply with OMB or agency guidelines.*" 67 Fed. Reg. at 8459 (emphasis added). The agency cited, but did not quote fully, this statement, or the other similar statements, but only quoted the words "where appropriate."

141. *Id*. at 11.

142. *Id.* at 11-13.

143. Blaske Marine, Inc.'s Reply Mem. to Fed. Defs.' Opp. to Motion for Sum. J. on Eleventh Claim, Information Quality Act 3.

144. *Id*. at 3-4.

145. 363 F.Supp.2d 1145, at 1174-75.

history indicated the scope of the terms "objectivity" and "utility," so there was no "meaningful standard" to apply to the agency's actions. There was no analysis in this brief final section of the opinion, and, as in the pleadings and memoranda, the court did not mention the OMB or agency guideline definitions of objectivity or reproducibility or the context for use of the term "appropriate" in guideline statements regarding corrections.

Blaske did not include IQA issues in its appeal, and the Eighth Circuit opinion did not mention them.

C. Salt Inst. v. Thompson and Salt Inst. v. Leavitt[146]

This case deserves special attention because the government (DOJ) has consistently relied on portions of two sentences from the Fourth Circuit opinion as primary support for its arguments against any IQA judicial review, and until recently this was the only circuit court opinion to arguably address judicial reviewability of IQA issues. It is important to understand the administrative background of the case and the full opinions in order to interpret properly both the district and circuit court opinions.

A central issue regarding interpretation of *Salt Inst.*, particularly the Fourth Circuit opinion, is whether it was an opinion on general IQA judicial reviewability or whether it was only an opinion on judicial reviewability of a data *access* request under the Freedom of Information Act and the so-called "Shelby Amendment,"[147] with the data access request presented in an IQA petition for "correction," based on the "reproducibility" requirements of the OMB guidelines.[148]

The IQA provides for petitions to "seek and obtain *correction*" (emphasis added) of agency information disseminations that do not comply with the OMB guidelines, and those guidelines include requirements that "influential" scientific, financial, or technical information must be "reproducible," as an element of "objectivity," by providing data sufficient for a qualified person to substantially reproduce (and thereby validate or invalidate) the disseminated information. Thus, an RFC (or "complaint" as it is also called in the IQA) which alleges that agency influential information is not "reproducible" and seeks to obtain the necessary additional data that will allow for reproducibility is necessarily referred to as a request for "correction," even though it cannot be ascertained at that time that the language of the disseminated agency information is incorrect in a particular respect in the absence of such additional data. In other words, the "correction" sought is compliance with the OMB reproducibility requirements, even though "correction" might seem to imply some change to the substance of the disseminated information.

146. Salt Inst. v Thompson 345 F. Supp. 2d 589 (E. D. Va. 2004), *aff'd on other grounds sub nom*. Salt Inst. v. Leavitt, 440 F.3d 156 (4th Cir. 2006).

147. The "Shelby Amendment" (also sometimes referred to as the "Data Access Act") is not an official title. It is a legislative provision contained in the Omnibus Appropriations Act for FY1999 requiring OMB to amend its Circular A-110 to Federal agencies "to ensure that all data produced under an award will be made available to the public through the procedures established under the Freedom of Information Act . . . ." Pub. L. No. 105-277, 112 Stat. 2681-495 (1998). The final OMB amendments to Circular A-110 to comply with this mandate were published at 64 Fed. Reg. 54,926 (Oct. 8, 1999).

148. For the reproducibility requirements, see the OMB final government-wide IQA guidelines, 67 Fed. Reg. 8452, at 8460.

The Salt Institute (joined by the U.S. Chamber of Commerce) began the proceedings by filing an IQA "petition" with the National Heart, Lung, and Blood Institute (part of the National Institutes of Health within the Department of Health and Human Services) on May 14, 2003.[149] The petition stated that it sought "correction" of a number of NHLBI information disseminations that stated or suggested that reduced sodium consumption would result in lower blood pressure in all individuals in the U.S. The petition alleged that the disseminated information was "highly influential," and that the accuracy of the agency statements could not be substantially reproduced unless, as required by the OMB and HHS information quality guidelines, NHLBI provided all the data on which two seminal non-governmental, but government-funded, studies, the DASH-Sodium trial and a follow-up analytical study, were based. The petition did not seek any changes to the several information disseminations by the agency; instead, it sought the unpublished underlying data from the outside government-funded studies so that it could assess the accuracy of those two studies and thereby the accuracy of the agency information disseminations that were based on them. In essence, therefore, the petition was one for compliance with the "reproducibility" requirements of the OMB guidelines, and obviously the Institute felt it needed to refer to non-compliance with those requirements as a needed "correction" of agency-disseminated information, given the wording of the IQA ("allowing affected persons to seek and obtain correction of information").

The petition stated:

> [W]e are not at this time directly challenging the substantive accuracy of the enumerated [agency] statements. Rather, this petition addresses the failure on the part of NIH to make publicly available underlying data that would allow affected parties, such as petitioners, to validate whether the agency's statements substantively comply with the Data Quality Act mandate of reproducibility.[150]

At the conclusion of the petition, the Salt Institute again made clear that the petition for "correction" was based solely on the agency's alleged need to comply with the reproducibility requirement of the OMB guidelines by making underlying data from the DASH-Sodium studies publicly available. The petition stated:

> Because this petition is based solely on the agency's failure to make study data publicly available, petitioners do not at this time request or recommend that the challenged information be removed from public view. However, should petitioners determine, upon review of the complete subgroup blood pressure data, that NHLBI's interpretations still cannot be reproduced, petitioners reserve the right to pursue additional Data Quality Act challenges. These challenges could include a request to remove the information from agency websites and other public domains.[151]

149. The original petition (referred to as a request for correction, or "RFC" by HHS), along with the subsequent Salt Institute request for reconsideration and HHS responses, is currently available on the HHS information quality website at https://aspe.hhs.gov/information-requests-corrections-and-hhs-responses, item no. 8 (last visited Dec. 2017).

150. Petition at 8.

151. *Id*. at 15.

The Salt Institute faced two clear legal obstacles in attempting to obtain the additional data from the DASH-Sodium studies under the IQA Guidelines. First, the agency did not have control over the data because it was in the hands of the collaborative group of private-sector scientists that had conducted the studies; and second, although the study had been federally funded, and therefore all data used in it could have been subject to the "Shelby Amendment" through submission of a FOIA request to the NHLBI, OMB had restricted application of the Shelby Amendment to new or continuing grants awarded after April 17, 2000, and the grants for the DASH-Sodium trial apparently were conceded not to have been awarded, or continuing, after that date.

In its response to the Salt Institute's RFC, the agency took the position that because the Institute was not seeking any correction (in the sense of a change) to agency disseminated documents, but rather was only seeking access to data developed and produced in grant-funded research, the Institute must proceed through a Freedom of Information Act request and OMB's Circular A-110 as revised pursuant to the Shelby Amendment.[152]

The agency subsequently rejected the Salt Institute FOIA request on grounds that because the data requested was not in its possession or under its control, the plaintiffs must proceed under the Shelby Amendment, and the Shelby Amendment was not applicable due to its effective date, and the reproducibility standard in the guidelines did not require the agency to obtain and release the grantee data under such circumstances.[153]

The Salt Institute filed a Request for Reconsideration in which it contended that its RFC was founded not only on the reproducibility requirement, but also on the objectivity requirement, and that the two requirements supplemented, and could not be limited by, FOIA, because the IQA reproducibility and objectivity requirements were separate from and more expansive than FOIA and the Shelby Amendment.[154]

The agency rejected the Institute's request for reconsideration, reiterating that the IQA and its guidelines did not require the agency to obtain grantee data that was not in its possession or under its control. The agency refused to request the data from the study investigators unless the data were covered by the Shelby Amendment, and it concluded that they were not.[155]

1. Salt Inst. v. Thompson

The Salt Institute filed for judicial review of its petition denial in district court, alleging that the agency was violating the IQA and the Shelby Amendment by not providing data underlying the DASH-Sodium study. With regard to the Shelby Amendment, the Institute alleged that the Shelby Amendment expressly required release of "all" grant-funded data, and that the restrictions regarding the effective date and use of the data only in directives having the force and effect of law in OMB Circular A-110 were contrary to the plain language of the Shelby Amendment. The principal relief requested was for the court to order the agency to produce the data requested by the Institute.

152. *See supra* note 147.
153. *Supra* note 149.
154. *Id.*
155. *Id.*

The district court granted motion to dismiss. Its first holding was that the Plaintiff's lacked Article III standing for a number of reasons, including failure to allege a concrete and particularized injury, lack of actual and imminent harm, and lack of redressability.

The court then stated that there was no judicial reviewability because (1) the language of the IQA indicated that Congress intended disputes to be resolved through administrative proceedings; (2) agency dissemination of information was not final agency action under the APA because it had no legal impact;[156] and (3) neither the IQA nor the OMB guidelines provide judicially manageable standards, with the OMB guidelines providing only for "the degree of correction that they [the agency] conclude is appropriate for the nature and timeliness of the information involved." The court also rejected the Institute's claim that NHLBI violated the Shelby Amendment because the claim was based on allegations that limitations placed on the Shelby Amendment (effective date and use of the requested data only in support of agency action with the force of law) were contrary to the Amendment because those limitations had been promulgated by OMB, and OMB was not a defendant.

2. Salt Inst. v. Leavitt

The Salt Institute (and the Chamber) appealed to the Fourth Circuit. The Fourth Circuit upheld the District Court on a limited basis. Due to the manner in which the suit was pleaded and argued by both sides the Circuit opinion and its wording can be misunderstood.

The government has consistently quoted two statements from the opinion that it contends are holdings that there is no judicial review whatever of agency action denying an IQA petition. The first such quotation states: "By its terms, this statute [the IQA] creates no legal rights in any third parties."[157] The second such quotation states: "[The IQA] does not create a legal right to access to information or to correctness."[158] Such statements must, however, be interpreted in the context of the facts of the case and other statements in the court's opinion. Also, and more importantly, the opinion says nothing about a right to judicial review under the APA.

The OMB IQA guidelines contain requirements for agency presentation of information to support "objectivity," and, in the case of "influential" scientific, financial, or statistical information," "reproducibility" is a requirement of "objectivity." The OMB guidelines state, as part of the general definition of the required "objectivity," that an agency "needs to identify . . . the supporting data and models so that the public can assess for itself whether there may be some reason to question the objectivity of the sources."[159] The definition of "objectivity" also states: "If an agency is responsible for disseminating influential scientific, financial, or statistical information, agency guidelines shall include a high degree of transparency about data and methods to facilitate the reproducibility of such information by qualified third parties." "Reproducibility"

156. The Salt Institute did not rely on the definitions of "agency action" in the APA, which include agency denial of a petition for relief, in 5 U.S.C. § 551, although § 551 is expressly incorporated by reference into 5 U.S.C. § 701, which Plaintiffs did cite. Nor was the APA inclusion of petition denials as covered agency actions otherwise argued before the court.

157. 440 F.3d 156 at 159.

158. *Id*. at 160.

159. 67 Fed. Reg. at 8459.

is then defined as meaning that "the information is capable of being substantially reproduced, subject to an acceptable degree of imprecision."[160]

The question then became whether the IQA right to "correction" of information to meet the requirements for "objectivity" and "reproducibility" in OMB's guidelines applied to obtaining data that was not in the hands of, or under the control of, the agency, or whether such data could only be obtained from the non-federal researchers through a FOIA request to the agency pursuant to the Shelby Amendment and OMB Circular A-110. And the court noted that there was no right to the information under FOIA because the grants for the non-federal research were not awarded after the Shelby Amendment and the OMB revisions to Circular A-110 took effect.[161]

In briefing and oral argument before the Circuit panel, the Government emphatically took a position consistent with the above interpretation of the opinion, arguing at the outset that there was no reason "to decide whether an agency's resolution of a correction request would be subject to judicial review"[162] and that the IQA "did not establish a mechanism for obtaining a grant recipient's data."[163]

At oral argument, the government stated:

> So then we come to what they call their request to correct information. And I would be happy to address all the legal issues that would have arisen if they had actually made a request, but reading from their letter to the agency – and they say this in various forms throughout the letter – This is page A-39 – "Because this petition is based solely on the agency's failure to make study data publicly available, petitioners do not at this time request or recommend the challenged information be removed from public view; however, should petitioners determine upon review of data that the interpretations cannot be reproduced, petitioners reserve the right to pursue additional Data Quality Act challenges." Which is fine – *we're not saying that there could never be a ripe question about whether you could get judicial review of a correction request under the IQA, we just don't have one here*.[164]

Only after the Circuit opinion was issued did government attorneys (DOJ) argue in other IQA cases, quoting the two isolated circuit court statements noted above, that the court had held that there was no right whatever to judicial review of agency denial of an IQA petition.[165]

The Fourth Circuit opinion, read in its entirety and considering the administrative proceedings forming the basis for the litigation, confirms that the court was ruling only on whether the IQA and its guidelines provided a right of action for obtaining access to non-governmental data outside the effective-date reach of the Shelby Amendment. The court characterized the Salt Institute's petition as "purported" to be filed under the IQA, and that the Institute "took issue" with the

160. 67 Fed. Reg. at 8460.
161. 440 F.3d 156, at 159 n. 1.
162. Br. for the Appellee 22.
163. *Id*. at 23.
164. Court recording of oral argument on CD-ROM at 16:48-17:37 (emphasis added).
165. At oral argument in two Ninth Circuit IQA-APA cases (ASA and Harkonen, *infra*) the judges indicated skepticism regarding this DOJ change from its original characterization of *Salt Inst.*

findings of the two non-governmental studies on which the agency relied. It then described the petition as requesting that NHLBI "'make publicly available' the raw data that supported the [two non-governmental but government-funded] studies' findings in order to allow appellants to test their validity for different groups of individuals," and that its "lone request was that information be made public."[166]

Farther on in the opinion, the court addressed arguments by the appellants that the opinions of the Supreme Court in *Fed. Election Comm'n v. Akins*[167] and *Public Citizen v. U.S. Dept. of Justice*[168] concerning a right to obtain information supported their standing to sue. The court explained that those opinions were not apposite because it (the Fourth Circuit in the case at hand) had not decided whether appellants alleged injury was sufficiently concrete and specific; rather, the court stated, "we have decided . . . the question whether Congress has granted *a legal right to the information in question* . . . . The IQA . . . does not grant any legal right *to* information or *its* correctness."[169] Thus, the court was clearly holding that the IQA itself did not grant a right to access to the federally funded information and that it could not be obtained through an IQA petition for correction.

Moreover, the Circuit opinion contains absolutely no analysis of a broad judicial review issue, which would be expected in view of the rights-granting "seek and obtain" language of the legislation. Nor does it state any conclusion regarding a right of action under the APA.[170]

Thus, the Circuit decision was an affirmance on the very narrow ground of absence of a right under the IQA to obtain (via a petition for "correction") information that could not be obtained under the Shelby Amendment.[171]

D. Haas v. Gutierrez

A district court opinion in *Reynolds v. Science Applications Int'l* dismissed three related cases,[172] one of which, *Haas v. Gutierrez*, contained an IQA claim. The *Haas* case focused on an unfinished report by the National Institute of Standards and Technology (NIST, an agency within the Department of Commerce) concerning the cause of destruction of World Trade Center Building 7

166. 440 F.3d 156, at 157

167. 524 U.S. 11 (1998) (Plaintiffs had a statutory right to access to certain voter information).

168. 491 U.S. 440 (1989) (Plaintiffs had a right under FACA to certain advisory committee information).

169. 440 F.3d 156, at 159 (emphasis added). *And see* Cary v. Hall, 2006 WL 6198320, at 9 (referencing the *Salt Institute* Circuit opinion as one concerning a claimed right to information.

170. Petitioners argued the applicability of the APA in detail, although they did not note the express inclusion of denial of a petition as a covered agency action. Appellants [sic] Brief at 31-36.

171. The Circuit opinion did not address the other conclusions of the District Court, including the lack of standing due to the absence of allegations of concrete and particularized harm.

172. The three cases were Morgan [Reynolds] v. Sci. Applications Int'l, No. 07-cv-4612, 2008 WL 2566747, (S.D.N.Y., June 26, 2008); Wood v. Applied Research Assoc's, Inc., No. 07-cv-3314, 2008, WL 2566728 (S.D.N.Y. June 26, 2008); and Haas v. Gutierrez, No. 07-cv-3623, 2008 WL 2566634 (S.D.N.Y., June 26, 2008). The *Reynolds* case is sometimes mistakenly cited as Morgan v. Sci. Applications Int'l, using Reynolds' first name of Morgan. The opinions issued in all three cases are identical, with each one dismissing all three cases.

(WTC 7), near the twin towers (WTC 1 and 2), on the same day (9/11/2001) that the twin towers were destroyed.[173]

Haas had filed an RFC with NIST, and at the time the suit began NIST had not responded, and Haas complained of unreasonable delay and also asked for an injunction against completion of the NIST report until it corrected certain allegedly inaccurate or incomplete preliminary information on grounds that it was internally contradictory. NIST rejected the RFC while the suit was under way, but had not completed its report at that time.[174]

Haas asserted in his RFC that he was an "affected person" within the meaning of the IQA, essentially because he was acting in the public interest; however, his court Complaint did not contain similar allegations, including any pertaining to Article III standing.

The District Court dismissed the case in a brief paragraph. It stated that "[t]he Information Quality Act does not create any legal rights, enforceable by unrelated third parties, to information or its correctness," citing the Fourth Circuit opinion in *Salt Inst.*, the District Court opinion in *Amer. For Safe Access* (later appealed, discussed *infra*), and *Missouri River*. The opinion also stated that "[n]either the Information Quality Act, nor the Administrative Procedure Act, create a private right of action upon which plaintiff may independently pursue this litigation."[175] There was no analysis. The case was not appealed.

E. Am. for Safe Access v. HHS[176]

On October 6, 2004, Americans for Safe Access, a non-profit organization in Oakland, CA, conducting advocacy and education on medical uses of marijuana, filed an RFC with HHS seeking correction of HHS-disseminated information which concluded that marijuana lacked any medical efficacy.[177] The main dissemination for which it sought correction was an HHS/FDA evaluation of medical marijuana published in the Federal Register in 2001 and which continued to be available on government websites.[178] That evaluation, which had been conducted in connection with a 1995

173. Building WTC 7 allegedly appeared to be destroyed by controlled demolition rather than as a result of collateral damage from the destruction of the twin towers because video showed it collapsing straight down into its own footprint in seconds when the damage to it from the twin towers was mostly on one side. Investigations by Science Applications, Inc. and its subcontractors, however, reported there was no evidence of controlled demolition.

174. The RFC of Dr. Judy Wood could not be located on the Dept. of Commerce website. Apparently DOC does not maintain a webpage listing of RFCs and agency responses with links. The RFC was at one time located on the non-governmental website http://www.drjudywood.com/NIST/NIST_WoodRFC_Response.html, but was no longer there as of Dec. 2017. The RFC is referenced in the lawsuit.

175. *Reynolds* at *6.

176. No. 07-01049, 2007 WL 2141289, (N.D. Cal. July 24, 2007) (first opinion); 2007 WL 4168511 (N.D. Cal., Nov. 20, 2007) (second opinion), *aff'd*, 399 Fed Appx. 314, No. 07-17388, 2010 WL 4024989 (9th Cir. 2010) (not reported and designated as not precedent in the 9th Cir., except as provided in 9th Cir. Rule 36-3).

177. Available, along with all HHS responses and petitions at https://aspe.hhs.gov/information-requests-corrections-and-hhs-responses, item no. 20 (last visited Dec. 2017).

178. 66 Fed. Reg. 20040 (2001). This dissemination through the Federal Register could have raised an issue regarding the OMB definition of "dissemination" due to its possible "archival" nature; however, no such issue was ever raised by the agency during the litigation, although the Circuit Court's comments (see below) regarding what it regarded as the "time-limited" nature of the dissemination appear closely related. Such a problem might have been overcome later because HHS/FDA and DEA issued a joint news release titled "Inter-Agency Advisory Regarding Claims that Smoked Marijuana Is a Medicine" on April 20, 2006, that contained basically the same points previously

rescheduling petition under the Controlled Substances Act (CSA)[179] concluded that "there have been no studies that have scientifically assessed the efficacy of marijuana for any medical condition." It was principally this statement that ASA challenged as inaccurate under the IQA, listing some 30 published studies, reviews, and commentaries on the subject. ASA's RFC asserted that HHS was in violation of the IQA for failing to reveal and discuss numerous reports and studies concerning marijuana's medical efficacy, for requiring that there be a "consensus" of medical experts on medical efficacy, and for not revealing the basis for its conclusion that such a consensus was lacking.

HHS denied the initial petition and a request for reconsideration after numerous interim responses, stating that it needed more time because the issue raised by the petition was under consideration by HHS in a pending petition proceeding at DEA under the CSA.[180]

ASA sought judicial review in district court under the IQA and APA.

Before the District Court, prior to the Amended Complaint, HHS argued that ASA lacked organizational, representational, and prudential standing, being merely an "advocacy" organization that disagreed with HHS' views. It also argued that HHS had not taken final agency action on the ASA petition because in its last response (the response to the appeal from denial of the RFC) the agency had deferred its evaluation to the pending CSA proceeding. HHS also contended that there was no private right of action in the IQA (but did not address the APA), and argued that every court to have considered whether there was a right to judicial review had decided against it, citing the District Court and Fourth Circuit opinions in *Salt Inst.* and the District Court opinion in *Missouri River*. It also argued that the APA did not provide a right of action because the OMB IQA guidelines, with their use of the term "appropriate," committed correction decisions

challenged by ASA, and there was allegedly 2004 Congressional testimony that referenced the HHS assessment in the 2001 Federal Register (no longer available online but cited in ASA briefs). ASA amended its Complaint to include these disseminations after the first District Court decision providing leave to amend. The "Inter-Agency Advisory" is available at http://medicalmarijuana.procon.org/sourcefiles/FDAAdvisory.pdf (last visited Dec. 2017). The "Advisory" essentially confirmed the 200l HHS assessment that smoked marijuana has no established medical efficacy. These disseminations, as well as the 2006 HHS assessment (not the press release) sent to DEA and published in the Federal Register with its CSA petition denial in 2011 (76 Fed. Reg. 40551, June 30, 2011) could also have raised an issue regarding applicability of the OMB peer review Bulletin, which had become effective for disseminations made after June 16, 2005, but that issue was never raised in the litigation. The 2006 Inter-Agency Advisory was not, in reality, simply a reaffirmation of the medical science evaluation by HHS in the 2001 Federal Register, since it was discovered via FOIA request that revealed that at the time the advisory was issued HHS had completed a new evaluation of the medical science in connection with the 2002 CSA petition.

179. 21 U.S.C. §811(a) states that the Attorney General "may" initiate formal rulemaking proceedings to change the scheduling of a drug "on the petition of any interested party." 21 U.S.C. § 877 provides for judicial review by any "person aggrieved" by any final determination, finding, or conclusion of the Attorney General regarding a decision on a petition. The Attorney General has delegated his authority under the CSA to DEA. HHS is responsible for conducting CSA medical and scientific evaluations, which are binding on DEA under § 811(b). DEA never initiated a formal rulemaking regarding the CSA petition that was pending at the time of the ASA litigation; instead, DEA simply denied the 1995 CSA petition in 2011.

180. A new rescheduling petition under the CSA had been filed in 2002. The final HHS response to the ASA petition stated that it expected to complete a comprehensive review of the science and provide its scientific assessment to DEA (not ASA or the public) by September 2006. This HHS review for DEA under the CSA was not made public until 2011 and did not address ASA's IQA petition.

to agency discretion. Finally, it contended that the APA was not applicable because the CSA provided an adequate and exclusive remedy.[181]

ASA argued that it had Article III standing under the Supreme Court's decision in *Havens Realty*[182] and similar cases, and that the APA expressly provided for judicial review of agency actions in the form of a denial of a petition (sections 701 and 551(11)), and that a CSA remedy was not adequate because it would violate the timeliness and harm avoidance provisions of the HHS IQA guidelines – particularly regarding medical information -- since the ASA petition had been pending for two and a half years and there was no guarantee of when HHS would complete its pending CSA assessment. Seeking judicial review of a DEA denial of a petition for rescheduling sometime in the future was not an adequate remedy, ASA argued, because ASA was not challenging a rescheduling petition denial, but only the current HHS information dissemination regarding medical efficacy. ASA also contended that the HHS final response to its petition, stating that it was deferring the issue to the CSA proceeding, was final agency action on the petition under the APA. [183]

In reply, HHS contested ASA's Article III standing, relying heavily on the statements regarding lack of effect on a "right" in the two *Salt Inst.* opinions and *Missouri River*. It did not address the APA provisions (5 U.S.C. §§ 701 and 551) defining subject "agency action" as including denial of a petition, and argued that the wording of the IQA showed that Congress intended that all review of correction requests should take place only administratively. Regarding the issue of timeliness, HHS argued that ASA had not alleged unreasonable delay under the APA.[184]

The District Court took the view that the final HHS response to the petition was not a denial, so there was no final agency action under the APA. It also held that there was no "right" affected by the HHS action, relying on the two *Salt Inst.* opinions and *Missouri River* as "persuasive." The court made no mention of the APA provisions defining a petition denial as a covered agency action, nor did it address the "seek and obtain" language of the IQA. The court did, however, grant ASA leave to amend its Complaint to include a claim of "unreasonable delay" in providing a "substantive response" to ASA's IQA petition in violation of the APA.

After further briefing, the District Court, in a very sparse opinion, dismissed the case for failure to state a claim, on grounds that the IQA and its guidelines did not establish a legal duty for HHS to provide a substantive response to the ASA petition. The court appeared to rely principally on the District Court opinion in *Salt Inst.*, while also stating that "[g]uidelines are by nature advisory," and that other courts had held language similar to that in the IQA guidelines, as being discretionary

181. Mem. of P & A in Supp. of Def.'s Mot. to Dismiss Pl.'s Compl., ECF No.31. Under the CSA, a person whose petition was denied by DEA could file a suit for judicial review in circuit court. 21 U.S.C. § 877 (2012). The APA does not apply if an aggrieved person has an adequate alternative remedy. 5 U.S.C. § 704 (2012).

182. Havens Realty Corp. v. Coleman, 455 U.S. 363 (1982) (holding that an organization meets the requirements for Article III standing if it alleges that the purportedly illegal action challenged has required the organization to expend monetary and human resources to protect and further its mission).

183. Pl. Mem. of P. & A. in Opp. to Mot. to Dismiss, ECF No. 35.

184. Reply Mem. in Supp. of Def.'s Mot. to Dismiss Pl.'s Compl., ECF No. 39.

and exempt from judicial review due to lack of meaningful standards ("law to apply"), citing *Steenholdt v. FAA.*[185]

ASA appealed to the Ninth Circuit. It asserted that the IQA "Guidelines" (both OMB's and HHS') were binding legislative rules that, along with the IQA itself, gave ASA, as a petitioner, a right to "seek and obtain" a timely correction, that the HHS final response on the ASA appeal of denial of its petition was a final agency action, and that the OMB Guidelines provide meaningful law to apply for providing a substantive response to the petition.[186]

HHS, in addition to continuing to argue that the CSA was the exclusive avenue for addressing controlled substances issues, claimed that its IQA guidelines allowed it to defer its medical science evaluation to the CSA proceeding as an existing procedure that allowed persons to raise information quality issues on a timely basis.[187]

In responding to the agency's claimed right to "deferral" of the ASA correction petition to the pending CSA petition proceeding, ASA observed that under the CSA, DEA controlled the decision on whether to conduct a CSA rulemaking and that any pending HHS assessment of the science would be provided to DEA with no time limits and no obligation of DEA to provide the assessment to ASA or the public. ASA called attention particularly to the specific language of the Guidelines allowing deferral, which provides that deferral had to provide a "timely" response, and that deferral was not proper if an earlier response (to a petition) would not unduly delay issuance of the deferral action and the complainant had shown likelihood of actual harm if the agency delayed a response to the deferral action. ASA pointed out that past CSA petitions and rulemaking proceedings had taken years to resolve, and the IQA and its Guidelines as a

185. 314 F.3d 633, 638 (D.C. Cir. 2003) (statute authorized the Administrator of FAA to rescind a designation of a standards-testing representative "at any time for any reason the Administrator considers appropriate.")

186. Appellant's Opening Br.

187. Br. for the Appellee 5, 22. The *HHS Information Quality Guidelines*, https://aspe.hhs.gov/report/hhs-guidelines-ensuring-and-maximizing-quality-objectivity-utility-and-integrity-information-disseminated-public Part I, sec. E (2002) (last visited Dec. 2017), provide in full:

> **Rulemakings and Other Public Comment Procedures**
> Existing public comment procedures for rule-makings and other formal agency actions already provide well established procedural safeguards that allow affected persons to raise information quality issues on a timely basis. Accordingly, agencies will use these existing procedures to respond to information quality complaints that arise in this process. 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 in those cases where in the agency's judgment issuing an earlier response would not unduly delay issuance of the 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.

HHS did not contend that the CSA process provided a petitioner with an opportunity to comment on, participate in, or call for a peer review on the HHS/FDA medical science evaluation (essentially a HISA).

whole were designed to produce timely responses to correction requests, thus making delay through an indefinite deferral an "unreasonable" delay under both the IQA and the APA.[188]

HHS also continued to rely on the Fourth Circuit's *Salt Inst*. opinion, and argued that *Salt Inst.* involved a "correction" petition, not just a request for access to underlying data under FOIA and the Shelby Amendment.[189]

HHS also argued that the many cases holding that agency disseminations were not reviewable final agency actions (all not involving denial of an IQA petition) had long established that agency information disseminations were not judicially reviewable.[190] Neither HHS nor the court addressed the APA definition of covered "agency action" as including denial of a petition for relief by affected persons.

ASA's reply argued that it was challenging not just the HHS evaluation disseminated in connection with the 2001 CSA petition denial, but also the 2006 "Interagency Advisory" on marijuana disseminated by FDA, and the FDA Congressional testimony in 2004, and neither of those information disseminations could be challenged through CSA proceedings. It also noted that a final CSA decision was the province of DEA, and DEA could avoid the issue raised by ASA concerning medical efficacy studies by basing its decision on other grounds, as it had done in 2001, when it based the decision solely on potential for abuse.[191]

ASA also pointed out that HHS had misstated the Supreme Court's test for final agency action as requiring "legal consequences." The correct Supreme Court statement[192] was that "generally" an agency action would be regarded as final if it determined "rights or obligations" "*or"* (emphasis added) was an action "from which legal consequences would flow." As ASA asserted, the IQA granted an "affected person" a right to "seek and obtain" correction of agency information disseminations that did not comply with the OMB guidelines.[193]

ASA argued in the alternative that, although ASA had apparently exhausted its administrative remedies and HHS had denied relief, if the court regarded the HHS final response as not "final" in the legal sense because it was non-substantive in relying on deferral

188. Appellant Opening Br. at 45-51; Appellant Pet. for Panel Rehrg. at 6-8.

189. Br. for the Appellee 15. The government relied extensively on both the district and circuit court opinions in *Salt. Inst*. At oral argument before the Fourth Circuit panel in *ASA*, the presiding judge questioned DOJ counsel intensively on how the "seek and obtain" language in the IQA could not be considered the granting of a right, and where in the *Salt Inst.* cir. ct. opinion the court had addressed that point. Oral argument court recording, on the Ninth Circuit website, No. 07-17388.

190. *Id* at 18-19. HHS also argued that accepting ASA contentions concerning establishment of a "right" by the IQA and judicial reviewability would open all government information disseminations to review and "enmesh the courts in countless standardless disputes about the 'quality' of such information." *Id*. at 15 and oral argument at 27.00-29.00. The OMB and conforming agency guidelines contain detailed "standards" for quality, objectivity, and utility, and Article III standing requirements greatly limit who can sue.

191. Appellant's Reply Br. at 4-12.

192. Bennett v. Spear, 520 U.S. 154, 178 (1997).

193. ASA argued that the denial of a legal right (to seek and obtain a correction) should also be regarded as a "legal consequence."

of the matter to the ongoing CSA process, the HHS failure to provide a substantive final denial should be determined to be "unreasonable delay" under the APA.

In the end, the Circuit Court held, in a short memorandum opinion, which it designated as not for publication and non-precedential,[194] that there was no valid APA claim because there was no final agency action due to the HHS decision to defer the issues raised by ASA to the CSA process. The Court decided that the deferral to the CSA process was proper without addressing the adequacy of the process (as required by the APA[195]), particularly with regard to timeliness, likelihood of harm while the alternative process was being pursued, and the existence of "procedural safeguards," especially opportunity for public comment, in the alternative process.[196]

There was no mention in the Circuit's opinion of the *Salt Inst*. decision, nor any language indicating the Court thought there was no right to judicial review if it had been determined that the agency action was final. The court also "note[d]" that the allegedly inaccurate statements by HHS in its evaluation published in 2001were "inherently time-bound" in that they stated that there was no "*currently*" (original emphasis) accepted medical use then, and the correction sought by ASA to that statement would be of no use currently, whereas the upcoming CSA evaluation to which the proceeding was being deferred should address the issue in the present. The court did not mention or discuss FDA's 2004 Congressional testimony or its issuance of the 2006 Joint Inter-Agency Advisory, both of which had been added to ASA's Amended Complaint to supplement its original allegation that HHS/FDA was continuing to disseminate the conclusions of its 2001 evaluation.[197]

---

194. Under Fed. R. App. Proc. 32.1, litigants can cite judicial opinions designated as not for publication if they were issued on or after Jan. 1, 2007. Under Ninth Circuit Rule 36.3(a), Ninth Circuit opinions that are unpublished generally cannot be cited as precedent in the Ninth Circuit.

195. The APA states that an agency action is reviewable if is "final agency action for which there is no other *adequate* remedy in a court . . . ." 5 U.S.C. §704 (emphasis added).

196. The Court stated that both its guidelines and the OMB guidelines permit it to "'use existing processes that are in place to address correction requests from the public.'" At *1. No citation was provided for this quotation, and it does not conform to statements in either the OMB or HHS guidelines. *See supra* note 186. *See also* the OMB Guidelines at 67 Fed. Reg. 8453, and the June 10, 2002, memorandum to agencies from OIRA, *supra* note 109. The statement in the HHS guidelines regarding use of existing procedures is referring to "rulemakings and other public comment procedures." Under the Court's and HHS's interpretation of those provisions, ASA would not be able to comment on the HHS scientific assessment before it became final, and could not challenge it in court until DEA issued a decision on the pending CSA petition. In a rulemaking, an affected person could challenge information in a proposed rulemaking allowing for public comment.

197. ASA filed a petition for reconsideration with the court on grounds that the court had failed to consider the full Guidelines explanation of what constituted an adequate alternative process to which a correction request could be deferred, and the failure of HHS/FDA to reveal that it had in fact completed its "comprehensive review" of the medical efficacy issue in 2006 prior to the Circuit Court appeal. The FDA's updated evaluation of the science was obtained by FOIA in 2010, and was disseminated to the public by DEA in a 2011 Federal Register notice denying the 1992 CSA rescheduling petition. 76 Fed. Reg. 40552 (July 8, 2011). An issue not addressed in the briefs or the opinion is whether the OMB peer review Bulletin requirements should have applied to the HHS scientific assessment provided to DEA for the joint news release in 2006, (and any subsequent HHS assessment for the 2011 CSA petition denial), since the Bulletin requirements for highly influential scientific assessments took effect on June 16, 2005. This might also be an important issue in future CSA petition proceedings. The HHS scientific assessments required by the CSA appear to be exactly what the OMB peer review Bulletin was designed to address; however, the DEA/HHS restrictive

F. Single Stick, Inc. v. Johanns and Prime Time Int'l, Inc. v. Vilsack[198]

Single Stick (which later changed its name to Prime Time Int'l) was a manufacturer of small cigars that came in packs of twenty. In 2004, Congress passed legislation, the Fair and Equitable Tobacco Reform Act (FETRA), requiring the Department of Agriculture to assess (tax) cigar and cigarette companies amounts that would offset subsidies given to tobacco farmers. Single Stick was assessed an amount that it contended was exorbitant and erroneous because USDA based the assessment on a market share derived from the number of cigars sold rather than the amount of tobacco in the cigars sold, treating small cigars the same as large cigars.

Single Stick was granted an administrative hearing, in which the hearing official determined that the assessment methodology employed by USDA was required by the statute, and that Single Stick could seek review of his ruling in federal district court.

Single Stick also filed an RFC alleging that USDA had failed to disclose the sources and data underlying its calculations, as required by the IQA Guidelines. USDA did not respond to the IQA petition or an appeal.[199]

1. Single Stick, Inc. v. Johanns

In its District Court Complaint, Single Stick alleged that USDA's assessment calculations violated FETRA, and had also violated the IQA by failing to correct the assessments, by failing to make available the statistical data the agency used in making its calculations, and by failing totally to make any response to its IQA petition and appeal, thereby depriving it of the information it needed for a full and fair hearing. Single Stick's claims were brought under APA § 702, among other authorities, and the assessment information was described as "influential." Single Stick also alleged that it had submitted a FOIA request for the underlying data, but that it had been denied on the basis that the information requested was protected as confidential by statute (as excise tax information). Single Stick's Complaint did not make any reference to the objectivity and reproducibility requirements of the OMB and agency guidelines,[200] nor did it refer to the provisions of the APA defining reviewable agency action as including denial of a petition for relief (§§ 551 and 701).

---

regulatory definition of medical efficacy, and the lack of a provision requiring public review of the charge to peer reviewers in the current Bulletin, could nevertheless be obstacles. *See* the OMB guidance Memorandum to agencies, *supra* note 109, at 15, which essentially interprets the IQA as being in pari materia with other statutues ("VI. MELDING THE STATUTORY REQUIREMENTS OF SECTION 515 INTO THE PROCEDURAL REQUIREMENTS OF OTHER STATUTES").

198 Single Stick, Inc v. Johanns, 601 F.Supp.2d 307 (D.D.C. 2009), *aff'd on other grounds sub nom* Prime Time Int'l, Inc. v. Vilsack, 599 F.3d 678 (D.C. Cir. 2010).

199. The IQA petition is attached to Single Stick's Complaint as Exhibit 8, although there is no documentation of an appeal. The petition and any further documentation is not available online because it appears that USDA's Commodity Credit Corporation and Farm Service Agency do not maintain an online-accessible listing of IQA petitions and appeals.

200. Single Stick's RFC alleged that the agency had violated the objectivity and reproducibility requirements of the IQA guidelines by not disclosing supporting data and methods.

The agency moved to dismiss based on failure to state a cause of action. Regarding the IQA allegations, it argued that the IQA created no right of action, relying principally on *Salt Inst*. (cir. ct.) and *Missouri River*.[201] It also argued that the IQA and its guidelines contained no meaningful legal standards to apply, citing *Heckler v. Chaney* and *Steenholdt*, and emphasizing the use of the word "appropriate" with regard to agency corrections. It also contended that the IQA guidelines expressly protected confidential information of the sort Single Stick was seeking.

Single Stick argued that the "seek and obtain" language in the IQA was intended to confer a right, and that the cases cited by the agency had not even considered that language and the issue of a right to judicial review.[202] It characterized the agency's argument that there was no "law to apply" as "frivolous" in view of the detailed and mandatory language of the OMB and agency guidelines.[203]

The agency's reply memorandum basically repeated the arguments made in its principal brief, again relying largely on the *Salt Inst*. opinions.

The District Court granted the agency's motion to dismiss for failure to state a claim upon which relief can be granted, holding that "the IQA does not create any individual right to the production or correction of information."[204] The court also held that there could be no review under the APA of the agency's failure to respond to Single Stick's RFC because there was no final agency action, and because there was no "right" of Single Stick under the IQA that had been determined by agency action, citing *Salt Inst*. and *Bennett v. Spear*, as well as the District Court opinion in *ASA*.[205]

2. Prime Time Int'l, Inc. v. Vilsack

On appeal, Prime Time appeared to concede that the *Salt Inst.* opinions held that the IQA conferred no right to judicial review, while also characterizing the opinions as "troublesome" and "problematic" because the issue of a right to judicial review had not been raised, briefed, or argued, because the Fourth Circuit opinion did not even consider whether the language of the IQA concerning establishment of an administrative mechanism allowing affected persons to "seek and obtain" correction of disseminated information that did not comply with the OMB guidance was rights-creating language, and because it did not consider a right to judicial review under the APA. "[I]t is the APA, not the IQA, that creates the right to sue," argued Prime Time.[206] Prime Time

201. The agency also briefly augmented the Government's usual precedent-based arguments against IQA judicial review in stating: "[B]ecause both an enforceable right and mechanism to remedy that right are required to sue the sovereign, the possibility that the APA may provide a remedy means nothing where the IQA does not provide the underlying right. See Gonzaga Univ., 536 U.S. at 283-84; Alexander, 532 U.S. at 286." Defs.' Mot. to Dismiss Pursuant to Rule 12(b)(6), ECF No. 8, at 20. Neither *Gonzaga* nor *Alexander* were APA cases. An APA right to judicial review is discussed *infra* in Part V, sec. B.

202. Single Stick did state that the APA expressly created a right of action, but did not stress the point and included it in its discussion of "law to apply." Pl. Reply to Def. Mot. to Dismiss, ECF No. 9, at 22.

203. *Id.* at 24.

204. 601 F.Supp.2d at 310.

205. 601 F. Supp. at 316-17.

206. Br. of Appellant 38.

argued that the IQA "seek and obtain" language created a right to a response from the agency, and the lack of a response was a "failure to act," which was expressly a type of reviewable "agency action" under the APA.[207]

With regard to the District Court's conclusion that there were no meaningful standards to apply, Prime Time noted that the District Court did not consider the OMB Guidelines, which are "uniquely rich in detail" regarding the quality standards to be applied.[208]

In response, the agency argued for the first time that the agency information challenged by Prime Time was expressly exempted from the IQA by the OMB Guidelines as information that was distributed, but not "disseminated," as part of an adjudicative process.[209] With regard to a right to judicial review under the IQA or the APA, the agency argued that Congress intended only an administrative remedy for possible corrections and "did not . . . enmesh the courts in countless standardless disputes about the 'quality' of information provided by federal agencies."[210]

Prime Time argued that it was not relying on an implied right of action in the IQA to support judicial review, but rather on the right to judicial review embodied in the APA, and that the challenged agency action was final because it determined the obligation of the agency to make a correction to comply with the OMB guidelines and also determined Prime Time's right to "seek and obtain" a correction from the agency.[211] With regard to the exemption for information distributed in the course of adjudicatory proceedings, it claimed that the agency had waived that issue by not raising it before the District Court.

The D.C. Circuit remanded to the District Court on the issue of interpretation of the FETRA provisions, and dismissed Prime Time's claim under the IQA on grounds that there was no doubt that the information sought by Prime Time was information distributed in the course of an adjudication, and was not a "dissemination," and therefore it was expressly exempted from the IQA and its guidelines. The Circuit Court did not discuss any aspect of the IQA portion of the District Court opinion.

Importantly, the D.C. Circuit held that the IQA exemption for information distributed in the course of adjudicatory proceedings was a part of binding legislative regulations that had the force and effect of law. The Court stated: "[B]because Congress delegated to OMB authority to develop binding guidelines implementing the IQA, we defer to OMB's reasonable construction of the statute. *See United States v. Mead*, 533 U.S. 218, 226–27,121 S. Ct. 2164, 150 L.Ed.2d 292 (2001)."[212] The Court's citation of *Mead* makes clear that by "binding," it meant that it held the IQA guidelines to be legally binding – *i.e.*, legislative rules having the force of law. The portion of *Mead* it cited, at pages 226-27, states: "We hold that administrative implementation of a particular statutory provision qualifies for *Chevron* deference when it appears that Congress delegated authority to the agency generally to make rules carrying the force of law, and that

207. *Id*. at 39.

208. *Id*. at 41. However, Prime Time did not specify the allegedly defective information to which a particular IQA guideline standard applied.

209. Proof Br. of Appellees 12, 26-27.

210. *Id*. at 29.

211. Reply Br. of Appellant 17-19.

212. 599 F.3d at 685.

the agency interpretation claiming deference was promulgated in the exercise of that authority.'"[213] *Mead* contrasted such legally binding rules with "rulings [that] are best treated like 'interpretations contained in policy statements, agency manuals, and enforcement guidelines' [that] . . . are beyond the *Chevron* pale."[214]

G. Family Farm Alliance v. Salazar and San Luis & Delta-Mendota Water Auth. v. Salazar

These were two related district court opinions addressing claims that a U.S. Fish and Wildlife Services (FWS) final Biological Opinion (BiOp) under the Endangered Species Act (ESA) violated the IQA.[215] The basic controversy concerned whether there needed to be alterations in irrigation water withdrawals from the Sacramento-San Joaquin Delta (in northern California's Central Valley Project, east of San Francisco) in order to preserve the delta smelt, a finger-sized fish that had been determined to be a "threatened" species under the ESA.

Multiple cases based on the ESA filed by farmers and related interests challenged the scientific information in the BiOp and were consolidated. One of the cases, that filed by Family Farm Alliance (FFA), contained three claims based on the IQA. The district court determined that the first FFA claim, which concerned the scientific information in the BiOp and its compliance with the IQA, overlapped with the consolidated cases and their ESA claims and would be addressed in connection with them, while the second and third claims of FFA, based on the IQA (unreasonable delay and lack of independence in peer reviewers) would be addressed separately.[216]

The district court first ruled on the third FFA IQA claim (peer review) in the *Family Farm Alliance* opinion; it then ruled on the first FFA IQA claim (presentation and analysis of scientific data) in the *San Luis & Delta-Mendota* opinion. The second FFA claim (unreasonable delay) was dismissed as moot.

Prior to the court proceedings, FFA had filed a RFC that encompassed both the issues of IQA compliance with the scientific information standards and also compliance with its peer review procedures. The RFC included 25 separate requests for correction. The FWS denied all the requests for correction. For most, it refuted FFS claims of inaccuracy or lack of scientific basis for assumptions; and for many it responded that FFS had not provided specific information or studies to support its claims (i.e., it had not satisfied its burden of proof). FFA

213. The Government filed a petition for rehearing, requesting that the Court "amend its opinion to clarify that the Court did not decide whether the Information Quality Act ('IQA') creates judicially enforceable rights." The Court rejected the petition without an opinion.

214. 533 U.S. at 220 (internal citations omitted).

215. Family Farm Alliance v. Salazar, 749 F. Supp. 2d 1083 (E.D. Cal. 2010) and San Luis & Delta-Mendota Water Auth. v. Salazar 760 F. Supp. 2d 855 (E.D. Cal. 2010), *aff'd in part, reversed in part on other grounds sub nom* San Luis & Delta-Mendota Water Authority v. Jewell, 747 F.3d 581 (9th Cir. 2014). FFA initially appealed on the IQA issues, but then voluntarily withdrew its appeal. These consolidated cases are sometimes referred to as the "Delta Smelt cases."

216. ECF No. 44.

pursued an administrative appeal, and the FWS denial of the appeal was largely in line with its previous RFC denial.[217]

1. Family Farm Alliance v. Salazar

FFA alleged that the external peer review sponsored by FWS had been conducted in part by individuals who lacked the degree of independence required by the OMB peer review Bulletin for highly influential scientific assessments, particularly because two reviewers had authored papers relied on in the BiOp. This was the first case to include a claim of non-compliance with peer review requirements in IQA/PRA guidance.

FWS moved to dismiss with regard to IQA judicial review generally. It asserted: "Not only has Congress *not* expressly authorized suit under the IQA, but every court to have considered the matter has concluded that the language of the IQA in fact reflects Congressional intent *not* to permit lawsuits such as the one at bar."[218] In a more detailed statement it asserted that "[i]n every case to come before the Federal courts since the IQA was enacted, courts have unanimously held that Congress has precluded judicial review of alleged IQA violations," citing both *Salt Inst.* opinions, *Missouri River*, *Single Stick* and *Prime Time*, *Haas*, *ASA* (d. ct.), *Wood*, and *Morgan*.[219] The government also noted that the general FWS IQA guidelines contained a disclaimer of judicial reviewability.[220]

With regard solely to the FFA peer review claim, the government asserted that it was "critical" that the OMB Bulletin contained an express disclaimer of judicial review, which it quoted, and that, even if there were judicial review, the Bulletin contained no legal requirement for external peer review and that the requirements regarding independence of reviewers were discretionary under the facts of the case.[221] Finally, the government argued that it could not be demonstrated, and was highly unlikely, how any correction of the peer review violations alleged by FFA would have led to a different overall result in the BiOP.[222]

The district court opinion held that there could be no judicial review of FWS compliance with either the OMB peer review Bulletin or the FWS guidelines because the OMB Bulletin contained a judicial review disclaimer.[223] The court also found that there was no Article III standing because there were no enforceable legal rights created by the IQA or its guidelines due to lack of law to apply, relying on the circuit opinion in *Salt Inst.* and the OMB peer review Bulletin's judicial review disclaimer.[224]

---

217. The FFA RFC documents and FWS responses can be found at https://www.fws.gov/informationquality/ (last visited Dec. 2017). Some of these documents are also attached to pleadings in the court proceedings.

218. Def. Mot. for Sum. Judg. and in Opp'n. to Pl. Mot. for Sum. Judg. 1.

219. *Id.* at 11.

220. *Id*. at 5, 14.

221. *Id*. at 20-24.

222. *Id*. at 24-25. The government invoked the need for a reviewing court to take into account the "rule of prejudicial error" as required by 5 U.S.C. § 706.

223. 749 F.Supp.2d at 1095.

224. *Id*. at 1095, 1103-04.

2. San Luis & Delta-Mendota Water Auth. v. Salazar

FFA had submitted an RFC containing a large number of requests for correction of the BiOp on the basis that portions were incomplete, inaccurate, unsupported, biased, or unclear. The requests were not tied to specific requirements in the IQA guidelines and were not supported by documentation or explanation supporting a particular alleged need for correction

In opposition to the IQA claim of FFA, the Government made its by-now usual arguments: Other district courts had unanimously held that there was no IQA right of action, citing *Missouri River, Salt Inst., Single Stick, Haas,* and *ASA*; there could be no reviewable final agency action under the APA because the BiOp had no legal impact; and agency action was committed by law to agency discretion due to use of the word "appropriate" regarding the degree of correction required in response to an RFC.[225]

The District Court opinion was written by the same judge who had ruled on FFA's peer review claims. The court held that the BiOp scientific analysis was exempt from judicial review under the APA because neither the legislation nor the OMB Guidelines provide judicially manageable standards, citing the district court opinion in *Salt Inst.*as construing the OMB Guidelines language that an agency is "required to undertake only the degree of correction that they conclude is appropriate for the nature and timeliness of the information involved" as "insulat[ing] the agency's determinations of *when* correction of information . . . is warranted."[226] The court went on to examine the language of the FWS IQA guidelines and concluded that, contrary to FFA's assertions, they did not require the agency to follow any particular scientific approach, but rather, only required that it prepare "some kind of 'narrative' that documents the strengths and weaknesses of the data." The opinion concluded its analysis of law to apply under the APA by stating that "[n]one of the guidelines set forth any 'judicially manageable standards' against which the presentation, use or analysis of data can be measured." Finally, the court observed that the FWS guidelines contained a judicial review disclaimer.[227]

There was no appeal.

H. Holistic Candlers and Consumer Ass'n v. FDA[228]

Plaintiffs sued FDA because the agency had issued a warning letter to them asserting that their devices for removing ear wax were medical devices requiring FDA approval, and FDA might take legal action if the Plaintiffs did not cease or alter their marketing of the devices.

The Plaintiffs had not filed an RFC. Their court Complaint alleged only that the agency was bound by the "Data Quality Act" to produce and disseminate only truthful information and it had "woefully failed in that duty and are thereby harming these Plaintiffs."[229]

225. Mem. in Supp. of Fed. Def. Opp. And Cross-Mot. for Sum. Judg., ECF No. 660.
226. 760 F. Supp. 2d 855, at 961-62 (emphasis added).
227. *Id*. at 962-964.
228. 70 F. Supp.2d 156 (D.D.C. 2011).
229. Complaint ¶ 8.

The District Court found at the outset that the Plaintiffs lacked standing and the court had no subject matter jurisdiction because there was no imminent threat of concrete harm and no final agency action. The only mention of the IQA is in a one-sentence footnote referencing the *Salt Inst.* circuit court opinion in support of a statement that the IQA does not provide a private right of action.[230]

I. Habitat for Horses v. Salazar

A number of organizations sued the Department of the Interior's Bureau of Land Management to stop a roundup of wild horses in Colorado. They first sought a preliminary injunction, and then review under the APA. Consequently, there were two opinions issued by the district court, one denying the preliminary injunction[231] and another denying APA review and dismissing the Complaint. [232]

The Complaint contained a very brief claim alleging that the BLM Decision Record was "based on a pattern and practice of intentionally relying on information of insufficient quality, objectivity, utility and integrity to meet the standards demanded by the IQA."[233] The Complaint provided no specifics. In addition, plaintiffs had not utilized the RFC process.

In denying the motion for a preliminary injunction the court held that Plaintiff's pleadings and memoranda contained only bare conclusions and offered no support for their IQA claim and the allegations would be insufficient to survive a motion to dismiss. The court added, citing the *Salt Inst*. district court opinion as an example, that other courts had held that the IQA provided no private right of action.

In opposing both the preliminary injunction and then moving to dismiss, the government made its usual arguments against IQA review.[234] It did add a new twist this time by arguing that the IQA only addresses the quality of information dissemination and "Plaintiffs do not (and cannot) cite to any provision of the IQA that limits the type of information that a federal agency may rely on in reaching decisions . . . ."[235]

In its decision on the plaintiffs' request for APA review on the merits, the court concluded that the IQA provided only standards for information disseminations, and that "Plaintiffs are mistaken that the IQA provides any limit on the types of information on which an agency may *rely* in reaching its decision. Rather, the IQA applies only to the quality of information '*disseminated*' by federal agencies."[236] The court added that, in any event, the IQA "creates no legal rights in any third parties," quoting the *Salt Inst*. circuit court opinion and the district court opinions in *Single*

230. *Id*. at 165 n. 16.

231. No. 10-7684, 2011 WL 4343306 (S.D. N.Y., Sept. 7, 2011).

232. 745 F.Supp.2d at 455-56.

233. Compl. ¶¶ 96-98.

234. Mem. of Law in Supp. of Def. Mot. to Dismiss the Compl. for Lack of Subj. Matter Jur. and for Failure to State a Claim and for Summ. Judg., ECF No. 31, at 21-22.

235. *Id.* at 21.

236. 2011 WL 4343306, at *7 (original emphasis).

Stick, *ASA*, and *Missouri River*. The court also stated that it could not locate any authority supporting Plaintiffs' contention that they could sue under the APA.[237]

J. Am. Petrol. Inst. v. EPA[238]

EPA issued a final rule establishing a new short-term air quality standard for nitrogen dioxide,[239] and API petitioned for review of the rule in the D.C. Circuit under the judicial review provisions of the Clean Air Act ("CAA").[240]

API contended that EPA had violated the OMB IQA guidelines and its own general IQA guidelines and internal peer review policies by supporting the final rule with certain new scientific studies that had not been peer reviewed or published, while other studies that did not support the rule had been ignored. API did not mention the OMB peer review Bulletin in its arguments.[241]

The court concluded that the EPA peer review policies and the EPA IQA guidelines were non-binding, and that, in any event, the peer review that had been conducted by CASAC several years before should be considered sufficient. In viewing the EPA IQA guidelines as non-binding, the court stated: "By its terms . . . the [EPA] Guidelines provide only 'non-binding policy and procedural guidance.'" However, the court then acknowledged that under its decision in *Appalachian Power Co. v. EPA*,[242] such a disclaimer "would not override a specific commitment made elsewhere in the document . . . but the petitioners point to none."[243] The court also noted that the EPA Guidelines used the discretionary terms "should" and "generally," and that they "expressly commit 'the decision whether to employ peer review' to the discretion of agency management." It found the same to be true of the EPA Peer Review Handbook.[244] The opinion did not mention the OMB general IQA guidelines nor the OMB peer review Bulletin.

K. Styrene Info. and Res. Ctr., Inc. v. Sebelius[245]

SIRC filed a very detailed RFC regarding information contained in scientific documents prepared by the Report on Carcinogens Program (RoC, administered by NIH and its National Toxicology Program) that provided the support for a decision by HHS to list styrene in the RoC as "reasonably anticipated" to be a human carcinogen.

---

237. *Id.*

238. 684 F.3d 1342 (D.C. Cir. 2012).

239. 75 Fed. Reg. 6474 (Feb. 9, 2010).

240. 42 U.S.C. §7607(b)(1). API did not need to file a RFC because it addressed the peer review issues in its comments on the proposed rule. *See* 75 Fed. Reg. 6474 at 6487. The National Association of Manufacturers had filed an RFC addressing alleged peer review deficiencies, but it did not mention the OMB peer review Bulletin.

241. There are several general references to the OMB IQA guidelines, but not specifically to its peer review Bulletin. Pet'r's Opening Br. 2, 7, 31; Pet'r Reply Br. 1, 3 n. 4, 4 n. 5, and 8.

242. 208 F.3d 1015, 1022-23 (D.C. Cir. 2000)

243. 684 F.3d at 1348. The *Appalachian Power* opinion held that EPA regulatory action based on "guidelines" that were clearly worded as mandatory could not escape judicial review with such a disclaimer. That case, and the subject of binding "legislative rules," is discussed further *infra* Part V, Section E.

244. *Id*. at 1348-49. If the court had reviewed the alleged peer review violations it would have applied the stringent review standards that apply to procedural violations in the Clean Air Act at 42 U.S.C. §§ 7607(d)(8) and (9).

245. 944 F. Supp. 2d 71, 82, 83-84 (D.D.C. 2013).

The RFC complained that the main scientific document supporting the listing decision (the "Background Document") violated the IQA and its OMB Guideline requirements for objectivity and utility because, in numerous detailed ways, it was incomplete, biased, mischaracterized and misrepresented study findings, and lacked transparency and reproducibility, as well as not being in compliance with the NIH-adopted version of the SDWA risk amendments in its agency-specific IQA guidelines.[246] The Background Document had been peer reviewed by outside peer reviewers, and SIRC did not allege that there had been violations of the OMB peer review Bulletin.[247]

HHS denied the original RFC in large part, and SIRC appealed. HHS denied an IQA appeal a few days before issuing the listing, and SIRC filed suit.

The Complaint sought judicial review of the RoC Background Document and Substance Profile[248] under the APA, alleging that they were arbitrary and capricious and not in accordance with law. It included allegations that the peer review of the draft Background Document was non-compliant with the OMB peer review Bulletin because it incorporated analysis that the peer reviewers developed during the course of the review, and such analysis was not published study information and the peer reviewers review of it constituted review of their own work, which was prohibited by the IQA guidelines. The Complaint also alleged bias in the conduct of the new analysis by the peer reviewers.[249] The Complaint further alleged that HHS had not conducted a "weight of the evidence" analysis that provided complete information on data not supporting a listing, but did not specify this conduct as a violation of the IQA guidelines.[250]

Both parties filed motions for summary judgment.

In its brief, SIRC did not allege that the RFC denial was the final agency action being challenged, but instead relied on the D.C. Circuit's decision in *Tozzi v. HHS*[251] as holding that RoC listing decisions are subject to APA judicial review under certain circumstances.[252]

Also in its brief, SIRC stated that "Plaintiffs do not seek to enforce the IQA." Rather, it stated that the agency's failure to comply with its IQA obligations demonstrated, and was "further

246. The RFC documents and agency responses are available at https://aspe.hhs.gov/information-requests-corrections-and-hhs-responses, item No. 36 (last visited Dec. 2017). Unlike many other RFCs, including those involved in other litigation discussed herein, the SIRC RFC contained very specific allegations tied to the IQA guidelines regarding objectivity/bias and lack of completeness, along with documentation to support its allegations.

247. The draft Background Document was reviewed by an independent expert panel that voted 10 Yes/0 No that the document was sufficient for drawing RoC conclusions regarding carcinogenicity, applying the RoC listing criteria.

248. The Substance Profile, which is what is actually published in the Report on Carcinogens, is a summary of the Background Document.

249. Complaint ¶¶ 37-49.

250. Complaint ¶¶ 56-59.

251. 271 F.3d 301 (D.C. Cir. 2001). In *Tozzi*, the Plaintiff was able to show that the RoC listing would have legal consequences, such as activating OSHA hazard communication requirements and influencing State legal proceedings. SIRC made similar allegations.

252. Pl. Mem. in Supp. of Mot. For Summ. Judg., ECF No. 41-1, at 32.

evidence," that the agency was acting arbitrarily and capriciously and not in accordance with the law under the APA.[253]

The agency's briefs claimed that the IQA is not judicially enforceable, relying on the statements in the *Salt Inst.* circuit court opinion that "[b]y its terms, [the IQA] creates no legal rights in any third party," and "does not create a legal right to access to information or to correctness." It also cited the district court decisions in *Single Stick* and *Holistic Candlers*. The agency argued that APA review of IQA claims is "expressly precluded" because IQA implementation is "'committed to agency discretion by law," citing *Steenholdt v. FAA*, the *Salt Inst*. district court opinion, and *FFA* (the "IQA itself contains *absolutely no substantive standards*" [original emphasis from FFA opinion]), and the statement in the OMB guidelines that "'agencies, in making their determination of whether or not to correct information . . . are required to undertake only the degree of correction that they conclude is appropriate for the nature and timeliness of the information involved'," citing the *Salt Inst*. district court opinion. The government also relied on the judicial review disclaimer in the OMB peer review Bulletin.[254]

The district court held that SIRC had offered nothing to rebut the Government's arguments and therefore they were conceded. The court added that even without those concessions, it would adopt the "persuasive reasoning" of the *Salt Inst*. and *FFA* district court decisions regarding lack of judicially manageable standards to support APA review.[255]

L. Mississippi v. EPA[256]

This was a consolidated Clean Air Act case challenging the validity of a revised (lower) ozone standard promulgated by EPA, so, as in the API case, *supra*, the case was brought directly in the D.C. Circuit under the CAA judicial review provisions.

Petitioners raised the issue of IQA non-compliance in their comments on the CAA proposed rule.[257] They claimed that the rule was arbitrary and capricious under the APA because the scientific data EPA relied on was not objective and complete under the IQA and its guidelines in specific respects.

Petitioners argued that because the CAA expressly requires that air quality criteria "accurately reflect the latest scientific knowledge," the IQA must inform EPA scientific analysis in terms of

253. *Id*. at 55. *And see* Styrene Info. and Res. Ctr.'s Opp. to Defs.' and Intervenor-Defs.' Cross-Mots. for Summ. Judg. and Reply to Defs.' and Intervenor Defs.' Opps. to Pls.' Mot. for Summ. Judg., ECF No. 48, at 18-19 ("This Is Not an Information Quality Act ('IQA') Challenge"). The court indicated that it believed that this framing of the issues by SIRC was an attempt to avoid the numerous precedents holding the IQA to be not judicially reviewable. 944 F. Supp. 2d at 84.

254. Mem. in Opp. to Pl. Motion for Summ. Judg. and in Supp. of Def. Cross-Motion for Summ. Judg., ECF No. 47, 26-29; Reply in Supp. of Def. Cross-Mot. for Summ. Judg., ECF No. 51, at 1, 13.

255. 944 F.Supp.2d at 82.

256. Mississippi v. EPA, 723 F.3d 246 (D.C. Cir. 2013), *amended in part on reconsid.*, 744 F.3d 1334 (D.C. Cir. 2013), *cert. denied sub nom.* Utility Air Reg. Group v. EPA, 2014 WL 1478397 (2014). In the amended opinion there were no changes in the language of the first opinion addressing the IQA, and citations herein are to the amended opinion.

257. *See, e.g*., comments of the Amer. Chemistry Council, one of the joint plaintiffs, EPA-HQ-OAR-2005-0172-4159, www.regulations.gov, at 34. *See also* reference to other IQA comments *infra* in the' Joint Opening Br. 49-50.

objectivity and utility, and EPA's IQA guidelines provide the standards for judging accuracy.[258] More specifically, they argued that EPA had mischaracterized certain clinical studies, had relied on poor epidemiologic studies, had failed to disclose alternative explanations for some findings, and had conducted unpublished reanalysis of certain data.[259] Petitioners contended that the IQA and its guideline requirements regarding information disseminated in connection with rulemaking must be considered *in pari materia* with the CAA requirement that air quality criteria "accurately reflect the latest scientific knowledge."[260]

In response, the Government argued that the IQA could not import any additional legal test into the CAA because the court lacked jurisdiction to review the IQA allegations, citing *Salt Inst*. (cir. ct.), *San Luis & Delta-Mendota*, and *Missouri River*. The Government also argued that the EPA guidelines were not judicially enforceable because they expressly stated that they were only guidelines and did not impose any legally enforceable standards.[261] Lastly, the Government argued that the *in pari materia* doctrine did not apply and that the IQA did not specifically set forth what agencies must do to ensure the accuracy of data and analyses in regulatory decisionmaking, and therefore in determining what the CAA might require, the IQA "provides no independent basis for the Court to depart from its longstanding approach of simply requiring EPA to demonstrate that the NAAQS are the product of reasoned decisionmaking."[262] Even if the IQA were applicable, they argued, EPA did not omit or mischaracterize any scientific information, and to the extent the Petitioners might be disputing the conclusions EPA drew from the scientific data, neither the IQA nor the CAA provided grounds for such a dispute and the agency's conclusions were entitled to deference in determining whether they were reasonable and supported by the record.[263]

Petitioners replied that they were not arguing that the IQA imported a new legal test into the CAA, but only that the IQA "serves 'as persuasive authority' informing interpretation of the CAA, and the two statutes should be interpreted consistently with one another."[264] Petitioners also appeared to concede that the EPA IQA guidelines were non-binding, but noted that certain analytical data used by the agency had not been peer-reviewed by CASAC.[265]

During the lengthy oral argument, the IQA was barely mentioned. Most or the discussion was about the science, the CASAC review, and the role of policy discretion in the final EPA decision. Government counsel only stated, with regard to the Appellants' claims of lack of objectivity and accuracy, that the EPA IQA guidelines were non-binding and added nothing to the CAA standard for review.[266]

---

258. Joint Opening Br. of Pet'r State of Miss. and Industry Pet'rs 4-6.

259. *Id*. at 20-21, 31-32, 48-53, 57-60.

260. *Id*. at 47-48.

261. Initial Br. for Resp. 77-78. There was no mention of *Prime Time*, which held that the OMB Guidelines were legally binding.

262. *Id*. at 78-79.

263. *Id*. at 79-80.

264. Joint Reply Br. of Pet'r State of Miss. and Industry Pet'rs 27.

265. *Id*. at 28. Petitioners' briefs did not cite the D.C. Circuit's holding in *Prime Time* that the OMB Guidelines are binding legislative rules.

266. Oral argument in case 08-1200 on Nov. 16, 2012, at 52.30-53.40. In the oral argument, government counsel also stated that when CASAC conducts air quality standard (NAAQS) reviews, its reports and recommendations incorporate policy views into its scientific review. *Id.*at 104.00-108.00. This is contrary to the OMB peer review

The court concluded that EPA had adequately considered the overall body of scientific evidence and its strengths and weaknesses, and had satisfied a minimal standard of reasonableness. It emphasized that the final decision was a "weight of the evidence" decision and that any flaws in the criteria document and other information on which it was based had not been demonstrated to undermine the decision. It also concluded that in the statutory scheme of determining a standard that would protect the public "with an adequate margin of safety," there was clearly a policy element involved, and, in addition, EPA was free to disagree rationally with individual scientific findings (and CASAC recommendations) and re-analyze findings.[267]

In considering the Petitioners' IQA challenges, the court began its analysis from the point of "[h]aving already discussed the reasonableness of EPA's threshold decision to revise the NAAQS," and then proceeded to consider whether violation of the IQA's "procedural" standards could "independently" render the agency's decision unlawful.[268]

Addressing the IQA arguments directly in a single paragraph, the court stated that Petitioners had failed "to show the IQA is an independent measure of EPA's NAAQS decision."[269] The court summarized the OMB portion of the IQA and noted that the OMB guidelines indicated that its guidelines were intended to be implemented flexibly by each agency in accordance with an agency's individual programs. It then noted that the EPA guidelines "purport" to be non-binding. Finally, the court stated that "Mississippi points to nothing indicating that any part of this [IQA] scheme committed EPA to having done things differently." Following this last statement, the court cited the *API* and *Salt Inst.* (cir. ct.) opinions.[270] The court did not require EPA to make any corrections to the criteria document's presentation of the scientific data.

In stating, in effect, that it rejected the notion that the IQA is an "independent measure" of EPA's decision (an argument not made by Petitioners), the court appears to have dodged Petitioners' *in pari materia* argument and found that a simple showing of some IQA violations would not undermine a finding that overall EPA's decision met the APA's and CAA's standard of reasonableness if, examining the undisputed science and EPA's reasoning overall, the court found that the agency's decision met minimum standards of reasonableness.[271]

Bulletin directions that peer reviews must not incorporate policy views. *Compare* 70 Fed. Reg. 2664, at 2669, 2675, *with* 42 U.S.C. §§ 7409(d)(2), 7408 (note use of term "should" at 70 Fed. Reg. at 2669 (preamble) versus use of term "shall" at 70 Fed. Reg. at 2675 (substantive portion)).

267. The criteria document, which provided the scientific basis for the final rule, was peer reviewed by EPA's Clean Air Scientific Advisory Committee (CASAC), as discussed in the court's opinion, and no challenge was raised to the lawfulness of the peer review proceedings under the OMB peer review Bulletin.

268. 744 F.3d at 1346. Neither the court nor the government made any mention of the CAA's explicit provisions governing review of procedural violations at 42 U.S.C. §§ 7607(d)(8) and (9). The D.C. Circuit has indicated its view that those standards are stricter than normal APA judicial review standards for procedural violations and has questioned whether Congress intended those CAA provisions to apply to all types of procedural violations. *See* Small Refiner Lead Phase-Down Task Force v. EPA, 705 F.2d 506, 521–23 (D.C. Cir. 1983).

269. 744 F.3d at 1347.

270. *Id*. The court's citation to *API* is to the portion that acknowledges that an EPA statement that its guidelines are non-binding might be negated by *Appalachian Power* if the Petitioners had explained how *Appalachian Power* applied.

271. It is not clear what the court meant by "independent measure." In the context of the whole opinion, it appears to be an oblique reference to the general administrative law "harmless error" rule. *See, e.g., Ali v. United States*, 849 F.3d 510, 514-15 (1st Cir. 2017), and cases cited and quoted therein. That rule is incorporated into the

M. Miss. Comm'n on Envtl. Quality v. EPA[272]

In a sequel to the above *Mississippi* cases, several states and other entities petitioned for D.C. Circuit review of EPA determinations that certain geographical areas were not in attainment of the new ozone standard.

The Petitioners claimed that EPA had failed to demonstrate compliance with the OMB and EPA IQA guidelines,[273] particularly the requirement in the EPA guidelines that it use "the best available science," and compared the requirements of the IQA guidelines to the procedural requirements of NEPA.[274] Petitioners gave some general indications of lack of compliance (improper modeling, failing to discuss all error sources and methods and analyses needed to ensure reproducibility, failing to analyze confounding effects, and reaching conclusions without a sound scientific basis);[275] however, these allegations were not explained with specificity. Petitioners also argued that there was no need to explain how IQA compliance would lead to a different EPA decision.[276]

EPA responded that the Petitioners had never raised the IQA issues during or after the rulemaking.[277] EPA also followed its now well-established gamebook of arguing that "every court to address the issue [of jurisdiction] has held [that] the Information Quality Act "creates no legal rights in any third parties," citing *Salt Inst.* (cir. ct.), *San Luis & Delta-Mendota*, *Single Stick*, and *Missouri River*. EPA also pointed to the judicial review disclaimer in the EPA Guidelines and to the recent *Mississippi. v. EPA* decision (*supra*) stating that the IQA and its guidelines are not an "independent measure" of EPA decisions reached pursuant to statute.[278]

EPA also argued that "the IQA does not impose any enforceable requirements; the IQA itself merely directs federal agencies to issue guidelines . . . but leaves open the question of the meaning of the words 'quality, objectivity, utility, and integrity.'"[279]

In its reply, Petitioners did not attempt to distinguish or question the validity of the cases cited by EPA for lack of a cause of action (*Salt Inst.* etc.), but simply stated that their standing was "self-evident" from the administrative record.[280] While conceding that "[i]nformation quality does not

"Scope of review" provisions of the APA, 5 U.S.C. § 706, in the statement that in conducting judicial review "due account shall be taken of the rule of prejudicial error." In other words, the court could have been indicating that even several errors under the IQA Guidelines or Bulletin would not necessarily, by that fact alone, undermine an overall finding of reasonableness, which it appears to have been made by the court before even considering the IQA arguments. However, it should be recognized that even a single significant procedural defect (as in the case, for example, of failure to provide notice and comment or independent peer review) could be an "independent measure" of non-compliance with the law's procedural requirements and a basis for setting aside agency action. *See* Mid Continent Nail Corp. v. United States, and cases cited therein, 846 F.3d 1364, 1383-85 (Fed. Cir. 2017).

272. 790 F.3d 138, 184-85 (D.C. Cir. 2015).
273. Corrected Joint Br. of the State and County Pet'rs 3, 17, 19, 46-47, 48, 140.
274. *Id*. at 19 n.19.
275. *Id*. at 46-47.
276. *Id*. at 48.
277. Resp't's Initial Br. 27-28, 139.
278. *Id*. at 137-39. *And see* 140 re the "independent measure" issue.
279. *Id*. at 140.
280. Joint Reply Br. of the State and County Pet'rs 3-4.

determine the fate of an agency's contemplated action,"[281] it argued that the IQA set out procedural requirements with the force of law (citing *Prime Time* and OMB statements regarding the binding nature of the IQA guidelines) that EPA must comply with even in the course of decisionmaking.[282]

The court addressed the IQA arguments in a relatively brief single paragraph close to the end of a lengthy opinion. First, it noted the EPA contention that "almost every court that has addressed an Information Quality Act challenge has held that the statute 'creates no legal rights in any third parties'," citing *Salt Inst*. (cir. ct.) with a qualifying footnote regarding *Prime Time*, and cases collected in the district court opinion in *Harkonen* (*infra*).[283] But the court did not engage in any commentary or analysis of those cited cases or express agreement with them, and it began the next sentence with "And this court has held . . . ." The court then proceeded in the end to invoke its decision in *Mississippi* (*supra*) for the position that the IQA is concerned only with the quality of information disseminations and is not a statutory mechanism for challenging agency conclusions drawn from that information.[284]

N. Harkonen v. U.S. Dept. of Justice[285]

The Department of Justice (DOJ) obtained a conviction against Dr. Harkonen, the CEO of a biotech company, for mischaracterizing the results of a study of one of its drugs that was undergoing FDA review. After the conviction, DOJ issued a press release describing the grounds for the conviction, which Dr. Harkonen alleged incorrectly stated or strongly implied that he had been found to have falsified test data, and that the mischaracterizations and falsifications had diverted considerable financial resources from the Veterans Administration.

Harkonen filed two separate RFCs, alleging that the press release was inaccurate and that it must be corrected pursuant to the IQA and its guidelines. DOJ denied both RFCs, including appeals,

281. As a general proposition, this is inaccurate. The accuracy of the information that an agency relies on in a rulemaking can certainly determine the outcome. However, as noted *supra* note 271, the court must apply the rule of prejudicial (or "harmless") error in APA § 706.

282. *Supra* note 280 at 6-8.

283. 790 F.3d at 184-85 & n. 29. The footnote reads: "But see Prime Time, 599 F.3d at 685-86 (affirming dismissal of information Quality Act challenge on different grounds without addressing argument that the statute creates no legal right in third parties)." This footnote was apparently intended to qualify that portion of the court's statement regarding "almost every court." A similar qualification would apply to the other circuit court opinions that dismissed IQA challenges (*ASA*, *Mississippi*., and *Harkonen*).

284. *Id*. at 185. As explained above *supra* in note 271, this court conclusion appears to be incorrect. The legislative history and OMB's explanations of its Guidelines and Bulletin make it clear that those rules were intended to ensure that agency regulatory decisions are based on accurate information, just as NEPA was intended to ensure that agency decisions affecting the environment would be based on thorough and accurate environmental information. In the context of rulemaking, information quality issues will usually arise at the proposal stage as procedural issues. Review standards for such procedural issues must be addressed under APA section 706. This issue is also partially addressed *infra* in Part V, sec. F in that portion of the "Standing" discussion on procedural standing and related pleading.

285. No. C 12-629, 2012 WL 6019571 (N.D. Cal. 2012), *aff'd on other grounds*, 800 F.3d 1143 (9th Cir. 2015). OMB was also a defendant, apparently due to its inclusion of press releases as an exemption (later qualified) in its government-wide IQA guidelines.

solely on the basis that press releases were expressly exempted from the OMB and DOJ IQA guidelines.[286]

Harkonen sought judicial review under the IQA and APA.

The Government moved to dismiss. It argued that courts had consistently held that the IQA does not establish a private right of action, and therefore any cause of action must be based on the APA. Regarding the APA, the Government argued that "[b]ecause the IQA explicitly states that no legal rights attach to it, an agency's action under the IQA does not cause any legal consequences and, therefore, is not final agency action," citing *Single Stick* and the district court opinions in *Salt Inst.* and *ASA*.[287] It also argued that other courts had dismissed IQA cases on grounds that the IQA contains no judicially manageable standards, citing *Missouri River*, *FFA*, *Salt Inst.* district court opinions and *Steenholdt*.[288] It argued further that the labels "guidelines" and "policy and procedural guidance" indicated an intent that the guidelines should be advisory only, and that the discretionary language regarding how to correct information gave the agency discretion and insulated it from judicial review under the "law to apply" provision of the APA.[289] The government's memorandum did not cite or discuss *Prime Time*, and did not present any argument to support the validity of the press release exemptions in the OMB and DOJ guidelines, on which it had relied in its denial of the Harkonen RFCs.

Harkonen responded and in turn moved for summary judgment. He argued that the DOJ denials of his "petitions" were final agency actions under the APA because they concluded agency consideration of the petitions and because they denied him the right, set out in the IQA, to "seek and obtain" correction of the information in the press release.[290] Harkonen also addressed the DOJ claim of an express exemption from the OMB guidelines for press releases. He argued that the exemption was contrary to the ordinary meaning of "dissemination" and therefore contrary to Supreme Court law under *Chevron*. He also noted that the exemption was contrary to the dissemination provisions of the PRA that were expressly incorporated into the IQA, which state that OMB must issue guidance on information dissemination that would "apply to Federal agency dissemination of public information, regardless of the form or format in which such information is disseminated . . . ."[291] Harkonen also noted that the exemption had not been included in the OMB guidelines when they were proposed, and that when it was inserted into the interim final and

---

286. The OMB government-wide guidelines define "dissemination" as not including, among other things, "distribution limited to correspondence with individuals or persons, press releases, archival records, public filings, subpoenas or adjudicative processes." 67 Fed. Reg. 8452, 8460 (2002). The DOJ guidelines state that they do not apply to "[DOJ] information disseminated in the context of . . . press releases, fact sheets, press conferences or similar communications (in any medium) that announce, support or give public notice of information *in DOJ*." https://www.justice.gov/iqpr/information-quality (last visited Dec. 2017) (emphasis added).

287. Mem. in Supp. of Def. Mot. to Dismiss, ECF No. 8, at 9-10. The assertion regarding "explicitly states" is patently inaccurate.

288. *Id.* at 10-11.

289. *Id.* at 12-13.

290. Pl.'s Notice of Motion and Motion for Summ. J. and Resp. to Def's' Mot. to Dismiss, ECF No. 21, at 12-15. Harkonen did not reference the "petition" language in the APA definition of "agency action" in 5 U.S.C. §§ 701 and 551, but relied largely on cases reviewing requests for correction of military records.

291. *Id.* at 21-22.

final guidelines the rationale for its inclusion was never explained and it was obviously contrary to the Congressional policy expressed in the IQA and PRA.[292]

The DOJ reply brief restated most of the arguments it had made in previous IQA cases against allowing judicial review: Every court to address the issue had decided against judicial review;[293] there could be no final agency action because no right was established and determined because the IQA only required that agencies establish administrative procedures;[294] agency action was committed to agency discretion because the IQA contains no meaningful standards;[295] and the language in the OMB guidelines regarding agencies being required to undertake only the degree of correction that was "appropriate" considering the nature and timeliness of the matter indicated an intent to confer complete discretion regarding "whether" to make a correction at all.[296]

Regarding, the press release exemption, DOJ argued that the IQA "does not prescribe any policy that mandates coverage of press releases,"[297] and that OMB had adequately described the reason for the exemption in its final government-wide guidelines."[298] DOJ did not address the issue of the ordinary and plain meaning of "dissemination" or the language from PRA section 3504(d)(1), incorporated into the IQA, stating that dissemination covers "public information, regardless of the form or format in which such information is disseminated . . . ."

Harkonen replied again that the press release exemption was contrary to the plain and ordinary meaning of "dissemination" of information and therefore was illegal under *Chevron* step one, was contrary to PRA section 3504(d)(1), and that OMB had not explained the basis for the exemption as it was required to do.[299] He also observed that DOJ had abandoned the position that a private right of action under the IQA was necessary in an APA case. He challenged the notion that the IQA conferred no right to a correction (although he did not attempt to challenge DOJ's use of *Salt Inst*. to support the proposition that the IQA does not confer a right to correction). He argued that there was no implied preclusion under APA case law.

The district court dismissed the case. It relied on *Salt Inst.* (cir. ct.) and the many district cases citing it for the proposition that the IQA does not create any rights and therefore there was no final agency action. The court reasoned that the "seek and obtain" language of the statute did not confer a right because it did not confer the right directly but rather directed OMB and the agencies to provide the right. The court also stated that the IQA was silent on standards for judging a request for correction (although it had previously acknowledged that standards could be found in agency regulations), and it quoted the guidelines language providing discretion to make corrections that are "appropriate for the nature and timeliness of the information involved." The district court did

292. *Id.* at 23.
293. Defs.' Reply in Further Supp. of Defs' Mot. to Dismiss and Opp. to Pl.'s Mot. for Summ. J., ECF No. 29, at 6-7.
294. *Id*. at 8.
295. *Id.* at 14.
296. *Id.* at 17-18.
297. *Id*. at 23-24.
298. *Id.* at 21-23.
299. Reply in Supp. of Pl. Mot. for Summ. J., ECF No. 30, at 9-11.

not address the validity of the press release exemption in the OMB and DOJ guidelines under *Chevron* principles.[300]

Harkonen appealed to the Ninth Circuit. His appellate brief contained a more detailed explanation of why the *Salt Inst.* (cir. ct.) opinion should not be considered relevant,[301] and explained that OMB had "urged" all agencies to interpret the press release exemption as qualified to refer only to press releases that announced the availability of other information disseminated by the agency that would be subject to a petition, which made the exemption inapplicable to the DOJ press release at issue.[302] Harkonen also renewed his *Chevron* argument that an exemption for press releases would be contrary to the plain and common meaning of "dissemination" in the IQA and PRA section 3504(d)(1), incorporated into the IQA.[303]

DOJ cited numerous cases not based on the IQA which held that issuance of government information could not be considered final agency action. DOJ expressed the view that Congress did not intend to alter the longstanding principle embodied in those cases (not citing any authority or evidence of legislative intent). In support of this argument it simply quoted the statement from *Salt Inst.* (cir. ct.) that the IQA conferred "no legal rights on any third party."[304]

It then argued that there were no standards in the IQA or the OMB guidelines by which to judge petitions for correction because the guidelines only required agencies "to undertake only the degree of correction that they conclude is appropriate for the nature and timeliness of the information involved," which, DOJ argued, quoting the lower court opinion, was "akin to saying that the decision is committed to the agency's discretion."[305] It attempted to rebut Harkonen's assertion that *Salt Inst.* was an information access case, not an information quality judicial review case, by quoting from the cir. ct. opinion a statement that the Plaintiff had filed a petition seeking "correction" of agency statements.[306] As usual, it argued that "All other courts" to consider the issue of judicial reviewability had decided against it (although it did not distinguish between

300. *Supra* note 285.

301. Br. of Dr. W. Scott Harkonen, ECF No. 8, at 28-29.

302. *Id*. at 51-52. An amicus brief also detailed OMB's subsequent modification of the press release exemption in this way. Br. of *Amicus Curiae* Ctr. for Regulatory Effectiveness in Supp. of Appellant and in Supp. of Reversal, ECF No. 12, at 10. The Ninth Circuit opinion ignored this OMB interpretation, even though it was a matter of public record subject to judicial notice and the PRA gives OMB responsibility for IQA policy and requires agency compliance with such policy. The amicus brief also explained in detail why the *Salt Inst.* opinion was only a data access decision, not a decision on general IQA judicial review and noted how the government had claimed emphatically during the case that it was only that. *Id*. at 12-13. Neither the government brief nor the Circuit opinion contained any mention of the additional information and argument in the amicus brief or addressed its new information or arguments. This was arguably consistent with Ninth Circuit precedent regarding court consideration of arguments raised in an amicus brief, but also arguably inconsistent with other case law and the intent of Fed. Rule App. Proc. 29. *Compare* Zango v. Kaspersky Lab., Inc., 568 F.3d 1169, 1177 n. 8 (9th Cir. 2009) and Artichoke Joe's California Grand Casino v. Norton, 353 F.3d 712, 719 n. 10 (9th Cir. 2003), *with* Eldred v. Ashcroft, No. 99-5430, 2001 WL 950999, at **1-2 (D.C. Cir. 2001) (dissent from vote denying petition for reconsideration en banc), and Committee Notes on Rules–1998 Amendments, Fed. R. App. Proc. 29 ("An *amicus curiae* which brings relevant matter to the attention of the Court that has not already been brought to its attention by the parties is of considerable help to the Court.").

303. *Id*. at 46-49.

304. Br. for Appellees, ECF No. 22, at 14-17.

305. *Id.* at 23-24.

306. *Id.* at 17-18.

district and appellate opinions).[307] It argued that the IQA did not bestow a right to "seek and obtain" corrections, but rather simply ordered OMB and the agencies to establish mechanisms conferring that right.[308]

Finally, with regard to the press release exemption, it argued that Congress did not dictate the scope of the guidelines, but left that to the discretion of OMB, and stated that section 3504(d)(1) of the PRA – the section mandating OMB to develop rules and regulations for agency "dissemination of public information, regardless of the form or format in which such information is disseminated . . . ." – "is not part of the IQA" and does not define dissemination.[309] The DOJ brief did not address *Chevron's* plain and ordinary meaning analytical step with regard to the term "dissemination."

Harkonen's reply brief concurred in an amicus brief analysis that the *Salt Inst*. case was decided as a Shelby Amendment/FOIA case rather than an IQA case addressing judicial review in general.[310] It again argued strongly that final agency action in the present case was denial of a right to petition, citing many supporting cases, and noting that all the non-IQA cases cited by DOJ for the proposition that agency issuance of information is not final agency action did not involve denial of a petition in a process provided by statute. Harkonen did not, however, note that section 551 of the APA expressly includes denial of a petition in the definition of agency action. Harkonen also refuted DOJ's position that section 3504(d)(1) of the PRA was not part of the IQA by noting that that section (as well as other provisions of the PRA pertaining to information dissemination) was expressly incorporated into the IQA.[311]

At oral argument,[312] Harkonen only touched on the press release exemption issue from the standpoint of practical consequences and did not bring up the issue of the plain and ordinary meaning of "dissemination" under *Chevron* principles. He affirmed that he was relying on the APA, not the IQA, and emphasized the case law providing APA judicial review in cases involving petitions for correction of military records.

Likewise, DOJ did not raise the *Chevron* issue during its portion of oral argument; rather, it emphasized the cases denying a right to correct information that were not brought under the IQA.[313] It acknowledged that its stated position before the Fourth Circuit in *Salt Inst*., as quoted in the amicus brief, was that it was a data access case and did not raise the issue of IQA judicial review, but it took the position that the Fourth Circuit had disagreed with its position and "squarely

307. *Id*. at 18-19.
308. *Id*. at 19-20.
309. *Id.* at 29.
310. Br. of Amicus Curiae Center for Regulatory Effectiveness in Support of Appellant and in Support of Reversal, ECF No. 12.
311. Reply Br. of Dr. W. Scott Harkonen, ECF No. 28.
312. The recording is on the Ninth Circuit website, No. 13-15197.
313. DOJ gave considerable emphasis to a quotation from a Fourth Circuit opinion in a non-IQA case – *Flue-Cured Tobacco* --with regard to there being no right of action – that Congress did not intend to allow persons "to challenge the inevitable objectionable impressions created whenever controversial information by a federal agency is published." Oral argument recording at 20.45-21.00.

held" that the there was no right to correction under the IQA.[314] DOJ also asserted that if the Ninth Circuit allowed judicial review, it would create a conflict with the Fourth Circuit.[315]

The Ninth Circuit expressly declined to address the broad judicial review issue, stating: "We have no reason in this case to reach the broad question of whether the IQA confers upon a private individual the right to seek judicial review of the correctness of all information published by the government."[316] The court then proceeded to address the issue of whether the (apparent) exemption of press releases in OMB's 2002 government-wide guidelines was within OMB's authority, applying a *Chevron* analysis. Surprisingly, the court decided, under the first step of *Chevron* analysis, that the term "disseminated" was ambiguous. This conclusion was based not on the common dictionary definition of the term, but on the court's observations that the term was not defined in the IQA or the PRA, its meaning was apparently not addressed in the "minimal" legislative history, and the main concerns addressed in the IQA were that (1) information "shared" by government agencies be of maximal quality, and (2) access to information possessed by government agencies be ensured. The court also noted that the D.C. Circuit in *Prime Time* had determined that interpretation of the term "disseminated" was committed to OMB's discretion. The court made no reference to the "regardless of form or format" language of PRA section 3504(d)(1).

Proceeding to the second step of *Chevron* analysis, the court held that the exclusion of press releases from disseminated information was a permissible construction of the statute "[g]iven the deference accorded to agency interpretations of ambiguous statutes and the careful consideration OMB, and DOJ, gave to the relevant issues" (citing *Prime Time*).[317] The court also addressed whether DOJ permissibly interpreted the exclusionary language in its guidelines--"does not apply to information disseminated in . . . press releases fact sheets, press conferences or similar communications (in any medium) that announce, support or give public notice of information in DOJ"— so as not to apply to the Harkonen press release. Harkonen had argued that the information on his conviction was not "in DOJ" but rather only in the criminal courts. The court applied *Auer* deference[318] to DOJ's interpretation of that language to the Harkonen press release and approved it.[319]

---

314. *Id*. at 21.15, 21.33, 22.20. The judge who questioned the DOJ attorney on this point appeared to disagree (22.29-30), and the court's opinion did not mention the *Salt Inst*. opinion.

315. *Id*. at 21.04.

316. 800 F.3d at 1148.

317. 800 F.3d at 1150. The court referred to comments by other agencies on the exemptions in the proposed OMB guidelines, but did not provide any specifics or citations to support its statement regarding "careful consideration." Neither the interim final guidelines nor the final guidelines contain any discussion or explanation of the basis for addition of the press release exemption, which was not in the proposed guidelines.

318. 519 U.S. 452 (1997). *Auer* held that an agency's interpretation of its own regulation was "controlling unless plainly erroneous or inconsistent with the regulation." 519 U.S. at 461 (internal citations and quotation marks omitted). In *Harkonen*, however, OMB was interpreting both its own regulation and the statute, and the original interpretation (addressed by the court, but later modified) appears to have been "plainly erroneous." Because the PRA bestows primary authority on OMB for establishing information dissemination policy, the court should have given *Auer* deference to OMB rather than DOJ. OMB could correct this situation by amending its original Guidelines to omit the reference to press releases or expressly interpreting it in accordance with its later clarification..

319. The court made no mention of the information contained in the CRE amicus curiae brief, *supra* note 310, regarding OMB's subsequent clarification of the press release exemption. In it's the Notice of Availability of its OMB-specific IQA guidelines of Oct. 1, 2002, OMB stated: "In paragraph IV.2, OMB modifies the exemption for a press release to provide that the information in the press release has been previously disseminated by OMB or another

O. Zero Zone, Inc. v. DOE[320]

Zero Zone is the most recent, and the first, circuit court opinion to clearly address APA judicial review of IQA issues and hold that the APA provides a cause of action for claims of violation of IQA guidelines. The *Zero Zone* holding seems to have so far escaped the notice of those in the legal and regulatory communities who follow IQA and APA case law developments.

On September 4, 2013, a group of U.S. trade associations filed a "Petition for Correction" with DOE under the IQA challenging various aspects of a DOE Technical Support Document containing estimates of the "social costs of carbon" (SCC) for possible use in future regulations and regulatory impact analyses. The petition alleged insufficient transparency/reproducibility, lack of sufficient peer review of modeling, failure to fully disclose and quantify uncertainties, and improper inclusion of estimates of reduction of global SCC.[321]

One week later, DOE issued a Notice of Proposed Rulemaking (NPRM) on "Energy Conservation Standards for Commercial Refrigeration Equipment" under the Energy Policy and Conservation Act of 1975, as amended (EPCA).[322] The notice of proposed rulemaking relied on the Technical Support Document challenged in the above IQA petition.[323] A slightly different group of trade associations, led by the U.S. Chamber of Commerce, filed comments on the NPRM that incorporated the IQA petition.[324]

DOE issued a final rule on March 28, 2014 containing more stringent energy standards for commercial refrigeration equipment (CRE).[325] In the preamble to the final rule, DOE responded to the above comments and IQA petition by the Chamber of Commerce et al., as well as five other

---

Federal agency in compliance with the Agency-wide Guidelines or the these [sic] OMB guidelines. (See June 5, 2002 memorandum, page 4)." 67 Fed. Reg. 61,701, 61,702 (2002). The language in the DOJ guidelines referring to press releases regarding information "in DOJ" is arguably consistent with this OMB clarification. The full text of the OMB-specific guidelines is available at https://obamawhitehouse.archives.gov/sites/default/files/omb/assets/omb/inforeg/iqg_oct2002.pdf (last visited Dec. 2017). The reference in the Notice to a June 5, 2002 memorandum is apparently a reference to the OMB Memorandum to the President's Management Council that is dated June 10, 2002, *supra* note 109, and has the relevant material at p. 4, but which may have been actually released prior to June 10. Because OMB was a joint defendant, one must wonder what say it had in the arguments made by the DOJ attorneys, especially since § 3506 of the PRA requires all agencies to comply with OMB policy determinations.

320. 832 F.3d 654 (7th Cir. 2016).

321. *Petition for Correction: Technical Support Document: Social Cost of Carbon for Regulatory Impact Analysis under Executive Order 12866 (February 2010) and Technical Support Document: Technical Update of the Social Cost of Carbon for Regulatory Impact Analysis under Executive Order 12866 (May 2013)*, September 4, 2013, submitted by the American Natural Gas Association, the American Chemistry Council, the American Petroleum Institute, the National Association of Home Builders, the National Association of Manufacturers, the Portland Cement Association, and the U.S. Chamber of Commerce. It appears that DOE does not maintain a webpage providing access to such petitions and agency responses. The petition is available at https://www.uschamber.com/sites/default/files/legacy/hill-letters/090413_IQA%20Petition%20on%20Social%20Cost%20of%20Carbon.pdf (last visited Dec. 2017).

322. 78 Fed. Reg. 55,890 (Sept. 11, 2013).

323. *Id*. at 55,944.

324. Docket No. EERE-2010-BT-STD-0003, document No. 0079, Nov. 12, 2013 (available via docket search at https://www.regulations.gov) (last visited Oct. 2017).

325. 79 Fed. Reg. 17,726 (Mar. 28, 2014).

similar comments.[326] DOE acknowledged limitations in the SCC estimates, and, specifically, uncertainties in the assumptions employed, but stated that it considered that the SCC estimates used a reasonable range of discount values, and that the models used to estimate the SCC had been sufficiently peer reviewed. In conclusion, DOE stated that it believed it had complied with OMB's peer review Bulletin and its own guidelines for implementation of the IQA.[327] The final rule also contained the "certification" required by OMB's peer review Bulletin[328] that explained what the agency had done to comply with the Bulletin, including a reference to issuance of a peer review report in 2007, although the certification was lacking in detail, especially with regard to the agenda, planning, and public participation requirements of the OMB Bulletin.[329]

Zero Zone, Inc.[330] and various food equipment and energy trade associations petitioned for review of the final rule in the Seventh Circuit under the judicial review provisions of EPCA and the APA. The petitioning brief of Zero Zone and the Air-Conditioning, Heating, and Refrigeration Institute (AHRI) argued that DOE's Social Cost of Carbon Analysis "Flunks the IQA's Decisionmaking Standards."[331] The brief largely adopted the trade associations' IQA petition, and then gave three examples of IQA flaws that were never addressed by DOE in the final rule. First was failure to disclose the agencies and personnel involved in the SCC analysis that DOE adopted. Second was failure to peer review the models and model inputs for climate effects of future emissions. Third was the reliance on arbitrary climate-effects damage functions that had been challenged as unfounded by a well-reputed economist.[332]

The agency responded in its brief that petitioners misapprehended the purpose of the IQA in arguing that it imposed "decisionmaking standards," because it only addresses the quality of information disseminations, and, quoting the opinion in *Miss. Comm'n*, "does not constitute a statutory mechanism by which [an agency's] conclusions . . . can be challenged."[333] The brief also cited and quoted the *Salt Inst.* (cir. ct.) statement that "By its terms, this statute creates no legal rights in any third parties." Therefore, the government argued, the IQA "provides no basis for challenging the standards rule."[334]

In its reply brief, Petitioners emphasized that they were not relying on the IQA as the basis for a cause of action, but rather on the APA, and drew an analogy with the APA-enforceability of NEPA.

---

326. *Id.* at 17,779.

327. *Id.*

328. 70 Fed. Reg. 2664, 2677 (Jan. 14, 2005).

329. 79 Fed. Reg. 17,726 at 17,816. The OMB agenda and planning requirements are at 70 Fed. Reg. 2676-77. It appears to be arguable whether the peer review that generated the report cited in the final rule's certification was begun prior to the effective date of the OMB Bulletin; however, the report appears to concede that the peer review was subject to the Bulletin. There could also have been a question whether a peer review conducted mainly in 2006 was timely enough for review of the technical basis for a rule finalized in 2014.

330. Zero Zone was a small manufacturer of commercial food refrigeration equipment. When its petition was consolidated with those of the trade associations, it was named as the lead plaintiff.

331. Br. of Pet'rs Zero Zone, Inc. & Air-Conditioning, Heating and Refrigeration Inst. 25-28, May 8, 2015 (corrected May 28, 2015), ECF No. 36.

332. These alleged examples of IQA non-compliance were not, as in the petition itself, supported by linkage to specific mandatory language in the OMB peer review Bulletin or other IQA guidelines.

333. Br. for Resp'ts, ECF No. 40, at 35-36. But see *Mississippi*, 744 F.3d 1334 at 1347, in which the court stated that Petitioners had failed "to show the IQA is an *independent* measure of EPA's NAAQS decision." (Emphasis added.)

334. Br. for Resp'ts at 36.

They observed that the courts in *Miss. Comm'n* and *Salt Inst*. had not ruled on the APA as furnishing a cause of action and remedy. They also argued that DOE had dodged the substance of the IQA defects alleged in the IQA petition accepted into the record by DOE as a comment on the NPRM, and that DOE's brief acknowledgement of uncertainties involved in the defects alleged in the IQA petition and comments did not excuse it from remedying those defects.[335]

At oral argument, the court addressed the IQA issues in asking Petitioners whether they could cite any cases where a court had invalidated an agency rulemaking because the agency had not complied with the IQA and whether Petitioners were asking the court to split from the D.C. Circuit's opinion in *Miss. Comm'n*. Counsel for Petitioners answered by stating that IQA compliance was not a "main focus" of their case, but rather was emblematic of the agency's careless analysis in the rule.[336]

In its opinion, the court reviewed the allegations of IQA non-compliance made in the IQA petition that was accepted into the record as comments on the NPRM and how the agency had responded to the comments. The court concluded that despite the concerns expressed in the comments, and the lack of DOE response to the specific concerns, the agency's response to the general concerns "was neither arbitrary nor capricious."[337]

Although the petitioners alleged that the SCC estimates had not been peer reviewed in accordance with OMB's peer review Bulletin, they did not specifically invoke the APA's section 706 judicial review standard of "agency action, findings, and conclusions found to be . . . without observance of procedure required by law . . . ." or any specific provisions of the Bulletin.[338] The Circuit Court appears to have addressed this issue briefly,[339] but it upheld the agency action on a not "arbitrary and capricious" basis rather than a lack of procedural injury basis.

Of particular significance was the court's insertion of note 25 at the outset of the IQA review section of its opinion. In that note, the court made clear that it was reviewing the IQA issue under the APA, and it affirmed that, despite DOE's reliance on *Miss. Comm'n* and *Salt Inst*., the APA provided a cause of action for judicial review of the IQA issues. Note 25 states in full:

> AHRI and Zero Zone frame this issue as a violation of the Information Quality Act. *See* 44 U.S.C. § 3516 note (a). However, "almost every court that has addressed an Information Quality Act challenge has held that the statute 'creates no legal right in any third parties.'" *Miss. Comm'n on Envtl. Quality v. EPA*, 790 F.3d 138, 184 (D.C. Cir. 2015) (quoting *Salt Inst. v. Leavitt*, 440 F.3d 156, 159 (4th Cir. 2006)).

335. Reply Br. of Pet'rs Zero Zone, Inc. & Air Air-Conditioning, Heating, and Refrigeration Inst., ECF No. 45, at 18-20.

336. Court oral argument online recording at 21:34-23:02. Although it was indicated that the IQA issue would be addressed further in rebuttal argument, it was not. It is not clear whether the court was referring to the statements in *Miss. Comm'n* that almost every court that has addressed an IQA challenge has ruled that the IQA provides no legal rights, or whether it was referring to the statement that the IQA does not provide an "independent measure" of an agency's conclusions.

337. 832 F.3d 654, at 678. The reference in the opinion to document 79-A2 in the administrative record is a reference to the IQA petition.

338. *See* Br. of Pet'rs Zero Zone, Inc. & Air-Conditioning, Heating & Refrigeration Institute at 25-26 and Reply Br. of Pet'rs Zero Zone, Inc. & Air-Conditioning, Heating & Refrigeration Institute at 20.

339. *See* 832 F.3d at 678 and *supra* note 337.

> *That being said, the APA still affords the petitioners the right to bring this challenge.*[340]

If DOJ adheres to its position (or the Fourth Circuit does not correct DOJ) that *Salt Inst*. (and possibly *Miss.Comm'n*) held that there is no judicial review of any IQA violation, it would be effectively asserting a circuit split with the Seventh Circuit.[341] However, it appears from the above Seventh Circuit statement that the key to its holding is that the Fourth Circuit opinion in *Salt Inst*., and the other opinions that the government has regularly cited for "no legal rights," were speaking only with regard to the IQA *itself* not providing a right of action, and not the APA, and therefore there is no conflict.[342]

IV. SUMMARY OF THE STATUS OF CURRENT CASE LAW

Even though *Salt Inst*. is essentially a Shelby Amendment (i.e., data access) case as finally decided, and not a general IQA judicial review precedent, the various agency defendants have managed to leverage both the district and circuit opinions in that case, as well as several other district court decisions lacking any significant analysis, into a string of district court opinions supporting no right to judicial review of information quality issues. They have also persuaded a number of district courts that there is no law to apply under the APA, despite the D.C. Circuit's opinion in *Prime Time* holding that the OMB Guidelines have the force of law and the many detailed mandates in the OMB Guidelines and Bulletin. However, no circuit court has ruled in line with the district court cases regarding lack of judicial reviewability, the government's interpretation of *Salt Inst*.**,** or the lack of law to apply, and the district court opinions are not supported by any significant analysis, with some being unpublished (likely indicating a lack of scrutiny).

Most recently, the Seventh Circuit has indisputably held in *Zero Zone* that there *is* a right to judicial review under the APA, and that it does not consider *Salt Inst*. (or *Miss. Comm'n*) as precedent pertinent to a right to judicial review under the APA.

---

340. 832 F.3d 654 at 690 n.25 (emphasis added). It is clear that "this challenge" refers to the IQA allegations, since the footnote is placed at the beginning of the portion of the court's review of the IQA issue and is appended to the citation to the IQA petition that was later submitted as rulemaking comments (App. R.6, Admin. R.79-A2).

341. DOJ should be obliged to bring this Seventh Circuit holding to the attention of the court in a future IQA case, at least in the 7th Circuit, in line with rules of professional ethics requiring "candor to the tribunal." *See* D.C. BAR CODE OF PROFESSIONAL ETHICS sec.3.3 and comment 3 (2016); ABA MODEL RULES OF PROFESSIONAL CONDUCT, *Rule 3.3 Candor Toward the Tribunal*, and associated comments (2016). *See also* FED. R. CIV. PROC. sec. 11(b)(2) (2016). All these codes and rules require disclosure of directly pertinent legal authority and prohibit knowingly false representations of law). *But see* Judith A. McMorrow, *The (F)Utility of Rules: Regulating Attorney Conduct in Federal Court Practice*, SMU LAW REV. 58 (2004) 3-49.

342. The *Zero Zone* opinion should also materially alter OIRA's annual reports to Congress containing information on IQA litigation. The most recent report addressing IQA litigation is the 2015 REPORT TO CONGRESS ON THE BENEFITS AND COST OF FEDERAL REGULATIONS AND AGENCY COMPLIANCE WITH THE UNFUNDED MANDATES REFORM ACT 65 (2016) https://obamawhitehouse.archives.gov/sites/default/files/omb/inforeg/2015_cb/2015-cost-benefit-report.pdf (last visited Dec. 2017)). A 2016 draft report has been issued for public comment, but it does not contain any material regarding the IQA. https://obamawhitehouse.archives.gov/omb/inforeg_regpol_reports_congress/ (last visited Feb. 2018). OMB failure to include the *Zero Zone* holding regarding availability of APA judicial review, and non-applicability of *Salt Inst*. and *Miss. Comm'n*, in a new report to Congress on IQA litigation could give rise to an IQA complaint.

The D.C. Circuit decisions in *Mississippi* and *Miss. Comm'n* raised, but did not clearly analyze and decide, the important issue of the role of the IQA Guidelines and peer review Bulletin in rulemaking. It is likely that this issue will receive further attention in future cases and other circuits, since the quality of information an agency relies on is usually determinative of the outcome of a rulemaking, and this is clearly reflected in the PRA and its legislative history.

V. KEY LEGAL ISSUES

A. Right to APA Judicial Review

Agency arguments that the APA does not apply because the IQA specifies an administrative petition remedy, and that the IQA only indicates that petition issues should be handled through agency reporting to OMB, are clearly erroneous under the express wording of the APA. Section 701 of the APA, governing judicial review, states that the judicial review provisions apply to all "agency actions" as defined in APA section 551. Section 551 expressly covers agency denial of a petition for relief. Section 551(13) defines "agency action" as including "relief, or the equivalent or denial thereof, or failure to act . . . ." In turn, section 551(11)(C) defines "relief" as including "taking of other action on the application or *petition* of, and beneficial to, a person . . . ." (emphasis added). IQA documents, both administrative and in court, authored by both the agencies and complainants, have consistently referred to "requests for correction" (RFCs) under the IQA and its guidelines as "petitions," and the ordinary definition of a "petition" is also in harmony with the language of the IQA as "a formal written request made to an official person or organized body."[343]

Agency arguments that the IQA was intended to confer only an administrative remedy lack any sense. Obviously, agency consideration and denial of an IQA petition involves an administrative process.

Agencies have also suggested in litigation arguments that Congress could not possibly have intended the IQA to change well-established case law disallowing judicial review of free-standing agency information disseminations. However, Congress must be presumed to be aware of its laws (i.e., the APA definition of "agency action" as including petition denials), and the legislative history recounted above indicates that Congressional committees were aware of, and dissatisfied with, existing case law and administration and DOJ positions in support of that case law,[344] and also that they were aware of GAO findings that it was difficult to identify informational errors without input from the private sector.[345] Moreover, as explained above, OMB Director Jacob Lew recognized the proposed IQA language in Congressional committee reports regarding an administrative process for petitions seeking correction as establishing a right to judicial review, and he expressed that view to appropriations committee members in a public hearing.[346]

343. See definition of "petition" at https://www.merriam-webster.com/dictionary/petition (last visited Dec. 2017).

344. *See supra* text associated with notes 34 and 80.

345. *See supra* text associated with notes 61-63.

346. *See supra* text associated with note 88-89.

Agency arguments and court opinion statements that the IQA does not provide a private right of action are, as some litigants have contended, simply irrelevant and potentially misleading. It is firmly established that when a statute does not provide a private right of action, the APA can provide a right of action and a remedy.[347] The lack of a private right of action in the IQA has been the erroneous basis for agency reliance on the Fourth Circuit's opinion in *Salt Inst.* (especially since the opinion says nothing about the APA), an error that the Seventh Circuit succinctly exposed in *Zero Zone*.[348]

In litigation over APA judicial review of agency action on correction requests under the IQA and its Guidelines and Bulletin, agencies, and several district courts, have frequently quoted a single partial sentence from the OMB government-wide Guidelines as indicating that the Guidelines give the agencies unfettered discretion on "whether" or "when" to respond in any manner whatever to correction requests, and that therefore the agency action is exempt from the APA judicial review provisions as "committed to agency discretion by law."[349]

That sentence, which is in the preamble and not the substantive portion of the Guidelines, states in full along with its immediate context:

> Overall, OMB does not envision administrative mechanisms that would burden agencies with frivolous claims. Instead, the correction process should serve to address the genuine and valid needs of the agency and its constituents without disrupting agency processes. Agencies, in making their determination of whether or not to correct information, *may reject claims made in bad faith or without justification*, and are *required* only to undertake the *degree* of correction that they conclude is *appropriate* for the nature and timeliness of the information involved, and explain such practices in their annual fiscal year reports to OMB.[350]

On its face, that statement does not amount to a grant of unfettered discretion. Moreover, the statement is taken out of context in emphasizing the word "appropriate" as a purported grant of unlimited discretion. There are three other statements, all similar, in the Guidelines—two in the preamble and one in the substantive portion[351]-- that are never quoted fully in agency briefs. The statement in the substantive portion of the final Federal Register notice reads:

> To facilitate public review, agencies *shall* establish administrative mechanisms allowing affected persons *to seek and obtain*, *where appropriate*, timely correction of

347. S*ee, e.g*., Japan Whaling Ass'n v. Amer. Cetacean Soc'y, 478 U.S. 221, 230 n.4 (1986) (rejecting contention that there was no private right of action because the APA provides the right without the need for any mention of the APA in the statute); Chrysler Corp. v. Brown, 441 U.S. 281, 316-17 (1979); Karst Envtl. Educ., Inc. v. EPA, 475 F.3d 1291, 1295 (D.C. Cir. 2007); Neighbors of Cuddy Mt. v. Alexander, 303 F.3d 1059, 1067 (9th Cir. 2002).

348. This is apart from the abundant evidence, discussed previously, that *Salt. Inst*. was a Shelby Amendment data access suit presented as an IQA reproducibility suit.

349. 5 U.S.C. § 701(a)(2). This is also often referred to as the "law to apply" exception to the APA judicial review provisions. See the discussion, *supra*, of agency briefs in *Missouri River, ASA, Single Stick, San Luis & Delta-Mendota, SIRC,* and *Harkonen*. District courts adopted the agency argument on this point in *ASA* (d. ct.), *Salt Inst*. (d. ct.), *San Luis & Delta-Mendota*, and *Harkonen* (d. ct.).

350. 67 Fed. Reg. 8452, at 8458 (2002) (emphasis added).

351. *Id*. at 8453 (two separate statements in the preamble) and 8459 (statement in substantive portion).

> information maintained and disseminated by the agency *that does not comply with OMB or agency guidelines.*[352]

Those three statements, in the context of the requirements of the statute and the Guidelines and Bulletin, indicate that "appropriate" refers to the need to make corrections in a manner that will achieve compliance with the Guidelines.

The agency argument, and the court conclusions, on this point, also appear to assume that the term "appropriate," indicates, as a matter of common understanding, complete discretion. That is not accurate. Even in the everyday world, what is "appropriate" at a backyard barbecue may not be at all appropriate at a wedding, in church, or before a court. The Supreme Court has recently spoken to this exact point, stating that "the word 'appropriate' is inherently context-dependent."[353]

Agencies defending against IQA challenges in several district court cases (*ASA*, *Single Stick*, *SIRC*, and *Harkonen*) have cited *Steenholt v. FAA* as authority for the proposition that the language, especially the term "appropriate, in the OMB Guidelines regarding being required to undertake only the "degree" of correction that they conclude is "appropriate," provides them with complete discretion. The district court in *ASA* adopted this position. But the language that was involved in *Steenholdt* provides a much different context to "appropriate," stating that the FAA may terminate the certification of certain officials "[f]or any reason the Administration [sic–should be Administrator] considers appropriate."[354] The OMB Guidelines do not contain any language similar to "for any reason;" instead, they circumscribe "appropriate" according to what type or degree of correction is appropriate to achieve compliance with the requirements of the Guidelines. In litigation over APA judicial review of agency action on correction requests under the IQA and its Guidelines and Bulletin, agencies, and several district courts, have frequently quoted a single partial sentence from the OMB government-wide Guidelines as indicating that the Guidelines give the agencies unfettered discretion on "whether" or "when" to respond in any manner whatever to correction requests, and that therefore the agency action is exempt from the APA judicial review provisions as "committed to agency discretion by law."[355]

That sentence, which is in the preamble and not the substantive portion of the Guidelines, states in full along with its immediate context:

---

352. *Id*. at 8459 (emphasis added).

353. Sossamon v. Texas, 563 U.S. 277, 286 (2011) (construing the term "appropriate relief" in legislation). *And see* Local 1219, Amer. Fed'n of Gov. Employees v. Donovan, No. 81-1385, 1981 WL 27266, at **2-3 (D.D.C., Oct. 8, 1981) ("appropriate remedial action" in regulations did not give the agency discretion, and its action was "'arbitrary and capricious,'" a "true 'abuse of discretion,'" and "decidedly contrary to law").

354. 314 F.3d 633, 638 (D.C. Cir. 2003). In the appeal of *Single Stick*, the *Prime Time* opinion held that the OMB Guidelines are binding legislative rules, which would have been an unnecessary holding if the law in the D.C. Circuit was that the Guidelines allowed the agency complete discretion on whether or how to respond to a request for correction. In *Single Stick*, the agency also cited *Heckler v. Chaney*, 470 U.S. 821 (1985), to support its argument for complete discretion. But *Heckler* was a case presenting an issue of enforcement discretion, and, as the Court stated there, in enforcement cases there is a presumption of agency discretion. *Id.* at 831, 837.

355. 5 U.S.C. § 701(a)(2). This is also often referred to as the "law to apply" exception to the APA judicial review provisions. See the discussion, *supra*, of agency briefs in *Missouri River, ASA, Single Stick, San Luis & Delta-Mendota, SIRC*, and *Harkonen*. District courts adopted the agency argument on this point in *ASA* (d. ct.), *Salt Inst.* (d. ct.), *San Luis & Delta-Mendota*, and *Harkonen* (d. ct.).

> Overall, OMB does not envision administrative mechanisms that would burden agencies with frivolous claims. Instead, the correction process should serve to address the genuine and valid needs of the agency and its constituents without disrupting agency processes. Agencies, in making their determination of whether or not to correct information, *may reject claims made in bad faith or without justification*, and are *required* only to undertake the *degree* of correction that they conclude is *appropriate* for the nature and timeliness of the information involved, and explain such practices in their annual fiscal year reports to OMB.[356]

On its face, that statement does not amount to a grant of unfettered discretion. Moreover, the statement is taken out of context in emphasizing the word "appropriate" as a purported grant of unlimited discretion. There are three other statements, all similar, in the Guidelines—two in the preamble and one in the substantive portion[357]-- that are never quoted fully in agency briefs. The statement in the substantive portion of the final Federal Register notice reads:

> To facilitate public review, agencies *shall* establish administrative mechanisms allowing affected persons *to seek and obtain, where appropriate*, timely correction of information maintained and disseminated by the agency *that does not comply with OMB or agency guidelines.*[358]

Those three statements, in the context of the requirements of the statute and the Guidelines and Bulletin, indicate that "appropriate" refers to the need to make corrections in a manner that will achieve compliance with the Guidelines.

The agency argument, and the court conclusions, on this point, also appear to assume that the term "appropriate," indicates, as a matter of common understanding, complete discretion. That is not accurate. Even in the everyday world, what is "appropriate" at a backyard barbecue may not be at all appropriate at a wedding, in church, or before a court. The Supreme Court has recently spoken to this exact point, stating that "the word 'appropriate' is inherently context-dependent."[359]

Agencies defending against IQA challenges in several district court cases (*ASA*, *Single Stick*, *SIRC*, and *Harkonen*) have cited *Steenholt v. FAA* as authority for the proposition that the language, especially the term "appropriate, in the OMB Guidelines regarding being required to undertake only the "degree" of correction that they conclude is "appropriate," provides them with complete discretion. The district court in *ASA* adopted this position. But the language that was involved in *Steenholdt* provides a much different context to "appropriate," stating that the FAA may terminate the certification of certain officials "[f]or any reason the Administration [sic–should be Administrator] considers appropriate."[360] The OMB Guidelines do not contain any language

356. 67 Fed. Reg. 8452, at 8458 (2002) (emphasis added).

357. *Id*. at 8453 (two separate statements in the preamble) and 8459 (statement in substantive portion).

358. *Id*. at 8459 (emphasis added).

359. Sossamon v. Texas, 563 U.S. 277, 286 (2011) (construing the term "appropriate relief" in legislation). *And see* Local 1219, Amer. Fed'n of Gov. Employees v. Donovan, No. 81-1385, 1981 WL 27266, at **2-3 (D.D.C., Oct. 8, 1981) ("appropriate remedial action" in regulations did not give the agency discretion, and its action was "'arbitrary and capricious,'" a "true 'abuse of discretion,'" and "decidedly contrary to law").

360. 314 F.3d 633, 638 (D.C. Cir. 2003). In the appeal of *Single Stick*, the *Prime Time* opinion held that the OMB Guidelines are binding legislative rules, which would have been an unnecessary holding if the law in the D.C.

similar to "for any reason;" instead, they circumscribe "appropriate" according to what type or degree of correction is appropriate to achieve compliance with the requirements of the Guidelines.

B. Guidelines and Bulletins As Legislative Rules

Under the APA, judicial review is available only for "final" agency action. One of the elements of finality is that the agency action must be one by which "rights or obligations have been determined, or from which legal consequences will flow."[361] Therefore, agency actions pursuant to directives or policy statements that are not legally binding legislative rules are generally not considered agency actions that determine rights or obligations and the APA will not be considered applicable.[362]

Agency briefs in IQA cases have sometimes argued that the agency action under the IQA and its Guidelines or Bulletin is not final agency action because it does not have "legal consequences." However, this formulation leaves out the phrase "or rights or obligations have been determined."[363] In the case of the IQA, an agency denial of a petition is not only a defined agency action under the APA, but the IQA also states that affected persons must be allowed to "seek and obtain" the correction of inaccurate information, which is certainly a "right" that is "determined" by an agency denial. Denial of a right is also a "legal consequence." The OMB Guidelines and Bulletin also impose legal obligations on agencies under both the express language of the PRA (requiring agencies to comply with policies established by OMB) and their mandatory, binding language.

The D.C. Circuit has already held, in *Prime Time*,[364] that the OMB government-wide Guidelines are binding legislative rules, and that holding was followed by the Ninth Circuit in *Harkonen*. Nevertheless, it appears that a further discussion of legislative rules is warranted, particularly since those holdings did not cover the OMB peer review Bulletin and there was no analysis.

Agency-specific guidelines,[365] court opinions,[366] and agency briefs[367] in IQA cases have sometimes expressed the view that the IQA "guidelines" label indicates that Congress intended the "Guidelines" to be advisory only. Presumably the same arguments would be raised with regard to the OMB peer review Bulletin. But case law does not support the argument that "guidelines" (or

---

Circuit was that the Guidelines allowed the agency complete discretion on whether or how to respond to a request for correction. In *Single Stick*, the agency also cited *Heckler v. Chaney*, 470 U.S. 821 (1985), to support its argument for complete discretion. But *Heckler* was a case presenting an issue of enforcement discretion, and, as the Court stated there, in enforcement cases there is a presumption of agency discretion. *Id.* at 831, 837.

361. Bennet v. Spear, 520 U.S. 154, 178 (1997).

362. *See, e.g.*, Ass'n of Flight Attendants v. Huerta, 785 F.3d 710, 716-18 (D.C. Cir. 2015); Col. Farm Bureau Fed'n v. U.S. Forest Serv., 220 F.3d 1171, 1173-74 (10th Cir. 2000).

363. Bennett at 177-78 (1997) (internal citation omitted)..

364. 800 F.3d at 1149, 1150.

365. *See, e.g.*, *supra* text associated with notes 111-112 and note 112.

366. *E.g.*, Am. for Safe Access, second district court opinion, 2007 WL 4168511 at *4 ("guidelines are by nature advisory").

367. *E.g.*, Mem. In Support of Def. Mot. to Dismiss in district court in *Harkonen*, ECF No. 8, at 12 (asserting that the terms "guidelines" and "policy and procedural guidance" in the IQA indicate Congressional intent that the guidelines are only advisory).

any other directive not labeled a rule, such as a "Bulletin") are by nature advisory (or interpretive rather than legislative).

A leading case addressing factors for determining a legislative rule is the Supreme Court's opinion in *Chrysler Corp. v. Brown*,[368] in which the Court identified two primary attributes of a legislative rule: (1) It was issued pursuant to statutory authority to implement a statute; and (2) it was issued in accordance with pertinent procedural requirements, such as those in the APA (notice and comment and Federal Register publication).[369] An additional attribute, which should be obvious, is that the rule contains requirements in mandatory language that affect rights or obligations. The D.C. Circuit in particular emphasizes this factor in determining whether a rule is legislative.[370]

The case law regarding the primary determinants of a legislative rule has become well-settled since *Chrysler*, and it is recognized that the label on an agency document is not one of those determinants – or at most a weak one that will be overridden by the other determinants.[371] Cases have found agency documents labeled as "guidelines" or "guidance" to be legislative rules,[372] and Congress, agencies, and courts have used the terms "guidance" or "guidelines" interchangeably with "rules" or "regulations."[373]

---

368. Chrysler Corp. v. Brown, 441 U.S. 281 (1979).

359. *Id*. at 301-303 (1979). *See also* Mayo Fdn. for Med. Educ. and Research v. United States, 562 U.S. 44, 45 (2011); Gen. Motors Corp. v. EPA, 363 F.3d 442, 448-49 (D.C. Cir. 2004); Perez v. Mortgage Bankers Ass'n, __ U.S. __, 135 S. Ct. 1199, 1203 (2015).

370. *See* Elec. Privacy Info. Ctr. v. U.S. Dept. of Homeland Sec., and cases cited therein, 653 F.3d 1, 7 (D.C. Cir. 2011); Appalachian Power Co. v. EPA, 208 F.3d 1015, 1020-23, 1020 n. 11 (D.C. Cir. 2000).

371. *See* Chao v. Rothermel, 327 F.3d 223, 228 (3d Cir. 2003) (Congressional label of "guidelines" was not determinative; however, substance indicated an interpretive, not legislative, rule); Ohio Dept. of Human Serv. v. HHS, 862 F.2d 1228, 1233-34 (6th Cir. 1988) ("'the agency's own label, while relevant, is not dispositive,'" quoting General Motors Corp. v. Ruckelshaus, 742 F.2d 1561, 1565 (D.C. Cir. 1984) (en banc), and the agency's label of "interpretive rule" was determined to be inaccurate, as the rule was legislative in substance). It should be kept in mind, however, that OMB is the agency Congress authorized to oversee issuance of the guidance, and OMB advised all agencies that its guidelines are binding. Moreover, under the PRA, all agencies must follow this OMB interpretation of the IQA; it is not each specific agency that has the authority to decide whether its own IQA/PRA guidelines are binding.

372. *See, e.g.,* Appalachian Power Co. v. EPA, 208 F.3d 1015, 1020-23, 1020 n. 11 (D.C. Cir. 2000) (EPA clean air "guidance" document held to be legislative rule due to its mandatory language. It is noteworthy that this decision was issued in April 2000, shortly before the IQA was passed.). *See also* Gen. Elec. Co. v. EPA, 290 F.3d 377, 381-85 (D.C. Cir. 2002) (purported guidance document was a legislative rule); McLouth Steel Prods. Corp. v. Thomas, 838 F.2d 1317, 1320-22 (D.C. Cir. 1988) (purported non-binding policy statement was a legislative rule).

373. *See* Heckler v. Campbell, 461 U.S. 458, 466-67 (1983) (Agency could rely on Social Security "guidelines" promulgated under its statutory authority to issue "rules and regulations" to determine disability benefits; guidelines referred to as "regulations"); "Clean Water Act" effluent limitation guidelines (ELGs), 33 U.S.C. § 1314(b) (requiring promulgation of ELGs as "regulations, providing guidelines") *And see also* 33 U.S.C. §§ 1288(a)(1) and 1328(b) (similar)); 73 Fed. Reg. 70418 (2008) (EPA "Guidelines" for concentrated animal feeding operations published in Federal Register as "Final rule" pursuant to Clean Water Act); Public Citizen v. NRC, 901 F.2d 147 (D.C. Cir. 1990) ("regulatory guidance" in Nuclear Waste Policy Act was mandatory in view of statutory reference to "requirements" in statute and its legislative history). *See also* 20 U.S.C. § 1234b(c) (Secretary of Education to determine the need for "regulatory or other guidance"); 42 U.S.C. § 7511a(c)(3)(B) and § 7511a(a)(2)(B)(ii) (requiring that all state Clean Air Act attainment plans "comply in all respects with guidance published in the Federal Register for vehicle inspection and maintenance programs, discussed as dicta in Natural Resources Defense Council, Inc. v. EPA, 22 F.3d 1125, 1146-47 (D.C. Cir. 1994); Wilson v. U.S. Parole Comm'n, 193 F.3d 195 (3d Cir. 1999) (Parole Comm'n "guidelines" treated as binding "regulations"); United States v. Booker, 543 U.S. 220 (2005) (holding that statutory provision

With regard to issuance of legislative rules under statutory authority, it is highly relevant that the IQA states at the outset that the information quality "guidelines" are to be issued "under sections 3504(d)(1) and 3516" of the PRA. Section 3504(d)(1) gives the Director of OMB the authority and responsibility to "develop and oversee the implementation of policies, principles, standards, and guidelines to . . . (1) apply to Federal agency dissemination of public information, regardless of the form or format in which such information is disseminated . . . ." Section 3516 then requires the Director, under the heading of "Rules and regulations," to promulgate "rules, regulations, or procedures necessary to exercise the authority provided by this subchapter." As discussed previously, the legislative history of the PRA shows that it was the intent of Congress that section 3516 would require OMB to exercise its authority by issuing "regulations" rather than through other means.[374] As a matter of plain legislative language and legislative history, the IQA "guidelines" are therefore "rules and regulations" containing binding guidance from OMB.[375] OMB has cited the IQA (or "section 515), which incorporates these provisions and legislative history, as the legal authority for its government-wide Guidelines, and the PRA for its peer review Bulletin, thus satisfying the first, and apparently the most important, attribute for identifying "legislative" rules – Congressional delegation of authority to issue binding rules to fill gaps in the legislative plan and issuance of rules (or guidance) pursuant to that authority.

The requirement for OMB to issue "Rules and regulations" in the form of "rules, regulations, or procedures" necessary to exercise its authority under the PRA also extends to the OMB peer review Bulletin as regulatory "procedures" that OMB has determined to be necessary to exercise its mandate to "ensure and maximize" the quality of information disseminated by Federal agencies. As with the Guidelines, OMB authority to promulgate those procedures has been delegated by Congress to OMB under section 3516 of the PRA, the Bulletin cites the PRA[376] and IQA as legal authority, and it was issued following notice and comment procedures (in fact, two proposed versions soliciting public comment). It contains numerous "requirements," and is designed to ensure and maximize the quality of information in agency scientific and technical assessments, particularly such information used in regulatory decisionmaking. The designation of the peer review requirements as a "Bulletin" is of little consequence, as is its judicial review disclaimer, since they are at odds with its actual content, legislative authority, and OMB interpretation.

OMB issuance of both its government-wide Guidelines and peer review Bulletin was also consistent with the second principal attribute for legislative rules – following pertinent statutory procedures, in this case notice and comment and Federal Register publication under the APA. The

making sentencing "guidelines" binding was unconstitutional due to deprivation of trial by jury). And note the use of the term "guidelines" in purpose (11) of the 1995 PRA, 44 U.S.C. § 3501(11), *supra* text accompanying note 46.

374. *See supra* text associated with notes 8-14.

375. The phrase "rules and regulations" is the ordinary language by which Congress delegates authority to agencies to promulgate legislative rules. *See, e.g.*, Mayo Fdn. for Med. Educ. and Research v. United States, 562 U.S. 44, 56-58, and cases cited therein (2011); Nat'l Cable & Telecomm. Ass'n v. Brand X Internet Serv., 545 U.S. 967, 980-81, and cases cited therein (2005). Federal statutes too numerous to cite employ this language. *See* Westlaw for "rules and regulations" in U.S.C.A.

376. The PRA provision quoted as one of the legal authorities for the peer review Bulletin (without a section citation) "requires OMB, among other things, to 'develop and oversee the implementation of policies, principles, standards, and guidelines to * * * apply to Federal agency dissemination of public information.'" 70 Fed. Reg. 2664 at 2666.

need for compliance with APA procedures was reinforced by the language in the IQA requiring that guidelines be developed "with public . . . involvement."[377]

In addition, the first section of the IQA states that the guidelines will be issued "in fulfillment of the purposes and provisions" of the PRA. One of the important PRA provisions is section 3506, which provides that each agency shall be responsible for "complying with the requirements of this chapter and related policies established by the Director [of OMB]." Under this provision, therefore, OMB's Guidelines and Bulletin established requirements that the agencies were required to follow, unless it was clear that a particular provision was intended to be advisory or discretionary through use of language such as "should," "may," or "encouraged." This provision for agency compliance should, by itself, establish the binding nature of the guidelines. But if the "rules and regulations" and agency compliance provisions were not enough, OMB utilized its supervisory authority under the PRA to instruct the agencies, in its June 10, 2002 Memorandum to the agencies while it was reviewing their draft agency-specific guidelines, that its government-wide guidelines were binding on all of them.[378]

C. Judicial Review Disclaimers

The OMB peer review Bulletin contains a judicial review disclaimer at the end,[379] and various agencies have included judicial review disclaimers in their agency-specific IQA guidance and their policies related to the OMB peer review Bulletin. Under *Appalachian Power Co. v. EPA*, such agency disclaimers are ineffective to nullify a legislative rule.[380] To allow agencies to self-

377. Much of the case law determining whether an agency document is a legislative rule or an interpretive rule (or general policy statement) has addressed the issue of whether the document was issued without the Federal Register notice and comment required for legislative rules.

378. See *supra* notes 109 and 110 and associated text. It is remarkable, and disturbing, that multiple agencies disregarded this instruction from OMB (despite the PRA requirement for agencies to comply with OMB policies) and that OMB nevertheless apparently approved their guidelines. *See, e.g.*, *supra* note 112 and associated text. One senses that there was a good deal of political controversy within the Administration (or the inter-agency working group) over the judicial review issue. It is ironic that in 2007 OMB issued a "Good Guidance Bulletin" in which it instructed agencies that guidelines should not contain any mandatory language. OMB Final Bulletin for Agency Good Guidance Practices, 72 Fed. Reg. 3432, 3433, 3440 (2007) ("Each significant guidance document shall . . . (h. Not include mandatory language such as 'shall,' 'must,' 'required' or 'requirement' . . . . ", referring to the "non-binding nature of guidance," and citing the IQA as one source of legal authority for the Bulletin). (In the case of the IQA, however, the label of "guidelines" was dictated by the IQA itself.) *See also* OMB CIRCULAR NO. A-1 REVISED § 1 (1952), which states that Bulletins are used by OMB "when the subject matter requires single or one-time action by the departments or establishments or is of a transitory nature." https://obamawhitehouse.archives.gov/omb/circulars_a001/ (last visited Dec. 2017).

379. 70 Fed. Reg. at 2677 ("*XII. Judicial Review.* This Bulletin is intended to improve the internal management of the executive branch, and is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity, against the United States, its agencies or other entities, its officers or employees, or any other person.").

380. 208 F.3d 1015, at 1022-23 (D.C. Cir. 2000). *And see* Am. Petroleum Inst. v. EPA, *supra* section III, J. The peer review Bulletin is replete with "requirements" that affect the rights of "affected persons" to obtain accurate information. The term "Bulletin" is not a term used in the IQA or PRA. The Congressional mandate to OMB under both the IQA and PRA is to "ensure and maximize" the quality of information disseminated to the public. This is what the peer review Bulletin was obviously intended to do with regard to scientific, medical, technical, and economic (and other social science) information. The disclaimer is simply a pretense in an attempt to fend off litigation..

immunize themselves from judicial review would create a serious separation of powers conflict between the legislative and executive branches.[381]

There can be no doubt that the OMB peer review Bulletin, like the original government-wide Guidelines, is a legislative rule, since it states that its legal authority is the IQA and the PRA,[382] and because it was developed through Federal Register notice and comment procedures and uses mandatory language ("requirements") in many of its provisions. In addition, the PRA requires all agencies to comply with guidance established by OMB. Moreover, the language of the disclaimer is contrived and inaccurate in stating that the Bulletin "is intended to improve the internal management of the executive branch," when it is obviously intended to "ensure and maximize" the quality of information disseminated to the public and used in making regulatory decisions affecting the public.

D. Exemptions

The OMB Guidelines and peer review Bulletin contain a number of "exemptions," or definitional exclusions, that appear to be contrary to the PRA as incorporated into the IQA. The PRA defines "public information," to which it applies, as meaning "any information, regardless of form or format, that an agency discloses, disseminates, or makes available to the public . . . ." In section 3504(d)(1) (a section expressly incorporated into the IQA) the PRA states: "With respect to information dissemination, the Director shall develop and oversee the implementation of policies, principles, standards, and guidelines to--(1) apply to Federal agency dissemination of *public information*, regardless of the form or format in which such information is disseminated . . . ." (Emphasis added) Throughout the PRA and the IQA, the terms "disseminated" and "dissemination" are clearly used in their plain language sense. The decision in *Harkonen* upholding the exclusion of "press releases" from the definition of "dissemination" in the OMB government-wide guidelines is contrary to those PRA provisions, and to a *Chevron* analysis and APA notice and comment requirements, and that exemption should be deleted or altered to reflect the later OMB clarification of the exclusion to apply only to press releases that announce the availability of information that would otherwise be subject to the RFC process.[383] The meaning of the exclusion for press releases (and fact sheets, press conferences, and similar information disseminations) was clarified by OMB when it gave policy guidance to agencies in its June 10, 2002 Memorandum[384] and announced modification of the exclusion language in connection with issuance of its OMB-specific guidelines. Since OMB was given clear leadership authority for

381. *See* Kucana v. Holder, 558 U.S. 233, 237 (2010) (Attorney General's regulation giving himself discretion could not be reconciled with the statute, with the court stating: "Separation-of-powers concerns, moreover, caution us against reading legislation, absent clear statement, to place in executive hands authority to remove cases from the Judiciary's domain.").

382. *Id*. at 2666. The statement of legal authority references both the IQA and § 3504(d)(1) of the PRA. This is a broader statement of legal authority than that contained in OMB's government-wide Guidelines, which did not make any reference to the PRA. Apparently this was considered necessary because the IQA itself arguably only required OMB to issue guidance that would be further implemented by agency-specific guidance, whereas the peer review Bulletin does not require agency issuance of any conforming agency-specific guidance.

383. See the OMB-specific IQA guidelines, which state that they exclude "communications such as press releases, interviews, speeches, and similar statements containing information that OMB or another Federal agency has previously disseminated in compliance with the Government-wide Guidelines or the OMB guidelines . . . ." at 7 (§ IV, 2, (e)), *supra* note 319.

384. *Supra* note 109, at 4, 5.

information dissemination policy in PRA sections 3504 and 3506, its clarification should be controlling. Nevertheless, it would be useful for OMB to also expressly modify its government-wide Guidelines in line with its clarification, especially since the 2006 "Inter-Agency Advisory Regarding Claims that Smoked Marijuana Is a Medicine" by FDA and DEA[385] provided a clear example of how the press release exclusion could be abused so as to disseminate important public information free of any IQA constraint, as sanctioned by the Ninth Circuit in *Harkonen*.

The "exemption" in the OMB peer review Bulletin for certain statistical and financial information[386] presents more of a problem. "Statistical information" is expressly covered (twice) in the IQA, and the OMB government-wide Guidelines issued pursuant to the IQA do not exempt such information. The PRA provisions for information quality also cover statistical information,[387] and the PRA mandates OMB to issue rules, regulations, or procedures to ensure and maximize all covered information, but it does not specify the particulars of those procedures. Arguably, therefore, OMB has discretion to decide that its specified peer review procedures should not cover the types of statistical and financial information exempted in the Bulletin. On the other hand, it could be argued that, given the broad intent of Congress for improving and maximizing all types of "public information," and the mandate to issue "rules, regulations, or procedures" to accomplish that end, the exemptions for statistical and financial information, while reasonable under *Chevron* to some extent, could be found to be overbroad with regard to highly important statistical information such as census data and Social Security cost of living adjustments. The exemptions for peer review of statistical information probably should be modified in some way to at least require peer review of highly important statistical information that poses significant methodological issues.

E. Administrative and Article III Standing

Some commentators and government litigators have suggested that allowing judicial review would lead to countless lawsuits due to the vast amount of information disseminated by agencies.[388] But such suggestions overlook the "irreducible" minimal constitutional requirements for Article III standing (based on the Constitution's Article III, § 2's "cases" and "controversies" language),[389] and the distinction between Article III judicial standing and administrative standing, which greatly restrict who can seek judicial review and for what sort of alleged violations of law.

---

385. *Supra* note 178.

386. 70 Fed. Reg. at 2677 ("Agencies need not have peer review conducted on information that is: . . . 5. Routine statistical information released by federal statistical agencies (*e.g.*, periodic demographic and economic statistics) and analyses of those date to compute standard indicators and trends (*e.g.*, unemployment and poverty rates); 6. Accounting, budget, actuarial, and financial information, including that which is generated or used by agencies that focus on interest rates, banking, currency, securities, commodities, futures or taxes, or 7. Information disseminated in connection with routine rules that materially alter entitlements, grants, user fees, or loan programs, or the rights and obligations of recipients thereof.")

387. 44 U.S.C. §§ 3501(9), 3504(a)(1)(B)(iii), 3504(e)(1)(B), 3504(e)(3)(C), 3506(e)(1) and (5), and 3514(a)(2)(B). See also the PRA definition of "public information," 44 U.S.C. § 3502(12).

388. *E.g.*, court recording of oral argument in *ASA* in the Ninth Circuit at 26.55-27.25.

389. The Supreme Court has summarized the constitutional requirements for standing as (1) concrete and particularized injury that is actual and imminent, not speculative or conjectural; (2) fairly traceable causation of the injury by the challenged conduct; and (3) likely redressability of the injury by the requested relief. *See, e.g.*, Lujan v. Def. of Wildlife, 504 U.S. 555, 560-61 (1992); Valley Forge Christian Coll. v. Am. United for Separation of Church & State, Inc., 454 U.S. 464, 472 (1982).

Article III requirements do not apply to administrative standing, and a person may have administrative standing under less stringent requirements than those applicable to Article III standing.[390]

Persons who have only a generalized interest in the information in question, or even a strong commitment to that type of information and its accuracy, have not thereby satisfied Article III standing requirements.[391] While Congress can create a new *type or category* of right, the infringement of which will be treated as an injury–as it has with its "seek and obtain" language in the IQA, and in other statutes such as FOIA, FACA, the Controlled Substances Act, and § 553(e) of the APA–a specific plaintiff must still demonstrate that such an injury is personal ("individualized") and concrete (often referred to as "injury in fact").[392] Few IQA cases have addressed standing, even where it would seem to have been an issue, perhaps due to some confusion over the meaning and effect of the term "affected person" in the IQA.[393]

The IQA right to "seek and obtain" correction of information that does not comply with the OMB guidelines is available only to "affected persons." There is no legislative history pertaining to the term "affected person," but on its face that term only applies to the administrative petition process. And OMB, which, as an executive agency, does not have the authority to address Article III standing, has addressed the meaning of "affected person" only for the purpose of access to the administrative process, and has not defined the term in the substantive portion of its Guidelines.

OMB first addressed the meaning of "affected person" in the preamble to its interim final government-wide Guidance, but did not provide a definite clarification; instead, it left the issue largely to the individual agencies. It stated:

> OMB considered these comments [on the meaning of "affected persons"] at length. Our conclusion is that "affected persons" are people who may benefit or be harmed by

---

390. *See, e.g.*, Gettman v. DEA, 290 F.3d 430, 433-34 (D.C. Cir. 2002) (petitioner for rescheduling of a controlled substance under the Controlled Substances Act, 21 U.S.C. at § 811(a), who had administrative standing as an "interested party;" did not thereby have the required Article III standing); Ecee, Inc. v. FERC, 645 F.2d 339, 349-50 (5th Cir. 1981).

391. *See, e.g.*, Sierra Club v. Morton, 405 U.S. 727, 738-39 (1972); Gettman, *supra*. *But cf*. Havens Realty *infra* and related cases (many cited in the *ASA* Plaintiff's/Petitioner's briefs).

392. *See* Lujan v. Defenders of Wildlife, 504 U.S. 555, 572 n.7, 578 (1992). The Supreme Court has emphasized that "the requirement of injury in fact is a 'hard floor' of Article III jurisdiction that cannot be removed by statute." Summers v. Earth Island Inst., 555 U.S. 488, 497 (2009). And see Spokeo v. Robins, ___ U.S. ___, 136 S. Ct. 1540, 1549-50 (2016). But deciding what constitutes injury in fact can be tricky. *Cf*. Fed. Election Comm'n v. Akins 524 U.S. 11 (1998) (denial of voting information to voting watchdog group was sufficient injury by itself); Public Citizen v. U.S. Dept. of Justice, 491 U.S. 440, 449 (1989) (denial of FACA request for information by itself creates standing); Havens Realty v. Coleman, 455 U.S. 363, 373-77, 378-79 (1982) (actual impairment or an organization's ability to carry out its mission was sufficient injury); Prisology, Inc. v. Fed. Bur. of Prisons, 852 F.3d 1114, 1117 (D.C. Cir. 2017) (dicta indicating that a FOIA requester has Article III standing simply by having been denied specific agency records); Byrd v. EPA, 174 F.3d 239, 243 (D.C. Cir.1999) (denial of information to which plaintiff had a right was sufficient to establish injury). *See generally* discussion and cases cited in Zivotofsky ex. rel. Ari Z. v. Sec'y of State, 444 F.3d 614, 617-19 (D.C. Cir. 2006), *aff'd on other grounds sub nom* Zivotofsky ex rel. Ari Z. v. Kerry, __U.S. __, 135 S. Ct. 2076 (2015) (denial of right to have information on country of birth in passport was sufficient to confer standing).

393. District courts found lack of Article III standing to raise IQA claims in *Salt Inst.* (d. ct.) and *Holistic Candlers*. Other cases that could have raised standing issues, but did not, include *CEI* and *Haas*.

> the disseminated information. This includes persons who are seeking to address information about themselves as well as persons who use information. However, each agency should consider how persons (which includes groups, organizations and corporations, as defined by the Paperwork Reduction Act) will be affected by the agency's information. Agencies should address the issue of "affected persons" in consultation with their constituents through the public comment process that agencies will provide after drafting their proposed guidelines and before submitting them for OMB review.[394]

As agencies began to submit their proposed agency-specific guidelines to OMB for review, OMB issued its June 10, 2002 Memorandum guidance to agencies,[395] in which it addressed further the term "affected persons." The transmittal cover to the Memorandum referred to the need for agencies to include guidance on the mechanisms to allow "the public" to seek corrections,[396] and the detailed policy discussion in the Attachment to the Memorandum elaborated on the term "affected persons":

> "Affected Person". Some agencies defined "affected person" quite broadly. For example, "The term 'affected person' means anyone who may benefit or be harmed by the disseminated information. This includes persons who are seeking to address information about themselves as well as persons who use information" (OFHEO, 5[397]). HHS took an even more open approach. Rather than defining "affected person," HHS just asks the complainant to *describe how the person submitting the complaint is affected by the information error*" (HHS, 13). This invites the complainant to describe how he/she is affected, *but specifically avoids any provision that would use this answer to limit or restrict who can point out an error in an agency's dissemination of information.*
>
> We prefer the HHS approach because it best ensures full public access to the complaint process, a goal of Section 515 and the OMB guidelines. The focus of the complaint process should be on the merits of the complaint, not on the possible interests or qualifications of the complainant. Other agencies need to adopt a similar approach.[398]

Persons seeking judicial, rather than administrative, review of a failure to comply with the IQA and its guidelines (both the original Guidelines and the peer review Bulletin) must utilize the APA, unless another statute provides different review procedures and standards. The APA can be utilized only by persons "suffering legal wrong because of agency action, or adversely affected or

---

394. 66 Fed. Reg. at 49721.

395. *Supra* note 109.

396. *Id.* at 1. (The 2-page transmittal cover Memorandum is not paginated.)

397. OFHEO stands for Office of Housing Enterprise Oversight, which has since been subsumed into the Federal Housing Finance Agency.

398. *Id*. at 11-12 of Attachment (word-processing incompatibility symbols removed. Emphasis as in original.) *See also* the definition of "affected" in the OMB-specific Guidelines, Part IV, §1 https://obamawhitehouse.archives.gov/sites/default/file s/omb/assets/omb/inforeg/iqg_oct2002.pdf, (last visited Dec. 2017).

aggrieved by agency action within the meaning of a relevant statute," and who can otherwise satisfy Article III standing criteria. [399]

The term "affected person" has not been interpreted in any case law addressing standing, and appears quite distinct from more general language such as "interested person," the "public," or "any person" that appears in other statutes in which Article III standing has been an issue. It appears that the most reasonable interpretation of the term "affected person" is that Congress wished, as suggested in the legislative history and consistent with OMB's interpretation, to cast a broad net for administrative standing, but to ensure adherence to the established Article III standing requirements for judicial review.

The requirements of the OMB peer review Bulletin present a different situation because they could give rise to a claim of "procedural injury," and the requirements of the Bulletin (as well as the OMB government-wide Guidelines) have sometimes been referred to by the courts and litigants as procedural.

The Article III requirements for procedural injuries are somewhat relaxed with regard to imminence and redressability because it is often not possible to predict with any assurance whether the omission of a required procedure would alter the agency information or its decision to proceed with a regulatory action based on that information.[400] For example, failure to prepare an EIS or an ESA Biological Opinion or to engage in ESA consultation, or failure to provide for public notice and comment, could be analogized to failure to conduct an appropriate peer review on a HISA or to allow public participation in the peer review under the OMB Bulletin. And, as the D.C. Circuit has stated:

> A plaintiff who alleges a deprivation of a procedural protection to which he is entitled never has to prove that if he had received the procedure the substantive result would have been altered. All that is necessary is to show that the procedural step was connected to the substantive result.[401]

399. 5 U.S.C. § 702. This section establishes a principle of prudential standing. That is, the plaintiff's complaint must be within the "zone of interests" which Congress intended to address in the relevant statute. Prudential standing does not confer jurisdiction, which can be established only by satisfying Article III requirements, particularly "injury in fact." *See* Nat'l Credit Union Admin. v. First Nat. Bank & Trust Co., 522 U.S. 479, 488-98 (1998). The prudential standing requirement should be fairly easy to satisfy in the case of an IQA judicial challenge, but it probably should be pleaded specifically.

400. See *Lujan*, note 380, *supra*, at 572 n. 7. ("There is much truth to the assertion that 'procedural rights' are special. The person who has been accorded a procedural right to protect his concrete interests can assert that right without meeting all the normal standards for redressability and immediacy. [A plaintiff asserting such a right to protect a concrete interest has standing] even though he cannot establish with any certainty that . . . [requiring the procedure] will cause [the government action at stake] to be withheld or altered, and even though [the government action] will not be completed for many years.") (Plaintiffs did not satisfy Article III injury-in-fact requirement to challenge EIS because they lived far away from the dam at issue.) Relaxation of redressability also incorporates relaxation of the causation element of Article III standing, since redressability depends on a causal link between the threat of injury and the procedural defect. *See* Carpenters Indus. Council v. Zinke, 854 F.3d 1, *6 n.1 (D.C. Cir. 2017).

401. Sugar Cane Growers Co-op of Fl. v. Veneman, 289 F.3d 89, 95 (D.C. Cir. 2002) (failure to provide for notice and comment).

The standard for a showing of procedural injury to support standing has been expressed in a number of ways. The Supreme Court has stated that all that is required is that "the procedures in question are designed to protect some threatened concrete interest of his [the plaintiff] that is the ultimate basis of his standing."[402] Many circuit cases reiterate this formulation,[403] while some elaborate by adding that it must be "reasonably probable" that the challenged agency action (not the alleged procedural breach) will threaten the plaintiff's concrete interests.[404]

An exception is the D.C. Circuit, which appears to have diverged from the Supreme Court's formulation of the procedural injury standards for standing stated in *Lujan* and cases in other circuits. This has caused some perplexity.[405] The D.C. Circuit's position stems from its 1986 en banc opinion in *Florida Audubon Soc'y v. Veneman*, which was decided by a narrow majority.[406] The opinion in that case contains several formulations of the standards for standing in procedural injury cases, but it is only one of them that appears unreasonable and incompatible with Supreme Court precedent and opinions in other circuits.

At the start of its analysis of standing for procedural challenges, the *Florida Audubon* majority appeared to follow the Supreme Court's opinion in *Lujan* in stating that a plaintiff can have standing if the procedural requirement at issue was "'designed to protect some threatened concrete interest of the plaintiff.'"[407] The opinion then went on to state that "the plaintiff must show that the government act performed without the procedure in question will cause a distinct risk to a particularized interest of the plaintiff."[408] No precedent was cited for this statement, although it does not appear inconsistent with the formulation in *Lujan* and other circuits. Next, the en banc opinion stated that the Supreme Court "has never freed a plaintiff alleging a procedural violation from showing a causal connection between the government action that supposedly required the disregarded procedure and some reasonably increased risk of injury to its particularized interest." Again, this statement appears reasonably consistent with precedent in the Supreme Court and other circuits. But then, at the end of its analysis, the court stated that "a procedural rights plaintiff must show not only that the defendant's acts omitted some procedural requirement, but also that it is *substantially probable* that the *procedural breach will cause* the essential injury to the plaintiff's

402. *Lujan*, 504 U.S. 555, at 573 n. 8.

403. *See, e.g.*, N. Mex. v. Dept. of the Interior, 854 F.3d 1207, 1215 (10th Cir. 2017); Salmon Spawning and Recovery Alliance v. Gutierrez, 545 F.3d 1220, 1229 (9th Cir. 2008). *But see* Sierra Club v. Johnson, 1269, 1278-79 (11th Cir. 2006) (citing and apparently following *Florida Audubon* in the D.C. Circuit, discussed *infra*).

404. *See, e.g.*, Friends of Tims Ford v. Tenn. Valley Auth., 585 F.3d 955, 968 (6th Cir. 2009); Ouachita Watch League v. Jacobs, 463 F.3d 1163, 1170 (11th Cir. 2006); City of Sausalito v. O'Neill, 386 F.3d 1186, 1197 (9th Cir. 2004). Violation of a procedural requirement may, in some instances, be sufficient by itself to satisfy the injury-in-fact requirement for Article III standing. *See* Spokeo v. Robins, ___ U.S. ___, 136 S. Ct. 1540, 1549-50 (2016) (citing Federal Election Comm'n v. Akins, 524 U.S. 11, 20-25 (1998), and Public Citizen v. Dep't of Justice, 491 U.S. 440, 449 (1989)).

405. *See* Richard J. Pierce, Jr., *Making Sense of Procedural Injury*, ADMIN. L. REV. 1-18 (Winter 2010) (suggesting that the D.C. Circuit's en banc *Fla. Audubon* opinion and subsequent conforming D.C. Circuit opinions are flawed in endorsing a probability standard in contrast to the plausibility standard endorsed in other circuits, and that the likelihood of causal impact should be addressed through a "harmless error" analysis in a review of the merits. Also suggesting that the court actually found lack of standing based on the tenuous and speculative chain of causation of the alleged injury.). *See* United States v. Johnson, 632 F.3d 912, 921 (5th Cir. 2011) (apparently adopting Pierce's harmless error analysis suggestion).

406. 94 F.3d 658 (D.C. Cir. 1996) (en banc).

407. *Id.* at 664 (quoting *Lujan* at 573).

408. *Id.*

own interest."[409] No authority was cited for this final statement regarding probability of injury, and it seems to be at odds with the court's other articulations of the standard – a threat or a risk of injury being quite different from a "substantial probability" of injury, which seems to indicate near certainty--with the "substantial probability" relating to the consequences of the procedural breach, not the agency action at issue.

This final statement regarding probability appears to be both extreme and at odds with precedent in other circuits and the Supreme Court (as discussed above). It is extreme because it is often impossible to predict or estimate the probability that lack of compliance with a procedural requirement would cause a certain, or different, result. This point has been expressed in other opinions, including D.C. Circuit opinions subsequent to *Fla. Audubon*.[410] Nevertheless, D.C. Circuit panels are obliged to follow this en banc opinion, and some have,[411] while others apparently have not.[412] In view of this situation in the D.C. Circuit, it appears that it could be of doubtful utility to attempt to bring an IQA suit based on noncompliance with the OMB peer review Bulletin in that circuit unless one is willing to mount a challenge to *Fla. Audubon* and its consistent progeny.

G. Exhaustion of Administrative Remedies

Exhaustion of administrative remedies (i.e., no RFC) was a potential issue in *Missouri River*, *Holistic Candlers*, and *Habitat for Horses*, and was raised several times in agency briefs, although failure to exhaust was never a stated basis in a court opinion for dismissing an IQA challenge.

The need for exhaustion before seeking judicial review was addressed by the Supreme Court in *Darby v. Cisneros*.[413] There, the Court confirmed that the need for exhaustion exists under the APA "to the extent that it is required by statute or by agency rule as a prerequisite to judicial review."[414] There are limited exceptions established by prior precedent, such as irreparable damage resulting from the delay involved in such review, futility, and bias.[415]

It appears that utilization of the administrative RFC process before going to court is necessary for judicial review of cases brought only for correction of disseminated information under the IQA, as opposed to suits based on alleged non-compliance with the OMB peer review Bulletin. This is because precedent prior to the IQA did not accept simple agency dissemination of information as an "agency action" subject to the APA, and it was the IQA that made such disseminations subject to APA review by requiring agency action on a petition for relief, which is a defined "agency

409. *Id*. at 664-65 (emphasis added).

410. *See* WildEarth Guardians v. Jewell, 738 F.3d 298, 306 (D.C. Cir. 2013).

411. *See, e.g.*, Nat'l Mall Tours of Washington, Inc. v. U.S. Dept. of the Interior, 862 F.3d 35, 45 (D.C. Cir. 2017); County of Del., Pa. v. Dept. of Transportation, 554 F.3d 143, 147 (D.C. Cir. 2009) (but also citing and quoting *Sugar Cane Growers* regarding no necessity to show that substantive result would have been altered); Ctr. for Law and Educ. v. Dep't of Educ., 396 F.3d 1152. 1159 (D.C. Cir. 2005).

412. *See* Sierra Club v. EPA, 699 F.3d 530, 533 (D.C. Cir. 2012); Elec. Power Supply Ass'n v. FERC, 391 F.3d 1255, 1262 (D.C. Cir. 2004); Gettman v. DEA., 290 F.3d 430, 433 (D.C. Cir. 2002) (quoting *Lujan* and *Sugar Cane Growers, supra)*; Animal Legal Defense Fund, Inc. v. Glickman, 204 F.3d 229, 236 (D.C. Cir. 2000) (citing *Lujan*).

413. 509 U.S. 137 (1993). *And see* DSE, Inc. v. United States, 169 F.3d 21, 26-27 (D.C. Cir. 1999).

414. *Id*. at 153.

415. *See* McCarthy v. Madigan, 503 U.S. 140, 146-49 (1992); Hettinga v. United States, 560 F.3d 498, 503 (D.C. Cir. 2009).

action" under the APA. By making the petition administrative process a prerequisite for APA judicial review, Congress thereby required exhaustion prior to judicial review. This brought IQA judicial review suits within the *Darby* exhaustion condition of "required by statute." However, the petition process does not apply to the peer review Bulletin.

However, the IQA itself says nothing about appeals (requests for reconsideration) from an initial agency denial of a petition. The appeals procedure was created by OMB, and OMB made appeals discretionary by stating only that agency-specific guidelines must provide that an appeal "may" be pursued.[416] Under *Darby*, such a discretionary appeal is generally not necessary to achieve exhaustion and final agency action under the APA. *Darby* states: "[W]here the APA applies, an appeal to 'superior agency authority' is a prerequisite to judicial review *only* when expressly required by statute or when an agency rule requires appeal before review and the administrative action is made inoperative pending that review."[417] This is not the case with the OMB IQA Guidelines.

Exhaustion would not apply to an APA suit brought to challenge "agency action, findings, and conclusions" arrived at "without observance of procedure required by law"[418] under the OMB peer review Bulletin. Although the Bulletin cites the IQA as one source of legal authority for the Bulletin, the IQA itself very arguably does not address procedural injury or procedural measures to maximize and ensure information quality. However, the Bulletin also cites and quotes as its legal authority provisions of the PRA regarding OMB's responsibility to, "among other things," implement "policies, principles, and procedures" to apply to agency dissemination of information.[419] Section 3516 of the PRA, which is not specifically cited in the Bulletin, requires OMB to "promulgate rules, regulations, or procedures necessary to exercise the authority provided by" the PRA. Because the peer review Bulletin does not require any resort to administrative procedures by an affected person, there is no need for exhaustion.

Finally, it should be noted that a challenge to an information dissemination appearing in a rule must normally be made in the form of public comments on the proposed rule. The agency response must then be made in the final rule, or sooner. Failure to raise an information quality challenge in public comments may be considered a failure to exhaust administrative remedies, according to some agency-specific guidelines.[420] An exception to this general rule would be an allegation of

---

416. 67 Fed. Reg. 8452 at 8459. However, even if an agency regulation states that a petition for reconsideration "may" be pursued, if the regulation also indicates that the agency decision will not be considered "final" until an appeal is decided, exhaustion will be required. *See* Marine Mammal Conservancy, Inc. v. USDA, 134 F.3d 409, 411 (D.C. Cir. 1998); Conservation Force v. Salazar, 919 F. Supp. 2d 85, 89-91 (D.D.C. 2013). Also, if a complainant chooses to file a discretionary appeal while also seeking judicial review, the agency action may be considered non-final or unripe. *See* Marcum v. Salazar, 694 F.3d 123, 127-28 (D.C. Cir. 2012).

417. 509 U.S. at 154 (original emphasis).

418. 5 U.S.C. § 706(2)(D).

419. 70 Fed. Reg. 2664 at 2666 (Jan. 14, 2005).

420. *See, e.g.*, EPA information quality guidelines § 8.5, at 33 https://www.epa.gov/sites/production/files/2017-03/documents/epa-info-quality-guidelines.pdf (last visited Dec. 2017); DOT information quality guidelines 25 https://www.transportation.gov/sites/dot.gov/files/docs/DOT%20Information%20Dissemination%20Quality%20Guidelines.pdf (last visited Dec. 2017). Other agency guidelines simply state that comments on the quality of information in a proposed rule for which public comment is requested will be responded to in the final rule. *See, e.g.*, HHS information quality guidelines Part I, E https://aspe.hhs.gov/report/hhs-guidelines-ensuring-and-maximizing-quality-objectivity-utility-and-integrity-information-disseminated-public (last visited Dec. 2017); DOL information quality guidelines 9 https://www.dol.gov/oasam/ocio/programs/InfoGuidelines/InfoQualityGuidelines.pdf (last visited Dec.

non-compliance with a significant procedural requirement that only comes to light at the time of issuance of the final rule or other regulatory action, such as a deficient charge to peer reviewers or a non-objective agency response to a peer review report pertaining to a peer review conducted on information first presented for comment in a proposed rule. [421]

F. Standard of Review and Burden of Proof

The APA has two distinct categories of claims into which IQA/PRA claims could fall. The first is "arbitrary and capricious, an abuse of discretion, or otherwise not in accordance with law."[422] The second is "without observance of procedure required by law."[423] Encompassing and modifying these (and all other) categories of APA claims is the important requirement that the court "shall review the whole record or those parts of it cited by a party, and due account shall be taken of the rule of prejudicial error."[424] "Prejudicial error" is not well-defined in the case law, and it is very fact-specific and may give the court excessive subjective discretion.

The rule of prejudicial error is also often referred to as the "harmless error" rule. In other words, if there is no harm, there is no prejudice. The Attorney General's Manual on the Administrative Procedure Act, prepared in 1947 immediately after enactment of the APA, described the rule as the traditional "harmless error rule," and described the rule as meaning that "errors which have no substantial bearing on the ultimate rights of the parties will be disregarded."[425] An example of application of the rule to two different categories of APA judicial review (procedural non-compliance and alleged arbitrary and capricious error) can be seen in the *Zero Zone* opinion,

---

2017); DOI information quality guidelines § III, at 5 https://www.doi.gov/sites/doi.opengov.ibmcloud.com/files/uploads/515Guides.pdf (last visited Dec. 2017).

421. There has been a growing trend in a number of circuits to decline to review challenges to rulemaking information that were not presented during a formal opportunity for public comment, although there are a number of exceptions to this position, such as when an issue with a proposed rule was raised by another commenter or the agency was otherwise on notice. *See* the many cases cited and discussed in the research report submitted to the Administrative Conference of the United States (ACUS) Judicial Review Committee by Jeffrey S. Lubbers, Fail to Comment at Your Own Risk: Does Issue Exhaustion Have a Place in Judicial Review of Rules? 21-30 (May 5, 2015) https://www.acus.gov/sites/default/files/documents/Final%20Issue%20Exhaustion%20Report%2005052014_1.pdf (last visited Dec. 2017). See also Recommendation Statement #19, ACUS Judicial Review Committee, Issue Exhaustion in Preenforcement Judicial Review of Administrative Rulemaking (Sept. 25, 2015), https://www.acus.gov/recommendation/statement-19-issue-exhaustion-preenforcement-judicial-review-administrative (last visited Dec. 2017), and see the ACUS recommendation at https://www.acus.gov/recommendation/statement-19-issue-exhaustion-preenforcement-judicial-review-administrative (last visited Dec. 2017).

422. 5 U.S.C. § 706(2)(A) (2012).

423. 5 U.S.C. § 706(2)(D) (2012).

424. Last sentence of 5 U.S.C. § 706.

425. U.S. Dep't of Justice, *Attorney General's Manual on the Administrative Procedure Act* 110 (1947) (citation to S. Ct. opinion omitted), available in print copy from HeinOnline; available online at https://www.oalj.dol.gov/PUBLIC/APA/REFERENCES/REFERENCE_WORKS/AG09.HTM#SECTION10E; also at OCLC 654506785. *And see* Shinseki v. Sanders, 556 U.S. 396, 406 (2009) (quoting and applying the prejudicial error language of the APA and the characterization in the Attorney General's Manual). The harmless error rule is also encoded in 28 U.S.C. § 2111 (2012) ("On the hearing of any appeal or writ of certiorari in any case, the court shall give judgment after an examination of the record without regard to errors or effects which do not affect the substantial rights of the parties.") and Fed. R. Civ. Pro. 61 ("At every stage of the proceeding, the court must disregard all errors and defects that do not affect any party's substantial rights.").

although the rule is not expressly referenced in the "arbitrary and capricious" portion of the opinion.[426]

While the harmless error rule applies to all categories of APA judicial review, its articulation and application may differ depending on whether the issue under review is substantive or procedural, much as standing requirements vary if a claim is based on substantive or procedural error, as discussed above in the standing section.

A claim for non-compliance with IQA/PRA information quality rules might be made in a number of different situations, each of which could affect the nature of the pleading and burden that applies: (1) an administrative petition (RFC) proceeding under the IQA; (2) a court challenge to agency rejection of an administrative petition; (3) a court challenge to a final regulatory decision involving a public notice and comment process; (4) a court challenge to a risk assessment or other scientific or economic information or analysis to which the OMB peer review Bulletin applies, whether as part of a final rulemaking or a standalone dissemination. With regard to each, the most pertinent questions are in which APA review category does it fall, and does that make any difference with regard to the burden of sustaining the claim?

Although it appears easy for an IQA administrative petitioner to assert and establish "affected person" status if they are challenging a standalone information dissemination in an administrative proceeding via petition (RFC), they have the burden of explaining exactly the non-compliance complained of and exactly how each aspect of the complaint is supported by the specific provisions of the OMB or agency guidelines. This point was emphasized by OMB during its review of the draft agency-specific IQA guidelines[427] and accordingly is stated clearly in most of those guidelines.[428]

---

426. 832 F.3d 65, at 682-83 (late submission of DOJ consultation letter was harmless error, as it could not have affected the outcome), 832 F.3d at 678 (DOE determination of social costs of carbon was not arbitrary and capricious despite alleged IQA flaws in its determination).

427. OMB Memorandum for President's Management Council, *supra* note 109, at 13:

> ARequesters [sic—see below] should be aware that they bear the >burden of proof= with respect to the necessity for correction as well as with respect to the type of correction they seek@ (Justice, 6). Having the burden of proof on the complainant is consistent with the OMB guidelines and will be helpful in permitting agencies to dismiss frivolous or speculative complaints. All agencies should make this clear in describing their complaint mechanism to the public.

(The typographical idiosyncrasies are obviously due to issues with software incompatibility at the time of posting.) A similar statement appears in this memorandum with regard to the burden of overcoming the presumption that peer-reviewed information is "objective." *Id*. at 9. *See also* John D. Graham, Ph.D, Administrator of OIRA, OMB'S Role in Overseeing Information Quality: Remarks to Public Workshop on Information-Quality Guidelines, Sponsored by the National Research Council/National Academy of Sciences (unpaginated pdf at 8) (Mar. 21, 2002) https://obamawhitehouse.archives.gov/sites/default/files/omb/assets/omb/inforeg/info-quality_march21.pdf and https://obamawhitehouse.archives.gov/omb/inforeg_infopoltech#iq (last visited Dec. 2017). ("The burden of proof is squarely on the affected parties: They must demonstrate that a specific dissemination does not meet the quality standards in the OMB guidelines or the agency-specific guidelines.").

428. *See, e.g.*, the EPA guidelines, EPA/260R-02-008, at 30 (2002) https://www.epa.gov/sites/production/files/2015-08/documents/epa-info-quality-guidelines.pdf (last visited Dec. 2017); HHS guidelines, at Part I, sec. E (Oct. 1, 2002) https://aspe.hhs.gov/report/hhs-guidelines-ensuring-and-maximizing-quality-objectivity-utility-and-integrity-information-disseminated-public (last visited Dec. 2017); DOE

The determinative IQA quality requirements to which all challenges to petition denials must be tied are primarily in the OMB government-wide Guidelines, not necessarily the agency-specific guidelines, since the agency-specific guidelines must be consistent with the OMB guidance. Under the 1995 PRA, as incorporated into the IQA, OMB is in charge of promulgating rules and regulations regarding dissemination of public information, and agencies must comply with the OMB guidance. This is expressly stated in the PRA and in the OMB guidance and policy interpretations, as previously discussed. If agency-specific guidance is not consistent with the OMB guidance, the OMB guidance controls.

In a petition-denial court challenge, the challenge should fall into the APA review category of "otherwise not in accordance with law" rather than "arbitrary and capricious" or "without observance of procedure required by law."[429] The quality definitions in the IQA guidelines are "law," and they are substantive in a petition context, not procedural. The definition of the arbitrary and capricious standard of review is usually very deferential to the agency, but it does not appear that the definition was intended to apply to the "otherwise not in accordance with law" standard, since it appears to refer to analytical agency actions involving discretion.[430] The "abuse of discretion" standard has been applied in cases that do not generally appear analogous to IQA/PRA situations, such as court or administrative judge rulings on evidence issues.[431]

The IQA/PRA legislative history shows that Congress intended that OMB regulatory authority over information quality would apply to information used and disseminated in agency rulemaking and other decisionmaking as well as standalone information disseminations.[432] OMB guidance[433] and agency-specific guidelines[434] reflect this. OMB guidance and agency-specific guidelines specify that in a notice and comment situation, a comment on the quality of information in a

---

guidelines in the request for correction section (not paginated) https://energy.gov/cio/request-correction (last visited Dec. 2017).

429. 5 U.S.C. § 706(2)(A). I have been unable to find cases in which the court has applied only the "not otherwise in accordance with law" portion of section 706(2)(A).

430. Most court opinions appear to refer to the "arbitrary and capricious" standard in section 706(2)(A) as if it were the sole governing substantive standard. The Supreme Court has stated that an agency action is arbitrary and capricious if the agency "has relied on factors which Congress had not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." And, courts "will . . . uphold a decision of less than ideal clarity if the agency's path may reasonably be discerned." Nat'l Ass'n of Homebuilders v. Defenders of Wildlife, 551 U.S. 644, 658 (2007); Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43 (1983). The "abuse of discretion" portion of section 706(2)(A) has been treated as separate from the "arbitrary and capricious" portion. *See, e.g.*, Cobell v. Norton, 428 F.3d 1070, 1078–79 (D.C. Cir. 2005); Zero Zone, 832 F.3d at 682.

431. One important provision of the OMB peer review guidelines that might be subject to this standard because it stipulates both a requirement for HISA peer review and also allows for limited discretion in the provision for allowing public participation in those peer reviews "whenever feasible and appropriate" and "whenever practical." 70 Fed. Reg. 2664, at 2676.

432. *See supra* legislative history associated with notes 43-45.

433. June 10, 2001 OMB guidance Memorandum to agencies, *supra* note 109, at 15-16; OMB interim final government-wide guidelines, 66 Fed. Reg 49,718, at 49,720-21.

434. See, e.g., DOE information quality guidelines para. 4 (unpaginated) (available at https://www.energy.gov/sites/prod/files/cioprod/documents/finalinfoqualityguidelines03072011.pdf, last visited Mar. 2018); EPA information quality guidelines sec. 5.3, p. 15, sec. 8.5, pp. 32-33 (available at https://www.epa.gov/sites/production/files/2017-03/documents/epa-info-quality-guidelines.pdf, last visited Mar. 2018).

regulatory proposal will be considered as if it were an RFC challenging the information in the proposal, and the final agency action will be considered the equivalent of action on an RFC.

A court challenge to a final rule or other agency regulatory decision in which there was public notice and comment should be considered as an APA claim against an agency action "without observance of procedure required by law." This is because the IQA quality standards do not control the final agency decision; rather, the agency decision only takes the information subject to the IQA into consideration in exercising its substantive decisionmaking discretion.

There are a number of cases in which agency action has been found to be "arbitrary and capricious" due to flaws in information the agency relied on, but most such cases were based on a determination of lack of sufficient notice for public comment as required by the APA.[435] Those cases could have been just as readily been decided under the APA's "without observance of procedure required by law" provision. However, the APA's requirement for notice and comment does not provide specific quality standards that could have been applied in many of those cases. Now the IQA guidelines do provide such standards, allowing for application of clearly defined "law." Application of the IQA quality standards, and judicial reliance on the procedural provisions of the APA, may allow for a more lenient burden on plaintiff/petitioners than if the classic definition of "arbitrary and capricious" were considered the correct standard. The information an agency relies on in its decisionmaking will often determine, wholly or partially, the final decision. The IQA quality standards were intended to improve agency regulatory decisionmaking as well as standalone information disseminations. If such standards are not followed, it is likely that the flaws will result in agency decisions that are flawed to some undeterminable degree.

The OMB peer review Bulletin clearly sets out procedural legal "requirements" that agencies must follow in developing scientific, technical, and financial information disseminations and regulatory decisions relying on such information. Therefore, such disseminations and decisions will be governed by the APA's provision regarding action taken "without observance of procedure required by law. In cases where there is a complete failure to follow the law, such as complete failure to conduct an independent peer review for a HISA (highly influential scientific assessment), such a failure could be analogized to a complete failure to provide for public notice and comment, which would ordinarily result in vacating the agency action in the D.C. Circuit because it is

435. *See, e.g.*, Treasure State Res. Indus. Ass'n v. EPA, 805 F.3d 300, 303004 (D.C. Cir. 2015) (allegedly outdated and inaccurate monitoring method was not shown likely to lead to faulty measurement and was not arbitrary and capricious); Native Village of Point Hope v. Jewell, 740 F.3d 489 (9th Cir. 2014) (agency estimate of exploitable oil deposit in EIS did not have an adequate basis and was therefore arbitrary and capricious); Kentucky Riverkeeper, Inc. v. Rowlette, 714 F.3d 402, 413 (6th Cir. 2013) (agency failure to follow procedures in NEPA regulations was arbitrary and capricious); Cal. Communities Against Toxics v. EPA, 688 F.3d 989, 993 (procedural error that might have prejudiced right to comment was harmless); Sierra Club v. EPA, 671 F.3d 955 968 (9th Cir. 2012) (agency failure to consider more current data was arbitrary and capricious); *Cf.* Zevallos v. Obama, 793 F.3d 106, 114-16 (D.C. Cir. 2015) (Although agency's loss of evidence and failure to notify of automatic withdrawal of lawsuit were violations of procedure required by law under 5 U.S.C. § 706(2)(D), the plaintiff had failed to show that the errors were anything more than harmless); Am Radio Relay League, Inc. v. FCC, 524 F.3d 227, 236-38 (D.C. Cir. 2008) (agency failed to satisfy APA notice and comment requirements when it omitted critical data and failed to explain why it rejected other data); St. James Hosp. v. Heckler, 760 F.2d 1460, 1468-70 (7th Cir. 1985) (agency was arbitrary and capricious when it failed to consider several important analytical aspects of the problem, and the explanation for the rule was not adequately supported by the data, and agency therefore also failed to comply with the APA's notice and comment requirements); Resolute Forest Products, Inc. v. USDA, 187 F. Supp. 3d 100, 123 (D.D.C. 2016) (agency reliance on unreliable statistics was arbitrary and capricious).

impossible to predict how the agency would have reached its decision if a proper peer review had been conducted.[436] Defects that might be considered of lesser importance – e.g., failure to provide an allegedly inaccurate or inadequate charge to the peer reviewers or an allegedly inadequate peer review report or agency response to the report – might require consideration under the APA's "harmless error" rule, and the plaintiff/petitioner would be required to provide allegations specifying how the plaintiff/petitioner was prejudiced by the error.[437]

SUMMARY

There is ample and pertinent legislative history for both the IQA itself and the PRA information quality and dissemination provisions that it expressly incorporates and implements. This legislative history material has been either overlooked or ignored by most of the legal community, and insistence by many that it does not exist may have contributed to the dismissive treatment of IQA non-compliance allegations observed in many of the district court opinions, although most of the appellate opinions have not adopted such district court holdings or addressed fundamental judicial review issues.

A number of agency-specific guidelines violate the PRA and IQA in stating that they are non-binding, contrary to the PRA, the D.C. Circuit's opinion in *Prime Time* (followed by the Ninth Circuit in *Harkonen*), OMB binding guidance, and case law on determination of legislative rules. A number also contain judicial review disclaimers that are at odds with case law (e.g., *Appalachian Power*) and the 7th Circuit's opinion in *Zero Zone*. Likewise, the judicial review disclaimer in the OMB peer review Bulletin in particular is at odds with established law.

Over the course of more than fourteen years since OMB and agency-specific guidelines have been issued pursuant to the IQA (and more than twelve years since the OMB peer review Bulletin was issued), there have been only fifteen cases filed containing allegations of IQA (or PRA) non-compliance, of which eight were appealed or were filed directly in circuit courts. Most of the

436. *Cf.* Ozark Auto. Distrib's v. NLRB, 779 F.3d 576, 583, 581-86 (D.C. Cir. 2015) (denial of an opportunity for discovery is ordinarily prejudicial because it is not possible to determine whether the outcome would have been different if it had been allowed); Cal. Wild. Coal. v. DOE, 631 F.3d 1072, 1090 (9th Cir. 2011) (defining harmless error as "clearly had no bearing on the procedure used or the substance of decision reached"); Sugar Cane Growers Co-op of Fla. v. Veneman, 289 F.3d 89, 96 (D.C. Cir. 2002) ("an utter failure to comply with notice and comment cannot be considered harmless if there is any uncertainty at all as to the effect of that failure," otherwise the APA's notice and comment requirements would be gutted).

437. Shinseki v. Sanders, 556 U.S. 396, 409 (2009) (the party claiming procedural error has the burden of showing that prejudice resulted); Zevallos v. Obama, 793 F.3d 106, 115 (D.C. Cir. 2015) (court would not invalidate an agency decision on the basis of procedural error "unless the errors alleged could have affected the outcome," cited and quoted in the Zero Zone discussion of alleged prejudicial error, at 682. *But see also* the subsequent statement in *Zevallos* that the plaintiff would have to show that compliance "would" have led to a different agency decision); Am. Radio Relay League at 44-45 (party claiming prejudice must show that it has "something useful to say" regarding omitted data); Chamber of Commerce of U.S. v. SEC, 443 F.3d 890, 905 (D.C. Cir. 2006) (party complaining of prejudice need not prove that its comments would have persuaded the Commission to reach a different outcome; it is sufficient that it demonstrate that it had something to say about the critical data); Gerber v. Norton, 294 F.3d 173, 182, 184 (D.C. Cir. 2002) (to show prejudice, plaintiff must indicate with reasonable specificity what issue(s) they would have commented on and present sufficient material to show that they could mount a credible challenge to the agency action); AFL-CIO v. Chao, 496 F. Supp. 2d 76, 90 (D.D.C. 2007) ("[A]ll that a challenger [of procedural error] must show is that it could 'mount a credible challenge to the rule – or make a 'colorable claim that it would have more thoroughly presented its arguments' – on remand."). *Cf. Cal. Wild. Coal*. *supra*.

opinions, in both district courts and courts of appeals, gave little attention to the IQA allegations. All of the district court opinions rejected IQA allegations on grounds that the IQA does not provide a private cause of action, either on grounds that agency action is committed by law to agency discretion or because the IQA does not grant a right providing standing to seek relief under the APA. One appellate opinion, the most recent – *Zero Zone* in the 7th Circuit – has held that the APA provides a cause of action for IQA non-compliance allegations, while there are no other circuit opinions holding that the APA does not apply.

The dearth of critical analysis of IQA issues in the court opinions may be attributable to a number of factors: (1) Insistence by many in the legal community (including some courts) that the IQA did not receive sufficient (or any) Congressional consideration, exacerbated by Congressional failure to change the title of the Paperwork Reduction Act to reflect the growing emphasis on the need for improved quality in disseminated information and information used in decisionmaking; (2) extreme advocacy by the Department of Justice, to which many of the district courts appear to have simply defaulted; and (3) a lack of specificity in pleading and analysis by many plaintiffs and petitioners. In particular, it is noteworthy that there has been little litigation over the requirements of the OMB peer review Bulletin, which may be attributable to a deterrent effect of the its judicial review disclaimer.

It may be that the relative paucity of litigation is due mainly to honest compliance with the OMB guidance by agencies. If so, the IQA and PRA may be proving to be very effective. Nevertheless, further judicial confirmation of rights to judicial review could prove to be a test for that supposition. And in the case of particularly controversial issues, the availability of judicial review could increase public confidence in agency actions.

In the meantime, Congress entrusted OMB with responsibility for oversight of the PRA and IQA information quality process (referred to broadly by Congress as Information Resource Management (IRM)). In many respects, OMB has done a heroic job of implementing the IQA and PRA provisions, particularly given the initial timelines that were dictated and the fact that the legislation and guidelines apply to roughly one hundred federal agencies. However, OMB has also allowed many agencies to flout its authority by issuing their own guidance containing claims that their guidance, and the OMB guidance, are not binding and do not create rights subject to judicial review. OMB has even inserted a judicial review disclaimer in its peer review Bulletin.

When it issued its government-wide original Guidelines in 2002, OMB expressed the view that it thought the IQA guidance would need improvement in the future, and that the original guidance was just a first step in an evolutionary process.[438] Perhaps the time has come for OMB to seek public comment on improvements and clarifications to both the original Guidelines and the peer review Bulletin.

438. 67 Fed. Reg. 8452, at 8458 (2002) ("OMB's issuance of these final guidelines is the beginning of an evolutionary process that will include draft agency guidelines, public comment, final agency guidelines, development of experience with OMB and agency guidelines, and continued refinement of both OMB and agency guidelines. Just as OMB requested public comment before issuing these final guidelines, OMB will refine these guidelines as experience develops and further public comment is obtained.") The broad exemptions for statistical information contained in the peer review guidelines are an example of guidance that may need revisiting, particularly in view of the numerous express inclusions of statistical information as information subject to the PRA and IQA provisions.