Simplified, the precautionary principle states in the face of scientific uncertainty one should take no action that may create harm. As there will always be uncertainty in the field of environmental science, this is a recipe for paralysis. Of course, that is the goal of some. Those pushing for the furthest application of the principle point to uncertainty to argue for ever stricter regulations. On the other end of the spectrum, “anti-regulationists” argue against making any regulations in the face of uncertainty. Most of the regulated community, regulators, and concerned citizens are somewhere on the continuum between these extremes. In an industrial society some level of regulation is appropriate to limit the risk of potentially dangerous activities. Disagreement originates from differences in beliefs about the relative value of environmental and economic factors, and is compounded by the inherent uncertainty in predicting risks and a lack of understanding of the risk assessment process.

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2 Henk van den Belt, Debating the Precautionary Principle: “Guilty until Proven Innocent” or “Innocent until Proven Guilty”? 132 PLANT PHYSIOLOGY 1122, 1124 (2003).
Most major federal environmental statutes authorize the promulgation of regulations based on a finding of potential harm to human health or the environment.\textsuperscript{3} For example, the Toxic Substances Control Act\textsuperscript{4} gives the Environmental Protection Agency (EPA) the authority to "regulate chemical substances and mixtures which present an unreasonable risk of injury to health or the environment."\textsuperscript{5} Risk assessment is the process for predicting the probability, nature, and potential extent of such an injury.\textsuperscript{6} Since the earliest days of the EPA, scientists understood risk assessments to be a mix of science and policy.\textsuperscript{7} Still, the agency and reasonable industrial interests understand that while risk assessments are far from perfect, they provide some technical basis for setting regulations.\textsuperscript{8} So while regulators and the regulated may disagree on the degree of danger of a particular compound or the most appropriate assumptions to use in a certain situation, they realize without this process regulations could be completely arbitrary.

\textsuperscript{3} RONALD E. GOTS, TOXIC RISK: SCIENCE, REGULATION, AND PERCEPTION, 123 (Lewis Publishers 1993); See Table 9.1 for a summary of the language that authorizes risk-based regulations for eight major environmental statutes.


\textsuperscript{5} Id. §2601(b)(2).

\textsuperscript{6} GOTS, supra note 3, at 122.

\textsuperscript{7} Amoco Oil Co. v. E.P.A., 501 F.2d 722, 741 (D.C. Cir. 1974). The court stated that EPA regulations may "turn on choices of policy, on an assessment of risks, or on predictions dealing with matters on the frontiers of scientific knowledge."

While mainstream industrial interests understand the value of risk assessments, anti-regulationists instigated a war against risk-based regulations in the guise of “sound science.” Under the premise that the public is more supportive of regulatory reform based on science than economics, those in the Sound Science Movement attack the quality of the EPA’s science by highlighting the inherent uncertainties in assessing risks and argue against mixing science and policy. Promoting it as a means of eliminating “junk science” from the regulatory process, congressional allies passed the Information Quality Act (IQA) as a rider to an appropriation bill in 2000. The Act required the business-friendly Office of Management and Budget (OMB) to develop a process that allows affected parties to challenge the “quality, objectivity, utility, and integrity” of any information disseminated by a federal agency. According to the vice president of the U.S. Chamber of Commerce, the OMB’s program would “have the most profound impact on federal regulations since the Administrative Procedures Act … by ensuring the EPA uses better science, and by giving industry additional grounds to sue.”

With such an introduction, it was not surprising those who support stricter regulations were concerned. The program raised

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potential conflicts\(^{14}\) with the EPA's statutory mandate to protect the public with an adequate margin of safety.\(^{15}\) Critics feared the sheer number of challenges could distract the agency and delay efforts toward improved regulations.\(^{16}\) Also, by attacking individual studies one at a time, anti-regulationists would weaken the weight-of-evidence approach needed to make decisions in the face of limited data.\(^{17}\) Finally, critics raised the concern that through judicial review of compliance, the IQA, would remove the responsibly for making critical decisions from policy and technical experts and put it in the hands of judges.\(^{18}\)

The goal of this paper is to analyze the EPA's response to the IQA. As opposed to the predictions from those on either end of the precautionary spectrum, it does not appear that the Act has had a significant impact on actions of the agency, or at least those

\(^{14}\) Id. at 100.

\(^{15}\) See, e.g., Clean Air Act, 42 U.S.C. § 7409(b)(1) (2000) (requiring the EPA to set standards that allow an adequate margin of safety to protect the public health).


\(^{17}\) 40 C.F.R. § 721.170(b) (2005) allows the EPA to determine whether a compound is a risk to health or the environment based on a weight-of-evidence analysis of test results. See also McGarity, 10 at 923. According to McGarity, the weight-of-the-evidence approach resembles the fact-finding function of the jury in civil trials in which testimony of varying degrees of quality and credibility is offered. This approach focuses upon the totality of the scientific information and asks whether a cause-effect conclusion seems warranted. While individual studies may have some flaws, they still provide more useful information than would be available without the studies. But if the goal is to prevent reaching a conclusion that could be the basis of a regulation, one seeks to first identify and exclude any flawed studies, and to reject any decisions based on such studies.

visible from the outside. This is because the EPA’s 30-year history of dealing with the issues of risk assessment and data quality made it possible to integrate processes designed to meet the IQA into long-standing programs. The first section of this paper introduces the basics of risk assessment, and explains how science and policy are impossibly intertwined. The next section reviews the history of the Sound Science Movement and how it resulted in passage of the Information Quality Act. The third section summarizes the Information Quality Guidelines developed by the OMB and EPA in response to the IQA. Section IV analyzes the actual IQA challenges submitted by the chemical industry, discusses how the EPA has responded, and evaluates whether the IQA is having the intended impact. Section VI summarizes arguments for and against judicial review of agency actions under the IQA. The final section discusses the OMB’s recent attempt to assert greater control over risk assessments conducted by federal agencies.

I. RISK ASSESSMENT: WHERE SCIENCE MEETS POLICY

To avoid having to wait to “count the dead bodies” prior to regulating certain chemicals or activities, many environmental statutes are precautionary in nature as they allow regulatory action in the absence of definite proof of harm. Examples include the Clean Water Act which allows the EPA to regulate substances that “present a ... danger to public health or welfare,” the Clean Air Act which grants regulatory authority over emissions if the EPA Administrator finds they “may reasonably be anticipated to endanger public health,” and the Solid Waste Disposal Act


21 Id. §1321(b)(2)(A).


23 Id. at §7521(a)(1) and §7545(c)(1)(A).
which allows regulation of waste that "may cause or significantly contribute to an increase in mortality or ... illness." Nevertheless, application of such precautionary language requires some method of identifying what action "may present a danger" or "contribute to increased mortality." In *Ethyl Corp. v EPA*, a 1976 case interpreting the language of the Clean Air Act, the D.C. Circuit Court stated an assessment of risk, based on all available information, is an appropriate means of determining whether regulated activities may reasonably be anticipated to endanger public health. The court recognized that when a statute is precautionary in nature and the evidence of harm is difficult to come by or is on the frontiers of scientific knowledge, the EPA need not prove a clear cause and effect, but provide only a sufficiently-reasoned methodology to justify regulatory action. This case suggested a proper risk assessment is a sufficient basis to overcome a challenge that an agency's application of a precautionary statute is arbitrary, capricious, or an abuse of discretion.

Risk assessment is a process of estimating the probability of harm under certain circumstances. While assessing the potential risk of chemicals in the environment has a foundation in scientific fields such as toxicology, physiology, and chemistry, the process of risk assessment will always be a mixture of science, mathematics, and policy. The word risk itself, defined as "a chance or probability of danger," is more a term of mathematics than of


25 *Id.* §6903(5).

26 *Ethyl Corp v EPA*, 541 F.2d 1, 7 (D.C. Cir 1976).

27 *Id.* at 31.

28 *Id.* at 28.

29 *Id.* at 34.

As will be shown below, the risk assessment process takes the results of scientific studies and tries to predict what environmental conditions will result in an acceptable risk. In addition to the inherent uncertainty of any scientific data, there are additional unknowns and uncertainties in each step of the process. As no amount of experimentation will fill all the data gaps, those conducting the assessment must make assumptions as to the type, extent, and duration of exposure, as well as how to extrapolate data from tests conducted only on animals to predict potential effects on humans.

By necessity, policy slips into the decision making process in the face of this uncertainty. Risk assessors ultimately calculated the risk in mathematical equations to relate a dose of a chemical to a potential for harm, and they deal with ambiguity by including uncertainty factors within the equations. Since there is no "correct" value for these factors, where a person is on the precautionary continuum can influence the number he or she selects. That is not to say scientists take the values out of thin air, for there is an entire field of inquiry and a range of valid technical arguments for determining appropriate uncertainty factors but the final choice incorporates a policy decision of how much to err on the side of safety. Still, by multiplying uncertainty factor upon


32 GOTS, supra note 3, at 148.

33 ILLING, supra note 30 at 78.

34 EPA, Risk Assessment Principles and Practices, 13 (EPA 2004); see also GOTS, supra note 3, at 148.

35 ILLING, supra note 30, at 78. Examples of uncertainty and conventional multiple factor: A. interspecies variation (use of animal data to predict effect on humans), x10; B. human variation (impact on more sensitive individuals), x10; C. Nature of toxicity, up to x10; D. Adequacy of available data, up to x100.

uncertainty factor, the calculated risk at a given concentration, based on the same underlying animal studies, may differ by a thousand fold or more.  

The development of soil clean up limits for an industrial site serves as an example of the application of regulatory risk assessment. In setting such risk-based concentration goals, risk assessors first seek to determine a “safe” target dose for the compound in question, and then attempt to calculate what environmental concentration of the compound would maintain the dose below the target. Determining the target dose depends on extrapolation of results from animal studies because such tests are conducted at higher doses, but for shorter periods than those expected for environmental exposure. The steps required to convert animal data depend on the nature of the tests conducted, the types and magnitude of effects detected, and whether or not the compound is considered a carcinogen. A number of different models, each with a range of potential factors, are available to predict potential effects at low dosage. A critical and controversial issue is whether there is some de minimis dose at which there is no risk. 

37 Id. at 45; see also Mark E, Shere, The Myth of Meaningful Environmental Risk Assessment, 19 HARV. ENVTL. L. REV. 409, 412 (1995), in which the author argues the excessive use of assumptions can result in uncertainty of a factor of a billion or more.

38 Magaw, supra note 9, at 23.

39 Id. at 24.

40 EPA, Guidelines for Carcinogen Risk Assessment, Chap. 3 (EPA 2005).


42 GOTS, supra note 3, at 146. According to the author, “One of the most profound arguments between proponents and opponents of the risk assessment process ... is the question of thresholds. That is might a chemical ... that produces cancer at a high dose in experimental animals, not produce it at all, ever, under low dose circumstances typical of environmental exposure. ... [But] all commonly accepted and utilized risk assessment approaches have built into
practical issues with testing the effects of potential carcinogens on humans, it is impossible to answer this question with controlled experiments. While risk assessors typically use a threshold concept for non-carcinogenic chemicals, under the current policy they consider any exposure to a carcinogen to have some calculable risk.\footnote{Id.} The EPA publishes target dose values for a number of compounds in its Integrated Risk Information System (IRIS).\footnote{Magaw, supra note 9, at 24.} But as the EPA admits, while the values listed are doses at which no adverse health effect should occur, they cannot be used to accurately predict the incidence of human disease or the effects chemical exposures may have on humans.\footnote{EPA, IRIS Limitations, available at http://www.epa.gov/iris/limits.htm (last updated Jan. 25, 2007).} Still, even with this disclaimer, IRIS is a critical source for toxicity information used in conducting risk assessments.

Even with all its uncertainty, the target dose is just the starting point of setting a risk-based concentration.\footnote{See Magaw, supra note 9, at 23.} To estimate the dose under real world conditions, risk assessors make assumption about the type of exposure pathways between the contaminated material and humans. For example, gasoline contaminated soil may be a source of benzene exposure through contact with the soil, ingestion of impacted groundwater, or inhalation of vapors.\footnote{American Society for Testing and Materials, ASTM Standards on Assessment and Remediation of Petroleum Release Sites. (ASTM, 1999).} Risk assessors make additional assumptions about the nature and extent of these pathways when they calculate the estimated exposure from each. For example, one equation relating soil concentration to potential risk has 15 variables, including such factors as the them the public policy notion of no threshold. And, because that notion is not known to be true, all generally accepted models, no matter how sophisticated, are more mathematical reflections of public policy than they are of scientific fact.”

\footnote{American Society for Testing and Materials, ASTM Standards on Assessment and Remediation of Petroleum Release Sites. (ASTM, 1999).}
exposure duration, soil ingestion rate, soil to skin adherence factor, and cross-media exchange rates. The specific value of each of these factors may either be published default values, actually measured at the site, or the result of other multi-factorial equations. Finally, assumptions about such widely dispersed issues as the living habits of a typical person, the fate of chemicals under various environmental conditions, and even the density of cracks in a basement floor can all influence the calculated risk-based concentration limit.

This point demonstrates the notion that creating and implementing risk-based regulations involves intertwined issues of scientific quality, uncertainty, and policy decision-making in the face of uncertainty. As the D.C. Circuit said in 1974, such regulations “turn on choices of policy, on an assessment of risks, [and] on predictions dealing with matters on the frontiers of scientific knowledge.” While experts agree it makes no sense to build the complex structure of a risk-based regulation on a foundation of shoddy experiments, scientific quality is much easier to assess and resolve than issues of policy and uncertainty. Not only do recognized fields of science have internal standards of quality for publication and acceptance by peers, the EPA has stringent regulatory requirements for many types of experiments under its Good Laboratory Practices program. Also, risk-based regulations rarely depend on only one study, but incorporate the results of multiple investigations using a weight-of-evidence approach. Risk assessors typically evaluate the quality of the

48 Id. at 34-35.
49 Id. at 36-37.
50 Id. at 37.
51 Amoco, 501 F.2d at 741.
52 54 Fed. Reg. 34,052. In general, Good Laboratory Practice standards provide methods to ensure the quality and integrity of data submitted to the EPA. This specific rule discusses the required methods for experiments related to testing the ecological effects and environmental fate of pesticides.
available data when deciding on how much weight to give the results of individual studies. Typically when critics raise questions of scientific quality, the real issue is that they disagree with regulations based on precautionary policies.

II. The Sound Science Movement

As the extent of risk-based regulations and the application of risk assessments increased, anti-regulationists looked for ways to reign in the EPA, and organized an effort to discredit the scientific basis for risk-based rules. The presidential election of 1980 gave those who supported anti-regulatory policies a greater voice in Washington. Focusing on the parallel issues of environmental regulations and toxic tort liability, the Reagan administration created the Task Force on Regulatory Relief and Tort Reform Policy Working Group. The first Bush administration combined these efforts when it created the Council on Competitiveness as an interagency effort to provide both liability and regulatory relief. Near the end of the administration’s term, Peter Huber, a Fellow at the conservative think tank the Manhattan Institute, published a book entitled Galileo's Revenge: Junk Science in the Courtroom. Whether this book introduced or just popularized the term junk science is unclear, but the Council on Competitiveness used it as a mantra in advancing its reform

53 EPA, Guidelines for Carcinogen Risk Assessment at 1-11.

54 ILLING, supra note 30, at 80.

55 Wagner, 66 LAW & CONTEMP. PROBS. at 77.

56 McGarity, supra note 10, at 905.

57 Id. at 902.

58 Id. at 904.

proposals based on increasing the judicial scrutiny of scientific expert testimony.\footnote{McGarity, supra note 10, at 905.}

At that time, conservatives were not the only ones raising concerns about the interplay of science and policy. In his book \textit{Breaking the Vicious Circle}, then soon-to-be Supreme Court Justice Steven Breyer argued against an over-application of precautionary policies in the face of scientific uncertainty because it often resulted in the overregulation of high profile chemicals, thus leaving insufficient resources to deal with more serious environmental and social problems.\footnote{\textit{Breyer}, supra note 36, at 19.} Wendy Wagner, currently one of the loudest critics of the Information Quality Act, blasted what she called the “Scientific Charade” used by agencies to mask policy decisions by assigning standard-setting tasks to scientists and associated technocrats.\footnote{Wendy E. Wagner, \textit{The Science Charade in Toxic Risk Regulation}, 95 \textit{Colum. L. Rev.} 1613, 1632 (1995).} She claimed this behavior not only put significant power in the hands of those not identified as policy makers,\footnote{\textit{Id.} at 1634.} it also gave the impression that policy decisions are based on science.\footnote{\textit{Id.} at 1628. “[T]he esoteric nature of science-policy problems in toxic risk regulation makes it possible for these decisionmakers to blur distinctions between science and policy without the distortions being detected by most lay observers, including elected or appointed officials. In fact, scientists have been known to deliberately misidentify the hazy line between science and policy in the past. Sociologists of science suggest that these efforts by scientists to recharacterize the demarcation between questions of science and nonscience occur in order to prevent … intrusions into their scientific provinces… . That science-policy decisionmakers might also be capable, either intentionally or inadvertently, of shifting the bounds between science and trans-science to suit their institutional ends when developing toxic risk standards seems equally plausible.”}

Still, it was Huber’s junk science that motivated the most active response. Anti-regulatory forces realized arguing against
regulations by claiming the EPA based them on junk science was more politically palatable than complaining about potential economic impacts on regulated industry. As Republican strategist Frank Luntz said, "Americans unanimously believe all environmental rules should be based on sound science and common sense." In fact, the phrase sound science has such appeal members of both parties use it. However, it was anti-regulationists who initiated a campaign to attack the credibility of potentially damaging scientific information, and more broadly, to shape the public perception of the role of science in environmental policy. By forming such groups such as The Advancement of Sound Science Coalition, Institute for Regulatory Policy, The Center for Regulatory Effectiveness, and Citizens for a Sound Economy, conservative forces used the call for sound science as a smoke screen for tort and regulatory reform.

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65 McGarity, supra note 10, at 901.

66 Id. at 908.

67 Chris Money, Beware 'Sound Science.' It's Doublespeak for Trouble, Wash. Post, Feb. 29, 2004, at B2. “When George W. Bush and members of his administration talk about environmental policy, the phrase “sound science” rarely goes unuttered. On issues ranging from climate change to the storage of nuclear waste in Nevada’s Yucca Mountain, our president has assured us that he’s backing up his decisions with careful attention to the best available research. *** It all sounds noble enough, but the phrases “sound science” ... does not necessarily mean what you might think. Instead, they’re part of a lexicon used to put a pro-science veneer on policies that most of the scientific community itself tends to be up in arms about. *** The fact that Democrats such as former EPA administrator Carol Browner and Sen. John F. Kerry have used the phrase to defend their views only furthers [the] goal of blurring distinctions on these issues.”

68 McGarity, supra note 10, at 901.

69 Money, supra note 67.

70 McGarity, supra note 10, at 908.

71 Id. at 906.
Given the bipartisan use of the term sound science, and the breadth of groups seeking to use it to limit regulations, it is not possible to state a single set of objectives of the Sound Science Movement. As one skeptic suggested, science supporting one's position is sound, while all other is junk science.\textsuperscript{72} A consistent theme of the movement is first arguing regulations should not be made unless risk is proven, and then arguing there is insufficient data to ever prove the risk of chemicals at low concentrations. Along with these arguments is an effort to switch the burden of proof from the regulated to the regulators, while continually raising the level of the burden.\textsuperscript{73} Those in the movement wish to eliminate the presumed discretion afforded to agencies, replacing it with a requirement to prove causation similar to a plaintiff in a tort case.\textsuperscript{74}

Another consistent complaint of the movement is that risk-based regulations should be devoid of policy and based solely on science.\textsuperscript{75} Since this demand would be impossible, it is unclear whether it shows a sign of hypocrisy, a misunderstanding of risk assessment, or both. Other inconsistencies include attacks on the insufficiency of data on one hand, and arguing against taking advantage of all the available information with a weight of evidence approach on the other.\textsuperscript{76} At the furthest extreme, some critics label any data suggesting man has an adverse effect on the environment as junk science.\textsuperscript{77}

\textsuperscript{72} Hornstein, supra note 12, at 237.


\textsuperscript{74} Truong, supra note 18, at 370.


\textsuperscript{76} Id. at 40.

An event that ultimately supported the Sound Science Movement was the Supreme Court case of *Daubert v Merrill Dow Pharmaceuticals Inc.*, which increased the role of trial judges as gatekeepers for scientific evidence and set new standards for evaluating the reliability of technical evidence. The Court rejected the "generally accepted" standard for scientific expert testimony, which had been operative for 50 years, holding that such an austere benchmark would be inconsistent with the Federal Rules of Evidence approach of relaxing the traditional barriers to opinion testimony. The Court went on to discuss four factors judges should use in assessing the validity of scientific evidence. While the opinion sought to loosen admissibility standards, some judges have adopted the factors as a formal test that must be passed for scientific theories to be introduced in court. In a subsequent case, the Court suggested each study used to reach a conclusion should be evaluated individually, thus limiting the weight-of-evidence approach often required to reach complex conclusions. While *Daubert* was a standard civil liability case, there have been attempts to use the concepts when challenging administrative actions through judicial review.

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79 Frye v. United States, 293 F. 1013 (D.C. Cir 1923).

80 See FED. R. EVID. 702.

81 *Daubert*, 509 U.S. at 588.

82 Id. at 592-94.

83 Id. at 588.


85 Edison Electric Inst. v. EPA, 391 F.3d 1267, 1269 (D.C. Cir. 2004). While the petitioners argued that EPA rulemaking had to comply with the standard for scientific evidence articulated in Federal Rules of Evidence as interpreted in *Daubert*, the court stated "evidentiary rules govern the admissibility of evidence at trial, not the establishment of the processes whereby such evidence will be
In what it hoped would give external forces and the more business friendly Office of Management and Budget greater leverage over the EPA’s use of science in setting regulations, the Sound Science Movement, following the Republican takeover of Congress, sought to create a mechanism for challenging the quality of the agency’s science. In 1997, former tobacco lobbyist, sound science devotee, and founder of the Center for Regulatory Effectiveness, Jim Tozzi issued a plan seeking legislation allowing persons affected by government information to challenge the science underlying the information. As a means of taking decision making out of the hands of those who may lean too far to the side of safety, the legislation would allow review of such a challenge through administrative mechanisms, external technical panels, the OMB, and ultimately the courts. Implementation of the plan over the next three years culminated in the passage of the Information Quality Act as a rider to the 2001 Consolidated Appropriation Act in December 2000.

III. THE INFORMATION QUALITY ACT AND AGENCY GUIDELINES

The IQA required the OMB to issue guidance on how to ensure the “quality, objectivity, utility, and integrity” of information disseminated by federal agencies. Within one year of the

 created,” so a Daubert standard need only be met if written into the agency’s own procedures.


87 Id. at 4.

88 Sec. 515 of Title V of Treasury and General Government Appropriations Act for FY 2001, Pub. L. 106-554. In summary, the Act states “The [OMB shall issue guidelines] that provide policy and procedural guidance Federal agencies for ensuring and maximizing the quality, objectivity, utility, and integrity of information (including statistical information) disseminated by Federal agencies *** [And] 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.”
release of the OMB guidelines, agencies were to issue their own guidelines to meet these goals, and to establish an administrative mechanism allowing affected persons to seek correction of information that did not comply with the act.\textsuperscript{89}

The OMB released its guidelines in February 2002\textsuperscript{90} Unfortunately, as the document defines the key ambiguous terms of "quality, objectivity, utility, and integrity" with other ambiguous terms, the guidelines do little to clarify when information meets the standard. For example, quality is defined as "comprising of utility, objectivity, and integrity," while objectivity "includes whether the disseminated information is being presented in an accurate, clear, complete, and unbiased manner."\textsuperscript{91} The OMB supports the use of peer review by stating independently reviewed information may be presumed to be of "acceptable objectivity."\textsuperscript{92} With regard to risk assessments, the guidelines require agencies to adopt or adapt the principles described in the Safe Drinking Water Act (SWDA).\textsuperscript{93} In addition to basing decisions on the best available, peer reviewed science, the SWDA\textsuperscript{94} requires agencies to 1) identify a range of calculated risk, as oppose to a single value; 2) identify the nature of uncertainties encountered in determining the risk; and 3) suggest studies to resolve the uncertainties.\textsuperscript{95}

Meeting the deadline set in the IQA, the EPA released its quality guidelines in October 2002.\textsuperscript{96} As a compliance strategy, the

\begin{itemize}
  \item \textsuperscript{89} \textit{Id.}
  \item \textsuperscript{90} 67 Fed. Reg. 8452 (2002).
  \item \textsuperscript{91} \textit{Id.} at 8456.
  \item \textsuperscript{92} \textit{Id.} at 8454.
  \item \textsuperscript{93} \textit{Id.} at 8457.
  \item \textsuperscript{94} Safe Water Drinking Act, 42 U.S.C.A. §§300f-300j-26 (West 2003).
  \item \textsuperscript{95} \textit{Id.} § 300g-1.
  \item \textsuperscript{96} EPA, \textit{Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the EPA} (EPA 2002) [hereinafter EPA, \textit{IQA Guidelines}].
\end{itemize}
agency adopted a common sense approach by building on existing procedures so as not to impose unnecessary burdens or inhibit the use and dissemination of information.\textsuperscript{97} While stating it incorporated the requirements laid out by the OMB,\textsuperscript{98} the EPA made it clear in the guidelines that issues concerning technical quality were nothing new at the EPA.\textsuperscript{99} In addition to the EPA's pre-IQA Quality System, each program area and regional office already had procedures for ensuring information quality.\textsuperscript{100} As it noted, Congress included regulatory expectations concerning quality in statutes governing the agency,\textsuperscript{101} and as opposed to the focus of the IQA on information at the point of dissemination, the agency incorporates quality principles at every step of the process.\textsuperscript{102} So while the EPA claimed to embrace the OMB guidance, it did so by relying on its extensive history of striving to ensure scientific quality.\textsuperscript{103}

The guidelines cite two key documents, \textit{The EPA Quality Manual for Environmental Programs}\textsuperscript{104} and \textit{The EPA Risk...
Characterization Policy and Handbook. Each explains in detail agency policies for ensuring information quality. The goal of the first is to ensure the EPA supports its programs and bases its decisions on data of sufficient quality. The second, published just weeks before passage of the IQA, discusses the agency's policies for dealing with the critical elements of data quality, uncertainty, and communication in the fields of risk assessment and management. Unlike the IQA and sound science devotees, this policy handbook recognizes that data quality and dealing with uncertainty are two distinct yet important issues.

Quality is the easier issue to resolve because it is based on comparing the methods used to generate data to an appropriate standard, and determining whether the standard was met. Scientific quality includes whether studies are well designed to develop defensible data suitable for the purpose claimed. For example, in an attempt to determine the impact of a chemical on a test species, scientist must make decisions concerning the number of subjects, use of controls, concentrations to be tested, and length of the study. Quality also plays a role when they conduct experiments as proper care must be taken throughout the test to ensure reliable results. Yet even the highest quality science can result in uncertainty. Some of this is due to the natural variability of living things and environmental factors. Additional uncertainty arises from the need

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105 EPA, RISK CHARACTERIZATION HANDBOOK.

106 EPA, supra note 104, at 1-1.

107 EPA, supra note 105, at 1. Setting the tone for this document, the first paragraph includes "scientific uncertainty is a fact of life and a balanced discussion of reliable conclusions and related uncertainties enhances, rather than detracts, from the overall credibility of each assessment ..." And, "while the role of science to inform but not make decisions is widely recognized in EPA, and in the larger risk assessment and regulatory community, these communities often use the risk assessment number as the stated reason for decisions, not always clearly highlighting the legal, economic, social and other non-scientific issues that also go into the decision."

108 Id. at 40.
to understand the unmeasurable, such as the relative sensitivity of different species or the impact of very low concentrations of compounds on humans.

While most of the EPA IQA guidelines discuss how current agency processes are consistent with the goal of maximizing information quality, the document also presents three additional issues. The first makes clear the guidelines are only that, and as such, are not regulations, so they neither impose legally binding requirements nor create legal rights.\textsuperscript{109} Therefore, the agency argues in its response to comments, decisions made based on the guidelines are not subject to judicial review.\textsuperscript{110} The second issue is the agency goes to some length to discuss the types of information covered by the new IQA process.\textsuperscript{111} Because most data are already subject to other quality processes,\textsuperscript{112} such as those described in the \textit{EPA Quality Manual}, the agency limits application to “disseminated information” as defined by the OMB.\textsuperscript{113} So while information distributed to the public in support of a regulation or agency position is covered by the IQA,\textsuperscript{114} similar information presented to Congress in connection with proposed legislation is not.\textsuperscript{115}

\textsuperscript{109} EPA, \textit{supra} note 96, at 4. “Our Guidelines reflect EPA’s best effort to present our goals and commitments for ensuring and maximizing the quality of information we disseminate. As such, they are not a regulation and do not change or substitute for any legal requirements. They provide non-binding policy and procedural guidance, and are therefore not intended to create legal rights, impose legally binding requirements or obligations on EPA or the public when applied in particular situations, or change or impact the status of information we disseminate, nor to contravene any other legal requirements that may apply to particular agency determinations or other actions.”

\textsuperscript{110} \textit{Id.} at 40.

\textsuperscript{111} \textit{Id.} at 17.

\textsuperscript{112} \textit{Id.} at 18.

\textsuperscript{113} \textit{Id.} at 15.

\textsuperscript{114} \textit{Id.}

\textsuperscript{115} \textit{Id.} at 16-18.
Additionally, the guidelines do not cover publication of the results of EPA-funded research unless it represents the agency's official position.\footnote{116}{Id. at 17.}

While noting that direct communication with those responsible for producing information,\footnote{117}{Id. at 30. ("If a person believes that information disseminated by EPA may not comply with the Guidelines, we encourage the person to consult informally with the contact person listed in the information product before submitting a request for correction of information. An informal contact can result in a quick and efficient resolution of questions about information quality.").} or use of the normal notice and comment process,\footnote{118}{Id. at 32. ("When EPA provides opportunities for public participation by seeking comments on information, the public comment process should address concerns about EPA's information . . . If a group or an individual raises a question regarding information supporting a proposed rule, EPA generally expects to treat it procedurally like a comment to the rulemaking, addressing it in the response to comments rather than through a separate response mechanism . . . EPA believes that the thorough consideration provided by the public comment process serves the purposes of the Guidelines, provides an opportunity for correction of any information that does not comply with the Guidelines, and does not duplicate or interfere with the orderly conduct of the action.").} are the preferred approaches for resolving technical issues, the guidelines lay out an administrative process allowing affected persons to seek the correction of information they feel is inconsistent with the IQA.\footnote{119}{Id. at 30-31.} Such a party must submit a Request for Correction (RFC). If the agency finds the information is covered by the guidelines and the request is not frivolous,\footnote{120}{Id. at 31-32.} the office responsible for the information prepares a response either declining to make any changes or stating what changes it considers appropriate.\footnote{121}{Id.} If it is not satisfied with the response, the complaining party may file a Request for
Reconsideration (RFR). Then a three-member Executive Panel reviews the request and makes the final agency judgment.

IV. APPLICATION OF THE IQA AT THE EPA

Since it issued its Information Quality Guidelines, the EPA has not been inundated with RFCs, as critics of the IQA feared. The agency publishes all the requests as well as its response and subsequent RFR on a website, making these documents available for review. Between October 2002, when the program started, and June 2006, only 37 RFCs have been submitted. Twenty-one of these were from representatives of the chemical industry, five were from government representatives, eight were from private citizens, and three were from the building trades. Fifteen of the chemical industry RFCs raised issues related to risk assessment, while the others discussed site-specific compliance or other issues.

While most of the 15 risk-related RFCs raised legitimate issues, it does not appear the RFC process has had a significant effect on actions of the EPA In many of the cases, the agency considered the RFC as an input to other ongoing processes such as notice and comment, peer review, or chemical registration efforts. For example, the Metam Sodium Alliance requested the EPA use a different, and supposedly more advanced, computer model to assess the risk of the termiticide Metam Sodium. In its response,

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122 Id. at 34.

123 Id. at 35-35.

124 Wagner, supra note 16, at 611.

125 EPA, Information Quality Guidelines: Requests for Correction (RFC) and Requests for Reconsideration (RFR) Submitted to EPA, available at http://www.epa.gov/quality/informationguidelines/iqg-list.html (last updated Aug. 24, 2006). All the RFC, RFR, and agency’s responses can be linked from this site.

126 Id.
the EPA said it would consider the request under the public comment component of an ongoing reregistration process, and noted that Alliance had already submitted similar comments.\textsuperscript{128} Similarly, the Center for Regulatory Effectiveness (CRE) requested the EPA incorporate recently published data into a document the agency used in assessing whether to include a class of chemicals in the Toxic Release Inventory.\textsuperscript{129} As the hazard assessment required for listing was still undergoing review, the EPA responded it would consider the RFC as a late comment under the notice and comment process, but also claimed the assessment met all IQA requirements.\textsuperscript{130}

In another case, the CRE, representing the Kansas Corn Growers, submitted an RFC challenging the use of specific experimental results in an ecological risk assessment conducted as part of the reregistration process for the herbicide atrazine.\textsuperscript{131} CRE was especially concerned with data suggesting the chemical may adversely effect amphibian reproduction.\textsuperscript{132} Using a Daubert approach, CRE focused its challenge on the studies of one scientist, and argued the data should be excluded because the EPA


had not developed an approved method for assessing low-level endocrine effects in frogs. The agency did not prepare a specific response to the RFC, but issued a detailed summary of all the comments received concerning the challenged risk assessment. The issue became moot as an IQA concern due to a consent decree with the National Resources Defense Council, under which the EPA empanelled a Science Advisory Panel to review all available data on the health and ecological effects of atrazine.

In very few cases has submitting an RFC effected change in agency policy. For instance, producers of barium filed an RFC concerning the recommended reference dose listed in the EPA IRIS database. The request contained the complainant’s interpretation of a number of toxicological studies as a basis for requesting an increase in the reference dose. In its response, the EPA noted the parties had been in discussion about these technical issues since 1998 and that the agency’s position is consistent with the Quality Guidelines. After the manufacturers reiterated all of their technical points in a Request of Reconsideration, the EPA agreed to convene a peer review process to consider all the available data including studies published after the IRIS listing was last updated. As a result, the IRIS reference dose for barium was increased three fold in 2005.

133 Center for Regulatory Effectiveness, supra note 131, at 4.


In another example, the American Chemistry Council raised specific issues with technical information contained on an EPA website concerning diisocyanates. In response, the EPA discussed each of the issues, agreed to make changes it deemed appropriate, and defended its position on the other issues. The Council initially filed an RFR, but withdrew it after the EPA shared unpublished data on the class of compounds.

In other cases, the agency only defended its positions and made no changes based on the RFC. For example, a group submitted a request concerning the proposed reference dose for the arsenic-containing herbicide Cacodylic Acid published in a draft report. The group argued the EPA should have considered the results of a particular animal study, and requested changes in the uncertainty factors leading to a three-hundred fold increase in the calculated target dose. Although the RFC raised valid technical issues, and responsible toxicologists could disagree, the EPA responded that it had reviewed the study but found it inappropriate for the current use as it did not look at a cancer endpoint.


145 Id. at 4.
In contrast to concerns raised when the IQA was passed, few of the RFCs have been general sound science attacks on the use of risk assessment. The U.S. Chamber of Commerce did submit one RFC complaining of inconsistencies between different EPA models and databases that list physical and chemical properties of compounds of concern. Differences in these properties, such as solubility and volatility, result in differences in the calculated mobility and uptake of a chemical, and hence, differences in the predicted risk. While the request raises a good point, the "correct" value for these properties is part of the scientific uncertainty. As one might imagine, it is difficult to accurately measure the solubility of essentially insoluble compounds. Thus, a range of values exist in the literature, and there can be technical disagreements as to which one is the most appropriate. In its response, the agency discussed reasons for the potential inconsistencies and how it tries to recommend methods for selecting appropriate model inputs. Still, it agreed to add additional disclaimers on the databases and to eliminate access to a key database from its website. While potentially inconvenient, the loss of the database is unlikely to have much effect on the ability of parties to conduct risk assessments as other sources of the information are available.

In a sound-science-based tirade, the Chamber's Request for Reconsideration accused the EPA of "abdicating the public trust" by failing to

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150 VERSCHUEREN, supra note 148.

151 U.S. Chamber of Commerce, supra note 147.
initiate an inter-government multi-agency effort to “take on the whole problem of data quality.” In essence, the Chamber demands that the agency discard all uncertain data and that it cease enacting risk-based regulations until the government recreates all the chemical property data using some yet to be defined quality process. Although the RFR was submitted in April 2005, the EPA has not released an official response as of June 2006.

The Washington Legal Foundation (WLF) and the American Council on Science and Health (ACSH) submitted an RFC on the EPA’s Guidelines for Carcinogen Risk Assessment. The Guidelines, published in March 2005, revise and update the agency’s recommendation for assessing cancer risks first published in 1986. The RFC is a general attack on the EPA’s use of risk assessments by leading anti-regulationists and sound science advocates. Promoting the sound science myth that risk assessment can be based solely on science without any influence of policy, they request such assessments no longer be prejudiced by consideration of the agency’s health-protective goals. The RFC argues it is inconsistent with both the IQA and the requirement for

152 Id. at 1.

153 Id. at 11.


156 Washington Legal Foundation, supra note 154, at 7. “WLF and ACSH respectfully submit that information contained in the Risk Assessment Guidelines, regarding the use of animal studies to assess whether substances … are human carcinogens [does not comply with] the EPA IQA Guidelines. WLF and ACSH call on EPA to withdraw the offending information and to amend the Risk Assessment Guidelines so that they mandate that hazard and risk assessment are undertaken “in accordance with sound and objective scientific practices,” not based on policy considerations divorced from the underlying science. *** What the OMB Guidelines and the EPA IQA Guidelines bar the agency from doing is to corrupt the scientific process by allowing extraneous policy consideration to color scientific fact-finding.”

decisions to be based on the best available science for the EPA to admit that in the face of uncertainty, the agency errs towards protecting public health.\textsuperscript{157}

In addition, the complainants seek to reduce the reliance on animal test data as an indicator of potential human carcinogenicity unless some yet to be defined independent scientific validation becomes available.\textsuperscript{158} Specifically, they request the elimination of a default assumption designating a compound as "likely to be carcinogenic to humans" based solely on animal data.\textsuperscript{159} While raising some valid points about the inherent difficulties of extrapolating results between species, the RFC ultimately loses technical credibility as it quotes only the ACSH's self-published America's War on "Carcinogens": Reassessing the Use of Animals Tests to Predict Human Cancer Risk as the basis for its scientific argument.\textsuperscript{160} As so-called promoters of quality science, their request for correction would have carried more weight if it quoted peer-reviewed articles from respected journals.

Although the IQA guidelines indicate the EPA should answer an RFCs within 90 days, it took 6 month for the agency to issue a poorly-drafted two-page response.\textsuperscript{161} It starts out by claiming the cancer guidelines are merely "non-binding statements of policy," not disseminated information as defined by IQA, and thus not subject to the Information Quality Act. While it may be true that the cancer guidelines are non-binding within the EPA, this claim is somewhat disingenuous as many outside risk assessors use such documents as a basis for defending their work to government regulators. It appears the agency tried to avoid debating the

\textsuperscript{157} 	extit{Id} at 12.

\textsuperscript{158} Washington Legal Foundation, \textit{supra} note 154.

\textsuperscript{159} 	extit{Id} at 3.

\textsuperscript{160} KATHLEEN MEISTER, AM. COUNCIL ON SCI., AMERICA'S WAR ON "CARCINOGENS": REASSESSING THE USE OF ANIMALS TESTS TO PREDICT HUMAN CANCER RISK, (American Council on Science 2005).

technical issues raised in the RFC. A better approach would have been to more clearly state that both quality science and policy decisions are required to conduct risk assessments, and the IQA does not require an agency to change its policies based on input from a single third party.

As one might expect, the WLF and ACSH called the EPA to task for claiming the issues raised in the RFC are not subject to the IQA. This resulted in their RFR being more of a debate as to the meaning of the word "information" and the requirements of the IQA than a discussion on the quality of the underlying science. As stated by the WLF, the EPA should have opposed the RFC on its merits and not pretended that the IQA was inapplicable. By focusing on procedure instead of merits, the EPA delayed resolution of an important issue and opened itself up to a potential request for judicial review of its response.

V. THE IQA, DAUBERT AND JUDICIAL REVIEW

While the EPA claims actions taken under its information quality guidelines are not subject to judicial review, others seek to use the review process as a means of increasing judicial oversight of risk-based regulations. With the IQA as his basis, Alan Raul argues for "Daubertizing" the review process. Glossing over the fact the Daubert standards were developed for tort cases where the plaintiff has the burden of proof, as opposed to the presumed deference afforded agencies by the courts, he


163 Id. at 9.

164 EPA, IQA Guidelines at 40.

165 Raul, supra note 75, at 17.

166 Id.
states the public should expect the same high standards of sound science litigants are entitled too.\textsuperscript{168} Using typical sound science rhetoric Raul seems shocked policy plays a role in EPA actions\textsuperscript{169} or that technical assumptions are used in risk assessments.\textsuperscript{170} Seeming to want it both ways, he criticizes the EPA for failing to conduct sufficient studies to support regulations, and for prioritizing scientific activity based on regulatory need.\textsuperscript{171} A further disingenuous argument against the quality of the EPA's science is that those at both ends of the precautionary principle spectrum, regulated industries and environmental activists, voice discontent with EPA decisions.\textsuperscript{172}

While peer review is a critical component of the \textit{Daubert} test,\textsuperscript{173} Raul downplays the role peer review plays in the EPA's application of science.\textsuperscript{174} So while external experts in the field are considered inadequate to evaluate quality, somehow judges, without resorting to either policy considerations or scientific expertise, are supposed to be better able to evaluate the integrity of the scientific process.\textsuperscript{175} Recommending even more than \textit{Daubert}

\textsuperscript{167} \textit{Ethyl Corp.}, 541 F.2d at 34. "[The] standard of review is a highly deferential one. It presumes agency action to be valid. Moreover, it forbids the court's substituting its judgment for that of the agency, and requires affirmance if a rational basis exists for the agency's decision." \textit{Id.} (internal citations omitted).

\textsuperscript{168} Raul, \textit{supra} note 75, at 7.

\textsuperscript{169} \textit{Id.} at 9.

\textsuperscript{170} \textit{Id.} at 12.

\textsuperscript{171} \textit{Id.} at 10.

\textsuperscript{172} \textit{Id.} at 11.

\textsuperscript{173} \textit{Daubert}, 509 U.S. at 593.

\textsuperscript{174} Raul, \textit{supra} note 75, at 13. "The peer-review process is designed to provide internal agency checks on science-based decisionmaking. Though peer review is an important component of the scientific process, the nature of peer review ... process at EPA render it insufficient to remedy problems with agency science or to ensure reasoned decisionmaking."

\textsuperscript{175} \textit{Id.} at 41.
requires, Raul wants courts in every case involving agency science to consider the reliability and relevancy of all scientific evidence used, as well as to assess all assumptions, all conclusions, and whether the agency engaged in reasoned decision making.\textsuperscript{176} Reaching his anti-regulationist goal, Raul argues any agency decision failing to meet these standards should be vacated for abuse of discretion.\textsuperscript{177}

Furthering this goal is the suggestion to bring two of the trappings of a civil trial to judicial review. The first is the judge's role as gatekeeper as the Court elucidated in Daubert,\textsuperscript{178} and the second is placing the burden of proof on the agency instead of on the party challenging its action.\textsuperscript{179} While a gatekeeper may make sense to insulate a jury from proposed evidence ultimately found unreliable, it has no role in judicial review where the judge is the sole decision maker. Raul argues for each individual study underlying an agency action to be subject to review and exclusion, thus weakening the agency's overall weight of evidence basis for a regulation.\textsuperscript{180} Although giving lip service to maintaining Chevron\textsuperscript{181} deference for agency actions,\textsuperscript{182} he wants courts to compel the EPA to defend the technical basis of its decisions, while not requiring those challenging the agency to present any conflicting evidence.\textsuperscript{183} Finally, while citing numerous cases of

\begin{footnotesize}
\begin{enumerate}
\item Id. at 26.
\item Id.
\item Id. at 40.
\item See id. at 34.
\item Id. at 40.
\item Chevron U.S.A. v. Natural Resources Defense Council, 467 US 837, 844 (1984). In the absence of conflicting Congressional language, the courts should defer to an agency and give its interpretation of a rule or policy controlling weight unless it is arbitrary, capricious, or manifestly contrary to the underlying statute.
\item Raul, supra note 75, at 36.
\end{enumerate}
\end{footnotesize}
judicial review of agency actions that held both for and against the agency, Raul fails to explain why this does not demonstrate the current system of review is working or why Daubertization is required.\footnote{Id. at 34.}

In response, Thomas McGarity argues against Raul's proposal, claiming that judicial adoption of Daubert when reviewing EPA actions will result in scientifically illiterate judges engaging in their own regulatory policymaking by continually remanding important regulations back to the agency for further development.\footnote{Id. at 25.} He raises three primary concerns. First is the possibility reviewing courts will discount the weight-of-evidence approach used to select appropriate factors for risk calculations, but instead evaluate each underlying study individually.\footnote{McGarity, supra note 10, at 155, 171.} As an example, McGarity noted in Joiner,\footnote{Id. at 172.} a case in which the Supreme Court refined the Daubert concepts, the Court excluded four studies used to suggest cancer causation because none of them could individually support the claim.\footnote{Joiner, 522 U.S. at 147.} His concern is that a study-by-study evaluation would eliminate the use of epidemiological data because real-world confounding factors lead to elevated uncertainty,\footnote{McGarity, supra note 10, at 173.} and also prevent the use of meta-analysis, a statistical approach for evaluating the combined results of various studies as an expanded data set.\footnote{Id.} Instead of improving decision making by using all the information available, the reviewing court could exclude potentially valuable data from consideration.
McGarity’s second concern is that industry will fund “diversionary research” to highlight uncertainty and support claims that agencies studies fail to meet the Daubert standard.\(^{191}\) Having as little faith in the peer review process as Raul, McGarity raises the specter of industry packing advisory boards with sympathetic scientists who could challenge the validity of unfavorable results.\(^{192}\) A third concern is the switch from the presumed deference afforded agency decision to requiring the agency to meet a civil plaintiff’s burden of proof.\(^{193}\) Together, McGarity argues Daubertization of judicial review will inhibit the regulatory process and provide an opportunity for regulated industries to dismantle current regulations.\(^{194}\)

In a recent article,\(^{195}\) Margaret Pak supports the EPA’s position that a response to an RFC is not subject to judicial review.\(^{196}\) While admitting the answer is as yet unsettled,\(^{197}\) she argues review is barred under both of the exemptions of §701(a) of the Administrative Procedure Act (APA).\(^{198}\) Under §701(a)(1), judicial review is not available if precluded by statute.\(^{199}\)

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\(^{191}\) *Id.* at 171. “[Regulated entities] will devote greater resources to sponsoring diversionary research. When adverse scientific studies are published, [they] will hire consultants to fill the scientific literature with critical and contrary commentary that [they] will later cite to support claims that the adverse studies are fatally flawed.”

\(^{192}\) *Id.*

\(^{193}\) *Id.*

\(^{194}\) McGarity, *supra* note 10, at 925.


\(^{196}\) EPA, *IQA Guidelines* at 40.

\(^{197}\) Pak, *supra* note 197, at 733.

\(^{198}\) *Id.* at 734.

evaluating statutes which are silent as to judicial review and have only a sparse legislative history, courts look to whether congressional intent is "fairly discernable" from the statutory scheme as a whole. Pak claims the statutory requirement for each agency to develop its own internal administrative mechanisms for reviewing RFRs, together with statutory silence as to the availability of a judicial mechanism, indicates congressional intent against the possibility of judicial review.

Also, under APA §701(a)(2), judicial review is not available if the agency action is committed to agency discretion by law. Statutes and subsequent regulations indicate such discretion when they are written in such broad terms that there is no law for the courts to apply. In this case, the IQA sets no standards, but defers to the OMB the discretion to develop guidelines for assuring quality. The OMB guidelines further defer to the EPA the responsibly of establishing standards for assuring compliance, and for evaluating its own response. As Congress left it to the OMB and other agencies to both define the key terms of "quality, objectivity, utility, and integrity" and to develop the processes for administrating compliance, Pak argues agency discretion is sufficient to meet the exemption to judicial review under §701(a)(2).

While the issue has not been decided at the appellate level, one federal court agreed the IQA does not provide a mechanism for judicial review of information quality or any avenue for judicial relief.

201 Pak, supra note 197, at 752.
204 Pak, supra note 197, at 744.
205 Id. at 754-55.
206 Id. at 755.
It appears the OMB believes the IQA has not been a successful method for controlling the EPA's use of risk assessment. In January 2006, the OMB released for public comment, and The National Academy of Sciences reviewed, a "Proposed Risk Assessment Bulletin" as part of its ongoing effort to improve the quality of scientific information. Apparently with a goal of taking control away from technical agencies, the OMB proposes a program, under authority of the IQA, where influential risk assessments will require approval by its own Office of Information and Regulatory Affairs, as well as the White House Office of Science and Technology Policy. Even assessments that do not meet the criteria to be considered influential require certification as to compliance with both the OMB bulletin and IQA. It is unclear whether this requirement will merely add another step in the internal review process or be a means of limiting the distribution of unfavorable information. In either case, the OMB attempts to forestall any judicial review of its action by claiming the bulletin is intended only to improve the internal

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207 Salt Institute v. Thompson, 345 F. Supp. 2d 589, 601 (E.D. Va. 2004). In reaching its conclusion, the court held "There is nothing in the IQA that provides a right of action in a court of law for alleged violations of its provisions... The statute also prescribes the process to be followed if a party complains that an agency has failed to adhere to the established guidelines... The language of the IQA reflects Congress's intent that any challenges to the quality of information disseminated by federal agencies should take place in administrative proceedings before federal agencies and not in the courts."


210 Id. at 21-22.

211 Id.
management of the Executive Branch and, as such, does not create any right enforceable at law against the OMB or other agency.\textsuperscript{212}

Interestingly, the technical requirements presented by the OMB show an understanding of the challenges inherent in assessing risk and are in many ways consistent with recommendations previously published by the EPA. While still basing its authority on the IQA, the document has little sound science rhetoric blaming uncertainty on the lack of technical quality.\textsuperscript{213} Following the lead of the EPA’s \textit{Risk Characterization Handbook}, the OMB recognizes uncertainty and the need for relying on assumptions will always be part of the process, but apparently believes that with proper communication, policy makers and the public will understand the outcome.\textsuperscript{214} While this notion may be unrealistic, as even many environmental specialists don’t fully understand all the components of an assessment, attempts at better communication with a non-technical audience should improve the value of assessments to decision makers.

Building on the EPA’s recommendation to identify the possible range of risk, not merely a single risk value,\textsuperscript{215} the OMB seeks to require the identification of a plausible range of risk estimates whenever there is uncertainty.\textsuperscript{216} While this makes sense technically, it will be interesting to see in practice how such

\textsuperscript{212} \textit{Id.} at 26.

\textsuperscript{213} \textit{Id.} at 3.


\textsuperscript{215} \textit{EPA, Risk Characterization Handbook} at 37; \textit{see also} \textit{EPA, An Examination of EPA Risk Assessment Principles and Practices}, at 16.

\textsuperscript{216} \textit{Office of Mgmt. & Budget, Proposed Risk Assessment Bulletin} at 17. “When there is uncertainty in estimates of risk, presentation of single estimates of risk is misleading and provides a false sense of precision. Presenting the range of plausible risk estimates, along with a central estimate, conveys a more objective characterization of the magnitude of the risks. Influential risk assessments should characterize uncertainty by highlighting central estimates as well high-end and low-end estimates of risk. The practice of highlighting only high-end or only low-end estimates of risk is discouraged.”
information will be used in setting or applying regulations. It may be that while risk assessments include such range information, a specific value or values will still be used in decision making. Critically, there are distinct policy differences between the agencies in selecting that value. While the EPA, with the goal of being protective, typically highlights risk at the high end of the range, the OMB specifically discourages this practice, recommending instead focusing on the center of the range. Given that the range of risk estimates may be several orders of magnitude, this can have a significant impact on the final understanding of risk.

The OMB’s effort to take control of risk assessments conducted by federal agencies suffered a serious blow with the release of the National Academy of Science’s review of the proposed bulletin. In its report, the Academy’s National Research Council calls the bulletin “fundamentally flawed,” concludes it cannot be rescued, and recommends that it be withdrawn. Among the Council’s concerns is the OMB’s recommendation to focus on the center of the range of estimated risk because this fails to protect sensitive populations. Another concern is the OMB’s suggestion that clinically apparent health effects be the measure of harm as this ignores the fundamental public-health goal of preventing impairment. The report notes

217 EPA, AN EXAMINATION OF EPA RISK ASSESSMENT PRINCIPLES AND PRACTICES at 20. “In response to both uncertainty and variability, EPA develops risk estimates using default assumptions based on empirical evidence or based on scientifically sound extrapolations. Further, EPA risk assessments are in fact a combination of both high-end and central tendency estimates. Consequently, the resulting risk estimates are expected to be on the high end of the range of risks but within the range of plausible outcomes.”

218 OFFICE OF MGMT. & BUDGET, PROPOSED RISK ASSESSMENT BULLETIN at 17.


220 Id. at 4.

221 Id. at 3.
that while the OMB's stated purpose is to improve the technical quality of risk assessments, implementation of the bulletin will have the opposite effect.\textsuperscript{223} In support of the status quo, the Council strongly recommends that efforts to improve the science of risk assessment be the responsibility of the technical agencies which have the required depth of experience.\textsuperscript{224}

VII. CONCLUSION

This review suggests the IQA has not had a significant impact on the workings of the EPA, at least those visible from the outside. Given the agencies experience in handling public input as part of the normal administrative notice and comment process, it should not be burdened by the relatively few Requests for Correction submitted. A typical response to an RFC is to consider it another public comment. Furthermore, instead of focusing on creating some separate bureaucratic mechanism, the EPA has sensibly integrated the IQA effort into its many technical review and quality assurance programs. What remains to be seen is whether control of the IQA compliance process will stay with the agency, or be taken over by either the OMB or the courts through judicial review.

The IQA has failed to have its predicted effect on the EPA for two primary reasons. First, its proponents' purposeful strategy to define the problem as one of scientific quality, and not policy differences on acceptable risks, makes it easy for the agency to comply by taking advantage of its ongoing quality improvement efforts. Secondly, as the EPA has been dealing with the issues and inherent problems of risk assessment since its inception, and has published countless recommendations and guidance documents on the topic, anti-regulationists might have been naive to believe that major changes could be made based on the 235 words of bureaucratic gobbledygook in the IQA. Or in other words, it is hard to change the direction of an aircraft carrier with a dinghy. Of course

\begin{flushleft}
\textsuperscript{222} Id.
\textsuperscript{223} Id. at 2.
\textsuperscript{224} Id. at 5.
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this could all change if judicial review finds the EPA strategy for dealing with IQA to be inconsistent with the Act, or if the OMB gains greater control of the risk assessment process.

This review suggests there has been little impact on the external working of the EPA. That is not to say information quality and sound science concepts are not being used to slow down regulatory efforts from within. An administration with a reputation of twisting information for its own purposes and of suppressing scientific findings inconsistent with White House ideology has many ways of exercising its influence over an agency. As the real issue is one of policy and not science, it is expected that agency actions will reflect the concerns of the executive branch. Nevertheless, such influence is part of the workings of the administrative state and could be done with or without the IQA.

A problem with focusing on quality instead of policy is that it distracts from efforts to make real improvements in the process. As currently practiced, risk-based methods lead to over-regulation of some high-profile compounds by utilizing overly stringent assumptions, while ignoring others for lack of information. There should be greater focus on the concept of relative risk. This includes consideration of the unintended consequences of attempting to eliminate de minimis risks as well as, promoting improvements in public health as a means of offsetting risks caused by industrial activity. While there will never be complete agreement, the debate should honestly focus on deciding the proper place along the precautionary continuum.

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