

**The Impact of the Data Quality Act on the Consumer Health and Safety Regulatory  
Process: An Analysis of Regulation Outlays**

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## Abstract

An examination of federal consumer safety and health spending on regulatory activity suggests that the little-known Data Quality Act, passed by Congress in 2000, may have had a noticeable impact on the creation and implementation of federal regulations.

This act, which makes it far easier to question scientific evidence used to justify regulations, has altered the regulatory process in several key ways. First, it has created new but vague standards for the acceptability of scientific research used as the basis for federal regulations. Each federal agency is now required to establish its own standards that could be used for evaluating the quality of the data it used to justify a new regulation. Second, it allows any party to challenge the credibility of the scientific evidence used to justify a regulation. Third, it has shifted authority for rule-making away from federal agencies and to the federal courts. And finally, it has made the entire regulatory process more cumbersome and subject to lengthy delays.

The DQA allows industry-sponsored studies to be used to counter the findings of peer-reviewed scientific research. Additionally, it gives the federal courts final authority to determine if scientific evidence is credible and sufficient enough to warrant new federal rules, a power previously held exclusively by government agencies.

Supporters claim that the DQA insures that government action is based on solid and reliable science. Critics, however, charge that this act exploits the fundamental uncertainty found in all scientific research and is a callous attempt to prevent the creation of needed health and environmental protections.

At a minimum, this act will produce additional costs associated with challenges to regulations; it will lengthen the time necessary for the establishment of regulations by adding several new potential obstacles; and if used to its fullest extent, it can be a powerful tool to hinder the development of a broad range of government regulations.

Since the Data Quality Act (DQA) took effect there have been 39 (32 by regulated industries) challenges to federal regulations. Lawsuits under the DQA have been filed by industry groups against the National Institutes of Health, the U.S. EPA, and several other federal agencies. Many of these cases have required some modification to issued regulations. Since the establishment and implementation of the required agency standards increases in regulatory spending outlays appear to have dropped. This may suggest that the act has had a negative impact on regulatory activity, but it is too early to suggest a causal connection.

## **Background**

In late 2000, the U. S. Congress passed a little known act that has created serious obstacles for the federal regulatory process. This act, usually referred to as the Data Quality Act (DQA) and officially known as the Quality Information Act of 2001, was passed as a rider to the 2001 Appropriations Bill without debate or any public or media attention. Despite its obscurity, the DQA has produced a major controversy. Since this act has the potential to significantly hinder federal agencies' efforts to produce a wide range of health and environmental regulations, it has generated widespread opposition from the public health and environmental community.

The DQA requires that all federal agencies base their regulatory actions on information that meets certain standards of quality and objectivity, and more controversial it allows any individual or group to challenge the credibility of scientific information disseminated by the government. This challenge-provision, strongly supported by industry and trade groups, has created considerable concern and apprehension within the federal bureaucracy.

This paper traces the history of the Data Quality Act and examines the political struggle that surrounds it. It identifies the primary participants in the controversy and examines the roles they play. This paper then analyzes the consequences of this act by examining selected case studies and discussing their ramifications. Finally, this paper summarizes the consequences of the DQA and projects its potential future implications.

## **The Antecedent Regulation Battle**

During the 1970s the passage of numerous environmental, health and safety protection laws greatly expanded the regulatory power of federal agencies (Kerwin 1999). While the regulatory power of federal departments, agencies, and bureaus had been a feature of American government since the passage of the Administrative Procedures Act in 1946, the decade of the 1970s witness s dramatic increase in new agencies with an environmental, health, and safety focus (Cohen, Kamieniecki, and Cahn, 2005). The legislation that created these new agencies also typically granted them broad regulatory power. New agencies such as the U.S. Environmental Protection Agency (EPA),and the Occupational Safety and Health Administration (OSHA) were two major examples of newly created agencies that were delegated considerable rule-making authority.

The establishment of this new regulatory force in the federal government motivated impacted industries to mount an aggressive opposition campaigns to the new regulatory power of federal agencies. Commercial-supported groups resisted the imposition of a wide range of regulations on their client industries that required them to alter their practices, change many of their procedures, and incur substantial new expenses. These groups utilized numerous legal and political means to oppose the regulations, but with varying degrees of success.

In the 1980s, in response the expansion of federal regulatory power during the preceding decade, the Reagan administration issued executive orders that added new restrictions to what it perceived as the unbridled regulatory power of the federal bureaucracy. The Reagan

administration's Executive Order 12291 initiated the practice of presidential oversight over the federal regulatory process by requiring that all proposed regulations be reviewed by the Office of Management and Budget (OMB). While in practice this new OMB participation only delayed many regulations, it was intended to insure that rules making reflected presidential priorities and less the wishes of an autonomous bureaucracy (Kerwin 1999).

Some scholars criticized the regulatory process for being overly confrontational by pitting the government against hostile regulated interested groups and instead advocated a face-to-face negotiated approach which an emphasis on bargaining and compromise (Harter 1982). The Congress responded to this and similar suggestions by adopting the Administrative Dispute Resolution Act in 1990, but some participants found the negotiating process cumbersome and does not produce better results (Coglianese 2004).

While individual congressional members frequently expressed concern about the uncontrolled bureaucracy, the U.S. Congress as an institution generally resisted efforts to restrict agency rule-making power until the 1990s. After the election of a Republican majority in 1994, the Congress exhibited a new sympathy toward reducing the discretionary power of federal agencies. The Congressional amendments to the Paper Reduction Act in 1995 was one of several efforts to limit the bureaucratic authority, however, the Congress' failure to authorize funding specifically for regulation review limited its impact.

While the Clinton administration had ordered that unnecessary, flawed and obsolete regulations be eliminated, its reversal of some of the earlier executive orders of the Reagan years indicated a less hostile attitude towards rule-making. Presidential oversight of the regulatory process was clearly less of a priority to the Clinton administration.

While numerous anti-regulation organizations continue to actively press for a less controlling government, there is also considerable political activity that supports increased regulatory activity. Well-organized public health and environmental organizations continue to press for more stringent regulations citing increased public danger from new products. These groups believe that the use of cost-benefit analysis could be used to allow unsafe products to remain on the market (O'Brien 2000). These groups often advocate the use of the "precautionary principle" that would reduce the amount of scientific evidence necessary to justify increased regulations (Raffensperger and Tickner 1999 ). This principle creates a new paradigm for regulatory action that shift the burden of proof from consumers to producers. It holds that a product should not be allowed to be sold until there is substantial evidence that it is safe, instead of the current practice of allowing a product to marketed until it is prove to have unacceptable dangers.

As the new millennium began there was no apparent abatement in what could be described as the "regulations war." Washington continues to be home to numerous anti and pro-regulation organizations trying to influence the future of the regulatory process. The changing partisan makeup of the Congress and the attitudes of the presidential administration continue to have an impact on how agencies conduct their rule-making activity. It is in this atmosphere that the Date Quality Act has emerged as the latest controversy in the continuous debate about the proper role of federal agencies in the regulatory process.

## **The Origins of the DQA**

The passage of the DQA reflected a general anti-regulation mentality that has been prevalent in some quarters of Washington DC since the mid 1990s. A major lobbying effort sponsored by Washington based anti-regulation groups began in the mid 1990 to support the passage of laws that would in effect “regulate the regulators.” This effort was designed to take advantage of the new Republican majority in the U.S. House of Representatives that was already predisposed to support restrictions on the government’s regulatory authority.

The origins of the DQA can be traced directly to the passage of amendments to the Paperwork Reduction Act by the U. S. Congress in 1995. This act, which contained provisions that ordered the White House Office of Management and Budget (OMB) to implement policies, principles, standards, and guidelines to ensure the quality of information used and disseminated by the federal government, went mostly unenforced. Supporters of regulatory restrictions were dismayed with the OMB’s lack of action and claimed it was in noncompliance of law because it was slow in developing the guidelines called for in the 1995 act.

Late in 2000, an anti-regulatory group started a behind the scenes lobbying effort to pass an additional law that would force rapid implementation of the data quality standards called for by the 1995 act. The Center for Regulatory Effectiveness, headed by Jim Tozzi, a former Department of Defense and White House Office of Management and Budget (OMB) employee, was the driving force behind the DQA (Sissell 2005). Tozzi wrote the act’s wording and quietly arranged for it to be added to an appropriation bill by convincing Congresswomen Jo Ann Emerson (R-Mo) to slip the passage into the House version of the 2001 Omnibus Appropriations Act. A similar action was taken in the U.S. Senate by Senator Richard Shelby (R-Ala). It is not clear if any other members of the Congress, or President Clinton who signed the bill, were aware of the existence of the wording when they voted for the appropriation bill. The wording was sandwiched between unrelated topics, which hid it from anyone except a painstakingly careful reader (Weiss 2004).

## **Impact of the DQA**

The two sentence addition to the 2001 Omnibus Appropriations Act that became the DQA required the OMB to develop government-wide standards for data quality in the form of guidelines. It mandated that after the OMB set the guidelines all federal agencies use them to adopt their own more specific standards to ensure and maximize the “quality, objectivity, utility, and integrity” of the information disseminate by the government. Additionally, the text of the DQA allowed any party to challenge the scientific objectivity of any information promulgated by federal agencies and petition for its correction.

The DQA for the first time put a deadline on the OMB and forced rapid implementation of quality guidelines. The change in Presidential administration that occurred after the 2000 election facilitated adherence to the act, and by 2002 the OMB had taken action. It established the initial guidelines, which while lengthy were still subject to interpretation. After the guidelines

were published, all federal agencies were required to issue their own more specific standard within a year. Most federal agencies complied with this deadline and posted their own standards the following year.

Once passed into law and after the standards had been published, the DQA soon attracted the support of numerous anti-regulation interest groups that actively pushed legal action based on its provisions. Within twenty months of its passage, 39 challenges to government information were filed. Most (32) were filed by industries and trade groups that objected to the validity of scientific evidence used as a basis for the regulations that impacted them. Several of these legal efforts have been at least partially successful in modifying regulations.

The larger legal issue involved in this act beyond the ability of private parties to challenge the objectivity information, is who has authority to render judgement on the appeals. Groups have brought the challenges of for lack of adherence primarily to the federal courts. Impacted agencies, however, have contended that any complaint about the validity of information should be submitted directly to them, and that they should have the authority to review the claim and render judgement on the objectivity of the information. At this point in time, however, the issues remains unresolved. So far the groups attempting to use the DQA have gone directly to the federal court system to gain redress. It is this practice that concerns federal agencies the most, and several are now attempting to change this method by claiming that it allows interest groups to tie up regulations in litigation for a substantial time and thus delay implementation of important rules. Ironically, it is the federal courts who will ultimately decided if they or federal agencies have jurisdiction of these challenges.

### **The Previous Criteria of Acceptable Evidence for Regulations**

Critics of the DQA contend that it is designed to exploit unavoidable uncertainty found in all scientific research. In order to justify the creation and enforcement of regulations intended to protect the public's health, the regulatory process has traditionally relied extensively on the findings of scientific research. If several studies had demonstrated that a particular substance or practice produced a measurable danger to the public's well-being, a regulation to limit or prohibit the use of the dangerous activity or product was considered appropriate.

The gold standard for scientific evidence has traditionally been research published in well-established, peer-reviewed scientific and medical journals. The assumption was that only research that had passed a rigorous review of experts in the field would be published in these types of journals. Scientific research, however is never absolutely conclusive. Individual studies can use different methodologies from other similar studies. This frequently produce somewhat different results, even if the general findings are similar. Additionally, many forms of scientific measurement are not precise and can only gauge tendencies or proclivities.

Consequently, building a body of scientific evidence is a long process and never produces complete uniformity. Because of the potential for variations in scientific research findings, agencies have adopted a process of looking at the 'preponderance of evidence.' A conclusion can be drawn even if it is not supported by every investigation, if a preponderance of published

scientific studies continuously produce comparable outcomes that indicate the same conclusion. This has become the generally accepted way to use scientific evidence to determine if a product or practice produced considerable danger to people or the environment. If enough evidence exists than an agency could justify taking regulatory action.

### **The Nature of Environmental Health Regulations**

This method of using the preponderance of evidence has been the accepted justification for the creation of environmental health regulations. Environmental health policy involves protecting the public from exposures to potentially harmful substances. One of the more significant aspects of this type of policy is the establishment of acceptable exposure standards for toxic emissions from consumer goods, such as pesticides, building materials, cleaners, and other petrochemical-based products. Determining the levels of exposure to toxic substances that are considered safe for humans, however, is not a simple task. It typically involves an elaborate process that integrates scientific evidence with economic factors and political deliberations.

Regulatory policy by its very nature forces someone to do something that they would not otherwise do (Dye 1998). Laws and regulations intended to protect people from toxic substances normally require manufacturers to alter their practices in order to reduce toxic emissions from their products. These changes to existing production and distribution methods are usually expensive and time consuming, and are frequently resisted by the manufacturers that produce them in order to avoid additional financial burdens.

Federal and state public health officials have the primary responsibility for creating appropriate standards for human exposure to potentially dangerous substances. These policymakers often encounter considerable difficulty in creating standards because of insufficient scientific evidence and extensive political pressure. Public environmental health policymakers are typically subjected to conflicting demands from commercial interests and patient advocacy groups that have mutually exclusive agendas. Thus, achieving agreements on accepted levels of toxicant agents is often elusive. Moreover, existing procedures for the development of environmental health regulation have certain potential structural weaknesses that raise serious concerns that the well being of the public is not being adequately protected (Powers and McCarty 1997).

Government involvement in the treatment and prevention of environmentally-induced illnesses also illustrates how public health policymakers can encounter major ethical dilemmas that inhibit the creation of effective policy. Environmental health decisions are fundamentally different from many other policy deliberations where rival economic interests battle over the government's direction. Environmental health decisions require policymakers to ponder various courses of action that impact the physical health and even survival of large segments of the public. Human suffering is not easily quantified into economic terms, and is difficult to balance against other societal needs. Environmental health policymaking methods that compare economic costs with the prevention of disabling illnesses, consequently, are interwoven with vexing ethical considerations, which pure scientific data can not resolve.

## **The Debate over the Data Quality Act's Revised Standards for Scientific Evidence**

While the DQA's call for regulations to be based on valid scientific evidence seems to be a reasonable objective, critics claim that it was actually an assault on the ability of the government to protect the health and well-being of the American public. Supporters originally contended that the DQA and other similar measures were necessary to insure that the government acted on "sound science," and didn't issue needless regulations based on opinion-laden and dubious evidence. Critics countered by saying that the desire for objective and transparent scientific information, sounds reasonable but in reality it is another industry-driven attack on the federal government's ability to protect the public from preventable dangers. They feel that this act, by allowing any individual or group to challenge the objectivity of scientific evidence, in fact is a tool that industry groups can use to obscure the overwhelming findings of credible scientific inquiry.

Critics charge that industry and commercial interests, by sponsoring their own research, now have the ability to design studies that are far more lenient in their methodology and may produce unfounded results that conflict with other more reliable investigations. This tactic can be utilized to confuse federal judges, who typically have little scientific background. At a minimum this practice can allow industry-groups to continuously challenge accepted scientific evidence, which could have the effect of delaying needed regulation of dangerous products for years.

### **Court Action: Who Has Authority to Determine the Quality of Information?**

Numerous cases have been filed under the provisions of the DQA since its passage. The Competitive Enterprise Institute (CEI) in 2003, for example, petitioned the White House Office of Science and Technology Policy to cease disseminating a report on global warming. Even though the information was derived from a peer-reviewed scientific journal, the petition contended that the review process had shortcomings and the information was faulty. The CEI filled a law suite that ultimately resulted in a disclaimer being added to the agency report that stated that its findings failed to meet basic standards of the Data Quality Act.

A more important case concerned the Salt Institute, and industry group for salt manufacturers, which sued the National Institutes of Health (NIH) in 2003. In this case the Salt Institute claimed that the information that the NIH made public about the health benefits of reduced salt-intact was based on data that failed to meet the guidelines of objectivity, reliability, and transparency, and thus violated the Data Quality Act. While the U.S. District Court (Eastern District of Virginia) rejected its claim, it was appealed to the federal Circuit Court of Appeal, and is still pending.

Another industry-backed group, the Center for Regulatory Effectiveness, in 2003, used the DQA to object to the validity of peer-reviewed scientific studies that the US Environmental Protection Agency used to prohibit Atrazine, a widely used herbicide (Sass and Devine 2004). Numerous studies had shown that Atrazine had unacceptable levels of toxicity and posed significant dangers to the environment, but the suite filed by this group claimed that the evidence was unreliable and additional testing was needed. An industry-sponsored study (not peer-reviewed) showed that the herbicide was not as toxic as previously determined. The EPA reviewed the industry study and concluded that it had a flawed research design and that it

overlooked key information. The industry group, rejected this finding and filed with the federal Courts, where action is still pending.

### **Regulatory Agency Spending**

A analysis of budgets figures from 17 agencies with consumer safety and health focus was conducted by the Weidbaum Center of Washington University, St. Louis (Brito and Warren, 2007). It can help illustrates the potential impact of the DQA on the regulatory process. Data was collected from the Consumer Product Safety Commission; The Department of Agriculture's Animal and Plant Health Inspection Service; Food Safety and Inspection Service; Grain Inspection, Packers and Stockyards; Risk management Agency. The department of Health and human Service's Food and Drug Administration; The Department of Housing and Urban Development's Consumer Protection Programs; office of Lead Hazard Control and Healthy Homes; Office of Federal Enterprise Oversight; the Department of Justices' Drug Enforcement Administration; Alcohol, Tobacco, Firearms and Explosives; the Department of the Treasury's Alcohol, and Tobacco Tax and Trade Bureau; Chemical safety and hazard Investigation Board; and Federal Mine safety and Health Review Committee.

The data reveled that outlays on regulatory activity for these agencies had consistently grown from 1960 to 2006 reaching its highest point in 2006 with a budget outlay of \$6,139,000,000. However, in 2007 the amount dropped to \$5,729,000,000. This is the same period when the full impact of the DQA began to be experienced by these agencies. It is impossible to demonstrate if this reduction is in any way a causal result of the DOA and much of this drop could be merely a co-occurrence, however, it is a potential association that will be worth observing in future budgets.

### **Consequences of the DQA**

The DQA is still evolving and it may be years before its final impact is known, however, certain things have become clear during its early stages. The cases sited above illustrate that new legal parameters will need to be set to determine the scope and nature of the DQA. It is apparent that in just five years the DQA has already had a significant influence on the federal regulatory process. The DQA is undisputedly a powerful device that can be used by regulated industries to confront the regulatory system. It has benefitted regulated industries in several ways. First, it allows a challenge on virtually every regulation issued by the federal government. Second, it gives additional credibility to industry-sponsored scientific research, which previously carried little weight in determining the preponderance of evidence used to justify regulatory action. And third, it removes authority from federal agencies and their trained experts, and shifts it to legally trained, but nonscientific schooled judges in the federal judiciary.

The provision of the DQA that allows anyone to challenge the evidence used to justify regulations has created new legal obstacles for federal agencies, which at a minimum are time consuming and add additional legal expenses. Additionally, the DQA may also pave the way for a continuous use of unreliable industry-sponsored scientific studies to be used as the bases to challenge credible scientific evidence. Ironically, this is the opposite of the stated intention of this act, which was designed to insure the use of objective data in the creation of regulations. In its current use, it allows the preponderance of scientific evidence to be continuously challenged

in court. And its acceptance of industry-sponsored research offered in opposition to peer-reviewed scientific studies, in the minds of many scientists and agency personnel, dilutes the credibility of the regulatory process. Moreover, its potential granting of authority over regulations to the courts is a serious shift of power away from federal agencies. Federal judges may be called upon to render rulings on the validity of scientific evidence, which previously was the domain of government scientists. All of these developments that are the direct result of the DQA raise serious questions about the future effectiveness of the federal regulatory process.

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