Federal Regulatory Reform: An Overview

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Prepared for Members and Committees of Congress
### Federal Regulatory Reform: An Overview

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Federal Regulatory Reform: An Overview

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Federal Regulatory Reform:
An Overview

Summary

Over the past several decades there have been numerous attempts in Congress and elsewhere to modify the federal rulemaking process. Underlying many of these “regulatory reform” efforts is a perceived need to reduce the burden associated with regulatory compliance. Proponents of reform contend that federal regulations are too costly, time consuming, complex, and intrusive for businesses and other regulated parties, and that better crafted rules can be developed through, among other things, the use of sophisticated analytical tools and greater oversight by the President and Congress. On the other hand, some contend that these reform efforts focus too much on the costs of regulations and do not adequately recognize the benefits that the rules provide. They also argue that additional requirements will have the effect of eroding existing regulatory protections or lengthening an already lengthy rulemaking process, thereby depriving the public of needed health, safety, and environmental improvements.

The purpose of this report is to provide Congress with a broad overview of significant congressional and presidential regulatory reform efforts within the past 20 to 30 years. Those efforts have generally centered on one or more of the following themes or categories: (1) requirements that agencies use various forms of regulatory analysis (e.g., cost-benefit analysis, cost-effectiveness analysis, and risk assessment) when developing regulations; (2) the development of presidential or congressional offices or procedures for the external review of agencies’ rules; (3) the development of regulatory accounting statements reflecting the costs and benefits of all agencies’ rules, possibly leading to the development of a regulatory budget; (4) efforts to encourage agencies to use alternatives to traditional “command and control” regulations, such as market incentives and performance standards; (5) the imposition of moratoriums on the development of new regulations, particularly at the change of presidential administrations; (6) “look back” reviews of agencies’ existing rules to determine whether they should be revised or eliminated; (7) reforms focusing specifically on paperwork burden; (8) reforms focusing on small businesses and other small entities; (9) efforts to improve the quality of information used in rulemaking or disseminated to the public; (10) the use of information technology to improve public participation in rulemaking and regulatory transparency; and (11) other regulatory reform efforts (e.g., to ensure that agencies recognize the effects of their rules on federalism and private property rights). Some of these initiatives have been adopted, while others have not.


This report will be updated if significant changes to the federal regulatory process are proposed.
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Federal Regulatory Reform: An Overview

Introduction

Federal regulation can be defined broadly as requirements, directives, standards, or procedures, backed by the use of penalties or other sanctions, intended specifically to modify the behavior of state and local governments, private institutions, businesses, and individuals. Regulations generally start with an act of Congress and are the means by which statutes are implemented and specific requirements are established. The terms “rule” or “regulation” are often used interchangeably in discussions of the federal regulatory process. The Administrative Procedure Act (APA) of 1946 defines a rule as “the whole or part of an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy.” The procedures that federal agencies are required to follow in writing regulations is called the rulemaking process. (For a description of the federal rulemaking process and the statutes and executive orders that govern that process, see CRS Report RI32240, Federal Rulemaking Process: An Overview, by Curtis W. Copeland.) Although the term “regulatory reform” can refer to efforts to deregulate certain industries (e.g., airlines or telecommunications), in this report the term refers to efforts to change the rulemaking process.

Origins of Regulatory Reform

The federal government has regulated economic activity since the nation was formed. For example, in the late 1700's, Congress gave the president the authority to develop regulations that set duties on foreign goods and to determine who traded with Indian tribes. Subsequently, economic regulation often occurred as a result of historical events and was often implemented through independent regulatory agencies established separate from executive departments and independent agencies. For example, Congress created the Interstate Commerce Commission in 1887 in response to public dissatisfaction with the railroad industry. The Securities and Exchange Commission was created in 1934 to address fraud and corruption in the securities and financial markets.

2 As used in this report, the term “independent regulatory agencies” refers to the boards and commissions identified as such in the Paperwork Reduction Act (44 U.S.C. 3502(5)), including the Federal Communications Commission, the Federal Energy Regulatory Commission, the Nuclear Regulatory Commission, and the Securities and Exchange Commission. The term “independent agencies” refers to other agencies that answer directly to the President, but are not part of Cabinet departments (e.g., the Environmental Protection Agency).
In contrast, social regulation in such areas as environmental quality, workplace safety, and consumer protection is a relatively recent phenomenon. Beginning in the 1960s, a number of new statutes were enacted in those areas, including the Clean Air Act and the Clean Water Act, the Toxic Substances Control Act, the Resource Conservation and Recovery Act, the Occupational Safety and Health Act, the Truth in Lending Act, and the Consumer Product Safety Act. Those and other statutes, reorganization plans, and executive orders created new regulatory agencies such as the Environmental Protection Agency (EPA), the Occupational Safety and Health Administration (OSHA), the National Highway Traffic Safety Administration (NHTSA), and the Consumer Product Safety Commission (CPSC).

By the late 1970's, an array of federal economic and social regulations were in place that affected many of the decisions made by American businesses. Strong concerns then began to be raised about whether the benefits that these regulations and regulatory agencies were attempting to achieve were worth the costs associated with compliance. Concerns were also being raised about the cumulative effects of all federal regulations on individual businesses. In 1980, President Reagan was elected on a platform critical of government's role in society in general and of federal regulations in particular. During his administration, substantial changes were made in how federal agencies develop and publish rules, and in the degree to which federal regulations were overseen by the Executive Office of the President. Each subsequent President has also made changes in the regulatory process a focus of activity within his administration, imposing moratoriums on new rules, attempting to focus on results, or trying to reduce regulatory burden or "red tape." Congress has also made several attempts to reform the rulemaking process, enacting such statutes as the Paperwork Reduction Act of 1980, the Regulatory Flexibility Act of 1980, the Unfunded Mandates Reform Act of 1995, and the Small Business Regulatory Enforcement Fairness Act of 1996. (Each of these statutes is discussed later in this report.) Additionally, Congress passed legislation deregulating specific sectors of the economy (e.g., airlines, telecommunications). Other efforts in the mid-to-late 1990s to enact more comprehensive regulatory reform bills were not successful.3

Proponents of regulatory reform contend that federal regulations are often too costly, time consuming, and intrusive. They argue that the public and private resources needed to address problems in health, safety, and environmental areas are limited, and that these resources must be allocated more efficiently to address the greatest needs of society in the most cost-effective manner, and that the costs of regulations should not exceed the benefits. They also contend that the existing regulatory system tends to be overly risk averse, and question a perceived lack of stringent analytical guidelines in the methodology used to assess risk hazards as well as costs and benefits when developing regulations. Reform proponents also contend that the scientific and technical information underlying regulations is often of poor quality. These perceived shortcomings, they argue, result in rules that are not well designed and that impede economic growth and development.

3 See, for example, S. 343, the Comprehensive Regulatory Reform Act of 1995, in the 104th Congress; S. 981, the Regulatory Improvement Act of 1997, in the 105th Congress; and S. 746, the Regulatory Improvement Act of 1999, in the 106th Congress.
Others, however, have expressed concerns regarding regulatory reform efforts, and believe that at least some of the reforms focus too much on regulatory costs and do not adequately recognize the benefits that federal regulations provide to the public. They argue that the real motivation behind many of the reforms is a relaxation or roll-back of regulatory requirements and a reduction in the costs associated with regulatory compliance, not improvements in net benefits, cost effectiveness, or information quality. They also maintain that the addition of new analytical or procedural requirements to the rulemaking process would have the intended or unintended effect of blocking new regulations and reducing the ability of regulatory agencies to safeguard the public’s health and safety and to protect the environment in a timely manner.

Several factors make it difficult to resolve these disputes regarding the need for regulatory reform. First, the contending parties often represent vastly different interests and constituencies, with business groups often advocating for reforms (in the hope that regulations will be less burdensome) and environmental groups often resistant to those efforts. Second, the empirical information needed to permit science or economics to resolve those differences of opinion regarding the need for regulation or the best way to regulate is rarely available, requiring decision makers to use assumptions or judgement to make public policy determinations. Finally, resources are rarely available for regulatory agencies to systematically examine the implementation of their regulations and to determine whether they should be continued without change, strengthened, altered to reduce compliance costs, or eliminated entirely.

Themes in Regulatory Reform

This report provides a broad overview of significant congressional and presidential regulatory reform efforts within recent decades. Those efforts encompass a wide range of issues and constituencies, ranging from how agencies design regulatory requirements to the review and possible elimination of those requirements after they have been put in place. The report is not intended to be a comprehensive summary of all regulatory reform initiatives, focusing instead on general themes that seem to underlie many of them. In general, efforts to reform the regulatory process seem to have focused on the following areas:

- requirements that agencies use various forms of regulatory analysis when developing regulations, including cost-benefit analysis, cost-effectiveness analysis, and risk assessment;

- the development of offices or procedures within the Executive Office of the President and the Congress for the external review of agencies’ rules;

- the development of regulatory accounting statements reflecting the total costs and benefits of agencies’ rules, and ultimately the development of a regulatory budget;
• efforts to encourage agencies to use alternatives to traditional "command and control" regulations;

• the imposition of moratoriums on the development of new regulations, particularly at the change of presidential administrations;

• reviews of agencies’ existing rules to determine whether they should be revised or eliminated;

• reform efforts focusing specifically on paperwork burden;

• reform efforts focusing specifically on small entities;

• attempts to ensure the quality of the information used to develop rules or otherwise disseminated to the public;

• efforts to increase the use of information technology in rulemaking to improve public participation and regulatory transparency; and

• other reform initiatives (e.g., efforts to protect property rights and the rights of state and local governments, and to encourage the use of negotiated rulemaking and plain language).

Regulatory Analysis Requirements

A common (and some would say the primary) concern voiced by proponents of regulatory reform in recent decades has been that the costs associated with regulations often outweigh the benefits that those regulations are intended to provide. Another, and somewhat related, view is that more intelligent regulatory policies could achieve the same social goals (e.g., cleaner environment, safer workplaces) at much less cost (or achieve more ambitious goals at the same cost). To improve the quality and effectiveness of federal rules and minimize burden, regulatory reform proponents have frequently advocated greater use of a range of analytic tools during the rulemaking process, including cost-benefit analysis (sometimes referred to as benefit-cost analysis), cost-effectiveness analysis, and risk assessment.

Cost-benefit analysis, in this context, involves the systematic identification of all costs and benefits associated with a forthcoming regulation, including nonquantitative and indirect costs and benefits, and how those costs and benefits are distributed across different groups in society. A proposed regulatory requirement is judged to pass the “cost-benefit test” if the sum of its anticipated benefits outweighs the sum of its present and future costs in present value terms.

These prospective (also known as ex ante) estimates of benefits and costs that are done before rules are issued are necessarily uncertain and heavily dependent on numerous assumptions. Particularly difficult to quantify are long-term or uncertain effects of rules where subtle interactions between various factors are often not well understood or directly measurable. Cost-benefit analysis is particularly controversial when it seeks to rationalize inherent value trade-offs and to place a value on benefits not traded in the market (e.g., health or lives). Also, as the Supreme Court affirmed in 2001, some statutes prohibit the consideration of costs when setting certain health standards. These concerns notwithstanding, most economists believe that, when used carefully and with adequate data, cost-benefit analysis can be an effective tool in regulatory decisionmaking.

Cost-effectiveness analysis seeks to determine how a given goal can be achieved at the least cost. In contrast to cost-benefit analysis, the concern in cost-effectiveness analysis is not with weighing the merits of the goal, but with identifying and analyzing the costs of alternatives to reach that goal (e.g., dollars per life saved). Cost-effectiveness analysis has been referred to as a "bang-for-the-buck" exercise in which the payoff is measured in health units rather than dollars. It is commonly seen as a better tool than cost-benefit analysis for uncovering cases in which large incremental costs result in minor gains. A disadvantage of this type of analysis is that misjudgments in determining the goal or the budget may go undetected.

Risk assessment, in this context, is the systematic evaluation of the probability of certain hazards occurring and their adverse effects, and can serve as the starting point for regulatory activity and for estimates of regulatory benefits. For example, risk assessment is often used to estimate the expected rate of illness or death in a population exposed to a hazardous chemical. The quality of the analysis depends on the adequacy of the underlying data and the validity of the methods and assumptions used. Advocates state that risk analysis may be used as an objective, scientific basis for planning, identifying management strategies to promote risk reduction. Conversely, critics argue that risk analysis is often not entirely objective, in part because of inadequate data regarding the health and ecological effects of most chemicals. Major concerns are that risk analysis may oversimplify problems, that its conclusions can be easily manipulated, and that when used in cost-benefit analyses it may undervalue benefits, especially when projected over time. Another concern is that risk analyses often focus on relatively small risks to the population as a whole, rather than larger risks to smaller groups. These concerns notwithstanding, many

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5 See, for example, Lisa Heinzerling and Frank Ackerman, *Pricing the Priceless: Cost-Benefit Analysis of Environmental Protection* (Washington: Georgetown University, 2002).


8 For example, EPA concluded that the full set of basic toxicity data was available for only about 7% of approximately 3,000 high-production-volume chemicals. See U.S. Environmental Protection Agency, *Chemical Hazard Data Availability Study: What Do We Really Know About the Safety of High Production Volume Chemicals?* (April 1998).
observers believe that risk analysis, carefully used and supported by adequate data, can be a valuable management tool in developing and directing regulatory programs.\(^9\)

**Presidential Initiatives.** Each President within the past 35 years has required some form of regulatory analysis before rules are published in the *Federal Register*. For example:

- In 1971, President Nixon required agencies to develop a summary of their proposals, a description of the alternatives that they considered, and the costs of those alternatives.

- In 1974, President Ford required agencies to develop an “inflation impact statement” for each major proposed rule.

- In 1978, President Carter required agencies to prepare a regulatory analysis that examined the cost-effectiveness of the alternative regulatory approaches for major rules.

Current cost-benefit analysis requirements in the rulemaking process are primarily traceable to President Reagan’s Executive Order 12291, issued in February 1981.\(^10\) Under that executive order, covered agencies (those other than independent regulatory agencies) were generally required to (1) refrain from taking regulatory action “unless the potential benefits to society for the regulation outweigh the potential costs to society,” (2) select regulatory objectives to maximize net benefits to society, and (3) select the regulatory alternative that involved the least net cost to society. The order also required covered agencies to prepare a “regulatory impact analysis” for each “major” rule, which was defined as any regulation likely to result in (among other things) an annual effect on the economy of $100 million. Those analyses were required to contain a description of the potential benefits and costs of the rule, a description of alternative approaches that could achieve the regulatory goal at lower cost (and why they weren’t selected), and a determination of the net benefits of the rule.

These analytical requirements remained in place until September 1993, when President Clinton issued Executive Order 12866.\(^11\) The new executive order, which is still in effect, revoked Executive Order 12291 but established analytical requirements that are similar (although not identical) to those it replaced. For example, regulatory principles under Executive Order 12866 include adoption of regulations only upon a “reasoned determination that the benefits of the intended

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\(^9\) For a more in-depth discussion, see CRS Issue Brief IB94036, *The Role of Risk Analysis and Risk Management in Environmental Protection*, by Linda-Jo Schierow.


regulation justify its costs"\textsuperscript{12} and tailoring regulations to impose the least burden on society needed to achieve the regulatory objective. The order also requires a cost-benefit analysis for all "economically significant" rules (essentially the same as "major" rules under Executive Order 12291) containing an assessment of the anticipated costs and benefits of the regulatory action and an assessment of the costs and benefits of alternatives to the regulatory action (with an explanation of why the planned action is preferable).

In January 1996, the Office of Management and Budget's (OMB) Office of Information and Regulatory Affairs (OIRA) published a document that described "best practices" for preparing the economic analyses called for by the executive order.\textsuperscript{13} In essence, the best practices document said that the analysis should (1) clearly state the need for the proposed action (e.g., market failure) and make clear why federal regulation (as opposed to other methods such as state regulation or subsidies) is the appropriate solution, (2) clearly show that the agency considered the most important alternative approaches (e.g., performance-oriented standards or market incentives), and (3) assess the incremental costs and benefits of the proposed action (taking into account such factors as the appropriate baseline and the use of discount rates when benefits and costs occur at different times). The best-practices document also stated that cost-effectiveness analysis should be used where possible to evaluate alternatives, and says that estimating the benefits and costs of risk reducing regulations requires a risk assessment that, in part, characterizes the probabilities of occurrence of outcomes of interest.

The General Accounting Office (GAO) and others have examined agencies' economic analyses of rules under the executive order and the 1996 best practices guidance.\textsuperscript{14} Several of the studies indicated that the agencies' analyses are not always consistent with the requirements in the order or the guidance. For example, in 1998 GAO reported that some of the 20 economic analyses that it examined did not discuss alternatives to the proposed regulatory action and, in many cases, it was not clear why the agencies used certain assumptions.\textsuperscript{15} Also, five of the analyses did not discuss uncertainty associated with the agencies' estimates of benefits or costs or document the agencies' reasons for not doing so. Other studies have criticized agencies for not

\textsuperscript{12} As previously mentioned, the standard in Executive Order 12291 was that regulatory benefits "outweigh" costs, not just that there be a "reasoned determination" that they "justify" those costs.

\textsuperscript{13} This "best practices" document was developed by an interagency group co-chaired by the Administrator of OIRA and a member of the Council of Economic Advisors. The document was revised and issued as guidance in 2000. To view a copy of the best practices document, see [http://www.whitehouse.gov/omb/inforeg/riaguide.htm]. As noted later in this report, this document and the 2000 guidance was later replaced by OMB Circular A-4.


providing quantitative information on net benefits in their analyses. Still other studies have examined the accuracy of agencies’ regulatory cost estimates, often concluding that costs are overestimated.

GAO and others have also examined agencies’ use of risk assessment in regulation. In 2001, GAO described selected agencies’ chemical risk assessment procedures, noting (among other things) that the statutory and legal context in which the assessments are conducted and how the agency plans to use the information play an important role in determining why certain risk assessment approaches are used. For example, some statutes require regulatory decisions to be based solely on risk, while others require standards to be based on the “best available control technology.” In general, GAO concluded that the agencies followed the four-step risk assessment process recommended by the National Academy of Sciences in 1983. The report also indicated that assumptions are an unavoidable part of risk assessment because science cannot always provide definitive answers to questions raised at various stages of an assessment.

President George W. Bush retained the general analytical requirements in Executive Order 12866. In September 2003, though, OMB and the Council of Economic Advisors finalized new guidance on regulatory analysis, refining and replacing the 1996 best practices document. Among other things, the new guidance (which has been formally issued as “OMB Circular A-4, Regulatory Analysis”) (1) places more emphasis on cost-effectiveness analysis as well as cost-benefit analysis, (2) requires formal probability analysis of future rulemakings with more than a $1 billion impact on the economy, and (3) requires more systematic evaluation of qualitative as well as quantified costs and benefits. The new guidance took effect on January 1, 2004, for regulatory analyses in support of proposed rules, and takes effect on January 1, 2005, for analyses in support of final rules. Industry groups have been generally supportive of the new guidance, but public advocacy groups have expressed concerns that it may result in less regulation protecting public health and the environment.

In addition to the broadly applicable analytical requirements in Executive Order 12866 and related guidance, a number of other presidential actions have required

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20 To view a copy of OMB Circular A-4, see [http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf].
analyses of regulations for particular purposes. For example, Executive Order 13132 on “federalism” requires agencies to prepare a “federalism summary impact statement” whenever they issue a rule that has “significant federalism implications.”21 The order goes on to say that the assessment is to contain “a description of the extent of the agency’s prior consultation with State and local officials, a summary of the nature of their concerns and the agency’s position supporting the need to issue the regulation, and a statement of the extent to which the concerns of State and local officials have been met.” Other executive orders specifically require agencies to assess the effect of their rules on children and on energy supply, distribution, or use. However, most of these orders give agencies substantial discretion to determine when the analytical requirements are triggered.

**Congressional Initiatives.** Congress has also required federal regulatory agencies to analyze the effect of their rules before they are issued. Some of the requirements are potentially applicable to a range of regulations while others are focused on particular types of rules. Perhaps the broadest of these requirements are in Title II of the Unfunded Mandates Reform Act (UMRA) of 1995 (2 U.S.C. 1532-1538).22 Before promulgating a rule containing a mandate that may result in the expenditure of $100 million or more by the private sector or state, local, and tribal governments in the aggregate, UMRA requires agencies (again, other than independent regulatory agencies) to prepare a written statement containing a “qualitative and quantitative assessment of the anticipated costs and benefits...as well as the effect of the Federal mandate on health, safety, and the natural environment.” These requirements are not triggered, though, if the agency issues a final rule without a previous notice of proposed rulemaking. (About half of all final rules do not have a prior proposed rule.) Also, as GAO pointed out in a 1998 report, the UMRA’s analytical requirements do not apply to most economically significant rules, give agencies substantial discretion regarding their implementation, and do not require much more than is already required in Executive Order 12866.23

Other statutory analytical requirements have been enacted with regard to particular issues or constituencies, such as the environment or small entities. For example, the National Environmental Policy Act (NEPA) of 1969 (42 U.S.C. 4321-4347) requires all federal agencies to include in every recommendation or report related to “major Federal actions significantly affecting the quality of the human environment” a detailed statement on the environmental impact of the proposed action. The environmental impact statement must delineate the direct, indirect, and cumulative effects of the proposed action. Agencies are also required to include in the statement (1) any adverse environmental effects that cannot be avoided should the proposal be implemented, (2) alternatives to the proposed action, (3) the relationship between local short-term uses of the environment and the maintenance and enhancement of long-term productivity, and (4) any irreversible and irretrievable

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22 Title I of UMRA contains requirements applicable to congressional consideration of bills containing mandates. For a more complete discussion of UMRA, see CRS Report RS20058, Unfunded Mandates Reform Act Summarized, by Keith Bea and Richard S. Beth.
commitments of resources that would be involved if the proposed action should be implemented. The adequacy of an agency's environmental impact statement is subject to judicial review.

The Regulatory Flexibility Act (RFA) of 1980 (5 U.S.C. 601-612) requires federal agencies to assess the impact of their forthcoming regulations on "small entities," which the act defines as including small businesses, small governmental jurisdictions, and certain small not-for-profit organizations. The RFA requires the analysis to describe, among other things, (1) the reasons why the regulatory action is being considered; (2) the small entities to which the proposed rule will apply and, where feasible, an estimate of their number; (3) the projected reporting, recordkeeping, and other compliance requirements of the proposed rule; and (4) any significant alternatives to the rule that would accomplish the statutory objectives while minimizing the impact on small entities. The RFA's analytical requirements are not triggered, though, if the head of the issuing agency certifies that the proposed rule would not have a "significant economic impact on a substantial number of small entities." The RFA does not define "significant economic impact" or "substantial number of small entities," thereby giving federal agencies substantial discretion regarding when the act's analytical requirements are triggered. Also, as in UMRA, the RFA's analytical requirements do not apply to final rules for which the agency does not publish a proposed rule. GAO has examined the implementation of the RFA several times within the past 10 to 15 years, and a recurring theme in GAO's reports is the varying interpretation of the RFA's requirements by federal agencies. In 2001, GAO testified that the promise of the RFA may never be realized until Congress or some other entity defines what a "significant economic impact" and a "substantial number of small entities" mean in a rulemaking setting.

In the mid-to-late 1990s, Congress considered several comprehensive regulatory reform legislative proposals that were intended to increase or improve the use of cost-benefit analysis, cost-effectiveness analysis, or risk assessment by federal agencies. The bills' particular requirements varied substantially, but all of them would have generally required federal agencies to analyze risks as well as costs and benefits when developing major rules. Some of the bills would have also required a cost-effectiveness analysis, and some required specific studies of how the rules would effect small businesses. Most of the bills would have required that benefits justify costs or that the agency select the most cost-effective alternative. On the other hand, most of the bills (particularly those in the 105th and 106th Congress) also indicated that these analytic requirements and decision criteria would not supersede the provisions in existing law (e.g., the Clean Air Act or the Safe Drinking Water Act)


regarding whether, and if so, how agencies should weigh costs and risks in developing regulations.\textsuperscript{27} One of the most controversial aspects of some of these bills were provisions that would have made agencies' cost-benefit analyses and risk assessments subject to judicial review. If these analyses were found to be deficient, the rules on which they were based could have been reversed.\textsuperscript{28} Some expressed concerns that the courts were ill-equipped to assess the quality or importance of such analyses to the underlying rules, and also indicated that the judicial review process could prohibit the speedy adoption of health, safety, and environmental rules. None of these comprehensive regulatory reform bills was enacted.

Bills requiring some type of regulatory analysis continue to be introduced. For example, in the 108\textsuperscript{th} Congress, H.R. 338 (the "Defense of Privacy Act") would, if enacted, require agencies to prepare and make available to the public a "privacy impact analysis" describing the effect of the rule on the privacy interests of individuals. The bill specifies that the analysis should describe the extent to which the rule provides notice of the collection of personally identifiable information, allows access to and permits correction of that information by those individuals, and provides security for the information. As in UMRA and the RFA, though, the analysis is not required if the agency issues a final rule without an associated proposed rule.

**Presidential and Congressional Review of Rules**

Other regulatory reform initiatives have established systematic processes by which agencies regulations are scrutinized by oversight bodies outside of the rulemaking agencies. Such oversight bodies and review processes have been established for both the President and the Congress.

**Presidential Initiatives.** As was the case regarding the previously mentioned analytic requirements, every President in recent decades has established some type of process within the Executive Office of the President by which regulatory agencies' rules would be reviewed before their publication in the \textit{Federal Register}. For example:

- President Nixon established a "Quality of Life Review" program in which agencies submitted all "significant" draft proposed and final rules pertaining to "environmental quality, consumer protection, and occupational and public health and safety" to OMB, which then circulated them to other agencies for comment.

\textsuperscript{27} As noted previously, some statutes forbid any consideration of costs in setting a health standard (e.g., national ambient air quality standards under the Clean Air Act). Other statutes establish other requirements (e.g., requiring agencies to regulate to the extent "feasible" or "achievable") whose effect on the use of cost-benefit analysis in decisionmaking is less clear.

\textsuperscript{28} In some cases (e.g., S. 746, the "Regulatory Improvement Act of 1999"), these bills permitted courts to remand or invalidate a rule if an agency had \textit{failed to perform a required analysis}, but could not do so because of the \textit{perceived inadequacy} of the analysis.
• President Ford required agencies to prepare an “inflation impact statement” for each “major” proposed rule before publication, and to send those statements to the Council on Wage and Price Stability for comment.

• President Carter established a “Regulatory Analysis Review Group” to review the economic analyses prepared for certain major rules, and to submit comments during the comment period. He also established a “Regulatory Council” to coordinate agencies’ actions to avoid conflicting requirements and duplication of effort.

According to many observers, the most significant development in this evolution of presidential review of rules occurred in 1981, when President Reagan issued Executive Order 12291. In addition to the previously discussed analytical requirements, the executive order required Cabinet departments and independent agencies to send a copy of each draft proposed and final rule to OMB before publication in the Federal Register, and authorized OMB to review “any preliminary or final Regulatory Impact Analysis, notice of proposed rulemaking, or final rule based on the requirements of this Order.” The scope of this requirement was, therefore, much broader than its predecessors, covering every proposed and final rule developed by the covered agencies, regardless of its significance or subject matter. The review responsibility within OMB was given to OIRA, which had been created by the Paperwork Reduction Act (PRA) of 1980 and whose primary responsibility had been to review agencies’ paperwork requests. After Executive Order 12291 was issued, OIRA also began reviewing the substance of between 2,000 and 3,000 federal rules each year. OIRA’s influence over agencies’ rules under this order was substantial. Unless a rule was required by Congress or the courts, the order allowed OIRA to effectively block the rule’s promulgation until the rulemaking agency responded to its concerns. OIRA’s influence was underscored by its location within OMB—the agency that reviews and approves rulemaking agencies’ budget requests. In 1981, President Reagan also created a “Task Force on Regulatory Relief,” headed by Vice President Bush, whose mission was to review pending regulations, study past regulations with an eye toward revising them, and recommend appropriate legislative remedies. OIRA also supported the work of this task force.

In 1985, President Reagan extended OIRA’s influence even further by issuing Executive Order 12498, which required agencies to submit a regulatory program to OMB for review each year that covered all of their significant regulatory actions underway or planned. This executive order expanded on similar requirements in Executive Order 12291, noting that OIRA could generally return any rule to the issuing agency for “reconsideration” if it was not in the agency’s regulatory program for that year or was “materially different” from what was described in the program.


As a result, OIRA could block the issuance of a rule even if it was otherwise consistent with the requirements in Executive Order 12291.

The expansion of the President’s, and more specifically OIRA’s, role in the rulemaking process via these executive orders and other actions was highly controversial. Members of Congress, public advocacy groups, and others raised a number of concerns, including whether OIRA’s role violated constitutional separation of powers and the effect that OIRA’s review had on public participation and the timeliness of agencies’ rules. In 1983, GAO concluded that the expansion of OIRA’s responsibilities under Executive Order 12291 had adversely affected the office’s ability to carry out its PRA responsibilities, and recommended that Congress consider amending the act to prohibit OIRA from carrying out other responsibilities like regulatory review. Additional concerns focused on the lack of transparency of OIRA’s reviews, specifically whether OIRA had become a clandestine conduit for outside influence in the rulemaking process. In 1987 the National Academy of Public Administration published a report that summarized the criticisms of the OIRA review process as well as the positions of its proponents. Both this report and a similar 1988 report by the Administrative Conference of the United States supported the concept of presidential review of rulemaking, but also offered suggestions to improve the transparency of the process.

Nevertheless, congressional concerns regarding OIRA’s influence on rules and opposition to some of its actions continued. In 1989, President George H. W. Bush’s nominee to head OIRA was not confirmed—in part because of lingering concerns about the office’s previous actions. In response to congressional inaction and because of continuing concerns about the costs of regulations, President Bush established the President’s Council on Competitiveness to review regulations issued by agencies. Chaired by Vice President Quayle, the council oversaw and was supported by OIRA, and reviewed particular rules that it believed would have a significant impact on the economy or particular industries. Many of the Competitiveness Council’s actions were highly controversial, with critics assailing both the effects of those actions (e.g., rolling back environmental or other requirements) and the secrecy in which the council acted.

**Executive Order 12866.** The current process of presidential review of rulemaking was established by President Clinton in 1993 through Executive Order 12866 on “Regulatory Planning and Review.” The executive order revoked Executive Orders 12291 and 12498 and abolished the Council on Competitiveness. While retaining the overall concept of presidential review of draft regulations, the order limited the scope of OIRA’s review to “significant” rules issued by Cabinet departments and independent agencies. The order defined a “significant” regulatory action as one that may, among other things, have a $100 million impact on the economy, create a serious inconsistency with actions by another agency, or raise “novel legal or policy issues arising out of legal mandates.” As a result of this

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limitation, the number of rules that OIRA reviewed fell from between 2,000 and 3,000 each year to between 500 and 700 each year.

Executive Order 12866 differs from its predecessors in other respects as well. For example, the order generally requires that OIRA complete its reviews of proposed and final rules within 90 calendar days, and requires both the agencies and OIRA to disclose certain information about how the regulatory reviews were conducted. Specifically, the order says that agencies should identify for the public (1) the substantive changes made to rules between the draft submitted to OIRA for review and the action subsequently announced, and (2) changes made at the suggestion or recommendation of OIRA. OIRA is also required to provide agencies with a copy of all written communications with parties outside of the executive branch, and to maintain a public log of all regulatory actions under review. The executive order retained a regulatory planning function, but did not explicitly permit OIRA to return rules that were not included in the issuing agency’s plan.33

During the Clinton Administration, concerns were raised that agencies’ rules were not being critically reviewed by OIRA.34 For example, critics pointed out that from 1994 through 2000, OIRA returned only seven rules to the agencies for reconsideration (less than one-half of 1% of the rules the office reviewed), and returned no rules during the last three years of this period. OIRA said that the number of returns was a poor measure of OIRA’s performance, and said it was working with agencies to improve their rules before they were formally submitted. Congress held oversight hearings and legislation was introduced (but ultimately not enacted) that would have codified and strengthened OIRA regulatory review function.

President George W. Bush retained Executive Order 12866 and the review process it delineated. He also nominated John Graham to head OIRA, whose confirmation was highly controversial. Shortly after taking office in July 2001, Graham instituted a number of changes in OIRA’s review practices, including greater use of return letters (21 returns in his first eight months), the issuance of “prompt letters” encouraging agency action in a particular area, an increased emphasis on economic analysis, stricter adherence to the 90-day review period, and improvements in the transparency of the review process. Underlying many of these changes was a shift in how Graham viewed OIRA’s role (i.e., as a “gatekeeper” guarding against the issuance of ill-advised rules) compared with his predecessors during the Clinton Administration (i.e., as a “counselor” to regulatory agencies in the development of their rules). In 2003, GAO completed a major review of OIRA’s regulatory review

33 Specifically, the order required all agencies (here, including independent regulatory agencies) to prepare an agenda of all regulations under development or review and a regulatory plan of the most important significant regulatory actions. Agencies’ agendas and plans are published in the Unified Agenda of Federal Regulatory and Deregulatory Actions.

34 See, for example, Susan E. Dudley and Angela Antonelli, “Congress and the Clinton OMB: Unwilling Partners in Regulatory Oversight?,” Regulation, vol. 20 (Fall 1997), pp. 17-23.
function, describing these and other changes in detail. GAO also reported on the extent to which OIRA’s reviews resulted in rules being changed, withdrawn, or returned to the agency. GAO concluded that although some improvements had been made in the transparency of the OIRA review process during Graham’s tenure, more improvements were needed.

**Congressional Initiatives.** Congressional influence on regulatory agencies and the rulemaking process can take many forms, including drafting legislation specifically delineating the scope of the agencies’ rulemaking authorities, advice and consent regarding nominees to head those agencies, reviews of the agencies’ performance during the annual appropriations process, and hearings on specific regulatory issues. During the late 1970s and early 1980s, Congress also used the “legislative veto” process to overturn some of the agencies’ final regulations. In that process, statutes applicable to several agencies and some programs were written to make final regulations subject to either a one-house or two-house veto before they could take effect. In 1983, however, the Supreme Court held in *Immigration and Naturalization Service v. Chadha* (462 U.S. 919) that a one-house veto of a deportation order by the Attorney General violated the separation of powers doctrine and was therefore unconstitutional. The Court subsequently applied the same logic in rulings regarding two-house vetos and vetos of rules issued by administrative agencies.

**Congressional Review Act.** In March 1996, the statutory provision commonly known as the “Congressional Review Act” (CRA) (5 U.S.C. 801-808) was included as part of the Small Business Regulatory Enforcement Fairness Act (SBREFA). The CRA established expedited procedures by which Congress may disapprove agencies’ rules by enacting a joint resolution of disapproval, with subsequent presentation to the President for signature or veto (thereby avoiding Chadha problems). Under the CRA, before any final rule can become effective it must be filed with each House of Congress and GAO. The act also requires federal agencies to submit to GAO and make available to each House of Congress a copy of any cost-benefit analysis prepared for the rule and a report on the agency’s actions related to the RFA, UMRA, and any other relevant act or executive order. The definition of a “rule” under the CRA is very broad, and the act applies to rules issued by Cabinet departments and independent agencies as well as independent regulatory agencies.

If OIRA considers the issuing agency’s rule to be “major” (e.g., has a $100 million impact on the economy), the agency must delay the rule’s effective date by 60 days after the date of publication in the Federal Register or submission to Congress and GAO, whichever is later. Within 15 calendar days of receiving a major

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37 For a detailed discussion of CRA procedures, see CRS report RL31160, *Disapproval of Regulations by Congress: Procedure Under the Congressional Review Act*, by Richard S. Beth.
rule, GAO is required to provide Congress with a report on the rule assessing the issuing agency’s compliance with the procedural steps required by the various acts and executive orders applicable to the rulemaking process. Although the CRA establishes these special requirements for major rules, the CRA procedures for disapproving regulations apply to all rules, whether or not they are declared to be major.

Within 60 days after Congress receives an agency’s rule, excluding periods when Congress is in recess or adjournment, a Member of Congress can introduce a resolution of disapproval that, if adopted by both Houses and enacted into law, can nullify the rule, even if it has already gone into effect. Congressional disapproval under the CRA also prevents the agency from proposing to issue a “substantially similar” rule without subsequent statutory authorization, but this provision is not intended to vitiate the agency’s power to establish regulations in the area in question.

The CRA provides that Senate action on a disapproval resolution under the Act must occur within 60 days of session after the regulation is submitted, and makes available during that period an expedited procedure intended to ensure that the Senate can take up and vote on the measure before the period expires. The Act establishes no such expedited procedure for the House. If Congress adjourns less than 60 days of session after a rule is submitted, a new 60 day period for disapproval under the Act begins on the 15th legislative day of the next session. If a disapproval resolution is rejected by either House of Congress, the rule can take effect immediately (or as provided by other governing law or rule).

As of March 2004, federal agencies had submitted nearly 34,000 rules to GAO (and presumably, Congress) since the CRA took effect in March 1996, including 535 major rules. Approximately 30 CRA joint resolutions of disapproval have been introduced regarding more than 20 rules, but only one rule has been overturned through CRA’s procedures—OSHA’s ergonomics standard in March 2001. One other rule—the Federal Communication Commission’s rule related to broadcast media ownership—was disapproved by the Senate, but had not been acted upon by the House as of the date of this report.

**Truth in Regulating Act.** Congress attempted to put in place another type of congressional oversight of federal agency rulemaking, but the reform was never implemented. In October 2000, Congress enacted the Truth in Regulating Act (TIRA) (P.L. 106-312), which was intended to improve the quality of the information

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38 GAO’s major rule reports under the CRA can be found on GAO’s Web site at [www.gao.gov]. The reports are located under the “GAO Legal Products” heading, and generally describe (but do not critically evaluate) agencies’ actions under various statutes and executive orders.

that Congress receives about certain rules. Under TIRA, the chairman or ranking member of any committee of jurisdiction could have requested that GAO conduct an in-depth review of an agency's estimate of a proposed or final economically significant rule's costs and benefits, an analysis of the alternatives that the agency considered, and the agency's compliance with relevant procedural and analytical requirements. Federal agencies were required to "promptly cooperate" with GAO in carrying out the act. TIRA established a three-year pilot project (starting in January 2001) that became effective upon the specific annual appropriation to GAO of $5.2 million (or the prorated portion thereof). Congress never provided that appropriation, though, so the three-year pilot project ended in January 2004 without being activated.

Like presidential review, congressional review of regulations is controversial. Proponents of congressional review believe it better ensures that Congress has an opportunity to reject unnecessary, overly intrusive, or excessively costly regulations. Critics argue that congressional review encroaches on agency independence, can politicize rulemaking, delays the timely issuance of regulations, and requires an expertise in subject areas that Congress does not have readily available to it (one of the reasons Congress delegates regulatory authority to agencies in the first place). Proponents respond, however, that congressional review enables Congress (to whom regulatory power is constitutionally given) to make the final decision on the need for specific regulations, and makes regulatory agencies more sensitive to congressional intent and Congress more accountable for regulators' actions. They also argue that the mere presence of a congressional review process can prevent poorly-conceived rules from being developed.

**Regulatory Accounting and Regulatory Budgets**

Regulation, like taxing and spending, is a basic function of government. Unlike taxing and spending, though, the costs that nonfederal entities pay to comply with federal regulations are not accounted for in the federal budget process. Some researchers have estimated those off-budget costs in the hundreds of billions of dollars, and the estimates of aggregate regulatory benefits are even higher.  

Congress decided that it needed more information on regulatory costs and benefits, so for several years it included language in appropriations bills that required OMB to submit annual reports to Congress. Most recently, section 624 of the Treasury and General Government Appropriations Act, 2001, (31 U.S.C. 1105 note), sometimes known as the "Regulatory Right-to-Know Act," put in place a permanent requirement for an OMB report on regulatory costs and benefits. Specifically, it requires OMB to prepare and submit with the budget an "accounting statement and associated report" containing an estimate of the costs and benefits (including quantifiable and nonquantifiable effects) of federal rules and paperwork, to the extent feasible, (1) in the aggregate, (2) by agency and agency program, and (3) by major rule. The accounting statement is also required to contain an analysis of impacts of

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40 See, for example, W. Mark Crain and Thomas D. Hopkins, *The Impact of Regulatory Costs on Small Firms* (Washington: Small Business Administration, 2001). The study estimated the total costs of federal regulations at $843 billion in 2000, of which $497 billion fell on business and $346 billion fell on consumers or governments.
federal regulation on state, local, and tribal governments, small businesses, wages, and economic growth.\footnote{For a discussion of these requirements and other researchers’ efforts to measure regulatory costs and benefits, see CRS Report RL32339, \textit{Federal Regulations: Efforts to Estimate Total Costs and Benefits of Rules}, by Curtis W. Copeland.}

From 1997 through 2001, OMB provided estimates of the total costs and benefits of federal rules, but presented those estimates with strong caveats. For example, in its 1998 report OMB said there was not a professional consensus on how regulatory costs and benefits should be measured, and discussed a number of methodological problems (e.g., determining what costs and benefits would have occurred in the absence of the regulation). OMB’s estimates (particularly of regulatory benefits) varied substantially from year to year,\footnote{For example, OMB’s estimate of regulatory benefits was $298 billion in 1997 and between $260 billion and $3.5 trillion in 1998. By 2000, OMB’s upper-end benefit estimate declined to nearly $1.8 trillion.} and also varied from estimates provided by other researchers.

Since 2001, OMB has not presented cost or benefit estimates for all rules. Instead, the office has reported information for all regulations that it reviewed within a particular time-frame (1) that had costs or benefits of at least $100 million annually and (2) whose costs and benefits had been monetized by either the rulemaking agency or OMB. In its 2002 report, OMB said its decision to present data for only certain rules during a limited time-frame was driven by the inconsistent and increasingly aged nature of many of the studies used to develop aggregate estimates. OMB went on to say that “we do not believe that the estimates of the costs and benefits of regulations issued over ten years ago are reliable or very useful for informing current policy decisions.” Therefore, OMB said that it decided not to provide aggregate estimates “in keeping with the spirit of OMB’s new information-quality guidelines."\footnote{As discussed later in this report, section 515 of the Treasury and General Government Appropriations Act for Fiscal Year 2001, generally known as the “Data Quality Act” or the “Information Quality Act,” amended the Paperwork Reduction Act and directed OMB to issue government-wide guidelines that “provide policy and procedural guidance to Federal agencies for ensuring and maximizing the quality, objectivity, utility, and integrity of information (including statistical information) disseminated by Federal agencies.” OMB issued a final version of those guidelines in February 2002.}

In its September 2003 report, OMB provided estimates of the costs and benefits of 107 regulations that it reviewed during the 10-year period from October 1992 to September 2002.\footnote{To view a copy of this report, see [http://www.whitehouse.gov/omb/inforeg/2003_cost-ben_final_rpt.pdf].} OMB’s estimate of the cost of these rules ranged from $36 billion to $42 billion, and the estimated benefits ranged from $146 billion to $230 billion (all in 2001 dollars). OMB said that it recognized that this information was not a complete accounting of the costs and benefits of all federal regulations, or even for all rules issued during the 10-year period, and said that the total costs and benefits of all federal rules in place “could easily be a factor of ten or more larger than the sum...
of the costs and benefits reported (for the 10-year period).” Nevertheless, OMB said that estimates prepared for rules adopted prior to the 10-year period “are of questionable relevance now.”

**Regulatory Budgets.** In addition to better informing Congress and the public about the costs and benefits of regulations, some observers have suggested using regulatory accounting information to create a “regulatory budget” to improve regulatory accountability and control. A regulatory budget might limit the total volume of regulatory programs, expenditures, and compliance costs, by setting a cap on the compliance costs each agency could impose on the economy. Therefore, an agency proposing to add additional compliance costs would be obligated to remove a commensurate amount of existing cost. Implementing a regulatory budget, however, can present many conceptual and empirical problems, including the scope of regulations to be covered (almost all federal programs involve some degree of regulation, the amount depending to some extent upon one’s definition of “regulation”); the accuracy of cost estimates (direct and indirect, including the impact on firms, industries, and consumers beyond compliance costs); the accuracy of benefit estimates (generally regarded as more difficult to determine than estimating costs); and redundancy or overlap with state and local regulations.

Legislation was introduced in the 108th Congress that could lay the groundwork for regulatory budgeting in the future. H.R. 2432, the “Paperwork and Regulatory Improvements Act of 2003,” would, if enacted, require OMB to designate at least five agencies (including at least EPA and the Departments of Labor and Transportation) as pilot projects in regulatory budgeting for fiscal years 2006 and 2007. The bill provides that the budgets “shall present, for one or more of the major regulatory programs of the agency, the varying levels of costs and benefits to the public that would result from different budgeted amounts.” The bill directs OMB to issue a report by February 2009 on the pilot project and “recommend whether legislation requiring regulatory budgets should be proposed.” During testimony in July 2003 on the bill, OMB suggested reducing the scope of the pilot projects, and clarifying that the budget levels set by OMB were not legally binding.

**Alternatives to Traditional Regulations**

Federal agencies have traditionally issued “command and control” regulations that specify what individuals and firms must do to meet an established standard or goal. For example, environmental regulations may require the use of specific pollution control devices, and inspection systems may require the performance of specific procedures. Although traditional command-and-control regulations are appropriate in some circumstances (and may, in fact, be required by statute), other more market-oriented or performance-based rules may permit the achievement of the regulatory objective at lower cost. Some statutes encourage the use of nontraditional regulatory approaches in specific areas or, more generally, across a range of

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45 In fact, the creation of a regulatory budget was contemplated in section 6(a)(6) of Executive Order 12291 in 1981.

regulations. For example, the Trade Agreements Act of 1979 (19 U.S.C. 2531-2533) requires, where appropriate, the use of performance standards rather than design standards and the consideration of international standards as the basis of domestic standards.

**Emission Trading.** A commonly cited example of the market approach to regulation is emission allowance trading under the Clean Air Act. Title IV of the act allows electric utilities to trade allowances to emit sulfur dioxide with other utilities. After setting the overall reductions in sulfur dioxide emissions to be achieved, Congress defined each source’s specific emissions limits for all sources combined to meet a total emissions cap. Utilities that reduce their emissions below the required levels can sell their extra allowances to other utilities to help them meet their requirements. Otherwise, utilities that exceed their emissions allowances must pay fines that are set at several times the estimated average cost of complying with the emissions limits. Emissions trading has also been used in other environmental programs. For example, the Clean Air Act Amendments of 1990 addressed the use of market-based approaches to attain and maintain the National Ambient Air Quality Standards for other pollutants, particularly ozone. Section 11(a)(2)(A) of the act says that in their implementation plans, states can use “economic incentives such as fees, marketable permits, and auctions of emissions rights” to meet the statutory requirements.

**Information Disclosure.** Another nontraditional approach to regulation involves information disclosure. Specifically, Congress and regulatory agencies may attempt to affect the behavior of regulated entities or others by simply revealing the nature of their actions rather than directly attempting to limit them. The EPA “toxics release inventory” (TRI) program is one of the most established examples of an information disclosure program. The TRI program is essentially a database created through collections of information imposed on businesses in order to inform the public about chemical hazards in their communities. TRI reporting is required by section 313 of the Emergency Planning and Community Right-to-Know Act of 1986 (42 U.S.C. 11001-11050, 11023). The act generally requires certain types of facilities to report the amounts of various toxic chemicals that they release to the environment above certain thresholds, and requires EPA to make this information available to the public. The expectation is that these facilities would reduce their use of these chemicals, thereby avoiding the disclosure requirements. Other examples of regulation by disclosure include food labeling requirements and requirements that medical errors be disclosed. Increased use of information technology could make this form of nontraditional regulation more prevalent in the future. However,

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47 TRI reporting is also required under the Pollution Prevention Act of 1990 (42 U.S.C. 13101-13109, 13106), which added reporting requirements beginning in 1991.


concerns in the wake of the terrorist attacks on September 11, 2001, have also led to restrictions on the disclosure of certain types of information.

**Presidential Encouragements.** In addition to these legislative requirements, most recent Presidents have also advocated the use of alternatives to traditional regulations. For example, in 1980 President Carter directed agencies to find areas where alternative techniques could be used in both existing and new regulatory programs. The President’s Regulatory Council created a project on alternative regulatory approaches, which published a series of guides on those approaches. Presidents Reagan and George H.W. Bush also supported the use of market approaches as an alternative to traditional regulation.

In September 1993, the National Performance Review (NPR), headed by Vice President Gore, published a report to the President containing 384 recommendations intended to make the government work better and cost less. One set of NPR recommendations was directed at improving regulatory systems, including the use of “innovative regulatory approaches” such as performance standards, marketable permits, monetary incentives, and information disclosure. Executive Order 12866 was issued later that month, and one of the “principles of regulation” included in the order was that each agency “shall identify and assess available alternatives to direct regulation, including providing economic incentives to encourage the desired behavior, such as user fees or marketable permits, or providing information upon which choices can be made by the public.” Another executive order principle says each agency “shall identify and assess alternative forms of regulation and shall, to the extent feasible, specify performance objectives rather than specifying the behavior or manner of compliance that regulated entities must adopt.”

OIRA’s September 2003 guidance on economic analysis under Executive Order 12866 recommends that alternatives to traditional regulatory action be explored. For example, the guidance states that performance standards “are generally superior to engineering or design standards because performance standards give the regulated parties the flexibility to achieve the regulatory objective in the most cost-effective way.” The guidance also says that market-oriented approaches that allow for averaging, banking, or trading of credits for achieving emissions reductions beyond the required standards “can be extremely valuable in reducing costs or achieving earlier or greater benefits,” but cautioned that they should not be used if they produce “unacceptable local air quality outcomes (such as ‘hot spots’ from local pollution concentration).” Finally, the guidance says that informational remedies such as rating systems, labeling requirements, and government publications “will often be preferred” when intervention is contemplated to address a market failure caused by inadequate or asymmetric information.

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Moratoriums on New Regulations

Imposing a moratorium on new rulemaking is a technique that has been used to assert control over the rulemaking process, particularly for an incoming presidential administration. For example, on January 29, 1981, shortly after taking office, President Reagan issued a memorandum to the heads of the Cabinet departments and the EPA Administrator directing them to take certain actions that would give the new administration time to implement a “new regulatory oversight process,” particularly for “last-minute decisions” made by the previous administration. Specifically, the memorandum said that agencies should, to the extent permitted by law, (1) postpone for 60 days the effective date of all final rules that were scheduled to take effect during that 60-day period and (2) refrain from promulgating any new final rules. Executive Order 12291, issued a few weeks later, contained another moratorium on rulemaking that supplemented, but did not supplant, the January 29, 1981, memorandum. Section 7 of the executive order directed agencies to “suspend or postpone the effective dates of all major rules that they have promulgated in final form as of the date of this Order, but that have not yet become effective.” Excluded were major rules that could not be legally postponed or suspended, and those that ought to become effective “for good cause.” Agencies were also directed to refrain from promulgating any new final rules until a final regulatory impact analysis had been conducted.

In January 1992, President George H.W. Bush imposed a 90-day moratorium on new regulations in response to criticisms that regulatory burden was increasing rapidly during his administration. The President instructed agencies to identify existing regulations and programs imposing unnecessary regulatory burdens and to develop programs to reduce or eliminate those burdens. Regulations that were issued in response to emergency situations, had statutory or judicial deadlines, dealt with military or foreign affairs, or were related to agency administrative matters were exempted from the moratorium. The moratorium was later extended, and remained in force until the end of the Bush Administration.

On January 22, 1993, the Director of OMB for the incoming Clinton Administration sent a memorandum to the heads and acting heads of Cabinet departments and independent agencies requesting them to (1) not send proposed or final rules to the Office of the Federal Register for publication until they have been approved by an agency head appointed by President Clinton and confirmed by the Senate, and (2) withdraw from the Office of the Federal Register all regulations that had not been published in the Federal Register and that could be withdrawn under existing procedures. The requirements did not apply, however, to any rules that had to be issued immediately because of a statutory or judicial deadline. The OMB Director said these actions were needed because it was “important that President Clinton’s appointees have an opportunity to review and approve new regulations.”

Most recently, on January 20, 2001, Andrew H. Card, Jr., Assistant to President George W. Bush and Chief of Staff, sent a memorandum (often referred to as the “Card memo”) to the heads and acting heads of all executive departments and agencies generally directing them to (1) not send proposed or final rules to the Office of the Federal Register, (2) withdraw from the Office rules that had not yet been published in the *Federal Register*, and (3) postpone for 60 days the effective date of rules that had been published but had not yet taken effect. The Card memo instructed agencies to exclude any rules promulgated pursuant to statutory or judicial deadlines, and to notify the OMB Director of any rules that should be excluded because they “impact critical health and safety functions of the agency.” The memo indicated that these actions were needed to “ensure that the President’s appointees have the opportunity to review any new or pending regulations.”

In February 2002, GAO reported on the delay of effective dates of final rules subject to the Card memo. GAO indicated that 371 final rules were subject to the Card memo, and federal agencies delayed the effective dates of at least 90 of them. As of the one-year anniversary of the Card memo, most of the 90 rules had taken effect, but one had been withdrawn and not replaced by a new rule, three had been withdrawn and replaced by new rules, and nine others had been altered (e.g., different implementation date or reporting requirement). The agencies generally did not permit the public to comment on the delays or changes.

All of these presidential moratoriums on rulemaking have generally exempted regulations issued by independent regulatory boards and commissions, as well as regulations issued in response to emergency situations or statutory or judicial deadlines. Critics claim that moratoriums disrupt the regulatory process and delay the implementation of important regulations. They have also raised concerns about changes in the effective dates of published rules without permitting public comment. In fact, some of the delays and changes initiated by these presidential moratoriums were later overturned by the courts. Supporters, on the other hand, assert that moratoriums help to block undesirable regulations and enable the new administration and federal agencies to revise or eliminate less desirable regulations.

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Reviews of Existing Regulations

Each year, federal agencies issue more than 4,000 final rules, which are then codified in the Code of Federal Regulations. Although most of the attention of regulatory reformers has been focused on new rules, reexamination of the large body of existing rules can reveal that they are no longer needed, or that improvements in the regulatory approach can make the program more effective or less burdensome. Reviews of existing regulations were recommended by the Administrative Conference of the United States, and have been initiated by both recent Presidents and the Congress.

Presidential Initiatives. Most recent Presidents have directed agencies to reconsider their existing regulations. For example, in 1979, President Carter issued Executive Order 12044, which required agencies to review their existing rules "periodically." One of the missions of President Reagan's task force on regulatory relief was to identify existing regulations and recommend changes. During the previously-mentioned moratorium on new rules during the administration of President George H.W. Bush, agencies were instructed "to evaluate existing regulations and programs and to identify and accelerate action on initiatives that will eliminate any unnecessary regulatory burden or otherwise promote economic growth."

Section 5 of Executive Order 12866, issued in September 1993, required agencies to submit to OIRA a plan for periodically reviewing their existing significant regulations to determine whether any should be modified or eliminated. According to the executive order, the purpose of the review is to make the agencies' regulatory programs more effective, less burdensome, or better aligned with the President’s priorities and the principles specified in the order. In its report on the first year's implementation of the executive order, OIRA said this review of existing rules was intended to be “a fundamental reengineering of entire regulatory systems,” not just “tinkering with regulatory provisions to consolidate or update provisions.”

Because of concerns that all agencies were not "taking the steps necessary to implement regulatory reform," President Clinton sent a memorandum to the heads of Cabinet departments and independent agencies in March 1995 directing them to, among other things, conduct a page-by-page review of all their regulations in force and eliminate or revise those that were outdated or in need of reform. In June 1995, the President announced that this effort had resulted in commitments to eliminate 16,000 pages from the CFR. GAO later reported, however, that four agencies’ page elimination totals did not take into account the pages that they had added to the CFR.

56 The Administrative Conference cautioned that such reviews should not be “one-size-fits-all,” but should be tailored to the agencies’ individual needs. For the specific recommendations, see Jeffrey S. Lubbers, A Guide to Federal Agency Rulemaking, 3rd ed. (Washington: American Bar Association, 1998), pp. 274-276.

while the eliminations were taking place. GAO also said that about half of the actions were likely to result in little or no reduction of regulatory burden.

The most recent OIRA-directed reviews of existing rules have involved the general public in the review process. In May 2001, OIRA asked the public to nominate rules that it believed should be modified or rescinded. In response, OIRA received 71 nominations from 33 commentators, and decided that 23 of the rules nominated merited "high priority review." In March 2002, OIRA again solicited public comments on regulations in need of reform, and in response received more than 300 suggestions from about 1,700 commentators, some of which suggested making rules more stringent or developing new rules. This time, OIRA forwarded the suggestions to the relevant federal agencies for review and prioritization. In February 2004, OIRA requested public nomination of promising regulatory reforms relevant to the manufacturing sector. Specifically, OIRA requested that commenters suggest reforms to regulations, guidance documents, or paperwork requirements that would "improve manufacturing regulation by reducing unnecessary costs, increasing effectiveness, enhancing competitiveness, reducing uncertainty and increasing flexibility."

**Congressional Initiatives.** Congress has also directed agencies to review the effects of their existing regulations. Some of these congressionally-initiated review requirements focus on rules issued under specific statutes. For example, section 812 of the 1990 amendments to the Clean Air Act required EPA to provide information about the economic costs and benefits and the health, welfare, and environmental impacts of the Clean Air Act. The 1990 amendments also directed an interagency group to report every four years, beginning in 1996, on the costs, benefits, and effectiveness of the acid rain program.

Other congressionally-directed regulatory reviews are more crosscutting, although still focused on particular types of rules. Section 610 of the Regulatory Flexibility Act requires each federal agency to develop a plan for the review of its existing rules that have or will have a "significant economic impact on a substantial number of small entities." The purpose of this "look-back" review is to determine whether the rules should be continued without change or should be amended or rescinded to minimize their impact on small entities. GAO reported in 1999, however, that regulatory agencies differed in how they interpreted this requirement.

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59 OIRA said it requested the nominations in response to a requirement in section 628(a)(3) of the fiscal year 2000 Treasury and General Government Appropriations Act that required OMB to submit "recommendations for reform" with its report on the costs and benefits of federal regulations.


For example, it was not clear whether agencies are supposed to review rules that currently have an impact on small entities, or those that had that impact at the time the rules were issued. In any event, it was clear that few section 610 reviews were being conducted.

Several of the comprehensive regulatory reform bills that Congress considered (but did not enact) during the mid-to-late 1990s would have required agencies to review virtually all of their existing rules, not just those issued under certain statutes or that affected small entities. For example, the “Regulatory Sunset and Review Act of 1995” (H.R. 994) would have required agencies to review each existing significant rule (and other rules upon request by affected parties or congressional committees) within four to seven years after the bill’s enactment and then to either issue a report continuing the rule or take action to modify, consolidate, or terminate it. Later, the “Regulatory Improvement Act of 1997” (S. 981) would have required agencies to review existing rules identified by an advisory committee representing a balanced cross section of public and private interests. The agencies would have then had to decide whether to retain, amend, or repeal the rules it reviewed.

**Paperwork Reduction Initiatives**

Other regulatory reform initiatives have focused specifically on controlling the paperwork that often accompanies regulations. Many information collections, recordkeeping requirements, and third-party disclosures are contained in, or are authorized by, regulations as monitoring or enforcement tools. In fact, these paperwork requirements are the essence of many agencies’ regulatory provisions. A large amount of federal paperwork is necessary, and is how many agencies carry out their missions. For example, IRS needs to collect information from taxpayers and their employers to know the correct amount of taxes owed. EPA uses information requirements to ensure compliance with its regulations, to evaluate the effectiveness of its programs, and for other purposes. Nevertheless, federal agencies are expected to minimize the paperwork burden that they impose.

**Paperwork Reduction Act.** The most notable of the various reform initiatives to control federal paperwork is the Paperwork Reduction Act (PRA) (44 U.S.C. 3501-3520), which was originally enacted in 1980 but was subsequently amended in 1986 and again in 1995. The original PRA replaced the ineffective Federal Reports Act of 1942, and established OIRA within OMB to provide central agency leadership and oversight of government-wide efforts to reduce unnecessary paperwork and improve the management of information resources. Currently, the act requires OIRA to maintain a government-wide strategic information resources management plan. Such a plan could help ensure that federal paperwork is the

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62 For example, EPA’s Toxics Release Inventory (TRI) program is essentially a database created through collections of information imposed on businesses in order to inform the public about chemical hazards in their communities. TRI reports require businesses in certain industries to report the quantity of any of more than 600 chemicals entering each environmental medium on site, transfers of the chemical in wastes to off-site locations, on-site treatment methods and efficiency, and source reduction and recycling activities.
minimum necessary and is well integrated into agencies' missions and objectives.\textsuperscript{63} GAO reported in February 2002, though, that OMB had not fully developed and implemented an information resources management plan that articulated a comprehensive federal vision for all aspects of government information.\textsuperscript{64}

The PRA also requires agencies to receive OIRA approval (signified by an OMB control number) for each information collection request before it is implemented. Under the PRA's "public protection" provision, no one can be penalized for failing to comply with a collection of information subject to the act if it has not been approved by OIRA within the previous three years. Each year, however, OIRA reports that agencies impose hundreds of paperwork requirements without OIRA approval (although the number of such PRA violations have declined in recent years).\textsuperscript{65} OIRA can disapprove any collection of information (and generally stop any associated regulation) if it believes the collection is inconsistent with the requirements of the PRA.\textsuperscript{66}

The 1995 amendments to the PRA required OIRA to set a goal of at least a 10% reduction in the government-wide burden-hour estimate for each of fiscal years 1996 and 1997, a 5% goal for each of the next four fiscal years, and annual agency goals that reduce burden to the "maximum practicable opportunity." Therefore, if these goals had been met, the amount of federal paperwork would have fallen by 35%--from about 7 billion burden hours at the end of fiscal year 1995 to about 4.6 billion hours at the end of fiscal year 2001. This anticipated reduction did not occur, though. In fact, by the end of fiscal year 2002, the government-wide paperwork estimate stood at more than 8.2 billion hours--a 17% increase since the PRA amendments took effect at the end of fiscal year 1995. The agencies often contend that they cannot reduce their paperwork requirements without changes in their authorizing statutes, many of which require the collection of certain types of information.

Other Paperwork Initiatives. In addition to the PRA, Congress has enacted other statutes in an attempt to reduce or at least control federal paperwork burden. For example, in June 2002, Congress enacted, and the President signed, the Small Business Paperwork Relief Act of 2002 (P.L. 107-198). The act amended the PRA to, among other things, require each agency to establish a single point of contact to act as a liaison for small business concerns with regard to information collection and


\textsuperscript{65} For a summary of this trend, see U.S. General Accounting Office, \textit{Paperwork Reduction Act: Record Increase in Agencies' Burden Estimates}, GAO-03-691T, April 11, 2003.

\textsuperscript{66} Independent regulatory agencies can, by majority vote, void any OIRA disapproval of a proposed collection of information. Also, OIRA disapproval does not overrule a specific statutory requirement that certain information be collected.
paperwork issues. It also directed agencies to make a special effort to reduce information collection burdens for small businesses with fewer than 25 employees, and established a task force to study the feasibility of streamlining information collection requirements on small businesses. The task force delivered its first report in June 2003, and its final report is due in June 2004.

Statutory reforms have been introduced in each Congress in an attempt to address paperwork requirements in particular areas. For example, in the 108th Congress, H.R. 464, the “IDEA Paperwork Reduction Act of 2003,” was intended to “provide relief to teachers, administrators, and related service providers from excessive paperwork burden” required under the Individuals with Disabilities Act. Other bills have focused on such issues as the suspension of fines under certain circumstances for first-time paperwork violations for small businesses.

Initiatives Focusing on Small Entities

A number of regulatory reforms implemented in recent decades have attempted to get agencies to recognize the effect that their rules can have on small businesses and other small entities. Advocates of these initiatives note the important role that small entities play in the economy (e.g., about 50% of the gross domestic product) and point to research indicating that small entities are disproportionately affected by federal regulations. Others indicate, however, that special regulatory treatment of small entities is “both unjustified and socially destructive.”

Although there have been some presidential initiatives in this area, most of the significant rulemaking requirements affecting small entities have been imposed by Congress. As noted previously, the Regulatory Flexibility Act of 1980 requires agencies to examine the effects of their rules on small entities and, if the agency concluded the rule had a “significant economic effect on a substantial number of small entities,” to conduct a regulatory flexibility analysis. The act gives regulatory agencies substantial discretion to decide when these analytical requirements are triggered. Other previously mentioned reforms focusing on small entities include the “look back” requirement in section 610 of the RFA and the requirements in the Small

67 OMB posted compliance assistance resources and points of contact on its Web site at [http://www.whitehouse.gov/omb/inforeg/infocoll.html#sbpra].
68 To view a copy of this report, see [http://www.whitehouse.gov/omb/inforeg/sbpr2003.pdf].
71 For example, Executive Order 13272 on “Proper Consideration of Small Entities in Agency Rulemaking” (67 Federal Register 53461, Aug. 16, 2002), among other things, required agencies to issue written procedures and policies to ensure that the potential impacts of draft rules on small entities are properly considered during rulemaking.
Business Paperwork Relief Act (e.g., a single point of contact for small businesses regarding paperwork).

A number of statutory reforms directed at small entities’ concerns were included in the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA). Perhaps most notably, SBREFA amended the RFA and permitted judicial review of agencies’ compliance with initial and final regulatory flexibility analysis requirements, their use of the “no significant impact” exclusion, and compliance with the “look back” requirement in section 610. (The original RFA prohibited judicial review.) As discussed below, other SBREFA provisions included requirements that agencies develop compliance guides for small entities, provide small entities with penalty relief, permit more equal access to justice, and ensure that small entities’ interests are represented on boards and panels involved in the rulemaking process.

**Compliance Guides and Other Guidance.** Section 212 of SBREFA requires agencies to publish one or more compliance guides for each rule or group of related rules for which the agency is required to prepare a final regulatory flexibility analysis under the RFA. Because this provision in SBREFA was built on the RFA, all of the discretion inherent in the RFA regarding whether to do an analysis also applies to whether compliance guides must be developed. For example, if the agency concludes that the final rule would not, in its opinion, have a “significant” impact on a “substantial” number of small entities, the agency is not required to prepare a compliance guide. When they are prepared, section 212 requires the guides to be published, to be designated as “small entity compliance guides,” and to explain the actions a small entity is required to take to comply with the associated final rule. In other areas, though, section 212 gives agencies broad discretion. For example, the statute says agencies “may” prepare separate guides covering groups or classes of similarly affected small entities, and “may” cooperate with associations of small entities to develop and distribute the guides. Agencies are given “sole discretion” in the use of plain language in the guides, and the statute does not indicate when the guides must be developed or how they must be published. Therefore, under section 212, an agency could develop a compliance guide years after a final rule is published with no input from small entities. In 2001, GAO reviewed agencies’ implementation of section 212 and concluded that the requirement did not appear to have had much of an impact on agencies’ rulemaking actions.\(^2\)

Section 213 of SBREFA requires federal agencies regulating the activities of small entities to establish a program for responding to inquiries concerning compliance with applicable statutes and regulations. The section also says that in any civil or administrative action against a small entity, such guidance “may be considered as evidence of the reasonableness or appropriateness of any proposed fines, penalties or damages sought against such small entity.”

**Penalty Relief.** By the mid-1990s, concerns were being expressed about the impact that civil penalties can have on small businesses and other small entities, particularly for infractions that may be relatively minor in nature. In April 1995,

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President Clinton issued a memorandum directing the heads of 27 departments and agencies to modify the penalties for small businesses "to the extent permitted by law." For example, the memorandum said agencies "shall exercise their enforcement discretion to waive the imposition of all or a portion of a penalty when the violation is corrected within a time period appropriate to the violation in question." The memorandum also directed each agency to submit a plan to the Director of OMB describing the actions the agency would take, and said the plans should identify how notification of the agencies' policies would be given to frontline workers and small businesses.

Similar requirements were included in SBREFA, which was enacted less than a year later in March 1996. Section 223 of SBREFA, entitled "Rights of Small Entities in Enforcement Actions," requires agencies to provide small entities with some form of relief from civil monetary penalties. Specifically, the statute requires federal agencies regulating the activities of small entities to establish a policy or program by the end of March 1997 for the reduction and, under appropriate circumstances, the waiver of civil penalties on small entities. It also required agencies to submit a one-time report to four congressional committees by the end of March 1998 on the scope of their programs or policies and the implementation of their penalty reduction efforts. Section 223 also gave federal agencies substantial discretion in how these requirements were to be carried out. In 2001 GAO examined the implementation of section 223 and determined that the agencies were using that discretion extensively. For example, some of the agencies’ policies covered only certain civil penalty enforcement actions, and some of the policies gave small entities no more penalty relief than large entities. The agencies also varied in how key terms were defined and in their conditions and exclusions. GAO made several recommendations to strengthen penalty relief and improve congressional oversight.

Ombudsman and Fairness Boards. Section 222 of SBREFA amended the Small Business Act (15 U.S.C. 631 et seq.) to require the SBA Administrator to designate a “Small Business and Agriculture Regulatory Enforcement Ombudsman,” who was directed to work with each agency to ensure that small business concerns have an opportunity to comment on agencies’ enforcement actions. The ombudsman was directed to annually evaluate and report on each agency’s enforcement activities, including a rating of the “responsiveness to small business” of each agency’s regional and program offices. Section 222 also required the Administrator to establish a “Small Business Regulatory Fairness Board” in each SBA regional office to report to and advise the ombudsman on “excessive enforcement actions of agencies against small business concerns.

Equal Access to Justice Act Amendments. The Equal Access to Justice Act (28 U.S.C. 2412 and 5 U.S.C. 504) was originally enacted in 1980 to allow certain parties to recover attorney’s fees from the government in civil actions and


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administrative adjudication. Subtitle C (sections 231 and 232) of SBREFA amended this act in three ways: (1) raising the hourly cap on attorneys' fees to $125 per hour, (2) generally permitting eligible parties to claim fees and other expenses related to defending against demands "substantially in excess of the judgment finally obtained" (not just if they prevailed in the case) and, (3) in these "excessive demand" cases, expanding the definition of an eligible party to include small entities as defined in the RFA. 75

Advocacy Review Panels. Section 244 of SBREFA put in place special requirements for proposed rules issued by EPA and OSHA. EPA and OSHA are required to convene "advocacy review panels" before publishing a regulatory flexibility analysis for a proposed rule. Specifically, the agency issuing the regulation (OSHA or EPA) must notify the SBA Chief Counsel for Advocacy and provide information on the draft rule's potential impacts on small entities and the type of small entities that might be affected. The Chief Counsel then must identify representatives of affected small entities within 15 days of the notification. The review panel must consist of full-time federal employees from the rulemaking agency, OMB, and SBA's Chief Counsel for Advocacy. During the panel process, the panel must collect the advice and recommendations of representatives of affected small entities about the potential impact of the draft rule. The panel must report on the comments received and on the panel's recommendations no later than 60 days after the panel is convened, and the panel's report must be made public as part of the rulemaking record. An agency may or may not adopt the panel's recommendations. GAO examined the initial implementation of these requirements and reported that the participants generally agreed that the panels were worthwhile, but suggested several changes to make them work better. 76

Data Quality and Peer Review

A relatively recent emphasis from advocates of regulatory reform has been a focus on the quality of the underlying information that federal agencies use to develop their rules or otherwise disseminate to the public. The most significant development in this area has been the enactment of section 515 of the Treasury and General Government Appropriations Act for Fiscal Year 2001, generally known as the "Data Quality Act" (DQA) or the "Information Quality Act." The DQA amended the Paperwork Reduction Act and directed OMB to issue government-wide guidelines that "provide policy and procedural guidance to Federal agencies for ensuring and maximizing the quality, objectivity, utility, and integrity of information (including statistical information) disseminated by Federal agencies." 77 OMB's


guidelines define “dissemination” as “agency initiated or sponsored distribution of information to the public,” and specifically indicates that this includes risk assessments prepared by an agency to “inform the agency’s formulation of possible regulatory or other action.” The guidelines also define such terms as “quality,” “utility,” “objectivity,” and “integrity.”

The DQA also instructed all agencies (both Cabinet departments and independent agencies as well as independent regulatory agencies) to issue their own guidelines not more than one year after the issuance of OMB’s government-wide guidelines, and to establish administrative mechanisms allowing affected persons to seek and obtain correction of information maintained and disseminated by the agency. The act required agencies to report periodically to the Director of OMB on the number and nature of complaints received and how such complaints were handled by the agency. The first agency reports were due by January 1, 2004.

The DQA builds upon existing agency responsibilities to assure the quality of information collected, used, or disseminated to the public. Proponents of the act contend that the law and the OMB and agency guidelines will improve the quality of agency science and regulation and force agencies to regulate based on the best science available. Some of these proponents also maintain that the act will help agencies defend their regulations against lawsuits and reduce the number of lawsuits filed. They also point out that, in any requests for correction of information, the DQA places the burden of proof on the affected parties making the request; they must demonstrate that a specific dissemination does not meet the standards of either the OMB guidelines or the agency-specific guidelines.

On the other hand, opponents of the act and the guidelines contend they may have a chilling effect on agency distribution and use of scientific information. These opponents foresee a flood of data quality challenges, correction requests, and court suits on a wide range of scientific issues, which may tie up agency resources and significantly delay health, safety, and environmental regulations. Opponents have also noted that, since “quality” is a subjective term and some regulations are based on “best available data,” regulations could be arbitrarily rejected under this new law.

Some observers see judicial review as the crucial test of the act’s future effectiveness, although there does not seem to be any consensus in the legal community as to whether an agency’s response to a data quality challenge is subject

77 (...continued)
22, 2002, p. 8452. To view a copy of these guidelines, see [http://www.whitehouse.gov/omb/fedreg/reproducible2.pdf].
78 Links to agencies' guidelines are available at [http://www.whitehouse.gov/omb/inforeg/agency_info_quality_links.html].
79 For example, Public Law 105-277 (popularly known as the Shelby amendment) directed OMB to revise its Circular A-110 to make data from federally funded research governed by the circular available to the public through the Freedom of Information Act. For a discussion of this requirement, see RL30376, Public Access to Data From Federally Funded Research: OMB Circular A-110 and Issues for Congress, by Eric A. Fischer and Genevieve J. Knezo.
to judicial review. Some clarity on that issue may result from a lawsuit filed on March 31, 2004, by the U.S. Chamber of Commerce and the Salt Institute challenging a federally funded study about the blood pressure effects of dietary salt.\footnote{Salt Institute and the Chamber of Commerce of the United States v. Tommy G. Thompson, Secretary, U.S. Department of Health and Human Services, U.S. District Court for the Eastern District of Virginia, case no. 04-CV-359. A previously filed lawsuit under the DQA was settled out of court.} Judicial review of agencies' rulemaking actions in light of the DQA would be a major development in administrative law, and would represent a significant new way for affected parties to challenge those actions.

**Peer Review.** In a development closely related to the issue of data quality, OMB published a proposed bulletin in August 2003 on “Peer Review and Information Quality” that would, when made final, provide a standardized process by which all significant regulatory information would be peer reviewed.\footnote{Office of Management and Budget, Executive Office of the President, “Proposed Bulletin on Peer Review and Information Quality,” Federal Register, vol. 68, no. 178, Sept. 15, 2003, p. 54023.} The authorities that OMB cited for this action were the DQA, the PRA, and Executive Order 12866. The proposed bulletin defined “peer review” as “a scientifically rigorous review and critique of a study’s methods, results, and findings by others in the field with requisite training and expertise.” “Regulatory information” was defined in the bulletin as any scientific or technical study that “might” be used by federal, state, local, or international regulatory bodies.

Specifically, the bulletin proposed requiring each federal agency (each executive agency and independent regulatory agency) to take three actions: (1) have all “significant regulatory information” that it intends to disseminate peer reviewed (with information defined as “significant” if OMB determines that it will have a clear and substantial impact on important public policies or private sector decisions); (2) have “especially significant regulatory information” subject to the above requirements peer reviewed according to even higher standards (with information deemed “especially significant” if, among other things, it supports a regulatory action with a $100 million or more impact on the economy or “is relevant to an Administration policy priority”); and (3) provide OMB at least once each year with information about upcoming significant regulatory disseminations and the agency’s plans for conducting peer reviews. The proposed bulletin also said agencies that are likely to disseminate “significant” or “especially significant” regulatory information must supplement or amend their data quality guidelines to incorporate the requirements of the proposed peer review bulletin for “significant” and “especially significant” information. The proposed bulletin indicated that OMB could waive the requirements for peer review if an agency makes “a compelling case” that a waiver is necessary (e.g., an imminent health hazard or homeland security threat). The bulletin permitted agencies to retain an outside firm to oversee the peer review process (selecting and supervising the peer review panels), indicating that in doing so the agencies could avoid the requirements of the Federal Advisory Committee Act.
OMB received 187 comments from the public and other agencies on its August 2003 proposed peer review bulletin, with some supporting its issuance in final and others calling for its withdrawal and reconsideration. On April 15, 2004, OMB published a revised bulletin, and again asked the public for comments. The proposed revisions would, if made final, do the following:

- focus the bulletin’s coverage on “influential” scientific information, not just “regulatory” information (because critics said it was hard to determine which information would be used to support regulatory action);

- narrow the scope of the section describing the characteristics of peer review for the most important types of information so that it covers only “scientific assessments” (not all influential information) that, among other things, have a $500 million annual impact (rather than a $100 impact on the economy).

- clarify that regulatory impact analyses are not covered by the bulletin (because they are already covered by OMB Circular A-4), but the models and data underlying them are covered;

- clarify that the bulletin does not cover information products released by government-funded scientists unless it represents an official view of a federal department or agency;

- specify that the responsibility for determining the need for a waiver from the bulletin’s peer review requirements in the event of an emergency or otherwise “compelling need” rests with the agencies;

- provide agencies with greater flexibility (e.g., in determining the appropriate intensity of peer review, when the comments of specific reviewers should be disclosed, and in the use of alternative scientific procedures); and

- clarify that researchers that receive research grants based on “investigator-initiated, peer reviewed competitions” can still serve as peer reviewers.

OMB indicated that the bulletin’s requirements generally applied to information disseminated four months after its publication, except that the requirements regarding peer review planning for “influential” (but not “especially significant”) information applied one year after the publication of such documents.

For a copy of the revised peer review bulletin, see [http://www.whitehouse.gov/omb/inforeg/peerreview041404.pdf]. For a summary of the public and agency comments provided regarding the first bulletin, see [http://www.whitehouse.gov/omb/inforeg/peerreview_comment.pdf]. Copies of the comments can be viewed at [http://www.whitehouse.gov/omb/inforeg/2003iq/iq_list.html].
OMB and supporters of the proposed peer review bulletin indicate that peer review standards across the government are currently inconsistent, and that more consistent use of peer review can increase the technical quality and credibility of regulatory science.\(^8^3\) They also assert that peer review can protect science-based regulations from political criticism and litigation. Opponents view the proposed bulletin as an effort to inject political considerations into the world of science and to use the uncertainty that inevitably surrounds science as an excuse to delay new rules that could cost regulated entities millions or even billions of dollars. They also expressed concerns that the bulletin appears more concerned about peer reviewers’ possible conflicts of interest due to their associations with agencies than associations with regulated industries.

**Electronic Rulemaking**

Federal agencies have recently initiated a number of efforts to use information technology (IT) in their rulemaking and other regulatory processes. The impetus for some of these efforts were congressional or presidential directives to better utilize IT in a range of administrative areas, but many were started at the initiative of career officials involved in the rulemaking process.

**Presidential Initiatives.** In its September 1993 report, the National Performance Review recommended increased use of information technology to increase opportunities for early, frequent, and interactive public participation in the rulemaking process. Shortly thereafter, an interagency Regulatory Working Group (established by Executive Order 12866) created a subgroup on information technology and rulemaking. By December 1994, several agencies (including the Nuclear Regulatory Commission and the Department of Agriculture’s Animal and Plant Health Inspection Service) were accepting comments on proposed rules through electronic bulletin boards. For example, the Department of Labor (DOL) used electronic bulletin boards to support a negotiated regulatory process developing rules to protect workers building steel structures.

In the next several years, many federal agencies used IT in the rulemaking process to varying degrees. Many of these efforts centered on the facilitation of public participation in rulemaking.\(^8^4\) Most notably, the Department of Transportation developed its “Docket Management System,” an electronic, image-based database covering every agency and every rulemaking within the department. The system permitted electronic comments and access to regulatory supporting materials (e.g., economic analyses, comments of others) for all rules. Other agencies’ IT initiatives focused on other aspects of regulatory management (e.g., compliance assistance,

\(^8^3\) In a September 20, 2001, memorandum to the President’s Management Council, the OIRA Administrator previously indicated that, during its reviews of agencies’ draft rules under Executive Order 12866, it would give a “measure of deference” to regulatory analyses that had been peer reviewed.

information collection and dissemination, and regulatory enforcement). For example, DOL developed a sophisticated set of interactive advisors on the Internet to help workers and small businesses understand their rights and responsibilities under federal employment laws and regulations.

In July 2001, President Bush identified the expansion of e-government as one of the five priorities of his management agenda. To support this priority, OMB developed an implementation strategy that identified 24 e-government initiatives, one of which was e-rulemaking. This initiative is intended to provide a single portal for businesses and citizens to access the federal rulemaking process and comment on proposed rules. In May 2002, the Director of OMB sent a memorandum to the heads of executive departments and agencies advising them of “our intention to consolidate redundant IT systems relating to the President’s on-line rulemaking initiative,” and indicated that consolidation of those systems could save millions of dollars. In late 2002, EPA was named lead agency for the e-rulemaking initiative. In January 2003, the Bush Administration launched the “Regulations.gov” Web site as the first module of its e-rulemaking initiative. The Web site permits the public to identify proposed rules that are open for comment government-wide, and permits the public to comment electronically on those rules. Although OMB indicated in March 2004 that Regulations.gov was being accessed by the public more than 15,000 times per month (e.g., to locate rules open for comment), other data indicated that fewer than 50 electronic comments per month were received from the public via the Web site in its first 10 months of operation.

The second module of the e-rulemaking initiative is intended to create one or more electronic dockets for proposed and final rules, thereby allowing the public to access regulatory supporting materials and the comments of others from one Web site. EPA indicated that the e-rulemaking team would test a centralized, governmentwide online docket in the fall of 2004 in four or five agencies, with full implementation expected in early 2005.

**Congressional Initiatives.** Congress has also taken numerous steps in recent years to encourage federal agencies to use IT in carrying out their missions. Some of these efforts have been specifically directed at the regulatory process, while others had an indirect effect on that process. For example, in 1998, Congress enacted the Government Paperwork Elimination Act (GPEA) (44 U.S.C. 3504 note), which required that, by October 21, 2003, Federal agencies provide the public, when practicable, with the option of submitting, maintaining, and disclosing information electronically, instead of on paper. GPEA makes OMB responsible for ensuring that federal agencies meet the act’s implementation deadline. Although the act did not specifically mention rulemaking, both OMB and rulemaking agencies have indicated

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that its requirements provided an impetus for developing IT-based approaches to regulatory management.

The E-Government Act of 2002 (44 U.S.C.A. 3601 note) has been described as "the most far-reaching federal government effort to date for promoting online public involvement," and contains requirements specific to rulemaking. Section 206 of the act requires agencies, to the extent practicable, to accept public comments on proposed rules "by electronic means." That section also requires agencies (again, to the extent practicable) to ensure that a publicly accessible federal Web site contains "electronic dockets" for their proposed rules containing all comments submitted on the rules as well as "other materials that by agency rule or practice are included in the rulemaking docket under (the APA), whether or not submitted electronically." The E-Government Act also requires agencies to conduct a "privacy impact assessment" before initiating a new collection of information that uses information technology and contains individually identifying information. In addition, the act established an Office of Electronic Government within OMB, headed by an Administrator appointed by the President. It requires the Administrator of that office to work with the Administrator of OIRA in establishing the strategic direction of the e-government program, and to oversee its implementation.

Other Regulatory Reform Initiatives

A number of other regulatory reform initiatives have been undertaken in recent decades, including efforts to encourage agencies to (1) recognize the effect that their rules have on federalism and private property rights, (2) develop rules through negotiations with affected parties, (3) write their rules using plain language.

Federalism. Both Congress and various Presidents have put in place reforms intended to ensure that federal agencies take the interests of state, local, and tribal governments into consideration as they develop rules. The effectiveness of these requirements, however, is questionable. As mentioned in an earlier section of this report, the Unfunded Mandates Reform Act requires federal agencies to analyze their rules and prepare a written statement when their rules require $100 million in expenditures by state, local, or tribal governments, in the aggregate. GAO concluded, however, that this requirement applies to few rules and requires little beyond what the agencies were already required to do.88

In 1987, President Reagan issued Executive Order 12612 on "Federalism," which established a set of fundamental principles and criteria for executive departments and agencies to use when formulating and implementing policies that have federalism implications.89 The executive order also required federal agencies to prepare a "federalism assessment" whenever the responsible agency official

88 GAO/GGD-98-30, Unfunded Mandates: Reform Act Has Had Little Effect on Agencies' Rulemaking Efforts.
determines that a proposed policy had sufficient federalism implications to warrant the preparation of the assessment. The assessment was required to contain certain elements (e.g., identifying the extent to which the policy would impose additional costs or burdens on the states), and was to accompany any rule submitted to OMB for review under Executive Order 12866. GAO examined the implementation of Executive Order 12612 and concluded that, like UMRA, it had little effect on agency rulemaking. Agencies prepared few federalism assessments, even when the rules preempted state or local law. In 1999, President Clinton issued Executive Order 13132 on “Federalism,” which revoked Executive Order 12612. Like its predecessor, though, the new executive order provides agencies with substantial flexibility to determine which of their actions have “federalism implications” and, therefore, when they should prepare a “federalism summary impact statement.”

Private Property Rights. Each year federal agencies issue a number of regulatory actions that can affect the use of private property, such as limiting the development of land that includes critical wildlife habitat or wetlands. In such “takings” cases, the property owner may be owed just compensation under the Fifth Amendment to the Constitution. To obtain compensation, a property owner claiming that a regulatory action has effected a taking must initiate a lawsuit against the government.

In 1988, President Reagan issued Executive Order 12630, which addressed this subject. The stated purpose of the order was to ensure that regulations and other government actions are undertaken on a well-reasoned basis with due regard for the potential financial impacts imposed on the government by the just compensation clause of the Fifth Amendment. The executive order requires executive branch agencies, among other things, to (1) consider the potential takings implications of their proposed actions and to document significant takings implications in notices of proposed rulemaking, (2) designate an agency official responsible for implementing the order, (3) prepare annual compilations of awards of just compensation resulting from landowner lawsuits alleging takings, and (4) account for takings awards levied against them in their annual budget submissions. The order also required the Department of Justice to issue guidelines on the implementation of its requirements.

In December 1998, the Congressional Budget Office (CBO) reported that of the thousands of actions that agencies take each year that could affect property rights or values, agencies prepare only a few takings analyses. CBO concluded that agencies have considerable discretion in preparing the analyses, and rely on only a few arguments to justify their conclusions. As a result, CBO concluded that the requirements in Executive Order 12630 for takings analyses “does little to assuage the public’s concerns that agencies may fail to consider the effects of their proposed actions on private property rights.”

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In September 2003, GAO examined the implementation of this executive order and reported that some agencies and judicial experts believed that the Justice Department’s 1988 guidelines needed to be updated.\textsuperscript{93} GAO also reported that OMB issued guidance in 1994 informing agencies that information on just compensation awards no longer needed to be compiled or reported, and that the executive order’s requirement that agencies consider the takings implications of their actions applied to relatively few cases and often were not documented.\textsuperscript{94}

In the mid-1990s, several bills were introduced (either as part of comprehensive regulatory reform legislation or separately) that would have required the federal government to compensate property owners if a regulation restricted the use of the land by a certain amount (e.g., 10% or 50%). These bills were not enacted.

**Negotiated Rulemaking.** The concept of negotiated rulemaking (sometimes referred to as regulatory negotiation or “reg-neg”) emerged in the 1980s as a supplement to the traditional procedure for developing regulations. In 1982, the Administrative Conference of the United States established criteria identifying rulemaking situations in which negotiated rulemaking is likely to be successful.\textsuperscript{95} In 1990, Congress enacted the Negotiated Rulemaking Act of 1990 (5 U.S.C. 561-570a), and the act was amended and permanently authorized in 1996 (110 Stat. 3870). The act encourages (but does not require) agencies to consider convening a negotiated rulemaking committee before developing and issuing a proposed regulation under the Administrative Procedure Act. The committee, composed of representatives of the agency and the various interest groups that would be affected by the proposed regulation, addresses the issues involved in the hope that it can reach agreement on the contents of a proposed regulation. The agency can, if it agrees, then issue the agreement as a proposed rule, and eventually a final rule under existing APA requirements. Any proposal agreed to by the negotiated rulemaking committee is not, however, binding on the agency or other parties. The act also generally requires that the committee consist of at least one member of the agency and no more than 25 members, that the agency select an impartial “facilitator” to chair meetings, and that an agreement on any negotiated rulemaking must be unanimous. The act allows agencies to pay reasonable travel and *per diem* expenses, and reasonable compensation, to committee members under certain conditions.

Negotiated rulemaking has also been encourage through presidential initiatives. For example, in September 1993, Executive Order 12866 directed agencies to “explore and, where appropriate, use consensual mechanisms for developing regulations, including negotiated rulemaking.” Also in September 1993, the President


ordered executive branch agencies to submit to OIRA within 90 days a list of
regulations for which they planned to use negotiated rulemaking.96

Although the use of negotiated rulemaking was expected to improve rulemaking
timeliness and reduce litigation, an examination of agencies’ efforts in this area
indicates that those expectations are not being fulfilled.97 Another study, however,
indicated that negotiated rulemaking can improve participants’ perception of the final
rule and of the overall process.98

Plain Language. One problem that regulated entities have frequently cited is
a lack of clarity in the rules that federal agencies publish. The rules often use legally
precise but sometimes unintelligible language to convey what they require and how
to comply. Several regulatory reform initiatives in recent decades have attempted to
address this problem. For example, section 1 of President Carter’s Executive Order
12044 said that regulations should be “as simple and clear as possible.” More
recently, one of the “principles of regulation” in Executive Order 12866 is that “each
agency shall draft its regulations to be simple and easy to understand, with the goal
of minimizing the potential for uncertainty and litigation arising from such
uncertainty.” On June 1, 1998, President Clinton reemphasized this issue by sending
a memorandum to the heads of executive departments and agencies directing them
to use “plain language” in all proposed and final rulemaking documents published
in the Federal Register for the first time after January 1, 1999. The memo also
suggested that the agencies rewrite existing regulations in plain language “when you
have the opportunity and resources to do so.” The Office of the Vice President and
the Office of the Federal Register subsequently developed guidance on how to
comply with the memorandum and provided a list of related resources. Some
individual agencies have published revised “plain language” regulations, sometimes
in a “question and answer” format designed to facilitate understanding of the rules’
requirements.

Conclusion

Regulatory reform has taken a number of different forms in recent decades, from
requirements that agencies conduct analytical reviews in advance of a rule’s
publication to the retrospective examinations that agencies are sometimes required
to do after their rules are codified in the Federal Register. Some of the reforms were
initiated by Congress, some by Presidents, and many were prompted by both.
Regardless of the type or source of reform, an underlying theme in many of these
efforts is the minimization of regulatory burden in its various forms. The costs
associated with federal regulations are formidable, and it is generally accepted that

96 U.S. President (Clinton), “Negotiated Rulemaking,” Memorandum of Sept. 30, 1993,
97 Cary Coglianese, “Assessing Consensus: The Promise and Performance of Negotiated
98 Laura I. Langbein and Cornelius M. Kerwin, “Regulatory Negotiation versus
Conventional Rulemaking: Claims, Counterclaims, and Empirical Evidence,” Journal of
compliance costs should be the minimum necessary to accomplish the rules’ objectives. As OMB’s recent regulatory accounting reports indicate, though, the benefits of federal regulations are generally viewed as greater than their costs in the aggregate and for most of the agencies’ individual major rules. Nevertheless, it is often unclear whether greater net benefits could be achieved through other regulatory methods, or even whether alternatives to federal regulation would have been more effective or efficient.

Debates concerning regulatory reform are likely to continue. Profound differences of opinion exist among those for and against reform regarding the merits of such analytical tools as cost-benefit analysis and risk assessment, often because of the assumptions that underlie the analyses. Those assumptions are often necessary because empirical data are not available to provide definitive answers to such questions such as the extent to which humans are exposed to a particular chemical or the level of toxicity associated with human exposure. Philosophical differences also exist between such groups regarding the degree to which agencies should exercise precaution in proactively regulating potential risks, from bioengineered food to the transport of nuclear waste. The groups also differ regarding the extent to which the health and ecological benefits expected from regulations can or even should be monetized, and whether future health benefits should be discounted.99

Possible areas for future reform of the regulatory process are numerous but difficult to predict. Some have mentioned the possibility of examining the statutes that currently limit agencies’ ability to consider costs when developing rules. Another possibility is extending the reach of executive review of rules to those issued by independent regulatory agencies. These and other possible areas of reform are highly controversial and likely to generate strong resistance. As mentioned previously, regulatory reform legislation introduced in the 108th Congress includes additional analytical requirements (privacy) and pilot tests of regulatory budgets.

Future efforts to reform either the substance of regulations or the processes by which they are developed can be greatly informed by previous efforts. For example, many of the analytical requirements in the statutory reforms that have been enacted (e.g., the Regulatory Flexibility Act, the Small Business Regulatory Enforcement Fairness Act, and the Unfunded Mandates Reform Act) focus on proposed rules or final rules for which a notice of proposed rulemaking has been developed. About half of all final rules, however, do not have a corresponding proposed rule, including many of the agencies’ significant and major rules.100 Therefore, the reform requirements automatically do not apply to about half of all rules. Also, many of the regulatory reform statutes and executive orders do not define key terms (e.g., “significant economic impact” or “significant federalism implications”), thereby permitting the agencies broad discretion to determine when the requirements apply

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99 Discounting can have a significant effect on the present value of future health benefits. For example, in a February 2003 speech the OIRA Administrator noted that the present value of 1,000 lives saved 50 years in the future is only 34 lives in present value when evaluated at a 7% discount rate.

to their rules. Care in crafting these requirements can ensure that they achieve the results that were intended.

Finally, the cumulative weight of federal rulemaking requirements is substantial. Currently, dozens of statutes and executive orders govern the federal rulemaking process, requiring numerous forms of analyses and processes before rules can take effect. Those analytical and procedural requirements are not free, and the requirements sometimes overlap or even conflict with one another (e.g., requirements to increase public participation and to speed the development of rules). Some observers have called for a rationalization of these rulemaking requirements, integrating them in such a way that the overlaps and conflicting provisions are recognized and the burden that they impose on regulatory agencies does not prevent them from carrying out their missions. On the other hand, advocates of reform have more commonly expressed concerns about the burden that regulatory agencies impose on the public through their rules than the burden that reforms place on the agencies.

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For Additional Reading

CRS Reports


Other Readings


Selected World Wide Web Sites

Information regarding current and past regulatory policies and administrative procedures is available at the following Web sites.

AEI-Brookings Joint Center for Regulatory Studies [http://www.aei.brookings.org]
Center for Regulatory Effectiveness
[http://www.thecre.com]

General Accounting Office (GAO)
[http://www.gao.gov]

Government Printing Office (GPO)
[http://www.access.gpo.gov/nara]

OMB Watch
[http://www.ombwatch.org/regs]