REGULATORY PROGRAM OF THE UNITED STATES GOVERNMENT

APRIL 1, 1990 - MARCH 31, 1991

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THE REGULATORY MESSAGE OF THE PRESIDENT

TO THE CONGRESS OF THE UNITED STATES:

The annual *Regulatory Program of the United States Government* sets forth the Administration's regulatory priorities for the coming year. This is my Administration's first *Regulatory Program* published pursuant to Executive Order No. 12498. It represents my long-standing commitment to prudent and cost-effective Federal regulation.

The decade of the nineties will demand governmental action to meet a broad range of challenges and opportunities. Cleaning up the environment, encouraging the use of new technologies, maintaining America's global competitiveness—these are just a few of the issues that will vitally affect the quality of life of all Americans.

My Administration is committed to using necessary Federal regulation, reasonably applied, as an effective tool for positive change. At the same time, imprudent and unnecessary regulation can create greater cost than benefit. Further, many regulations burden the economy by staying on the books long after their useful life is over.

Federal regulations impose estimated direct costs on the economy as high as $175 billion annually—more than $1,700 for every taxpayer in the United States. These costs are in effect indirect "taxes" on the American public—taxes that should only be levied when the benefits clearly exceed the costs.

I strongly believe in the commonsense regulatory principles that I helped develop and implement when as Vice President I chaired the Task Force on Regulatory Relief. These principles provide that regulations should be issued only when they are necessary, economically sensible, responsive to public comments and concerns, and understandable. Except where prevented by law, agencies should not take regulatory actions unless the benefits outweigh the costs. Regulations should also improve the quality of life for all Americans, rather than benefit a narrow special interest.

Agencies need to consider the effect of new regulations in the context of existing ones. The overall regulatory structure should be coherent, and obsolete regulations should be eliminated or revised. After considering all of these factors, agencies should select the best regulatory options from among the available alternatives. In doing so, they should select alternatives that minimize paperwork burdens on the public. Agencies should, where appropriate, establish performance standards that allow American businesses (and the marketplace) to choose the most cost-effective way to reach those standards; they should avoid command-and-control regulations that dictate specific solutions. I count on our Cabinet Secretaries and agency heads to use these principles of prudence and cost-effectiveness in developing regulations consistent with law.

To ensure that this Administration continues to remove unnecessary regulatory burdens from the American people, I have asked the Council on Competitiveness, chaired by Vice President Quayle, in conjunction with the Office of Information and Regulatory Affairs, to oversee the regulatory review process established by Executive Orders Nos. 12291 and 12498. Such review should bolster our Nation's competitiveness and strengthen the economy.

Regulatory reform is a continual, dynamic process. In the coming months, agencies within the executive branch will propose, under the guidance of the Council on Competitiveness, new and revised regulatory reforms to reflect the priorities and policies of this Administration. I expect our agency heads to report to me on their progress in these areas. I also expect our regulatory review process will continue to lead to important improvements in the regulatory program of the United States.

GEORGE BUSH

THE WHITE HOUSE,
August 3, 1990

PART I. OVERVIEW

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This is the *Regulatory Program of the United States Government* issued pursuant to Executive Order 12498, and the first of the Administration of President George Bush. Part I, entitled "Overview," describes the functions of the 1990 Regulatory Program, and how it relates to the overall structure of regulatory oversight President Bush has adopted. Part II, entitled "The Regulatory Program by Agency," contains the regulatory programs for 1990–1991 of 24 agencies.

Regulation is a key governmental tool for moderating public health and safety risks and for protecting the effective operation of free markets. At the beginning of a new decade, the United States Government continues to utilize regulations to meet a number of significant challenges: cleaning up our environment, protecting the health and safety of our consumers and workers, and maximizing the value of our human capital. New regulations will be needed. Old ones will have to be overhauled or taken off the books.

Presidential regulatory oversight is a process necessary to ensure that agencies of the United States Government meet those challenges in a manner consistent with Administration policies and statutory direction. This document reflects the President's commitment to that process. The Office of Information and Regulatory Affairs (OIRA) in the Office of Management and Budget (OMB) has been charged with continuing its role as steward of Presidential regulatory oversight.

The regulatory review process is intended to help resolve the continuing dilemma America faces: regulation is necessary, but its cost can increasingly put the United States at a competitive disadvantage in a global economy. Costs have to be paid if the Government is to mandate reduction in some of the risks that living in a highly complex, modern society poses to Americans. And regulatory interventions may be necessary to protect the free markets that are the underpinning of America's free enterprise system. However, the costs of regulation add to the prices that consumers pay for goods and services and that industries charge for exports. President Bush seeks a regulatory structure that appropriately balances the benefits and costs of Federal regulations for the country's long-term well-being, and ensures that the regulatory activity of the Government produces net benefits for its citizens.

Two Executive orders establish principles of sound regulatory management for agencies to follow in developing regulations. The orders combine with the Paperwork Reduction Act of 1980 to ensure that the paperwork and regulatory burdens the Government imposes are necessary, tolerable, and cost-effective.

Both Executive orders are the outgrowth of successive Presidents' efforts since the 1960s to establish procedures for Executive regulatory oversight. Executive Order 12291 (see appendix I for the complete text) sets out fundamental regulatory principles: it directs agencies to justify the need for regulations, weigh their costs and benefits, and choose the most cost-effective regulatory options. It also directs OIRA to review the agencies' rationales and assumptions and to ensure that agency regulations are consistent with Presidential policies and statutory intent. Executive Order 12498 established the *Regulatory Program of the United States Government* as a vehicle for agency regulatory planning and coordination (see appendix II for the complete text).

Taken together, the two Executive Orders form a coherent framework for creating a regulatory structure that is humane, effective, and economically sensible. Congress and the President, through the enactment and approval of agency enabling legislation, have charged agencies with the ultimate responsibility for acting within their specific policy areas. Presidential regulatory oversight promotes a careful weighing of such actions, and also seeks to harmonize conflicts between competing agency mandates. It thus fulfills the President's Constitutional obligation to manage the executive branch. The establishment of a formal oversight process during the past decade provides a method for rationalizing the Federal Government's maze of regulatory requirements, increasing benefits and lowering costs. In the 1990s, this process will guide the continuing evolution of regulations that are both effective and prudent.

The Regulatory Program of the United States and Executive Order 12498

Executive Order 12498 requires the annual publication of the *Regulatory Program of the United States Government.* This document outlines the regulatory priorities and important upcoming actions of all the regulatory agencies. Most important is what the document represents—a process for planning and coordinating agency actions in advance of rulemaking.

The 1990–1991 Regulatory Program sets forth each agency's objectives for the 1990 program year, spanning April 1, 1990, to March 31, 1991. It outlines the issues agencies see as requiring immediate attention, as well as the steps each agency is taking to ensure the cost-effectiveness of the regulatory approach it proposes. The Regulatory Program thus allows Congress and the American people to understand the policy directions of the regulatory agencies. The actions listed in the Regulatory Program represent the major initiatives of the regulatory agencies, and may be substantially revised over time, through Administration decisions to guide and coordinate these agency actions.

Future Policies and Proposed Conferences

This overview discusses areas for further action on regulatory issues, including possible next steps in reforming economic regulation, efforts to develop a system of regulatory budgeting, key issues in developing scientific risk assessments as a part of the development of sound regulatory policy, and the use of information as a regulatory tool. The review also provides a discussion of OMB's final regulatory impact analysis (RIA) guidelines, and OIRA's response to the comments received on the draft guidelines published for comment in the 1988 Regulatory Program. Earlier Regulatory Programs identified some major inconsistencies and shortcomings in Federal agency analysis of major regulatory actions.[1] Because of these inconsistencies and shortcomings, and the potentially large net benefits that would result from improved analysis, OMB recognized the need for specific guidelines for preparing RIAs. The revised final RIA guidelines are published in this Regulatory Program in Appendix V.

OIRA plans to seek advice on these regulatory issues from the affected public and from academic and other experts on regulations and regulatory policies

[1] Regulatory Program (1986–1987), pp. xix–xxvi; Regulatory Program 1987–1988, pp. xv–xxii; and Regulatory Program 1988–1989, pp. 31–37.

and practices. OMB is considering a series of workshops and conferences, open to the public, on the following:

- The impact of the regulatory reform initiatives of the 1980s;
- Guidance and coordination for ranking risks (risk assessment, management, and communication);
- The potential for development of the regulatory budget concept; and
- The use of information strategies and public disclosure requirements to complement and possibly replace more direct regulatory intervention.

Introductory discussions of these topics are presented below in the sections entitled "Reforming Economic Regulation," "Regulatory Review and the Case for a Regulatory Budget," "Current Regulatory Issues in Risk Assessment," and "Information as a Regulatory Strategy." OIRA seeks comments on all these topics. Please send comments to the Office of Information and Regulatory Affairs, Washington, DC 20503.

The Council on Competitiveness

Maintaining American economic competitiveness into the next century depends on the initiative and innovativeness of the private sector. The Federal Government can foster competitiveness by encouraging a vigorous and competitive market environment both in this country and in the world economy. One of the more important steps the Federal Government can take in promoting a competitive market environment is to avoid unnecessary regulation.

Government regulation has an important role in advancing societal goals—such as public health and safety—where the market fails to protect such goals. But regulation can also impose substantial costs on American business, State and local governments, and consumers that burden our competitiveness abroad and our welfare at home. It is thus important to assess, on a continuing basis, the need for both new and existing regulations, balance the immediate objectives of such regulation with the broader objectives of promoting the Nation's welfare, and promote a reliance on markets wherever such opportunities exist.

To assist regulatory oversight, President Bush announced in *Building a Better America*, on February 9, 1989, that Vice President Quayle would chair the Council on Competitiveness:

> The Council will review regulatory issues, and such other issues as may be referred by the President, bearing on competitiveness. In reviewing regulatory matters, the Council will be continuing the work of the former President's Task Force on Regulatory Relief—chaired in the Reagan Administration by then Vice President Bush.

The Council will work closely with OIRA to augment the regulatory review process, ensure that the benefits of regulation outweigh their costs, and coordinate development of legislative and administrative initiatives to reduce unnecessary regulatory burdens.

Reforming Economic Regulation

The United States has traditionally relied on a "cost-of-service" approach to setting prices or rates for public utilities or other industries that are considered to be "natural monopolies." Cost-of-service regulation involves cumbersome and highly judgmental determinations of (1) the value of a firm's rate base, that is, its assets dedicated to providing a good or service; (2) the fair rate of profit (return) on those assets; and (3) all other costs associated with providing the good or service. In addition, the process of determining the "price" involves substantial costs to both the regulatory commission and the regulated industry because of complex and time-consuming ratemaking procedures.

Most students of public utility regulation believe that regulated industries are not as efficient or as innovative as they could be.[2] When regulated rates are tied directly to an individual firm's costs, those firms have a reduced incentive to achieve long-term cost reductions. Under this regulatory system, all cost savings are eventually "passed through" to consumers; the firm benefits only during the period of "regulatory lag," (that is, until rates are adjusted to reflect the firm's reduced costs). Firms subject to cost-of-service

[2] See Alfred E. Kahn, *The Economics of Regulation: Principles and Institutions*, New York: John Wiley & Sons, 1970, Chapter 2, pp. 47-94.

regulation may thus have an incentive to overinvest in capital, to inflate their rate bases, and to develop technologies that are more capital-intensive than optimal. The fact that allowable industry profits are a function of such past investments tends to discourage conversion to newer, more cost-effective technologies. In addition, cost-of-service regulation can distort the choice of research and development (R&D) projects and the level of R&D efforts by underrewarding R&D investments in some cases and overrewarding such investments in other cases.

Finally, cost-of-service regulation has often been associated with government-imposed restrictions on entry into the industry. This further reduces a regulated firm's need to seek innovations so as to remain competitive.[3]

DEREGULATION AS AN APPROACH TO REGULATORY REFORM

The last decade has witnessed regulatory reform in many of the industries once subject to traditional rate-of-return regulation. Some industries, such as trucking and airlines, have been almost completely deregulated because they are subject to pervasive competition. Others, like railroads, have been deregulated only as to services they perform in a competitive context.

In the railroad industry, the Interstate Commerce Commission (ICC) has used its authority under the Staggers Rail Act of 1980 to rely on market forces where railroads face intense competition from trucks. Similarly, in the telephone industry, customer-premises equipment has been completely deregulated, and entry has been allowed in the long-distance market, although the Federal Communications Commission (FCC) continues to regulate American Telephone and Telegraph's (AT&T's) rates. Such reductions in the scope of regulation, where feasible, eliminate enormous regulatory costs and burdens for both industry and the Government, reduce the prices paid for goods and services by consumers, and contribute to the efficient allocation of the Nation's resources.[4]

Regulatory reform has yielded substantial benefits for the consumers and firms served by the natural-monopoly industries. For example, the Council of Economic Advisers reported that airline deregulation has produced gains to airlines and travelers of approximately $15 billion per year.[5] Trucking deregulation has generated estimated savings in excess of $30 billion annually.[6] Finally, about $15 billion in annual benefits have resulted from an increased reliance on market forces in the railroad industry.[7]

ALTERNATIVE APPROACHES: FORMS OF INCENTIVE REGULATION

In those markets that cannot reasonably be expected to produce competitive outcomes, alternative approaches to cost-of-service regulation might improve industry performance over traditional public utility regulation. Various forms of "incentive regulation" are being considered, including the use of a cap on rates or prices. Price-cap regulation operates by setting (or capping) initial rates—or an index for a group of rates—and then allowing adjustment of the cap based on variables or factors that reflect changes in the underlying cost of providing service and are, at the same time, beyond the influence of the regulated firm. The crucial feature of price-cap regulation is that it severs the direct link between rates and individual company costs that characterizes cost-of-service regulation. If price caps are adjusted only for changes in costs that occur independently of a firm's behavior, improvements in efficiency that lower costs will translate into higher profits. Thus, a price-cap approach provides substantial incentives for cost-reducing efficiency improvements.

There are some difficult issues, however, that must be addressed in designing a price-cap approach. These issues include setting the price cap for the base period, designing a mechanism for adjustment in the price cap that reflects changes in the underlying cost of providing service, and avoiding a deterioration in the quality of service. A base price arbitrarily adjusted over an extended period by the consumer price index, for example, may bear little resemblance to the costs of providing service. The cumulative effect of an inappropriate adjustment would either lead the regulated industry to bankruptcy or allow it to realize monopoly profits. If frequent intervention by a regulatory agency is required to correct cumulative errors in adjusting the price cap, price-cap regulation may

[3] For example, Kahn reports that in those situations where it is feasible, "Competition is far more powerful than regulation in forcing businesses to explore the slope of their cost functions and elasticity of their demands, and to push down costs." Ibid., p. 112.

[4] While such partial deregulation has the potential to increase efficiency and reduce regulatory burden, it may also provide opportunities for the regulated firm to avoid regulation, by shifting accounting costs from nonregulated operations to the regulated rate base.

[5] *Economic Report of the President*, Washington, DC: Executive Office of the President, 1988, p. 206.

[6] Diane S. Owen, *Deregulation in the Trucking Industry*, Washington, DC: Federal Trade Commission, Bureau of Economics, May 1988.

[7] Christopher C. Barnekov and Andrew N. Kleit, "The Efficiency Effects of Railroad Deregulation in the United States," *International Journal of Transport Economics*, Volume 17, No. 1, February 1990.

result in the same disincentives or distortions as cost-of-service regulation.

In some cases, though, there may be industry-specific ways of developing an effective approach for rate-cap adjustment. For example, the price of similar products or services in competitive markets could be used as a basis for adjusting the price cap in those markets where the regulated firm retains market power. Alternatively, a rate-cap approach might be appropriate where some markets are in transition to a workably competitive structure and a price-cap approach is designed to be in place for a limited period before regulation would be removed completely.

RECENT INITIATIVES

The Administration has already taken some important steps that would reduce the scope of regulations or increase the incentives of regulated firms to behave efficiently. These steps include support for the deregulation of natural gas wellhead prices, the transmittal of legislation that would deregulate oil pipelines, actions to improve electrical power regulation, and recent FCC action to establish an alternative incentive-based regulation of long-distance telecommunications services. Each of these initiatives is described below.

Oil Pipeline Regulatory Reform

Oil pipelines have been federally regulated since 1906. However, the industry differs from the trucking or railroad industries in that regulation has been directed at prices only, without any restrictions on entry or exit. Therefore, the pipeline industry has remained quite competitive even with Federal regulation. In fact, Federal regulatory agencies—first the ICC, and now the Federal Energy Regulatory Commission (FERC)—set pipeline rates that, in most cases, have been nonbinding because competitive forces have kept actual rates lower.

In 1984 the D.C. Circuit Court of Appeals, construing the existing legislation, ordered the FERC to develop a methodology for imposing strict rates of return on oil pipelines based on historical costs. Strict rate regulation could have serious consequences for both the industry and the Nation by discouraging new investment in pipelines and perhaps even deterring the development of new oil fields.

Characteristics of the Industry

In 1986, the Department of Justice (DOJ) completed a study of the oil pipeline industry.[8] It concluded that although pipelines appear to have all the characteristics of a natural monopoly, they actually face significant competition in many markets from other pipelines, from local crude oil producers and refineries, and in port areas, from river barges and ocean-going tankers. Recognizing this, the DOJ study examined the markets in which oil pipelines operate, to distinguish between competitive markets and those where pipelines may have substantial market power. The study concluded that all crude pipelines and most product pipelines (accounting for over 70 percent of 1983 barrel-miles) were operating under sufficiently competitive conditions in all of their markets to be safely deregulated.

The Regulatory Reform Initiative

As a result, proposals for regulatory reform were developed to deregulate those pipelines operating under competitive conditions while using price-cap regulation of 11 product pipelines that could potentially exercise market power. On July 28, 1989, the Administration transmitted the Oil Pipeline Regulatory Reform Act to Congress, that would deregulate all competitive pipeline markets.[9] For the small proportion of remaining markets where pipelines retain market power, the bill would set base prices at their current level (unless that level is determined to be the result of market power). In these remaining markets, it would adjust base prices semiannually by a "Competitive Pipeline Price Index," which is calculated as the change in average revenue per barrel-mile (total revenue of all the competitive pipelines divided by total barrel-miles). This index is independent of the actions of an individual pipeline, but it effectively captures events that affect the cost of operation.

For those 11 pipelines that would still be regulated under the bill, system-wide regulation to address market power in discrete geographic areas does not appear to be the best regulatory solution. Traditional cost-of-service regulation (setting a maximum allowed rate of return) provides the pipeline substantial flexibility in setting prices in individual geographic markets. This flexibility makes regulation ineffective in these noncompetitive markets. Cost-allocation problems alone preclude the use of this approach on a market-by-market basis. Price caps, on the other hand, offer a means of deregulating these pipelines in all but those specific areas where they may exercise market power. Price caps also avoid the generic drawbacks of cost-of-service regulation, which distorts investment, innovation, and entry.

[8] U.S. Department of Justice, *Oil Pipeline Deregulation*, Washington, DC: Author, May 1986.

[9] An earlier version was transmitted to Congress by the Administration in August 1988.

The proposed Oil Pipeline Regulatory Reform Act approach promises to be both less intrusive and more effective than traditional cost-of-service regulation. First, most of the industry can be deregulated, and second, regulatory attention can be focused on the small number of noncompetitive markets. Because the majority of the industry is competitive, prices in the regulated markets can be pegged to prices charged in competitive markets. By targeting markets for regulation instead of entire pipelines, this approach not only reduces the scope of regulation, but more effectively regulates the few pockets of market power that remain.

Natural Gas Price Regulation

The Natural Gas Act (1938) imposed Federal rate regulation on interstate pipelines carrying natural gas, on the theory that they were natural monopolies. The Supreme Court's *Phillips* Decision (1954) extended rate regulation to wellhead prices for natural gas sold to the interstate market. Legislative efforts to deregulate wellhead prices for natural gas began immediately after the *Phillips* Decision, but failed for a variety of reasons.

In the 1970s, the regulation of the wellhead price for gas sold in the interstate market created severe shortages in the "consuming" States in the Midwest and along the Eastern Seaboard, in that unregulated gas could be sold at higher prices in the intrastate markets of producing States. This disparity in performance between the regulated interstate and the unregulated intrastate markets served to highlight the problems with wellhead price regulation. The Natural Gas Policy Act of 1978 extended Federal regulation of wellhead prices to the intrastate market in order to "correct" the distortions that had been created by dual regulation. This bill eliminated the regulatory distinction between the interstate and intrastate markets, replacing it with a new kind of two-tiered market: a deregulated market for certain "new" categories of gas, and an "old" gas market price-capped at a lower level.

This distinction between "old" and "new" gas introduced a new distortion into the natural gas market. Investments that would enhance the production of "old" gas were not undertaken, while far more costly investments were made to bring "new" gas into production. These production decisions, coupled with an unexpected fall in the world price of oil, produced the anomalous result of both higher gas prices and an attendant surplus (or "bubble") in natural gas production.

The FERC has taken several steps to introduce more freedom into natural gas markets in the past few years. The chief effect has been to allow consumers greater opportunity to shop around for the lowest-cost suppliers. Two statutory constraints have limited the effect of FERC's administrative reforms: the ceiling price on "old" gas that makes it uneconomical to produce; and the inability of consumers to arrange transportation from the low-cost supplier to the point of consumption.

The Reagan administration made several attempts to deregulate natural gas wellhead prices, including the transmission to Congress of a comprehensive proposal entitled "Natural Gas Consumer Regulatory Reform Amendments of 1983." Despite the efforts of the Administration and extensive debate by both the House and the Senate, however, neither House passed a bill.

Legislation in the Bush Administration

The success of oil deregulation and the experience with regulation in natural gas markets has persuaded most people that deregulation of wellhead prices is in the interest of consumers. In his first budget message to Congress, President Bush expressed the belief that ". . . at long last the Federal Government should fully decontrol natural gas." As a result, the Administration actively supported legislation as it moved through Congress, and President Bush signed the legislation phasing out wellhead price controls on July 26, 1989.

Electric Power Regulation

The Federal Power Act (FPA) was enacted as part of the Public Utility Act of 1935, in part to provide Federal rate regulation over interstate sales and transmission of electricity by investor-owned electric utilities. Regulation of "intrastate" sales remained with the States. The Public Utility Holding Company Act (PUHCA) was also enacted as part of the Public Utility Act of 1935, to dismantle inefficient holding-company systems and regulate the nonrate aspects of public utility holding companies. Congress, however, exempted certain public companies from PUHCA (e.g., holding companies whose electric utilities operate within a single State or in contiguous States).

Since many electric utilities were not interconnected in 1935, the potential for interstate sales was limited to roughly 10 percent of all sales of electricity. However, since 1935 interconnected transmission systems have become commonplace. Today, interstate sales account for in excess of 25 percent of all power sales. Essentially all wholesale electricity sales, with the exception of sales in Hawaii, Alaska, and part of Texas, are subject to the jurisdiction of the Federal Energy Regulatory Commission (FERC).

In the 1970s, increases in both fuel prices and the cost of new generating capacity brought to an end several decades of declining electricity prices (in real

terms). The resulting reduction in growth of demand left the industry with capacity under construction far in excess of its needs. Ratepayers generally bore the brunt of the cost of this excess capacity, although in a number of States shareholders absorbed these costs, because regulators did not allow the costs of some plants into the rate base (either because they were imprudently constructed or because the plant was not needed).

This experience prompted utility managers and regulators to seek solutions to the traditional rate-of-return regulation problem that limits shareholders' return on investment while exposing them to potentially large risks. One approach is to determine, up front, the prudent costs needed to meet future demand growth, thus limiting utility regulatory risk. Another approach is to provide incentive-return mechanisms. Under incentive-return approaches, the utility or power producer realizes as additional profit a portion of any reduction in costs from "projected" cost levels that can be achieved by the power producer. FERC has the flexibility under current statutes to carry out either approach, although the Commission has to date not utilized the first approach (up-front prudence). In its regulation of cogenerators, small power producers, and so-called independent power producers, the Commission has explored the use of incentive mechanisms.

Under the Public Utility Regulatory Policies Act of 1978 (PURPA), incentives were provided for encouraging the development of cogeneration and small power-production facilities, termed "qualifying facilities" (QFs). These incentives include relief from most Federal and State regulation and an obligation on the part of electric utilities to take power from these facilities at a price equal to the utilities' "avoided cost." However, PURPA places restrictions on the size of small power-production facilities and the technologies that qualify for these incentives. In addition, setting avoided cost through an administrative process has proven to be difficult and subject to influence. To overcome this problem, competitive bidding is now being used in some States. Experience to date suggests that some administrative changes are warranted to make the current program more effective in meeting the need for additional capacity in the 1990s.

FERC attempted to address some of these problems with PURPA in several notices of proposed rulemaking (NPRMs) issued in 1988. Two NPRMs dealt with the administrative determination of avoided costs and some other technical aspects of the QF program. A third NPRM addressed the legality of using bidding to set avoided costs under PURPA.

The experience gained from PURPA indicates that the generation of electric power may no longer exhibit the attributes of a natural monopoly. As a result, FERC has issued a fourth NPRM that deals with the regulatory treatment of a new class of power producers, the independent power producers (IPPs). These producers do not qualify for PURPA incentives, but fall outside of the traditional regulatory concern of the FPA because they lack market power. The NPRM proposed to relax rate and nonrate regulation of these producers (so long as they lack market power) under the FPA to allow them to charge the market price. Although these rulemakings are still pending and are unlikely to go forward in their current form, FERC is approving a relaxed regulatory treatment in a wide variety of case-by-case situations.

Apart from these several NPRM initiatives, FERC also recognizes the importance of transmission access. A report of the FERC Transmission Task Force to the Commission in the fall of 1989 concluded that open access to transmission was essential for the full development of competitive generation markets. The task force examined various proposals for encouraging broader access and found that, for the time being, no legislative action was necessary. As a result, the Commission recently conditioned approval of the PP&L-UP&L merger on acceptance by the utility of an open-access transmission policy. This was the first time such conditioning authority has been claimed or used by the Commission.

Finally, PUHCA may be a major barrier to the development of IPPs and a competitive market for procuring electric capacity. Legislation is now before committees in the Senate and the House to reform PUHCA by providing an exemption for wholesale generators that lack market power.

Telecommunications Regulation

The settlement of the Government's antitrust suit against AT&T resulted in AT&T's divestiture of its local operating companies in 1984. As a result, AT&T can no longer control access to local exchange markets to monopolize long-distance service. Since the divestiture, competition in long-distance markets has in-

creased. In 1980, prior to divestiture, AT&T earned about 96 percent of long-distance revenues.[10] By late 1988, AT&T's share of revenues had fallen to about 78 percent, while the shares of two competitors, MCI and Sprint, had grown to about 10 percent and 7 percent, respectively.[11] In addition, AT&T now faces one or more competitors in all but a few geographic areas. Finally, AT&T appears to be responding to competitive pressure from its rivals. It has been modernizing its network and taking other steps to cut costs and provide better service.[12] AT&T also recently filed a request with the Federal Communications Commission (FCC) to cut its rates to reflect reductions in costs, including access charges.[13]

Under current FCC regulations, only AT&T is considered to be dominant among the major long-distance carriers, and therefore subject to regulation. MCI, Sprint, and other providers are presumed to be nondominant carriers; they must report their costs and prices to the FCC, but their rates of return are not constrained.

AT&T claims that rate-of-return regulation imposes heavy administrative costs—for example, it spent about $250 million on regulatory compliance in 1984.[14] However, the primary problem associated with rate-of-return regulation of long-distance service is that it substantially limits carrier incentives to reduce their costs. Cost inflation may take the form of excessive investment in capital, or the even more profitable practice of cross-subsidization—accounting procedures that shift costs from a firm's unregulated businesses to its regulated ones. The effect of this real (or accounting) cost shifting is regulatory evasion that raises the allowed prices for the regulated product or service. In the context of the current market structure of long-distance telecommunications, rate caps may offer a significantly more efficient regulatory alternative.

The FCC's Price-Cap Approach to Incentive Regulation

Effective July 1, 1989, the FCC began implementing price-cap regulation of AT&T long-distance services. Under this new incentive regulatory scheme, AT&T's rates are separated into three baskets of services that are regulated by means of a price cap. The FCC will also monitor carrier operations, profits, and service quality under price caps, and, at the end of three years, it will conduct a comprehensive review of the entire price-cap approach. The FCC believes that this approach will provide the carrier with greater flexibility to reduce costs and at the same time it will significantly streamline the tariff filing process.

The rates in each of the service baskets will be subject to a formula that reflects changes in the cost of doing business plus an annual 3 percent decrease in rates, to reflect AT&T's historic gain in productivity, including a consumer productivity dividend of 0.5 percent.

The first of these service baskets involves residential and small-business services. AT&T will be permitted to change prices for the six separate categories in this basket so long as the aggregate weighted price for all services in the basket does not exceed the price cap. In addition, AT&T may raise prices in any of these categories a maximum of about 5 percent per year above the change in the price-cap index without triggering a rate review. Increases greater than the annual limit must be justified to the FCC's satisfaction by additional cost data. As an added protection to residential users, the FCC is requiring that AT&T calculate an average residential rate for all services in the residential basket and guarantee that this average rate will not increase by more than 1 percent per year.

The second basket covers "800" services, a market where the FCC believes AT&T still retains substantial market power. Rates for individual service categories in this service basket cannot increase by more than 5 percent annually without triggering detailed review by the FCC. The final basket consists of all other AT&T business services, the most competitive portion of the telecommunications market. Rate increases or decreases larger than 5 percent annually in any of these categories would trigger more detailed review by the FCC.

As noted above, AT&T currently faces one or more competitors in most of its markets, and this competition is expected to be sufficient, in the absence of regulation, to discipline AT&T's pricing in these markets. Since the Federal Communications Act of

[10] M. Porter, "Competition in the Long Distance Telecommunications Market: An Industry Structure Analysis," (Appendix A to AT&T Comments to FCC in CC Docket No. 87-313).

[11] A. Myerson, "Ganging Up on the Big Boys," *New York Times*, October 16, 1988, p. F5.

[12] J. Guyon, "AT&T's Third-Quarter Net Rose 17 Percent; $5 Billion Write-Off Possible for Year," *Wall Street Journal*, October 21, 1988, p. A2.

[13] J. Guyon, "AT&T to Cut Long-Distance Rates by 3.8 Percent," *Wall Street Journal*, October 18, 1988, p. A5.

[14] National Telecommunications and Information Administration, *NTIA Regulatory Alternatives Report*, Washington, DC: Author, July 1987, p. 22.

1934 may prevent the FCC from moving to complete deregulation, the FCC believes that a price-cap approach will improve competitive incentives and provide the management flexibility necessary to allow efficient behavior in long-distance telecommunications. AT&T's competitors will assure that service quality will be maintained and that some of the gains of this more flexible regulatory approach will be passed on to the consumer.[15]

Finally, the FCC is continuing to explore the application of incentive approaches to local telephone exchange carrier (LEC) access charges and has asked for public comment on a specific price-cap approach. Since most LECs have a monopoly in their local markets, local exchange is likely to require long-term regulation. The FCC has proposed changes in its current tariff-filing rule which would replace its current rate-of-return regulatory model with a price-cap approach that directly limits local exhange carriers' rates. Under the proposed price-cap approach, local exchange carriers would file tariffs annually. Carriers would also be required to file quarterly service-quality-monitoring reports to avoid any degradation of service to the consumer. LECs would still be required to file rate-of-return reports annually as a check to ensure that prices remained just and reasonable, as required by the Communications Act of 1934. The FCC is currently reviewing comments on the proposal.

Setting up a regulatory incentive approach for the LECs presents a more difficult problem because, under long-term regulation, cumulative errors in the method that is used to adjust the price cap over time may result in a cap that is too high, allowing the firm to charge the monopoly price, or a cap that is too low, forcing the firm into bankruptcy. The possibility of a cap that is too high is much less of a problem in markets that are in transition to competition, since market forces will tend to discipline the firm's pricing even in the absence of a binding cap. For this reason, it is much more important for regulation of local exchange markets to devise an adjustment mechanism that closely tracks the LECs' costs without actually being tied directly to these costs.

While further study should be done, one possible approach would be to base the price-adjustment mechanism for each LEC on an index of the costs of all other LECs. This would divorce the allowed prices for each LEC from its own costs while maintaining a fixed link between costs and prices system-wide.[16] In addition to increasing the efficiency of Federal regulation, implementation of such a system by the FCC could encourage States to shift to a similar price-cap mechanism for local telephone services, increasing the efficiency of State regulation and, possibly, permitting the elimination of State restrictions on new competitive entry into the provision of local exchange services.

NEXT STEPS

There continue to be some important areas where improvements are needed in Federal regulation of prices and entry—especially in the energy area. Progress in these areas presents a greater challenge, because it is more difficult to identify appropriate regulatory solutions. Incentive regulation approaches, properly tailored for application in each industry, could provide regulated firms with greater flexibility to pursue innovative approaches and ultimately reduce costs to the consumer. As a result, an assessment of next steps for regulatory reform in these areas should be undertaken.

Regulatory Review and the Case for a Regulatory Budget

Executive Order 12291 requires the evaluation of individual regulatory actions to assure that new rules yield the greatest net benefit to society.[17] Some argue that a more comprehensive process is needed, as a complement to the Executive Order 12291 process, in order to control the substantial aggregate costs that Federal regulation places on the American economy. One approach that has gained widespread interest in recent years is the development of a regulatory budget process. A regulatory budget would be implemented by setting overall caps on the total cost of Federal regulation and the regulatory costs imposed by individual agencies. Supporters of this approach argue that it would provide a decentralized process allowing each agency (within the allowed level of total regulatory costs) the flexibility to select a regulatory strategy

[15] The United Kingdom adopted a price-cap regulatory approach for British Telecom in 1984, and recent evidence on British Telecom's performance suggests that this approach has succeeded in improving efficiency.

[16] In developing an LEC cost index, one would have to examine how factors such as business volume affect unit costs.

[17] Because this review process tends to concentrate on individual regulations, OMB also develops the Regulatory Program, pursuant to E.O. 12498, as an annual review of the scope of the major regulatory initiatives, to provide a broader perspective on the major forthcoming regulatory actions.

that best meets its basic goals. At the same time, it would require both Congress and the Executive Branch to recognize explicitly the increasing regulatory burden on the private sector and the need to address tradeoffs among different regulatory programs.

REGULATORY PROGRAMS: ANALOGUE TO FEDERALLY FUNDED PROGRAMS

Federal regulatory programs are in many ways similar to directly funded Federal programs. The expenditures that regulations require, for example, have many of the same effects on production, employment, prices, and growth as budget outlays. The Federal Government taxes and borrows to fund programs, diverting those resources from the private sector. Regulations similarly divert these resources when businesses are forced to borrow, increase prices, or reduce dividends, to finance compliance.

Furthermore, the expenditures required by regulations may be an alternative means of achieving policy objectives that otherwise might be accomplished through budget outlays, taxes, or loan guarantees. Regulations, for example, may require firms to treat their wastewater before discharging it. Another alternative would be for the Government to build or improve sewage treatment plants. The basic allocative effects are similar, although one approach might prove more efficient.[18] Thus, regulations and federally funded programs raise many similar economic issues.

Because of these similarities in the effects of direct Federal expenditures and private expenditures caused by Federal regulatory programs, supporters of the regulatory budget approach argue that there are important reasons—analogous to those justifying the fiscal budget process—to establish a process to account for and coordinate Federal regulation. Such a process would provide more information to the public on the cost of regulation, and would establish the same kind of public accountability that applies to the fiscal budget.

FIRST STEPS AND PROPOSALS IN REGULATORY COST BUDGETING

The regulatory budget process could evolve, over time, as did the fiscal budget process, beginning with the use of currently available information.[19] Analysis of regulatory costs began in 1974 when President Ford issued Executive Order 11821, which required agencies to prepare inflation impact statements for their major regulations. Presidents Carter and Reagan both issued additional Executive orders to extend, refine, and tighten this requirement. Agencies are now required to list all significant planned regulatory activities in the Regulatory Program, but they only need to prepare regulatory analysis for certain "major" regulations, generally ones with a projected impact of over $100 million.

This Regulatory Program moves the regulatory oversight process towards a regulatory budget process, but it does not yet deal systematically with the overall effect of regulatory activities, in that there is as yet no method for estimating the annual incremental costs that regulations impose.

President Reagan, in issuing the Economic Bill of Rights on July 3, 1987, proposed requiring cost estimates for legislative proposals, as well as for all new and proposed regulations. These "financial impact statements" were to include evaluations of the costs to the general economy and consumers, and of the impact on the international competitiveness of U.S. industries. These estimates were to be available for public comment and criticism, improving decisionmaking on regulations and legislation.

Requiring a "regulatory cost ceiling" in any legislation that imposes costs on the private sector and State and local governments would be a logical next step. Each new statute would include a cap on the total costs agencies could impose on the non-Federal sector in implementing a program. The ceiling could not be breached without legislative approval of a higher ceiling or offsetting changes in other regulatory programs that would keep total private-sector costs within the limit.

[18] There may be other differences as well. For example, a reliance on regulation may have different implications for income distribution. The incentives for working, saving, and investing may also be different under Federal regulatory programs than for an income tax program. Tax liability is more directly tied to earnings, profits, and interest income than are regulations. Regulation may more closely resemble user fees and excise taxes.

[19] The accounting concepts used for Government outlays and receipts have been continually refined as the fiscal budget evolved from the Treasury Act of 1789. However, a comprehensive Federal budget system was not established until the Budget and Accounting Act of 1921. The accounting principles and standards for the budget have continued to change as a result of both executive and legislative action. The information-collection budget has evolved in a similar manner. The Federal Reports Act of 1942 first required agencies to measure and control the paperwork burdens they impose. Executive Order 12174, entitled "Paperwork," was issued on November 30, 1979. The Order required agencies to plan and budget paperwork requirements, in much the same way as their fiscal budget requests. The Paperwork Reduction Act of 1980 directed OMB to establish general policies and procedures for controlling information collections.

Supporters of this system argue that it would provide an incentive for better estimates of the costs of legislative proposals and a basis for an explicit discussion of the costs and tradeoffs of such proposals. High cost ceilings would focus attention on the expected benefits of the program, and alternative approaches; cost ceilings that were too low would prevent agencies from issuing implementing regulations. Such an approach would, needless to say, give agencies an incentive to choose regulatory approaches that would produce the greatest benefits at the lowest costs.

ISSUES AND AREAS FOR FURTHER STUDY

While the fiscal budget process provides a continuous record of actual expenditures, there is no comparable record of the cost of meeting regulatory requirements.[20] Members of Congress and the past two Administrations have considered developing an accounting framework to record direct regulatory expenditures, but more work needs to be done to solve the practical accounting problems inherent in measuring the private expenditures that Federal regulations mandate. These include:

- Developing a record of actual expenditures while minimizing the recordkeeping burden on the private sector;
- Identifying an appropriate "baseline," recognizing that some costs would be incurred even in the absence of Federal regulation; and
- Estimating the costs of forgoing certain products where Federal regulation prohibits production or distribution.

Each of these raises difficult issues in designing an effective regulatory budget process. For example, the costs of banning a product are not directly measurable and can only be estimated using complex statistical models. However, measuring only the direct compliance costs for oversight purposes creates a bias toward banning substances and products instead of controlling them.

As a first step in determining the feasibility of the regulatory budget concept, OMB has begun systematically to collect the costs of all significant published regulatory actions. Analysis of these data should aid in the development of ways to overcome the problems of regulatory budgeting, uncover unforeseen problems in developing cost estimates, and more fully refine a workable regulatory budgeting process.

Current Regulatory Issues in Risk Assessment and Risk Management

Many Federal agency regulatory decisions are intended to reduce risks to human life and health. Government regulations control which agricultural chemicals may be used to reduce insect damage, increase farm yields, and improve the quality of food products. Other rules govern hazards in the Nation's workplaces and emissions from its factories. There are regulations directing the way in which automobiles must be manufactured, commercial aircraft maintained, and trains operated. Hardly any widespread human activity that entails risk is free of some degree of social control, often achieved through government regulation.

Regulatory decisions involving risk require agencies to address questions such as, "How safe is 'safe'?" and "How clean is 'clean'?" When government agencies promulgate regulations intended to reduce a risk or mitigate a hazard, they are engaging in what has become known as *risk management*. These policy choices inevitably involve consideration of both the risks entailed by the underlying activity and the social consequences of regulatory intervention. Thus, the first challenge of risk management is to set priorities to determine which risks are worth reducing and which are not.

For government to carry out its risk-management responsibilities, there must be an extensive investment in the careful assessment and quantification of risks. The term *risk assessment* means the application of credible scientific principles and statistical methods to develop estimates of the likely effects of natural phenomena and human activities.

The need to keep risk assessment and risk management separate has long been the objective of responsible public officials. In 1983, the National Academy of Sciences (NAS) studied the process of managing risk

[20] Researchers, using different methods, assumptions, and time periods, have formed incomplete estimates by adding up the cost of individual regulations. These estimates accordingly show considerable variation for current annual costs ranging from $60 billion to $175 billion a year—5 to 15 percent of current Federal outlays.

in the Federal Government and offered the following recommendations, among others:

> *Recommendation 1:* Regulatory agencies should take steps to establish and maintain a clear conceptual distinction between assessment of risks and the consideration of risk management alternatives; that is, the scientific findings and policy judgments embodied in risk assessments should be explicitly distinguished from the political, economic, and technical considerations that influence the design and choice of regulatory strategies.[21]

> *Recommendation 2:* Before an agency decides whether a substance should or should not be regulated as a health hazard, a detailed and comprehensive written risk assessment should be prepared and made publicly available. This written assessment should clearly distinguish between the scientific basis and the policy basis for the agency's conclusions.[22]

The belief that risk assessment and risk management should be kept separate enjoys widespread support among professional risk-assessment practitioners and risk-management officials. [23]Others have emphasized the importance of ensuring that policy biases do not distort the analysis of alternative risk-management choices.[24] The NAS principles have also have been endorsed by a number of Federal agencies, including the Office of Science and Technology Policy (OSTP), the Environmental Protection Agency (EPA), and the Department of Health and Human Services (HHS).[25]

Unfortunately, risk-assessment practices continue to rely on conservative models and assumptions that effectively intermingle important policy judgments within the scientific assessment of risk. Policymakers must make decisions based on risk assessments in which scientific findings cannot be readily differentiated from embedded policy judgments. This policy environment makes it difficult to discern serious hazards from trivial ones, and distorts the ordering of the Government's regulatory priorities. In some cases, the distortion of priorities may actually increase health and safety risks.

This section explores some of the continuing difficulties that plague the practice of risk assessment, and describes briefly their policy implications. It can be summarized in three observations:

The continued reliance on conservative (worst-case) assumptions distorts risk assessment, yielding estimates that may overstate likely risks by several orders of magnitude. Many risk assessments are based on animal bioassays utilizing sensitive rodent species dosed at extremely high levels. Conservative statistical models are used to predict low-dose human health risks, based on the assumption that human biological response mimics that observed in laboratory animals. Worst-case assumptions concerning actual human exposure are commonly used instead of empirical data, further exaggerating predicted risk levels.

Conservative biases embedded in risk assessment impart a substantial "margin of safety". The choice of an appropriate margin of safety should remain the province of responsible risk-management officials, and should not be preempted through biased risk assessments. Estimates of risk often fail to acknowledge the presence of considerable uncertainty, nor do they present the extent to which conservative assumptions overstate likely risks. Analyses of risk-management alternatives routinely ignore these uncertainties and treat the resulting upper-bound estimates as reliable guides to the likely consequences of regulatory action. Decisionmakers and the general public often incorrectly infer a level of scientific precision and accuracy in the risk-assessment process that does not exist.

Conservatism in risk assessment distorts the regulatory priorities of the Federal Government, directing societal resources to reduce what are often trivial carcinogenic risks while failing to address more substantial threats to life and health. Distortions are probably most severe in the area of cancer-risk assessment, because many conservative models and assumptions were developed specifically for estimat-

[21] National Academy of Sciences, *Risk Assessment in the Federal Government: Managing the Process*, Washington, DC: National Academy Press, 1983 (hereinafter, *NAS Risk Management Study*), p. 151.

[22] Ibid., p. 153.

[23] For representative views of risk-assessment practitioners see, e.g., Lester B. Lave, *The Strategy of Social Regulation: Decision Frameworks for Policy*, Washington, DC: Brookings, 1981; Lester B. Lave, "Methods of Risk Assessment," Chapter 2 in *Quantitative Risk Assessment in Regulation*, Lester B. Lave, ed., Washington, DC: Brookings, 1982, esp. pp. 52–54. For representative views of risk-management officials see, e.g., William D. Ruckelshaus, "Science, Risk, and Public Policy," *Vital Speeches of the Day*, Volume 49, No. 20, August 1, 1983, pp. 612-615.

[24] See, e.g., Howard Kunreuther and Lisa Bendixen, "Benefits Assessment for Regulatory Problems," and Baruch Fischhoff and Louis Anthony Cox, Jr., "Conceptual Framework for Regulatory Benefits Assessment," Chapters 3 and 4, respectively, in *Benefits Assessment: The State of the Art*, Judith D. Bentkover, Vincent T. Covello, and Jeryl Mumpower, eds., Dordrecht, Netherlands: D. Reidel, 1986, pp. 44–45, 59–61.

[25] See U.S. Office of Science and Technology Policy, "Chemical Carcinogens: A Review of the Science and Its Associated Principles," Principle 29 (50 FR 10378, March 14, 1985, hereinafter, *OSTP Risk Assessment Guidelines*); U.S. Environmental Protection Agency, "Guidelines for Carcinogen Risk Assessment," 51 FR 34001 (September 24, 1986, hereinafter, *EPA Carcinogen Risk Assessment Guidelines*); U.S. Department of Health and Human Services, *Risk Assessment and Risk Management of Toxic Substances*, April 1985, p. 20.

ing upper bounds for these risks. Risk-assessment methods with similar conservative biases are less common elsewhere, particularly in those areas where real-world data are available, or where the mechanism by which injury or illness occurs is better understood.

A renewed commitment to the NAS recommendations is clearly warranted. As quantitative risk assessment plays an increasingly significant role in risk management, the need to separate science from policy becomes ever more important, if either process is to maintain public confidence. As former EPA Administrator William D. Ruckelshaus has noted:

> Risk assessment...must be based on scientific evidence and scientific consensus *only*. Nothing will erode public confidence faster than the suspicion that policy considerations have been allowed to influence the assessment of risk. [26]

ALTERNATIVE RISK-ASSESSMENT METHODOLOGIES

Risk assessments of chemical substances in general (and of possible carcinogens in particular) involve a mixture of facts, models, and assumptions. There is considerable debate concerning the scientific merits of the models and assumptions commonly used in risk assessments. In some cases, a scientific consensus has developed to support a particular model or assumption. In other instances, however, certain models and assumptions are relied upon because they reflect past practices rather than the leading edge of science. Furthermore, a scientific basis for several of the most critical models and assumptions simply does not exist.

Most scientists agree that these models and assumptions impart a conservative bias: that is, they lead to risk projections that the actual (but unknown) risk is very unlikely to exceed. These "upper-bound" estimates are often useful as a screening device, to exclude from regulatory concern potential hazards that are insignificant even under worst-case conditions. Unfortunately, upper-bound risk estimates are routinely employed for altogether different purposes, such as estimating the likely benefits of regulatory actions. Policymakers are required to act on the basis of biased representations of both the magnitude of the underlying hazard and the extent to which Government action will ameliorate it.

Contemporary risk assessment relies heavily upon animal bioassay and epidemiology. Each approach has theoretical advantages and disadvantages. In practice, both can be misused to bolster preestablished conclusions. The following discussion emphasizes problems in carcinogenic risk assessment, because the prevention and cure of cancer plays such a major role in policy issues involving risks to life and health.

Animal Bioassay

Animal testing enables scientists to estimate risks ex ante, before human health effects materialize, whereas epidemiological studies can only detect such effects ex post. In addition, animal tests can be conducted under tightly controlled laboratory conditions, which provide more reliable estimates of exposure and avoid many of the confounding factors that often plague epidemiological investigations. The relatively short lifetimes of experimental mammals (such as rats and mice) allow scientists to ascertain the possible effects of long-term exposure in just a few years.

Animal testing suffers serious limitations, however, arising from certain critical assumptions. Despite its routine application, there is no accepted scientific basis for the assumption that results can be meaningfully extrapolated from test animals to humans.[27] Some scientists believe that animal data should not be used in assessing human health risks.[28]

Another critical limitation is the reliance on very high doses to generate adverse effects in test animals.[29] A mathematical model must be used to bridge the gap between these high-dose exposures and the low-dose exposures more typically faced by people. Many different mathematical models can be constructed to fit the data at high doses. These models often vary enormously, however, in their predictions of risk at low doses.

Beyond these unavoidable methodological constraints, the results of animal bioassays may be subject to conflicting scientific interpretation or strongly influenced by the choice of research method.

[26] William D. Ruckelshaus, (*op. cit.*), p. 614.
[27] *OSTP Guidelines*, Guideline 8, p. 10376.
[28] See, e.g., Bruce Ames, Renae Magaw, and Lois Swirsky Gold, "Ranking Possible Carcinogenic Hazards," *Science*, Vol. 236, April 17, 1987; Gio Batta Gori, "The Regulation of Carcinogenic Hazards," *Science*, Vol. 208, April 18, 1980.
[29] *OSTP Guidelines*, Guideline 11, p. 10377.

Tissue preparation and histology present obvious opportunities for error, as experts may disagree as to how slides should be interpreted.[30] This problem generally is not significant at high doses, where malignancies are often obvious. At low doses, however, pathologists often differ in how they distinguish tumors from hyperplasia. Subjectivity cannot be avoided where such interpretations of the data must be made.[31]

Epidemiology

Epidemiology is attractive because it largely avoids these two problems. It focuses on observable human health effects instead of on hypothesized outcomes based on animal experimentation, and it relies upon real-world exposures to generate empirical data. Many of the serious problems associated with animal studies can be avoided, allowing researchers to develop risk estimates that are directly related to human health.

Unfortunately, epidemiological research suffers from its own set of limitations. For example, retrospective studies often have difficulty correlating morbidity and mortality with exposure to specific substances. Exposure data are commonly lacking, incomplete, imprecise, or affected by systematic recall or selection biases. Furthermore, the risks these studies seek to detect are often very small relative to background, thus making statistically significant effects difficult to observe. When health effects are latent, correlating exposures to illness is even harder.

Besides these unavoidable methodological limitations, epidemiological studies often suffer from outright bias. Many studies employ scientifically questionable procedures aimed at demonstrating positive relationships between specific substances and human illness.[32] Some researchers use inappropriate statistical procedures to "mine" existing databases in search of associations. One result of these practices is that epidemiological studies often display contradictory results.[33]

Despite these constraints, properly conducted animal bioassays and epidemiological studies both have useful roles to play in quantitative risk assessment. Indeed, they are complementary. The usual weaknesses of epidemiological investigations—unreliable exposure data, confounding effects—are readily avoided in laboratory experiments on animals. The weaknesses of animal bioassays—high- to low-dose extrapolation, animal-to-man conversion—do not arise in epidemiological studies. Careful risk assessment incorporates both types of analysis to ensure that the emerging picture of human health risk is as complete as possible, and that inferences derived from this picture are themselves internally consistent.

ISSUES IN RISK ASSESSMENTS DERIVED LARGELY FROM ANIMAL BIOASSAYS

Animal bioassays tend to dominate current risk assessments. An important reason for this is that the derivation of dose-response relationships is a critical regulatory motive for performing quantitative risk assessment. Animal studies are ideally suited to serve this purpose by virtue of the controlled conditions under which dose and response can be calibrated. Epidemiological studies often are relegated to providing merely a "reality check" to ensure that the implications of animal bioassays are plausibly consistent with real-world experience. Because of this heavy emphasis on animal testing, the focus here is on several major problems that arise with respect to risk assessments primarily based on the results of animal bioassays.

The Use of Sensitive Test Animals

To enhance the power of animal tests, scientists typically rely on genetically sensitive test animals. It

[30] In the original analysis of the rat bioassay used to derive the dose-response function for dioxin, 9 of 85 controls were said to develop liver tumors. An independent review of this data resulted in 16 of the 85 controls being classified as having such tumors. See U.S. Environmental Protection Agency, *A Cancer Risk-Specific Dose Estimate for 2, 3, 7, 8-TCDD, Appendix A*, EPA/600/6-88/007Ab, June 1988 (hereinafter, *Dioxin Risk Assessment Appendix A*), pp. 2–3.

[31] Colin N. Park and Ronald D. Snee, "Quantitative Risk Assessment: State-of-the-Art for Carcinogenesis," Chapter 4 in *Risk Management of Existing Chemicals*, Rockville, MD: Government Institutes, 1983, p. 56.

[32] Alvan R. Feinstein, "Scientific Standards in Epidemiological Studies of the Menace of Daily Life," *Science*, Vol. 242, December 2, 1988, pp. 1257–1263.

[33] Linda C. Mayes, Ralph I. Horowitz, and Alvan R. Feinstein, "A Collection of 56 Topics with Contradictory Results in Case-Control Research," *International Journal of Epidemiology*, Vol. 17, No. 3 (1988), pp. 680–685.

is unclear whether these species accurately mimic biological responses in humans.

Some test species are extremely sensitive. For example, approximately one-third of all male B6C3F1 mice, a common test species, spontaneously develop liver tumors.[34] The same phenomenon occurred in an important bioassay concerning dioxin using female Sprague-Dawley (Spartan) rats. Tumors observed in dosed animals were predominantly located in the liver. However, approximately one-fifth of the animals in the control group also developed liver tumors.[35] The relevance of elevated liver tumors in hypersensitive species has been questioned by scientists and is not universally considered probative evidence of carcinogenicity. Nevertheless, cancer risk assessments often proceed on the assumption that these data are sufficient to conclude that a substance is indeed a carcinogen.[36]

The reliance on sensitive test animals also biases risk assessments in a more subtle way. It establishes powerful incentives to search for and develop increasingly sensitive test species. As test animals become more sensitive, repeated testing using identical protocols will tend to result in higher and higher estimates of risk even if all other factors are held constant.

Selective Use of Alternative Studies

In their respective risk-assessment guidelines, both OSTP and EPA recommend that relevant animal studies should be considered irrespective of whether they indicate a positive relationship.[37] In practice, however, studies that demonstrate a statistically significant positive relationship routinely receive more weight than studies that indicate no relationship at all.[38] For example, the plant growth regulator daminozide (Alar) and its metabolite unsymmetrical 1,1-dimethylhydrazine (UDMH) recently received B2 classifications ("probable human carcinogen"). Each of these classifications was based on a single positive animal bioassay.[39] Overcoming such a classification requires, at a minimum, two "essentially identical" studies showing no such relationship.[40] In the case of Alar and UDMH, however, a more stringent test was apparently applied: Three high-quality negative studies showed no significant effects; these studies appear to have received little or no weight in the classification decision.[41]

Selective Interpretation of Results

Risk-assessment guidelines generally give the greatest weight to the most sensitive test animals. Thus, if a substance has been found to cause cancer in one

[34] Ames *et al., (op. cit.)*, p. 276.

[35] *Dioxin Risk Assessment Appendix A,* pp. 2–3.

[36] See Ames *et al., (op. cit.)*, p. 276 (arguing that such data are irrevelant); *OSTP Guidelines* Guideline 9, p. 10377 (concluding that such data "must be approached carefully"); and *EPA Carcinogen Risk Assessment Guidelines,* p. 33995 (making the policy judgment that such data are sufficient evidence of carcinogenesis). Liver tumors dominated in EPA's dioxin risk assessment. See *Dioxin Risk Assessment,* appendix A, pp.2–3.

[37] See *OSTP Guidelines*, Guideline 25, p. 10378; *EPA Carcinogen Risk Assessment Guidelines*, p. 33995.

[38] See *EPA Carcinogen Risk Assessment Guidelines*, p. 33999–34000. A single animal test that shows a positive result "to an unusual degree" (p. 33999) is sufficient to warrant at least a B2 classification ("probable human carcinogen"), even if this result occurs in a species known to have a high rate of spontaneous tumors. A strong animal bioassay or epidemiological study showing no evidence of carcinogenic effect cannot overcome this presumption (p. 34000).

[39] See "Second Peer Review of Daminozide (Alar) and UDMH (Unsymmetrical 1,1-dimethylhydrazine)," Memorandum from John A. Quest to Mark Boodee, U.S. Environmental Protection Agency, OPTS, May 15, 1989 (hereinafter, *Alar/UDMH Internal Peer Review No. 2*). This internal OPTS panel reviewed several recent studies on Alar and UDMH.

One study of Alar yielded a statistically significant increase in common lung tumors in mice, but only for one of three dosage levels. Results were not statistically significant at one higher and two lower dosages, and controls also displayed unusually high tumor incidence. 90% of the lung tumors in dosed mice were benign, versus 89% in the controls.

One study of UDMH yielded statistically significant increases in common lung and uncommon liver tumors in mice, but only for the higher of two dosages. 97% of the lung tumors in dosed mice were benign, versus 100% in the controls. 29% of the liver tumors in dosed mice were benign; no tumors were observed in the controls.

Prior studies that purported to show a carcinogenic response had been judged inadequate by EPA's Scientific Advisory Panel, an external peer review group. The Office of Pesticides and Toxic Substances (OPTS) panel noted that a different internal EPA risk-assessment panel (the Carcinogen Assessment Group) considered these studies sufficient to justify B2 classifications when it evaluated them for EPA's Office of Solid Waste and Emergency Response. Despite the scientific controversy, the OPTS panel interpreted these prior studies as "supporting evidence" under EPA's risk-assessment guidelines.

[40] See *EPA Carcinogen Risk Assessment Guidelines,* p. 33995 (establishing the need for replicate identical studies showing no effect), and p. 33999 (establishing the minimum requirement of two well-designed studies showing no increased tumor incidence to warrant a "no evidence" determination).

[41] *Alar/UDMH Internal Peer Review No. 2*, pp. 6, 8, 9. EPA's scheme for carcinogen classification is itself an issue among scientists. See, e.g., U.S. Environmental Protection Agency, Risk Assessment Forum, *Workshop Report on EPA Guidelines for Carcinogen Risk Assessment*, EPA/625/3-89/015, Washington, DC: March 1989, pp. 21–26.

species or gender but shown to exhibit no effects elsewhere, the results pertaining to the sensitive species or gender typically will be used to develop estimates of human-health risks. For example, if male mice develop cancer from a substance but female mice and rats of both genders do not, then the results from the male mouse often will be used to derive estimates of cancer risks to humans.[42]

Once a positive result has been obtained in an animal bioassay, a substance often will be provisionally classified as a probable human carcinogen. The statistical burden of proof then shifts to the no-effect hypothesis. Because it is logically impossible to prove a negative, however, this practice establishes a virtually irrebuttable presumption in favor of the carcinogenesis hypothesis.

Severe Testing Conditions

Current risk-assessment protocols require the use of very high doses. Unfortunately, high doses are often toxic for reasons unrelated to their capacity to cause cancer. A common procedure is to use what is called the maximum tolerated dose (MTD), which is the most that can be administered to a test animal without causing acute toxicity. At such exposure levels, substances often cause severe inflammation and chronic cell killing. For example, formaldehyde causes nasal tumors in rats when administered in high doses. However, MTD administration severely inflames nasal passage tissues. It is therefore unclear whether the cancers induced are caused by formaldehyde per se or by the toxic effects of high doses.

Results such as these have caused some scientists to question the validity of rodent tests performed at the MTD for estimating human health risks that arise from exposure at low doses.[43] By combining very high doses with highly sensitive test subjects, some animal bioassays are predisposed to discover apparent carcinogenic effects.

Relevance of Animal Bioassay Results

An important reason why animals vary in their sensitivity is that they have different physiologies, metabolic processes, reproductive cycles, and a host of other species-specific characteristics that largely result from unique evolutionary paths. Each of these factors needs to be carefully considered in evaluating the significance of animal data with respect to human health. This is recognized in both the OSTP and EPA guidelines, but it is often neglected when the guidelines are applied to specific substances.[44]

The most important assumption in this regard is that animal test results can be meaningfully extrapolated to humans. A recent study of chemicals tested under the auspices of the U.S. National Toxicology Program shows that this assumption can lead to the erroneous classification of many chemicals as probable human carcinogens.[45] Positive associations have been obtained in either rats or mice for half of 214 chemicals tested. However, results were consistent across these two genetically similar species only 70 percent of the time. If it is assumed that rodent bioassays have the same sensitivity and selectivity with respect to human carcinogens as they do between rodent species, and it is further assumed that 10 percent of all chemicals are in fact human carcinogens, then 27 of every 100 randomly selected chemicals would be misclassified as probable human carcinogens. Only three chemicals would be misclassified as noncarcinogens. Thus, "false positives" would be 9 times more common than "false negatives."[46]

Of course, this ratio of false positives to false negatives reflects highly conservative "upper-bound" assumptions concerning sensitivity and selectivity. Given the high degree of similarity between rats and mice and the limited resemblance between rodents and humans, the sensitivity of rodent bioassays with respect to human carcinogenicity is probably much lower than 70 percent. Furthermore, other research indicates that selectivity may be as low as 5 percent.

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[42] See *EPA Carcinogen Risk Assessment Guidelines*, p. 33997 (data from long-term animal studies showing the greatest sensitivity should generally be given the greatest emphasis).

[43] See, e.g., Ames *et al., (op. cit.)*, pp. 276–277.

[44] *OSTP Guidelines*, Guideline 25, p. 10378; *EPA Carcinogen Risk Assessment Guidelines*, p. 34003 (responding to comments on the draft guidelines and affirming agreement with OSTP Guideline 25).

[45] Lester B. Lave, Fanny K. Ennever, Herbert S. Rosenkranz, and Gilbert S. Omenn, "Information Value of the Rodent Bioassay," *Nature*, Vol. 336 (December 15, 1988), pp. 631–633.

[46] *False negatives* occur when a test fails to detect effects when they are in fact present. *Sensitivity* refers to the capacity of a test to minimize false negatives. *False positives* occur when a test appears to detect effects that in fact are absent. *Selectivity* refers to a test's ability to minimize false positives. The 9 to 1 ratio of false positives to false negatives calculated by Lave *et al.* assumes that both selectivity and sensitivity equal about 70%.

Adjusting only for this lower selectivity suggests that false positives are almost 30 times more common than false negatives. This raises serious questions concerning the practical utility of the current approach to animal bioassays for the purpose of quantitative risk assessment.[47]

Other factors should also be considered when relying upon animal bioassay results as the primary basis for quantitative risk assessments. For example, certain substances are toxic or even carcinogenic by one pathway but not by others. Nevertheless, animal bioassay protocols often emphasize the most sensitive pathway. As long as human exposure is likely to arise the same way, then this choice may be reasonable. However, the pathway to which the test species is sensitive sometimes reflects an exposure route that is implausible or irrelevant for humans. For example, formaldehyde causes nasal tumors in rats at 12 times the rate observed in the next most sensitive animal species. This extreme sensitivity may be related to the fact that rats breathe only through the nose.

There may be important differences between animals and humans that make specific tumors irrelevant. For example, some chemicals cause cancer in the zymbal gland of the rat; because humans lack such a gland it is unclear whether these results matter in estimating human health risk. Other substances induce cancer through biochemical mechanisms not found in humans.

A greater controversy surrounds the question whether the same weight should be given to benign and malignant tumors. The scientific consensus is that benign and malignant tumors should be aggregated only when it is scientifically defensible to do so.[48] In practice, however, benign and malignant tumors are routinely aggregated unless a strong case can be made *against* the practice.[49] The difference between these default assumptions is significant: One approach counts only carcinomas that *are* present, whereas the other counts tumors that *might become* carcinomas. In an extreme case, a substance that promotes benign tumors but never causes cancer could be classified as a probable human carcinogen simply because benign and malignant tumors are treated equally.

In addition, tumor incidence is commonly pooled across sites to obtain a total estimate of carcinogenic effects.[50] This implicitly assumes that cancer induction is independent across sites and not the result of either metastasis or the same biological mechanism. Given the extreme sensitivity of test species and the regular use of MTD administration, other explanations for tumors occurring at multiple sites appear just as plausible.

The Choice of Dose-Response Model

No single mathematical model is accepted as generally superior for extrapolating from high to low doses.[51] Consequently, Federal agencies often use a variety of different models. Rather than being a scientific footnote to the risk-assessment process, however, the choice of model is actually an important policy issue. The multistage model appears to be the most commonly used method for estimating low-dose risks from chemicals, and there are two major sources of bias embedded in this choice: its inherent conservatism at low doses, and the routine use of the "linearized" form in which the 95 percent upper bound is used instead of the unbiased estimate.

The *multistage model* essentially involves fitting a polynomial to a data set, with the number of "stages" identified by the number of terms in the polynomial. Since animal bioassays rarely have more than three dose levels, it is unusual to see applications of the multistage model with more than two stages. Although the multistage model enjoys some scientific support because it is compatible with multistage theories of carcinogenesis, in practice the model fails to include enough stages, due to the absence of sufficient alternative exposure cohorts.

The multistage model typically yields low-dose risk estimates that are higher than most other models. For example, when five different dose-response models were analyzed in a recent risk assessment of cadmium, estimates of cancer risks at moderate doses varied by a factor of 100. This difference among

[47] Lave *et al., (op. cit.)*, p. 631. Adjusting also for less sensitivity reduces the ratio of false positives to false negatives. For example, if sensitivity is only 10 percent and all other parameters remain unchanged, then this ratio declines to 9.5 to 1. However, this implies that both types of statistical errors are rampant, which raises questions concerning the practical utility of animal bioassays. This is, in fact, precisely the concern raised by Lave *et al., (op. cit.)*, who conclude that such tests are cost-effective investments in information only under extraordinary conditions.

[48] *OSTP Guidelines*, p. 10376.

[49] *EPA Carcinogen Risk Assessment Guidelines*, p. 33997.

[50] *Id.*

[51] *OSTP Guidelines*, Guideline 26, p. 10378; Ames *et al., (op. cit.)*, p. 276.

estimates widened as doses declined toward the very low levels within the range of regulatory concern. At very low doses, two of the five models predicted excess lifetime cancer risks greater than one in one thousand (10^{-3}), a risk oftentimes regarded by policymakers as unacceptable. However, two other equally plausible models predicted essentially no excess cancer risk at all. Since none of the five models offers a scientifically superior basis for deriving low-dose risks, the choice of model is therefore a pivotal policy decision. The accepted practice under these circumstances is to develop a subjectively-derived "best" estimate while fully informing decisionmakers as to the extent of uncertainty surrounding it.[52] In the cadmium case, as in most others, this practice was not followed: Estimates of the number of statistical cancers that would be prevented by regulation were presented based only on the multistage model.[53]

The *linearized multistage model (LMS)* is a special version of the multistage model in which the 95 percent upper confidence limit of the linear term is used instead of the unbiased estimate. That is, the model identifies the largest value for the linear term that cannot be rejected at the 95 percent confidence level and uses it in place of the unbiased estimate. Assuming that the model has been correctly specified, there is only a 5 percent chance that the true risk exceeds this level.

The LMS has become the preferred statistical approach because estimates derived from it appear to be more "stable" than estimates obtained from the ordinary multistage model. The "stability" issue originally arose because unbiased estimates of low-dose risks are very sensitive to the maximum-likelihood estimate (MLE) of the value of the linear term. When the MLE of the linear term is positive, it dominates estimated risks at low doses. In some instances, however, the MLE of the linear term is zero, and low-dose risk estimates decline precipitously. Using the 95 percent upper confidence limit ensures that the linear term is always positive, thus eliminating the inherent "instability" of low-dose risk estimates derived from the multistage model. [54]

Another often-cited advantage of the LMS procedure is that it provides a "yardstick" for comparing potencies across chemicals.[55] A uniform risk-assessment procedure such as the LMS, it is argued, enables policymakers to better understand the relative significance of a broad array of chemical hazards and set regulatory priorities accordingly.

Finally, the LMS is often defended on the ground that it is prudent to err on the side of caution when dealing with potentially carcinogenic chemicals. Because the LMS generates upper-bound risk estimates, policymakers can be confident that actual risks are likely to be lower.

None of these purported advantages of the LMS approach has a sound statistical basis. It is a fundamental axiom of statistics that unbiased estimates are generally preferred to biased ones. Using the upper confidence limit instead of the unbiased estimate exaggerates underlying specification errors instead of eliminating them. "Instability" is overcome, but at the cost of greater errors in specification.

The inherent instability of the multistage model reflects a generalized misspecification of dose-response—that is, the real human dose-response relationship is often very different from what the multistage model constrains it to be. The model is extremely sensitive to small differences in observed tumor incidence, which can cause dramatic changes in estimated low-dose risks. The LMS procedure eliminates this sensitivity without remedying the underlying specification error. Proper statistical procedure requires correcting model misspecification, not masking its symptoms behind biased parameter estimates.

The LMS procedure inflates low-dose risk estimates by a factor of two or three when the MLE of the linear term is positive. However, it increases low-dose risk estimates by orders of magnitude when the MLE of the linear term is zero.[56] This means that the degree of hidden conservative bias is substantially greater for what are demonstrably lower risks.

By its very nature, the LMS cannot serve as a useful yardstick for comparing the relative risk of a variety of potential carcinogens. If a given statistical procedure generated identical biases across substances tested,

[52] See, e.g., *OSTP Guidelines*, Guidelines 27, 29, and 31, p. 10378; *EPA Carcinogen Risk Assessment Guidelines*, pp. 33999, 34003.

[53] Occupational Safety and Health Administration, "Occupational Exposure to Cadmium; Proposed Rule," 55 FR 4076 (February 6, 1990).

[54] Albert L. Nichols and Richard J. Zeckhauser, "The Dangers of Caution: Conservatism in Assessment and the Mismanagement of Risk," Chapter 3 in *Advances in Applied Micro-Economics, Volume 4: Risk, Uncertainty, and the Valuation of Benefits and Costs*, V. Kerry Smith, ed., Greenwich, CT: JAI Press, 1986, pp. 55–82, esp. pp. 62–63. A nontechnical version of this paper is available by the same authors as "The Perils of Prudence: How Conservative Risk Assessments Distort Regulation," *Regulation*, November/December 1986, pp. 13–24.

[55] U.S. Environmental Protection Agency, *A Cancer Risk-Specific Dose Estimate for 2,3,7,8-TCDD*, EPA/600/6-88/007Aa, June 1988 (hereinafter, *Dioxin Risk Assessment*), pp. 45–46.

[56] Nichols and Zeckhauser, *op. cit.*, pp. 62–63.

then it would still yield an accurate rank-ordering of theoretical hazards. Similarly, if the procedure added a stochastic bias from a uniformly distributed random variable, the resulting rank-ordering would still be accurate on an expected-value basis. The problem with the LMS is that it generates biases that intensify with the degree to which the multistage model misspecifies the true dose-response relationship. Even if the multistage model provided an accurate rank-ordering of hazards, the LMS could not do so, because it injects biases that are systematic with statistical misspecification.

The LMS procedure (and the multistage model itself) is also fatally flawed as a yardstick for regulatory priority setting because it fails to take account of human exposure in the calculation of unit risks. Regardless of the procedure's capacity to accurately rank-order *hazards*, failing to adjust unit risks by relative human *exposure* virtually guarantees that regulatory priorities will be misordered. Resources tend to be focused on reducing the greatest theoretical *hazards* rather than the most significant human health *risks*.[57]

Finally, the "margin of safety" argument in favor of the LMS unequivocally contradicts the widely recognized need to distinguish science from policy.[58] The LMS introduces into each risk assessment a conservative bias of varying but unknown magnitude. This practice fundamentally alters regulatory decisionmaking. Instead of leaving policy decisions to policymakers, the LMS disguises fundamental policy decisions concerning the appropriate margin of safety behind the veil of science.

In summary, the LMS cannot be justified as a method of scientific risk assessment. The "yardstick" defense implicitly asserts that scientific advancements in risk-assessment methodology should take a back seat to the preservation of an outdated and misguided statistical procedure. The "margin of safety" argument tacitly usurps from policymakers the authority and responsibility for risk-management decisions. Finally, the statistical "instability" overcome by the LMS is an artifact of specification error, not any scientific theory of human carcinogenesis that warrants the intentional use of biased parameter estimates. The habitual reliance upon either the multistage model or its LMS descendant cannot be supported by sound scientific principles.

Alternative models are available, of course, and they have been applied in many quantitative risk assessments. Because proper model specification is the foundation of applied statistical methodology, alternatives to the multistage model should be expected and encouraged. Indeed, innovation is the hallmark of scientific inquiry; policies that institutionalize any particular model specification effectively stifle scientific advancement.

Unfortunately, models other than the multistage model are often discouraged in practice.[59] Agencies may require substantial scientific evidence in support of an alternative model before allowing it to be used. Alternative models thus face a burden of demonstrating scientific plausibility that the multistage model cannot satisfy. Even in the extraordinary case in which this burden can be satisfied, estimates may be required from the linearized multistage model anyway.[60]

The potential human health threat posed by dioxins provides an excellent example of the problem of model selection. Using the same linearized multistage model, EPA, the Centers for Disease Control (CDC), and the Food and Drug Administration (FDA) have arrived at upper-bound risk estimates that span an order of magnitude.[61] Depending on the data and assumptions used, the linearized multistage model predicts unit risk factors that vary by as much as 1,200, with the

[57] Some scientists have attempted to devise alternative indexes of relative human health risk that explicitly account for variations in human exposure. Ames *et al.*, (*op. cit.*), pp. 272–273, describe one such alternative (the Human Exposure/Rodent Potency index, or HERP) and report index values for 36 substances. Because the HERP index is based on a relative rather than absolute scale, the distorting effect of conservative biases embedded in the underlying risk assessments has been significantly reduced. Many substances suspected of being environmental carcinogens rank very low on the HERP index, suggesting that regulatory priorities have been seriously misdirected.

[58] See, *e.g.*, *NAS Risk Management Study*, p. 161; *OSTP Risk Assessment Guidelines*, Principle 29, p. 10378; and *EPA Carcinogen Risk Assessment Guidelines*, p. 34001.

[59] See, *e.g.*, Ames *et al.*, *(op. cit.)*, p. 276 (continued reliance on linear models despite the accumulation of evidence against linearity); and Lester B. Lave, "Health and Safety Risk Analysis: Information for Better Decisions," *Science*, Vol. 236, April 17, 1987, pp. 291–295, esp. p. 292 (agencies often resist modeling improvements and data that yield lower risk estimates).

[60] *EPA Carcinogen Risk Assessment Guidelines*, pp. 33997–33998. "In the absence of adequate information to the contrary, the linearized multistage procedure will be employed. . . . Considerable uncertainty will remain concerning responses at low doses; therefore, in most cases, an upper-limit risk estimate using the linearized multistage procedure should also be presented."

[61] *Dioxin Risk Assessment Appendix A*, p. 13. Unbiased risk estimates vary by a similar factor.

three risk estimates mentioned earlier clustered at the high end of the range.[62] Risk assessments based on different models have led other governments to establish unit risk factors that are a thousand times less stringent than the most commonly used of these three; one study suggests that this particular estimate overstates the most likely risk estimate by a factor of almost 5,000.[63]

Conversion from Animals to Humans

Once risk has been extrapolated to low doses in rodents, scientists must convert them to human dose-equivalents. The two most common approaches involve the use of body-weight or surface-area conversions, and there are scientific reasons for choosing either approach in individual cases. The surface-area approach leads to estimates of risk that are between 7 and 12 times greater than those based on the body-weight method, depending upon the test species. Despite the ambiguity of the underlying science, the more conservative surface-area method is often applied reflexively.[64]

ISSUES ARISING FROM HUMAN EXPOSURE ESTIMATES

In addition to developing estimates of the dose-response function, agencies must estimate the likely level of human exposure. This section examines some of the issues and problems that arise in conducting an exposure assessment.

It is a generally accepted principle of exposure assessment that estimates should be based on the most likely scenario, with appropriate consideration of uncertainty.[65] Nevertheless, agencies often use conservative assumptions for exposure when real-world data are unavailable. When each of these assumptions tends to overstate likely human risks, the multiplicative effect of even a small overstatement at each stage in an exposure assessment will yield a substantial overestimate of actual exposure. For example, the multiplicative effect of overstating risk by a factor of two at five different points in an exposure assessment will overstate actual risk by a factor of thirty-two.

Worst-Case Environmental Conditions

When data are available they often relate to unusually sensitive environments or highly contaminated conditions. When estimating regional or nationwide exposures, agencies often use data from these local "hot spots" in developing more general national estimates of health risks. However, such data are never representative and estimates extrapolated from them are generally unreliable and misleading.

In addition, chemicals often degrade naturally after they have been released to the environment. In some cases, degradation occurs very quickly, whereas in others the process may take many years or even decades. A common practice in exposure assessment modeling is to assume that exposures remain constant over time—that is, chemicals are assumed never to degrade, or degradation by-products are assumed to pose identical risks.

The Maximum-Exposed Individual

In addition to estimating the amount of a substance that may actually be present in the environment, a risk analysis must also consider the conditions under which humans may be exposed. Actual risks vary considerably depending on location, mobility, and a host of other factors. Nevertheless, estimates often are based on the upper-bound lifetime cancer risk to the maximum-exposed individual (MEI), the hypothetical person whose exposure is greater than all others. Sometimes, risks to the entire population are estimated by assuming that everyone is exposed at the MEI level. Because environmental regulations are often justified using MEI-based risk assessments, actual risks may be substantially lower than what decisionmakers and the general public perceive them to be.

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[62] *Dioxin Risk Assessment,* pp. 46–49. 10-6 risk-specific doses (RsDs) derived from the linearized multistage model span the range from 0.001 to 1.2 picogram/kg/day. The RsDs of EPA, CDC, and FDA are 0.006, 0.03, and 0.06 pg/kg/day, respectively.

[63] *Dioxin Risk Assessment,* p. 4.

[64] *EPA Carcinogen Assessment Guidelines,* p. 33998. "EPA will continue to use this [surface area] scaling factor unless data on a specific agent suggest that a different scaling factor is justified."

[65] EPA guidance documents have historically called for unbiased estimates of exposure. See, e.g., U.S. Environmental Protection Agency, "Guidelines for Exposure Assessment," 50 FR 34042–34054 (September 24, 1986, hereinafter, *EPA Exposure Assessment Guidelines*); U.S. Environmental Protection Agency, *Superfund Public Health Evaluation Manual,* OSWER Directive 9285.4–1, October 1986; and U.S. Environmental Protection Agency, *Superfund Exposure Assessment Manual* (Revised Draft), OSWER Directive 9285.5–1, December 1986. EPA recently abandoned the calculation of unbiased exposure estimates for Superfund sites on the ground that it was insufficiently conservative. EPA's new protocol requires the estimation of "reasonable maximum exposure" instead of the average and upper-bound estimates. Reasonable maximum exposure constitutes a new term of art that EPA intends to be "well above the average case" but not as extreme as the upper-bound. It provides a new opportunity for embedding conservative assumptions into exposure assessment and exaggerating estimates of actual human-health risk at Superfund sites. See *Risk Assessment Guidance for Superfund, Volume I: Human Health Evaluation Manual (Part A), Interim Final,* EPA/540/1-89/002, December 1989, Chapter 6, pp. 5, 47–50.

In developing the MEI risk level, analyses invariably assume that the level of exposure is continuous over a 70-year lifetime. This assumption overstates actual risks, because people are mobile, encounter a constantly changing portfolio of daily risks to life and health, and can take actions that reduce risk.

Assumptions vs. Real-World Exposure Data

The thread that connects these exposure assessment issues is that simple constructs which overstate exposure are typically used in lieu of real-world data, often because such data are unavailable. The risk estimates generated by these models depend on the validity of their assumptions; even small biases in exposure assessment assumptions can result in a substantial overstatement of risk.

For example, regulatory agencies may not have statistically reliable real-world data on pesticide residues in agricultural products. They also may not know the proportion of a given crop that has been treated with a particular pesticide. A common resolution of these uncertainties is to assume that residues are equal to the regulatory "tolerance"—the maximum level allowed to be present in food sold in interstate commerce—and that 100 percent of the relevant crop has been treated. Both assumptions overstate actual exposure, but are encouraged by agency guidance as a way to instill conservatism in risk assessment.[66] When data are available, however, the extent of this conservative bias becomes evident. In a recent special review for the pesticide Captan, for example, EPA reduced its earlier upper-bound lifetime cancer risk estimate by two orders of magnitude when it replaced the original conservative assumptions with real-world data. Even with these improvements, EPA still reported that upper-bound risks were probably overstated. For example, field tests were performed based on applications at the maximum legal rate and as close to harvest as the label permits. Similarly, feeding studies assumed that animal diets were dominated by feedstuffs that happened to contain high residues relative to other feedstuffs, such as almond hulls and raisin waste. As EPA noted, even if these assumptions accurately represented typical animal diets, they would do so only for portions of California where these crops are grown; nationwide extrapolations based on these "hot-spots" would very likely overstate exposure.[67] Since two of the highest product-specific risks were attributed to milk and meat, these remaining conservative biases can be expected to be significant.

IMPLICATIONS OF CONSERVATIVE RISK ASSESSMENT FOR RISK MANAGEMENT AND REGULATORY DECISIONMAKING

The primary purpose of risk assessment is to provide data as a basis for risk management decisions. Providing useful data requires the synthesis of information concerning risks and exposure levels into a coherent package that can be used to develop regulatory options. Decisionmakers then can use these risk estimates in evaluating regulatory alternatives. Unfortunately, the way in which risk information is characterized tends to overstate risks, making them appear much greater than they are likely to be. As a result, decisionmakers may make regulatory choices that are very different from the ones they would make if they were fully informed.

Quantification of Uncertainty

In accordance with the recommendations of the National Academy of Sciences, the *OSTP Guidelines* explicitly call for the quantification of uncertainty, particularly as it arises in the selection of dose-response models and exposure assumptions.[68] Unfortunately, Federal regulatory proposals that utilize risk assessment rarely provide this information, nor do they analyze the implications of uncertainty for decisionmaking. Instead, many risk assessments only identify a lifetime upper-bound level of risk.[69]

The differences between upper-bound and expected-value estimates may be considerable. As we indicated earlier, the upper-bound risk estimate for dioxin may be 5,000 times greater than the most likely estimate. Plausible risk estimates for perchloroethylene (the primary solvent used in dry cleaning) vary by a factor of about 35,000.[70]

In some instances, decisionmakers may not be informed that risk estimates differ because of policy choices hidden in the risk-assessment methodology. In EPA's proposed rule limiting emissions from coke

[66] *EPA Exposure Assessment Guidelines,* p. 34053. "When there is uncertainty in the scientific facts, it is Agency policy to err on the side of public safety."

[67] See, e.g., U.S. Environmental Protection Agency, "Captan: Intent to Cancel Registrations; Conclusion of Special Review," 54 FR 8127–8128 (February 24, 1989).

[68] *OSTP Guidelines,* (Guideline 27), p. 10378.

[69] See, e.g., *EPA Carcinogen Risk Assessment Guidelines,* p. 33998.

[70] Nichols and Zeckhauser, *(op. cit.),* pp. 64–65.

ovens, for example, cancer risks were estimated based on the LMS model—a model that is designed to yield upper-bound estimates of risk. In previous rules involving similar types of risks, however, EPA used the unbiased maximum likelihood estimate. To the extent that decisionmakers were not informed that the higher estimate of risk was largely due to a different low-dose extrapolation procedure, regulatory decisions based on this risk assessment were likely to reflect misunderstanding rather than science.[71]

Plausible estimates of likely cancer risk can often be found buried in regulatory background documents. However, *Federal Register* rulemaking notices seldom present such estimates alongside upper-bound estimates. This practice overstates baseline human health threats, as well as the amount of risk reduction that may be accomplished by regulation. Policymakers and the public are misled because they typically see only the upper-bound estimates of the threat.

The prevalent Federal agency practice is to calculate the benefits of Federal regulatory initiatives based solely on upper-bound estimates of risk and exposure. In a recent proposal to reduce occupational exposure to cadmium, for example, the Occupational Safety and Health Administration (OSHA) developed risk estimates based on five alternative models for animal data, and two alternative models for human data. Across these seven data/model combinations, estimated excess lifetime cancer risk at the least stringent of the two proposed exposure standards varied from 0 to 153 cases per 10,000 workers occupationally exposed for 45 years. OSHA based its proposed exposure standards on *one* of these data/model combinations—the multistage model applied to animal data. This data/model combination predicted an excess lifetime cancer risk of 106 per 10,000 exposed workers, and was used to estimate aggregate cancer incidence and the risk-reduction benefits attributable to the new standard. Uncertainties in the underlying risk assessment, which span several orders of magnitude, were not carried forward through the exposure assessment and benefit calculation stages. This analytic error effectively obscured the uncertainty surrounding the true incidence of cadmium-induced lung cancer, and resulted in benefit estimates that may exceed actual reductions in occupational illness by several orders of magnitude.[72]

Misordered Priorities, Perverse Outcomes

Logically, one would expect that the routine overstatement of likely risks would lead to inefficient regulatory choices. Decisionmakers, convinced that a certain substance or activity poses a significant threat to public health, might well take actions that they would otherwise resist. Alternatively, they might take actions that address the wrong real-life risks.

To the extent that risk assessments differ in the degree to which they adopt conservative assumptions, it is difficult to determine which activities pose the greatest risks and hard to establish reasonable priorities for regulatory action. Because conservatism in risk assessment is especially severe with respect to carcinogens, it is reasonable to expect that other health and safety risks tend to receive relatively less attention and weight. As a result, society may actually incur greater total risk, because of misordered priorities caused by conservative biases in cancer risk assessment. [73]

A perverse and unfortunate outcome of using upper-bound estimates based on compounded conservative assumptions is that the practice may actually increase risk, even in situations where cancer is the only concern. Regulatory actions taken to address what are in fact insignificant threats may implicitly tolerate or ignore better known, documented risks that are far more serious. For example, before it was banned, ethylene dibromide (EDB) was used as a grain and soil fumigant to combat vermin and molds. Vermin transmit disease, and molds harbor the natural and potent carcinogen aflatoxin B. The estimated human cancer risk from the aflatoxin contained in one peanut butter sandwich is about 75 times greater than a full day's dietary risk from EDB exposure. On this basis alone, it might have been appropriate to accept a small increase in cancer risk from EDB to reduce the much larger cancer risk from aflatoxin. By eliminating the relatively small hazard from EDB, Federal risk managers may have intensi-

[71]Letter from Wendy Gramm (Administrator of the Office of Information and Regulatory Affairs) to Lee Thomas (Administrator of the Environmental Protection Agency), August 12, 1986, p. 3.

[72]Occupational Safety and Health Administration, "Occupational Exposure to Cadmium; Proposed Rule," 55 *Federal Register* 4076, 4080, 4093.

[73] This is precisely the policy issue raised by Nichols and Zeckhauser, (*op. cit.*), pp. 69–71, who note that EPA's 1985 decision to limit lead in gasoline was threatened by concerns about potential increases in benzene exposure. Any tradeoff between lead and benzene risks would have been biased against lead; as estimates of benzene risks are more conservative simply because it is a carcinogen, whereas lead is not.

fied the relatively potent threat of aflatoxin associated with an increase in the prevalence of mold contamination.[74]

The emphasis on risks faced by the maximum-exposed individual may also cause a perverse result by increasing overall population risks. For example, EPA's proposed regulation of the disposal of sewage sludge would probably create more public health risk than it eliminates. The proposal outlines a regulatory scheme that would shift disposal from generally safe practices to relatively risky alternatives. Thus, setting sludge quality standards to achieve an MEI upper-bound lifetime cancer risk of one in 100,000 (10^{-5}) would prevent 0.2 statistical cancer cases resulting from monofilling and land application. However, it would cause 2.0 additional statistical cancers by forcing a shift away from these disposal approaches toward incineration.[75]

These problems can be addressed by providing decisionmakers with the full range of information on the risks of a substance or an activity. Thus, decisionmakers should be given the likely risks as well as estimates of uncertainty and the outer ranges of the potential risk. Then, if regulatory decisionmakers want to choose a very cautious risk management strategy, they can do so and a margin of safety can be applied explicitly in the final decision. This approach is superior to one in which the expected risk and an unknown margin of safety are hidden behind the veil of a succession of upper-bound estimates adopted at key points in the risk-assessment process.

The public and affected parties also benefit from knowing both the expected risk and the margin of safety rather than being given upper-bound estimates that are probably very different from actual risks. People are likely to have a better intuitive understanding of the significance of averages than they have of unlikely extremes. To the extent that a margin of safety is appropriate—perhaps to protect unusually sensitive subpopulations—the magnitude of this margin can be more readily communicated if made explicit. In addition, providing information in this way should help improve public confidence in quantitative risk assessment as the basis for decisionmaking.

AVOIDING CONSERVATIVE BIASES IN RISK ASSESSMENT

Risk assessment remains a powerful and useful scientific tool for estimating many of the risks that arise in a technologically advanced society. Unfortunately, it is also susceptible to hidden biases that may undermine its scientific integrity and the basis for policymakers' reliance on such information in risk management decisions. For policymakers and the public to continue to rely on risk assessment in the development of regulatory initiatives, a renewed effort must be made to separate science from policy and provide risk information that is both meaningful and reliable.

Expected Value Estimates

Perhaps the most important current need in regulatory decisionmaking is for carefully prepared and scientifically credible estimates of the likely risks involved. Relying on worst-case analysis based on extremely conservative risk assessment and exposure models leads to widespread misunderstanding on the part of both Government officials and individual citizens. Decisionmakers at all levels need unbiased and impartial risk information so they can focus their attention on significant problems and avoid being distracted by minutiae.[76]

Weight-of-Evidence Determinations

Similar procedures are needed for assigning weights to each relevant study in the risk-assessment literature. Current practice gives undue weight to studies that show positive relationships. Resulting risk classifications are thus conservatively biased estimates derived from samples of similarly biased observations.

Full Disclosure

Efficient and responsible decisionmaking requires that policymakers and the public be fully informed about the implications of the regulatory alternatives among which they must choose. Meeting this requirement demands a careful discrimination between science and policy. When risk estimates depend on assumptions and judgments instead of data, the meaning and implications of these nonscientific parameters must be clearly articulated.

Avoiding Perverse Outcomes

Careful attention needs to be paid to the likely results of regulatory alternatives, with an eye toward avoiding choices that have the perverse effect of increasing net risk. All human activity involves risk.

[74] Ames *et al., (op. cit),* p. 273.

[75] U.S. Environmental Protection Agency, "Standards for the Disposal of Sewage Sludge; Proposed Rule," 54 FR 5746–5902 (February 6, 1989).

[76] Nichols and Zeckhauser, *op. cit.*, pp. 72–76.

Decisionmakers need to be sure that specific actions taken in the name of risk-reduction in one area do not make matters worse elsewhere. Quantitative risk assessment can help in this regard so long as the methods applied are not inherently biased in a way that undermines comparisons across alternatives, each of which entails some degree of risk.

Our discussion has covered only the highlights of risk-assessment methods, yet we have identified several independent places at which conservative assumptions are commonly used. Individually, each of these assumptions might appear to be prudent responses to scientific uncertainty. In combination, however, they result in a distortion equal to the product of the individual conservative biases. To illustrate, suppose that there are ten independent steps in a risk assessment and prudence dictates assumptions that in each instance result in risk estimates two times the expected value. Such a process would yield a summary risk estimate that is more than 1,000 times higher than the most likely risk estimate. Because there are usually many more than ten steps, and many of them will incorporate conservative biases that exceed an order of magnitude, risk estimates based on such practices will often exceed the most likely value by a factor of one million or more.

When risk assessments contain hidden value judgments, their scientific credibility is inevitably compromised. To the extent that policymakers and the public fail to understand the magnitude of the margin of safety embedded in quantitative risk assessments, policy choices are distorted from the course that would have been selected if decisionmakers had been better informed of the actual risks. Ironically, these policy decisions may actually increase total societal risk. Too much attention is focused on relatively small hazards that have been exaggerated by conservative risk assessments, leaving alone larger risks that have been estimated using unbiased procedures.

Information as an Alternative Regulatory Strategy

Federal regulation was initiated to deal with economic problems caused by monopoly and so-called "excess competition." Subsequent events have shown that, in general, economic regulation—fixing prices, establishing restrictive terms of trade, and erecting barriers to entry—is usually inefficient and detrimental to innovation. In response to these lessons, Federal regulation of this type has been under increasing criticism. As indicated above, however, much more needs to be done to reform economic regulation and restore competition.

Federal regulation has more recently been initiated to deal with what economists call externalities, situations in which participants in voluntary market transactions do not bear the full costs or capture all of the benefits of these exchanges. Common examples of externalities include environmental pollution and traffic congestion, common property resources such as fisheries and public forests, and "public goods" such as basic scientific research. In each of these instances, regulation may be an appropriate mechanism to modify or restore distorted market processes, or to establish markets where heretofore they have not existed, to maximize net social benefits (including environmental, health, and safety benefits). The key ingredient is the determination that existing markets are, in some significant manner, failing to perform efficiently.

The traditional regulatory approach to externalities has been the promulgation of standards. Because this approach often remedies existing externalities by creating new ones, economic incentive instruments are becoming an increasingly popular alternative to standards. The principal attraction of economic incentives is that they rely on market forces rather than attempt to suppress them.

This section explores another alternative regulatory strategy—the production, provision, or mandated disclosure of information. The first subsection briefly summarizes the economics of information as it relates to regulatory decisionmaking. Three points stand out in this discussion. First, because information is costly to acquire and the capacity to process it is limited, there is an optimal level of information for every market transaction. Second, differences in the amount and quality of information between buyers and sellers are normal and do not necessarily indicate market failure. Rather, these differences generally reflect variations in the costs and benefits that are attributable to information. Third, competitive markets provide powerful incentives for buyers and sellers to reveal relevant information. Market processes, not government regulations, provide the dominant motivation for generating, acquiring, and disclosing information. The role of government regulation thus should be to supplement these processes when they prove to be inadequate, not to supplant them when they work well.

The second subsection identifies three rationales for government intervention in the production or mandated disclosure of information. Two of these are economic—the public-good character of some types of

information, and the absence of actual or potential competition in markets where information production or disclosure is relatively important. The third rationale for intervention is strictly ethical—a policy judgment that there exists a broad "right to know" which justifies compelling certain market participants to produce or reveal information at their expense but for the benefit of others. This concept overlaps somewhat with the public-good notion. The distinguishing feature of the right-to-know rationale is that it applies only to those cases in which society's collective willingness-to-pay is insufficient to justify regulatory coercion based on economic efficiency alone.

The final section provides illustrative examples of how regulatory strategies utilizing information have been recently used or considered. The purpose of the regulatory approach in each of these cases involves communicating information concerning certain hazards that may bear upon where individuals choose to live and work, and what they eat. The intent here is to stimulate discussion, not to identify particular areas as "targets" for regulation (or regulatory reform).

EFFICIENCY IN THE PRODUCTION AND ACQUISITION OF INFORMATION

If information were free, more of it generally would be better than less. Like other commodities, however, information is costly to produce, acquire, and disseminate, and costs typically increase with quality. These costs differ considerably across market participants, but for no one does valuable information come free of charge. The more one already possesses, the more the cost of getting slightly more or better data tends to increase. In economic terms, the *marginal cost* of producing, acquiring, and disseminating information increases with the quantity (and quality) produced or acquired.

There are also practical limits to the amount of information anyone profitably can use. Consumers of information set priorities, searching for the most important data first and lesser material as time and money permit. Slightly more or better data is valued highly when one possesses very little information; as one's information base increases, however, similar improvements in quantity or quality contribute less. In economic terms, the *marginal benefit* of additional information generally declines the more one already possesses.

For each participant in the marketplace (and by extension, the economy as a whole), the right amount of information is achieved when the benefit from the last unit of information obtained precisely equals the additional cost of obtaining it. Any other combination of information expenditures and acquisitions either wastes resources in the pursuit of too much information or fails to exploit valuable learning opportunities by seeking too little. This means that buyers and sellers will rarely, if ever, have precisely the same amount or quality of information at their disposal before they make decisions.

Such an informational asymmetry by itself does not necessarily mean that either side to a transaction is disadvantaged. It simply reflects differences in the costs and benefits of producing and acquiring information. Similarly, mere ignorance or uncertainty does not necessarily mean that private markets have failed to provide the proper amount of information. Neither ignorance nor uncertainty can be fully vanquished; every market participant, in balancing the benefits of more information against its costs, must accept some measure of both ignorance and uncertainty.

Indeed, market processes often reduce ignorance and uncertainty by stimulating information exchanges. Those who have information or can produce it cheaply offer it to those who value it highly but cannot produce it except at great expense. In some markets it is sellers who control relevant information; in other instances, it is buyers who are better informed. In a competitive market where sellers possess information relevant to buyers, a decision by one seller to withhold it will be countered by other sellers who will be willing to disclose it. Buyers who choose not to reveal information relevant to sellers will be outbid by other buyers who willingly share what they know. Competition will elicit the efficient amount of information, ignorance, and uncertainty as long as there are numerous potential buyers and sellers.

RATIONALES FOR INFORMATION AS A REGULATORY STRATEGY

Private markets fail to display efficient informational attributes under two broad sets of circumstances. First, when information has strong public-good aspects, private markets will produce too little of it and thus inhibit or prevent efficient exchanges from taking place. Second, vital information may be subject to monopoly control and thus be underprovided. A regulatory strategy based on information must be designed with careful consideration of which of these problems is actually present. Errors in identifying the problem may result in regulatory prescriptions that fail to address the disorder and may even exacerbate it.

Information as a Public Good

Too little information will be produced if the benefits of information can be captured without having to pay

the full social cost of producing it. Efficient incentives to develop and disseminate information will be stifled, and government action may be warranted to overcome the limitations of private-market forces. Basic research is a common example of information that is not adequately generated by private markets—information that has widespread potential application and cannot be readily subjected to protection by patent or copyright laws.

Monopoly Control over Information

Too little information is produced (or disclosed) when particular market participants control access to information or the capacity to produce it. Certain types of information are more susceptible to monopoly control, such as data related to a specific firm, plant, process, or product. The capacity to control, however, is only a necessary condition for market failure, because all market participants possess information that is unavailable to others. The crucial economic test is whether the social value of this information—as measured by the collective willingness-to-pay of those who would benefit from it— exceeds the cost of production and dissemination, plus any attendant losses that disclosure would impose. This is a complex economic problem for which simple answers are generally unavailable.

Right-to-Know

A third rationale for regulatory intervention lies beyond the usual confines of economics, but in some respects may be more important. This rationale is founded not on the value of information to an individual or society as measured by willingness-to-pay, but on the ethical judgment that people have the right to be informed. Conventional economic analysis is often neglected when rights are involved, on the ground that no price can be placed on a right. Economic analysis is still useful, however, for measuring the relative informational content of alternative regulatory strategies that seek to advance a particular societal value. A cost-effective regulatory strategy based on a right-to-know rationale would utilize the least expensive means of achieving the desired informational state. Economic analysis also helps clarify the social cost of establishing such a right. Indeed, any ethical basis for a right-to-know rationale must logically encompass the right to know how much it costs to have it.

THE REGULATORY CONTEXT OF INFORMATION: ILLUSTRATIVE EXAMPLES

Information arises in a wide variety of regulatory contexts in each of these forms. Regulatory strategies utilizing information represent a valuable alternative to traditional approaches when informational issues appear to be important.

The remainder of this section offers three vignettes in which an informational strategy has been used or considered instead of the traditional standard-setting approach, concerning hazard communication in the workplace, hazard communication in the community, and Federal policy on food labeling. These vignettes are intended only to illustrate the issues involved. They do not establish or advance a particular point of view or seek to imply that discussion should be limited to a narrow set of applications.

OSHA's Hazard Communication Standard

The Occupational Safety and Health Act of 1970 states that safety and health standards "shall prescribe the use of labels or other appropriate forms of warnings as are necessary to ensure that employees are apprised of all hazards to which they are exposed . . . and proper conditions and precautions of safe use of exposure." (29 U.S.C., Section 655(b)(7)). In economic terms, such information requirements are warranted when employers are presumed to possess monopoly control over information concerning workplace hazards. If workers are not sufficiently informed, then their wages would fail to reflect premiums that economists contend would have to be present to compensate them for bearing greater risks.

In carrying out its mandate, OSHA in 1983 promulgated a Hazard Communication Standard (HCS) applicable to the manufacturing sector. The rule was designed to provide employees with information about the potential hazards of chemicals to which they may be exposed at work. The scope of the HCS was expanded in 1987 to encompass virtually all of the private sector.

The HCS requires chemical manufacturers and importers to evaluate the hazards of the chemicals they produce or import. They must develop technical hazard information for material safety data sheets (MSDSs) and labels for hazardous substances. This information must be transmitted downstream to users of these substances. All employers are required to pass on this information to their workers through a comprehensive hazard communication program that includes individual training. In calculating the potential benefits from this information—the prevention of occupational cancers and other illnesses—OSHA stated that ". . . it is not unreasonable to assume that if employers and employees are provided with meaningful risk information they will take appropriate protective action" (48 FR 53324).

However, OSHA recognized that the deceptively simple goal of informing workers about the hazards of

workplace chemicals becomes exceedingly complicated when applied to millions of different workplaces, work conditions, and products across the country. The sheer volume of paperwork was tremendous. In 1988 the HCS required employers to spend 54 million hours to comply with the paperwork requirements, making its paperwork requirement the fourth most burdensome in the entire Federal Government, exceeded only by the 1040 tax form and two Department of Defense procurement requirements. The logistics of coordinating the flow of information from manufacturers to end users proved formidable. Complaints arose about the quality of information that was provided. Confusion about the requirements was widespread, especially within the small-business community.

Under the authority of the Paperwork Reduction Act, OMB held two public meetings on the HCS.[77] Several problems were identified. Some of these were start-up problems inherent in any regulatory program of this magnitude. However, others raised questions about the basic design of the standard and its effectiveness in changing the behavior of employers and employees.

The most common problem mentioned was information overload. OSHA intended the HCS to be comprehensive, to inform employees of all potential safety or health risks from chemicals regardless of magnitude. OSHA therefore gave suppliers and employers little flexibility to assess exposures and risks before determining what information to provide. One result was that employers and employees were bombarded with information that had little relevance and, worse, diverted attention from real risks. Some employers even reported risk information concerning paper bags and hand soap.

There were also significant problems in ensuring that the information provided was accurate and comprehensible. Employers complained that the information was too technical to be understood and used by employers and employees, and that much of it was erroneous. These problems undermined the effectiveness of the HCS, and may indicate that revisions are needed in the standard if OSHA is to accomplish its objective of changing behavior in the workplace to reduce risks from hazardous chemicals.

The HCS case demonstrates the importance of fully understanding the rationale for regulatory intervention before promulgating rules of this scope. Instead of identifying those situations in which the private labor market had failed to achieve an efficient allocation of risk, OSHA established a comprehensive set of information requirements. In order to justify such a comprehensive program in economic terms, there would have to be a systematic market failure across virtually all potentially hazardous chemicals.

Even if the problem of workplace chemical risks was as widespread as OSHA believed, the HCS failed to distinguish serious from trivial risks. OSHA thus treated all risk-related information as if it were equally valuable to workers. This led to an information strategy that apparently was much broader than the underlying problem it was supposed to remedy.If the HCS appears to generate too much information of uneven quality, this may be evidence that the optimal amount of information is actually much smaller than initially believed.

EPA's Community Right-to-Know Program

In 1986, Congress passed the Emergency Planning and Community Right-to-Know Act (EPCRA).[78] Despite its name, EPCRA was primarily intended to provide a specific public good: enhanced emergency planning and response to (primarily) chemical-related accidents.

EPCRA established requirements for firms and individuals to report the quantities of potentially hazardous chemicals stored or released into the environment. In addition, Federal, State, and local governments are directed, under EPCRA, to use these reports to develop emergency-response plans that would reduce public health risks in the event of an accidental release. Users of potentially hazardous chemicals are required to report to their local fire departments information regarding the types and quantities of chemicals stored and where they are located. Furthermore, respondents are directed to provide information concerning the potential health effects that might result from exposure. Users also must report releases of these substances to the EPA and to their State governments. By law, both inventory and release reports must be updated annually.

In crafting these regulations, EPA faced the difficulty of balancing the cost of generating and disseminating this information against the social benefits of enhanced emergency response. The most important factor in determining total societal cost appears to be the minimum quantity of chemicals that triggers inventory and release reporting. The lower these

[77] In *Dole* v. *Steelworkers*, No. 88–1434 (February 21, 1990), the Supreme Court held that the public protection clause of the Paperwork Reduction Act (PRA) did not extend to agency rules mandating disclosure by regulated entities to third parties. Hence, much of the Hazard Communication Standard is no longer subject to OMB approval or disapproval under the PRA.

[78] EPCRA was incorporated as Title III of the Superfund Amendments and Reauthorization Act (SARA) (42 U.S.C. 9601 et seq.); thus, EPCRA is also known as SARA Title III.

thresholds, the more entities must submit reports, and the greater the total social cost. However, the importance of emergency-response planning to the community diminishes as the amounts of chemicals involved declines. Large potential releases suggest greater potential public health threats, whereas small potential releases may indicate relatively minor risks. In addition, local emergency-response planners face limits as to the amount of information they can effectively comprehend and manage. The more stringent the reporting thresholds, the more information they have to process to develop their emergency response plans.

EPCRA established an initial inventory-reporting threshold of 10,000 pounds per year. In the absence of EPA action, this threshold would have declined to zero pounds in 1990. EPA promulgated final inventory-reporting requirements in late 1987, with initial reports due at the end of 1988. These rules maintained the 10,000-pound threshold for over 250 chemicals. However, for any substance classified as an extremely hazardous substance," the threshold was set at 500 pounds. Based on these thresholds, EPA estimated that almost four million firms and individuals would be required to submit inventory reports. EPA estimated that the cost of these requirements would exceed $1 billion during the first year alone.

The gains to emergency-response planning arising from these reporting requirements depend on the likelihood and magnitude of possible releases, and the nature of the chemicals involved. However, in the regulatory impact analysis submitted in support of its implementing regulations, EPA was unable to estimate specific benefits. Thus, the regulations were developed without any idea as to how much information would be appropriate. Subsequent analysis attempting to measure the social utility of alternative thresholds has led EPA to propose a permanent threshold of 10,000 pounds.

Extensive reporting requirements such as these often overlap with other Federal information-collection requirements. This situation challenges regulators to identify and mitigate duplication wherever possible. For example, operators of over 500,000 facilities using underground storage tanks (such as gasoline retailers) have an existing requirement to submit a form to both EPA and their State governments which contains much the same data as required under the EPCRA regulations. In cooperation with EPA, OMB recently solicited comments on ways to reduce this duplicative reporting. Similarly, many of the data required under the EPCRA release reports are already submitted to EPA and the States to obtain operating permits under several other environmental statutes. As a result, regulators must be vigilant in their efforts to ensure that efforts to use information as a regulatory alternative are carefully targeted and that duplication is minimized.

Food Labeling as an Informational Strategy

Food marketing involves a significant investment in providing information to consumers through product labeling and promotion. Generic product names alone may be sufficient to convey the necessary information about some products, such as milk or skim milk. However, additional information on the nutritional value or ingredients is often desired by consumers and provided by producers. Finally, some consumers may require certain information about ingredients, perhaps because of specific food allergies or because they are concerned about the possible health risks of certain chemical constituents.

Government can act to enhance efficiency in food markets in a variety of ways, depending upon the nature of the underlying market imperfection. For example, some information may have public-good aspects that warrant governmental provision or subsidization. In certain cases, growers, food processors, brokers, or retailers may have monopoly control over information that consumers consider vital to informed decisionmaking.

Nutritional Labeling as a Public Good

Food marketers possess a substantial amount of information that is generally unavailable to consumers, such as information concerning fat, sodium, and cholesterol levels. The FDA currently requires food marketers to provide this information in a variety of circumstances, especially when producers seek to make nutritional claims concerning their products. For example, a label which asserts that a product is "low" in sodium, fat, or cholesterol must provide explicit quantitative information on the label to back up this claim. This requirement is intended to reduce the chance that consumers will misinterpret a nutritional claim or fail to understand its context.

As consumers become increasingly health conscious, competition has driven more and more producers to provide nutritional information. Many food products have been altered so as to satisfy these changes in consumer requirements for information. Nevertheless, not all products have nutritional information on their labels, and some observers have asserted that all food products should bear such labels. The FDA is planning to propose such a mandatory requirement. The question facing FDA is whether the public-good benefits of regulation would exceed the costs of imposing it.

Ingredient Labeling as a Public Good

Some food ingredients may pose a serious health risk to certain segments of the population. A recent example is the case of sulfites, a class of preservatives to which some people are known to be allergic. One approach is to simply ban the use of such ingredients, thereby assuring the protection of the most sensitive members of the public. This approach has two serious problems, however. First, it is unclear what the appropriate sensitivity threshold should be, either in terms of the severity of health effects or the numbers of persons affected. Second, ingredient bans prevent those who are not sensitive from realizing the benefits of continued use. In the case of sulfites, FDA determined that a ban was justified only in a limited number of uses. For most applications, however, FDA continues to rely on an informational approach. Mandated disclosure of sulfite use enables sensitive people to easily avoid products that contain them while preserving the benefits of continued use for the majority of consumers.

Health Messages as Public Goods

Until recently, Federal regulators have rigidly enforced prohibitions against the publication or other use of health messages by food marketers. Because such messages historically lacked any credible scientific basis, Federal action against them prevented the dissemination of information that was false and misleading.

More recently, however, Federal and private sector investments in basic health research—another public good—have created a considerable body of scientific literature concerning the health consequences of a variety of foods. For example, certain foods contain high levels of cholesterol or saturated fat, both of which have been associated with increased risk of heart disease. Other foods are now believed to reduce the risk of certain forms of cancer. Because so many Americans are concerned about these risks, food marketers have shown an increased interest in providing information concerning the health benefits of reducing dietary levels of cholesterol and saturated fat. At the same time, there is a strong public policy interest in promoting the dissemination of such information. Based on this research and increased interest, food marketers have launched promotional campaigns and sought label changes intended to inform interested consumers as to the health benefits of their products.

To the extent that consumer interest in such information drives food marketers to provide it, competitive markets yield the qualitatively correct result. The remaining question is whether socially optimal amounts and kinds of health-related information are provided. If not, then there may be public-good benefits to Federal regulations that allow such information, so long as it is truthful and not misleading. In cases where food marketers seek to provide information that corresponds to prevailing scientific consensus, then competitive markets have the capacity to disseminate the same kind of information that Federal risk managers want to communicate through public-service announcements and publications.

Monopoly Power in Food Marketing

It has been asserted that by virtue of their control over production, food marketers possess a form of monopoly control over information such that government intervention is necessary to prevent or eliminate a market failure. However, it is unclear how food marketing enterprises differ from firms in other industries in the extent to which they have incentives to reveal information. As we indicated earlier, competitive markets are typically sufficient to assure that sellers reveal favorable information about their products, as well as unfavorable information about the products of their competitors. As in other markets, only where competition is lacking will sellers retain any market power derived from superior information. Even in these instances, it is unclear how the exercise of such market power would result in food that is less safe. In any event, it is often difficult in these cases to see how the Federal Government can effectively intervene to correct such problems.

Food Safety and "Right-to-Know"

The public-good rationale discussed above covers the vast majority of cases in which government intervention may be warranted. In sum, a market failure exists when the collective willingness-to-pay of society exceeds the costs that individuals acting alone are willing to bear. Typically, these situations are limited to cases in which one individual's consumption does not affect the amount available for others to consume, and it is impractical to exclude individuals who are unwilling to pay ("free riders") from receiving benefits.

With respect to food, neither of these conditions appears to exist. Food that is consumed by one person cannot be made available for anyone else. Similarly, the quality attributes of any foodstuff can be enjoyed only by the person doing the consumption. Information about food, however, may appear to satisfy the usual conditions for a public good. Information does not vanish after it has been put to use by a single person, and the capacity to exclude "free riders" is severely limited. Thus, it is important to distinguish between food per se and information that may lead to more informed consumers.

Some citizens may believe that because food is a necessity no amount of information determined by market processes (or by government requirements to supplement the market in the case of public goods) can be sufficient. Instead, they may feel that the public should be given all relevant information irrespective of whether consumers value it. In this view, information concerning food safety is not a public good at all, but rather a right that should be enforced by government action.

Any such basis for government action lies outside of the field of economics. Nevertheless, economic analysis is well suited for measuring the social costs of establishing and enforcing such a right. These social costs come in several forms.

First, the establishment of a "right-to-know" constitutes an abandonment of existing private markets for information. This change would have significant effects on both food marketers and consumers. Food marketers no longer would have incentives to provide information in response to competition. They would cease investing resources in the production and dissemination of health-related information except to the extent required to comply with governmental mandates. The cost of compliance, of course, would be reflected in higher prices at the supermarket—an unambiguous social cost.

Similarly, consumers would face a uniform body of food-safety information that diverged substantially from what most of them had received in the past when information was traded in the market. Those who place a relatively low value on food-safety information would gain little in additional benefits, but they would pay higher food prices. In contrast, consumers who value food-safety information highly would gain disproportionate benefits. Because of the diversity of consumer demand for food-safety information, any uniform standard would be inefficient. On balance, any such requirement would have greater costs than benefits.

Second, Federal standards would be needed to implement such a "right-to-know," and it is unclear what basis would be used to determine the required level of disclosure. When rights are involved, design standards tend to be preferred over performance standards. In the case of information, the absence of meaningful units makes performance standards even more difficult to develop. The general inefficiency of design standards constitutes another significant social cost.

Third, the removal of food-safety information from a market context deters innovation and thus causes long-term damage to economic institutions. Firms' incentives to invest in new products and technologies would be severely weakened. Each new product or technology would face the additional hurdle of satisfying an informational transfer burden that might or might not provide benefits to consumers. These costs make innovation more expensive, and thus less of it would be expected to occur.

Finally, the equity implications of a "right-to-know" concerning food safety may also be unpleasant. "Right-to-know" would redistribute income from those consumers who do not value such information toward those consumers who do. To the extent that people who value food-safety information highly also tend to be wealthier, then the establishment of a "right-to-know" may cause a redistribution of wealth from the poor to the rich.

In situations where economic principles are intentionally abandoned in favor of rights, the role of economics is to put a price tag on this choice. Rights are neither free nor infinitely valuable. By calculating the social cost, economics informs both Federal policymakers and the general public as to the sacrifice that must be borne to provide such rights. An integral part of any "right-to-know" is the right to know what it will cost to have it.

Regulatory Impact Analysis Guidance: Discussion of Comments

In response to many department and agency requests, OMB published a draft guidance document in the 1988 Regulatory Program to help departments and agencies in the preparation of regulatory impact analyses (RIAs). A guidance document became necessary because of substantial uncertainty concerning the appropriate level of analysis to be performed for a satisfactory RIA. This uncertainty led to inconsistencies within and across departments and agencies that made it difficult for both OMB and outside parties to evaluate and compare RIAs.

Some departments and agencies wanted OMB to publish a detailed set of requirements that, if followed, would guarantee compliance with the RIA requirement of Executive Order 12291. We understand this desire for an analytical "cookbook," but concluded that such an approach would fail to take account of the diversity of regulatory initiatives subject to the

Executive order. OMB decided instead to prepare a guidance document that would establish a three-part performance standard. RIAs must include:

1. A statement of the potential need for a proposed regulatory initiative;
2. An examination of alternative regulatory approaches; and
3. An analysis of benefits and costs expected to result from the regulatory initiative.

This chapter discusses the significant comments we have received concerning issues and procedures discussed in the draft guidance. Written comments were received from the Departments of Agriculture, Commerce, Labor, Transportation, and Veterans Affairs, and from the Environmental Protection Agency.[79] The final guidance reflects changes made as a result of these comments and appears as Appendix V of this document.

STATEMENT OF POTENTIAL NEED FOR THE PROPOSAL

An essential element of a satisfactory RIA is a statement of need for regulatory action. According to the draft RIA guidance, "analysis should demonstrate that (a) market failure exists that is (b) not adequately resolved by measures other than Federal regulation." OMB received comments addressing (a) what constitutes market failure, and (b) what rationales besides market failure justify Federal regulatory action.

The Definition of Market Failure

The draft RIA guidance identified three types of market failure: externalities, natural monopoly, and inadequate information. Externalities arise when individual actions or market transactions impose costs upon (or generate benefits for) third parties. Natural monopoly is defined as the existence of economies of scale so extensive that lowest-cost production of a good or service is obtained when there is a single seller. Finally, inadequate information refers to a particular type of market failure in which competitive forces fail to generate either the efficient production of information or the efficient pattern of information disclosure. Information issues were treated separately in the draft guidelines not because they are different in kind from other types of externalities, but because they pose economic problems that deserve a somewhat different regulatory approach.

One commenter felt that OMB's classification scheme failed to take account of a rich variety of market failures that arise within the commenter's particular regulatory area. Most of the unusual forms of "market failure" listed by this commenter are captured within the externality and inadequate information frameworks outlined in the draft guidance. However, this commenter also identified several phenomena that are not "market failures." It was asserted, for example, that safety regulations may be justified because "safety is relative and probabilistic." In a similar vein, this commenter argued that "it is generally not acceptable to discover that a product is unsafe only after it is in widespread use and has killed many people."

These alleged market *failures* are in fact undesirable market *outcomes*. The "relative" or "probabilistic" character of product safety mirrors similar uncertainties with respect to almost all market transactions. The existence of uncertainty does not imply a market failure. Many products and activities are inherently risky; the mere presence of a safety hazard cannot be prima facie evidence of market failure.

Some commenters identified examples of "market failure" that cannot be properly attributable to markets. Many of these alleged market failures are actually undesirable market *responses* to prior regulatory actions. For example, a commonly accepted (but poorly documented) side effect of stringent hazardous waste disposal regulations is an increased propensity for some individuals and firms to engage in illegal disposal. Departments and agencies facing situations like this should devote considerable attention to understanding the incentive effects of regulations, and strive to design regulations that yield appropriate behavioral incentives. For purposes of analysis and policy justification, these problems should be characterized as a failure of regulation rather than a failure of markets.

Another often-heard justification for regulation is the need for a "level playing field." Despite the wide array of circumstances in which the need for a "level playing field" has been asserted, a generally accepted definition of the phrase has not emerged. Sometimes, the perceived need for leveling appears to result from the competitive or regulatory advantages of others. In other cases, it is assumed to be necessary for unspecified equity reasons. In neither instance, however, does the absence of a "level playing field" indicate any malfunction in market processes. Imbalances that result from government actions (e.g., incentive-distorting subsidies for the extraction and use of certain virgin natural resources) generally should be addressed by the elimination of these perverse incen-

[79] The full text of all written comments is available for inspection and copying in the docket library of the Office of Information and Regulatory Affairs, Office of Management and Budget.

tives, not by additional government actions (e.g., incentive-distorting subsidies for recycling) that attempt to overcome the perverse outcome without confronting the inefficient incentives that caused it.

Alternative Rationales for Federal Regulation

This requirement implements section 2(a) of Executive Order 12291 and section 3(b)(1) of Executive Order 12612 ("Federalism").[80] The Agency's discussion of the need for Federal regulation should be based on the principles of Executive Order 12291. These principles establish unequivocally that the basis for regulatory action is market failure—that is, distortions in market outcomes arising from natural monopoly, externality, or inadequate information. In each of these instances, regulation may be an appropriate mechanism to modify or restore distorted market processes or to establish markets where heretofore they have not existed, to maximize net social benefits (including environmental, health, and safety benefits). Moreover, the policy view enunciated by Executive Order 12612 is that Federal (as opposed to State or local) regulatory action must be premised on the conclusion that the underlying problem to be addressed is Federal in scope, and not merely common to the States. In combination, these Administration policy statements require that RIAs performed in support of proposed Federal regulatory actions document that market failure is the underlying cause of the problem they are intended to remedy, and that the market failures in question are Federal in scope rather than merely common to the States.

Some commenters felt that the draft guidance placed too much emphasis on market failure. These objections represent a challenge to Executive Order 12291, however, not to the draft RIA guidance. The basic philosophy of the Executive order clearly identifies market failure as the principal (if not exclusive) rationale for Federal regulation. The final guidance for conducting RIAs is based on the clear language and purpose of the Executive order; objections to the Executive order must be addressed in another forum.

Some commenters questioned the required documentation of market failure on the ground that it failed to take account of statutory limitations that may conflict with Executive Order 12291. For example, regulations may be promulgated to implement a variety of legislative missions that derive from other public purposes besides remedying market failure. These purposes may include such activities as the redistribution of income, or the provision of benefits to favored groups or sectors of the economy. These commenters feared that a strict application of a "market failure requirement" in the RIA guidance thus would be inconsistent with their fundamental government function.

These comments may reflect misunderstanding concerning the scope of Executive Order 12291. Nothing in the Executive order repeals or otherwise modifies statutory requirements. Section 2 of the order prescribes that regulatory actions adhere to the order's stated principles "to the extent permitted by law." When departments and agencies must implement laws that conflict with the Executive order, the relevant laws always govern. However, the Executive order requires departments and agencies to apply its fundamental principles to the extent that they have discretion in interpreting their statutory mandate.

Even when governing statutes clearly conflict with the principles of section 2 of Executive Order 12291, the order's good-government requirements for full public disclosure and careful analysis still apply.[81] Departments and agencies are expected to (a) state in such cases that their regulatory actions are based on specific statutory requirements, (b) clearly explain why these requirements conflict with Executive Order 12291, (c) indicate whether these requirements address a genuine market failure or serve some other public purpose, and (d) perform analysis required by the Executive order to estimate the social opportunity cost of these conflicts. OMB believes that full opportunity cost accounting of statutory conflicts is necessary to implement Executive Order 12291.

Identification of Specific Statutory Requirements that Conflict with Executive Order 12291

Departments and agencies often have considerable discretion in the interpretation of statutory authorities. Unambiguous conflicts between statutes and the Executive order are relatively rare. Nevertheless, such conflicts do arise and should be carefully documented. It is insufficient, however, to assert broad exceptions to the Executive order in lieu of identifying specific statutory bases for conflict.

[80] Executive Order 12291, Section 2(a): "Administrative actions shall be based on adequate information concerning *the need for* and consequences of *proposed government action*" (emphasis added); Executive Order 12612, Section 3(b)(1): "It is important to recognize the distinction between problems of national scope (which may justify Federal action) and problems that are merely common to the States (which will not justify Federal action because individual States, acting individually or together, can effectively deal with them."

[81] Section 3(d)(4) of Executive Order 12291 reads: "[Each preliminary and final RIA shall contain] . . . a description of alternative approaches that could substantially achieve the same regulatory goal at lower cost, together with an analysis of [the] potential benefits and costs and a brief explanation of the legal reasons why such alternatives, if proposed, could not be adopted."

Clear Explanation of Reasons for Conflict

Having identified specific statutory language that conflicts with the principles of the Executive order, departments and agencies must cogently explain the nature of these conflicts. Legislative histories and other documents may be helpful for developing such explanations. However, it is important that these sources not be used to displace plain statutory language. Departments and agencies bear the burden of showing how specific statutory requirements conflict with the principles of the Executive order.

Analysis Estimating the Opportunity Cost of Statutory Conflicts

Because Executive Order 12291 reflects cardinal principles for the conduct of good government, Federal regulatory actions that depart from these principles deserve unusual care and public scrutiny. An essential element of this effort involves the estimation of the social opportunity cost of such departures. Opportunity cost is the value of the resources society must sacrifice to accomplish conflicting statutory objectives.

Analysis is a necessary prerequisite to an informed electorate. It provides policymakers and citizens a better understanding of the consequences of governmental actions. For government, careful analysis satisfies a "truth in regulation" disclosure burden that ultimately results in more carefully reasoned policy choices.

EXAMINATION OF ALTERNATIVE APPROACHES

The draft guidance encouraged departments and agencies to consider a wide range of regulatory alternatives, and include in their RIAs analysis addressing "a manageable number of them." The draft guidance did not dictate a specific number of alternatives to analyze, noting that "there must be some balance between thoroughness of analysis and practical limits to the agency's capacity to carry out analysis." Alternative regulatory actions examined should be reasonably expected to remedy the identified market failure; it is not sufficient to identify legitimate market failures that cannot be remedied by the proposed governmental action.

Commenters generally supported the emphasis on breadth in the draft guidance, and the use of a "performance standard" approach which recognizes that all potential regulatory actions do not warrant equally intensive study. However, some commenters felt that the draft guidance imposed an unnecessarily heavy analytical burden that could not be satisfied in practice. OMB recognizes that the appropriate depth and level of analysis should vary with the nature and scope of the proposed regulatory action. However, OMB believes that the analytical burden imposed by the RIA requirement is never excessive given the magnitude of effects which result from "major" Federal regulations.[82]

The draft guidance also directed departments and agencies to examine innovative regulatory approaches. Foremost among these alternative approaches were performance-oriented standards, differential requirements for distinguishable sectors of the regulated community, information measures, and market-based incentive strategies. Commenters were either silent or supportive of this emphasis on creative, targeted, market-oriented solutions.

Finally, the draft guidance encouraged departments and agencies to consider reasonable alternatives that might be precluded by statute. Some commenters asserted that such analysis is unnecessary and contributes little to the regulatory process. OMB believes that the analysis of statutorily precluded alternatives is essential to inform long-run policy debate and thus is generally worth the effort, even if it has no immediate effect on short-run decisions. The final RIA guidance explicitly requires departments and agencies to evaluate statutorily precluded alternatives as necessary, thereby providing estimates of the opportunity cost imposed by statutory constraints.

ANALYSIS OF BENEFITS AND COSTS

Comments concerning the benefit-cost analysis requirement of the draft guidance generally fell into one of the following five categories: (1) the identification of values suitable for regulatory analysis, (2) appropriate methods for valuing nonmarket goods, (3) the derivation of benefit estimates based on quantitative risk assessment, (4) distributional effects, and (5) discounting.

Identification of Values Suitable for Analysis

Several commenters felt that the draft guidance gave inadequate attention to the problems of quantifying and monetizing benefits that accrue in the form of

[82] "Major" rules are defined by section 1(b) of Executive Order 12291 to include any regulatory action likely to result in (1) $100 million in annual effects on the economy; (2) a major increase in costs to consumers, industries, governments, or geographic regions; or (3) significant adverse effects on competition, employment, investment, productivity, innovation, or international competitiveness. Regulatory actions that do not appear to meet these criteria but establish important policy precedents may also qualify as major rules.

nonmarket goods such as environmental amenities. Commenters suggested a variety of measures for estimating the benefit of nonmarket goods, indicated by such terms as *use value, option price, option value, existence value, preservation value,* and *intrinsic value.* Unfortunately, there are considerable differences of opinion concerning the appropriate definitions for these terms, and even less agreement concerning their proper application. In the interest of consistency, we distinguish between the nature of a benefit and the methods used to estimate it.[83]

Physical and Psychological Use (Use Value)

The benefits from environmental amenities derive from a continuum of sources ranging from intensive physical use to intangible psychological enjoyment. Some individuals may value an environmental resource for the outdoors activities it provides, such as hunting, fishing, camping, or boating. Others may value it for timber that could be harvested to provide lumber for new homes. Still others may attach value to preserving an environmental resource as wilderness, free from intensive recreational and developmental uses. Both physical and psychological uses are fully captured by the term *use value*, even though psychological uses often are characterized by the terms *existence, intrinsic,* and *preservation values*. There is no difference in theoretical "legitimacy" between physical and psychological uses. Problems arise only with respect to measurement.

The principles of positive economics do not provide any means for ranking alternative sources of "utility" apart from willingness-to-pay. Rather, the objective task of economics is to ascertain such rankings based on the revealed or otherwise discernable preferences of individuals. In most cases, preferences are revealed through actual behavior, and market transactions provide the forum in which society, as a collection of independently acting individuals, communicates an aggregate valuation for these preferences. Market transactions provide tangible evidence of individuals' willingness-to-pay, thereby allocating goods and services to the highest-valued use. Markets reveal value, and positive economics treats virtually all market-determined values as ethically equivalent.[84]

The "problem" of valuing physical and psychological uses of environmental amenities does not appear to be significant where property rights are well-defined and readily enforceable by law. Owners and operators of such resources allocate them to their highest- valued uses, charging use or access fees that reflect market-determined values. Markets for common-property environmental amenities often can be created by establishing well-defined and enforceable property rights. The right to fish in a public lake is often constrained by the number of licenses available, which is generally limited by the carrying capacity of the lake. Opportunities to backpack in a Federal wilderness area similarly are limited by the number of permits, which exist to protect permit owners from the encroachment of others. In the absence of well-defined and enforceable property rights, however, market prices will be misleading where markets exist and generate resource allocations that are both economically inefficient and environmentally unsound. Common-property resources characterized by well-defined property rights, however, enable full opportunity-cost accounting to determine the highest-valued use.

Economics does not arbitrarily assign higher values to some uses than others. Nevertheless, some uses are more readily observed and estimated because there are market-based transactions that reveal individuals' willingness-to-pay. If property rights are well-defined and readily enforceable, markets will exist for such varied uses as timber harvesting, fishing, hiking, and birdwatching. In each case, individuals physically visit the environmental amenity to "consume" it. Where such markets exist, they should be relied upon to derive estimates of willingness-to-pay.

However, markets for the preservation of environmental amenities apart from physical use generally do not exist. The willingness-to-pay for preservation may be equal or greater than the willingness-to-pay for physical use, but high transactions costs typically prevent the formation of markets. Nevertheless, the same principle for measurement applies. A variety of analytic methods may be acceptable as long as they yield estimates that reflect market-based principles of valuation and comport with reasonable expectations of what markets would generate if in fact markets existed.

Innovative strategies for overcoming these problems have been developed in recent years. For example,

[83] The following discussion uses environmental amenities as a surrogate for all nonmarket goods.

[84] Many economists would exclude the utility obtained from illegal acts and transactions. As a general rule, however, the burden rests on those who would exclude certain sources of utility as illegitimate. Utility derived from legal markets is per se legitimate and cannot be excluded.

many States offer voluntary check-offs for environmental preservation on their income tax returns. These check-offs may provide a useful real-world measurement of willingness-to-pay for environmental preservation apart from physical use, where they increase taxpayers' financial liability to the State on a dollar-for-dollar basis.[85]

Option Price

This term reflects an individual's willingness-to-pay for the opportunity of future use. For a risk-neutral individual, it is equivalent to the present-value willingness-to-pay for physical or psychological use, multiplied by the probability that use will actually occur.[86] Risk-averse individuals will generally pay more than the expected value for actions that reduce variability in outcomes; for them, option price will exceed willingness-to-pay.

Option Value

This term is defined as the mathematical difference between option price (an ex ante measure of welfare change) and the expected value of consumer surplus (an ex post measure of welfare change). It reflects a risk-averse individual's willingness-to-pay for insurance against the threat of an undesirable event. Option value is zero for risk-neutral individuals because they are only concerned with the expected value of consumer surplus and are indifferent with respect to the amount of uncertainty surrounding the expected value. Because option value is a risk premium, it will not be a large fraction of the expected value of consumer surplus except for individuals who are extraordinarily risk averse. Moreover, option value for an individual will tend to be associated with unique resources. Even if option value is unusually large for an individual, it will not be substantial in the aggregate unless this uniqueness is shared by many such individuals.[87]

Other Valuation Terms

The remaining valuation terms suggested by commenters are either captured elsewhere, or they are unrelated to an individual's actual or potential "use" of an environmental amenity and should be excluded from consideration in regulatory analysis. *Bequest value* may be thought to represent an individual's interest in preserving a resource for the current or future enjoyment of others. To the extent that this constitutes a psychological "use," it is already captured within the use value definition. An alternative meaning for *bequest value*, however, is an individual's desire to bequeath an (environmental) amenity that is not part of the individual's asset portfolio. In this instance, bequest value is illegitimate, because it represents the individual's asserted claim on the disposition of assets owned by others.

Intrinsic value has been discussed in the context of other psychological uses, such as *preservation value* and *existence value*. However, the term is also used to refer to the "value" of animals, plants, and inanimate objects independent of the willingness-to-pay of individuals or societies. In this context, the term appears to be based on a valuation system that is independent of human experience. Because it is grounded in human wants and desires, policy analysis cannot be expected to accommodate this alternative definition of "value."

Valuation of Nonmarket Goods

Use value is theoretically equivalent to an individual's willingness-to-pay for access to and enjoyment of an environmental resource. In practice, physical use values can be estimated based on the observation of actual behavior or through the use of survey instruments. In general, neither approach is fully satisfactory. Survey instruments often suffer from biases because they attempt to measure hypothetical trade-offs; revealed preference methods sometimes require data that cannot be reasonably obtained.

Survey estimates may be necessary to estimate certain physical and psychological uses, because relevant behavior is unobservable. However, the problems that arise in the estimation of use value through survey methods are considerably more serious. Great care needs to be taken to ensure that survey designs do not introduce systematic biases by departing from market-based valuation principles. For example, slight changes in the way questions are presented can sometimes result in dramatic changes in responses, because of the hypothetical nature of data derived from survey instruments. This hypothetical character means that survey methods offer considerable opportunities for abuse. Analyses relying on survey instruments to estimate benefits should devote considerable efforts to quality control, data verification, and real-world hypothesis testing. Major

[85] Tax return check-offs give a lower bound of willingness-to-pay because of the existence of "free riders," individuals who obtain psychological enjoyment from preservation without actually contributing to it.

[86] Use may be automatic for psychological uses, because it is not contingent on the expenditure of additional scarce resources to convert from speculative to actual consumption. Option prices for psychological use should be identical to willingness-to-pay.

[87] For option value to be large in the aggregate, two conditions must apply: (1) individuals must be risk-averse; (2) use of the environmental amenity must constitute a very large proportion of each individual's asset portfolio.

departures from market-based principles can lead to serious distortions in the allocation of our Nation's scarce resources.

Because of the potential for misuse of survey methods, RIAs generally should avoid relying exclusively on value estimates derived through survey approaches. An exception to this rule may arise in special cases where nationally recognized unique resources (e.g., "national treasures") will suffer *irreversible* damage in the absence of regulatory action. This limitation allows the consideration of value estimates that are based solely on survey results in instances where they are most likely to be significant, while discouraging their widespread and indiscriminant application where they are likely to be small.

Finally, departments and agencies that develop benefit estimates which rely heavily on the results of survey instruments bear an extraordinary burden to show that estimates obtained are reasonably consistent with observable market behavior and common sense. For example, survey-derived estimates of willingness-to-pay for wilderness preservation should comport with observable behavior, such as voluntary income-tax return check-offs. Estimates of individuals' willingness-to-pay for *reversible* environmental harms, such as visibility impairment, may be even more difficult to corroborate based on observable behavior.

The Use of Quantitative Risk Assessments in the Development of Benefit Estimates

The draft RIA guidance focused considerable attention on how quantitative risk assessments should be employed in producing appropriate estimates of the benefits accruing from regulatory actions aimed at health and safety objectives. The draft guidance indicated that analytically sound benefit estimates can only be based on expected-value estimates of human health risks.[88] The use of upper-bound risk assessments and worst-case exposure assumptions leads to upwardly biased benefit measures. These biases transform objective benefit-cost accounting into a subjective procedure that inherently favors regulatory action.[89]

A few commenters objected to OMB's emphasis on expected-value risk assessment on two grounds. First, these commenters argued that expected-value estimates fail to take account of high-risk subpopulations, which deserve special regulatory protection. Second, the uncertainties surrounding quantitative risk assessment are so great that prudent public health policies warrant conservative risk estimates.

Both of these criticisms suffer from a misunderstanding of the purpose of estimating benefits. The National Academy of Sciences clearly articulated the basis for expected-value risk assessment in its seminal 1981 report:

> Regulatory agencies should take steps to establish and maintain a clear conceptual distinction between assessment of risks and the consideration of risk management alternatives; that is, the scientific findings and policy judgments embodied in risk assessments should be explicitly distinguished from the political, economic, and technical considerations that influence the design and choice of regulatory strategies.[90]

Regulatory agencies that fail to develop expected-value benefit estimates violate this fundamental principle.

The desire to protect certain high-risk subpopulations does not justify embedding conservative biases within ostensibly scientific risk assessments. Whether high-risk subpopulations deserve special consideration is a policy matter for which government risk managers are responsible. It has no bearing on the correct practice of policy analysis. Departments and agencies are free to quantify the effects of potential regulatory actions on sensitive subpopulations, particularly as quantification enriches policymakers' understanding of the tradeoffs across regulatory alternatives. However, it is not acceptable to focus on sensitive subpopulations *instead of* examining expected-value impacts.

Similarly, uncertainty per se cannot justify biased benefit estimates. Uncertainty is endemic to regulatory analysis. However, conservative biases and "margins of safety" embedded in the analysis of the effects of regulatory actions (e.g., those purporting to reduce environmental and occupational cancer risks) fundamentally distort public policy in unpredictable ways. Benefit estimates derived from upper-bound risk assessments and worst-case exposure assumptions mislead policymakers and the general public about the true dimensions of the underlying problem.

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[88] The full distribution of possible benefits is the theoretically preferred measure. Departments and agencies generally produce only a point estimate, however, in part because it is impossible to develop the full distribution. The RIA guidance calls for benefit estimates to be based on expected values whenever departments and agencies choose to provide only point estimates, because only the expected value is unbiased. OMB has long supported efforts to characterize the full distribution, rather than relying on point estimates.

[89] Issues concerning risk assessment are addressed in more detail earlier in this overview, in *Current Regulatory Issues in Risk Assessment and Risk Management*.

[90] National Academy of Sciences, *Risk Assessment in the Federal Government: Managing the Process*, Washington, DC: National Academy Press, 1983, p. 153.

Expected-value benefit estimation simply treats both sides of the ledger in the same manner. Departments and agencies do not (and should not) use upper bounds and worst-case assumptions to estimate regulatory costs; instead, they provide "best estimates" that are often subject to considerable uncertainty. Intellectual fairness demands a similar treatment of uncertainty on the benefit side. The severe uncertainties characteristic of quantitative cancer risk assessment are typical of the difficulties of performing rigorous policy analysis in general. Howver, instead of limiting analysis (or inserting a specific bias) government agencies have the duty to devote resources to reducing uncertainty when the value of this information exceeds the cost of providing it. This cannot be accomplished as long as agencies continue to construct biased benefit estimates derived from upper-bound risk assessments and worst-case exposure assumptions.

Distributional Effects

Several commenters suggested that the final RIA guidance should require that analyses present the distributional effects of regulations. Those persons who bear the costs of a regulation and those who enjoy its benefits are often not the same. For example, the costs of changes to production processes intended to improve worker safety are often borne by consumers, in the form of higher product prices. The costs and benefits of regulation can also be distributed unevenly over time, spanning several generations.

A strict regulatory decision framework designed to maximize net benefits does not take such distributional effects into account. Rather, it is based on the Kaldor-Hicks criterion, which states that policy A (e.g., a regulation) is preferred to policy B (e.g., the status quo) if the gainers could compensate the losers and still be better off. The Kaldor-Hicks criterion does not require that gainers actually compensate losers—something for which the Kaldor-Hicks criterion has been criticized. Ironically, requiring such compensation would intensify the implicit preference given to the status quo, by restricting changes to those which are Pareto-superior.

There is no generally accepted way to monetize (and thus incorporate directly into the benefit-cost analysis) potential distributional effects. However, policymakers may wish to take these effects into account. Therefore, in situations where there are potentially important differences between those who stand to gain and those who stand to lose under alternative regulatory options, the RIA should identify these groups and indicate the nature of the differential effects. It is not acceptable to merely assert the existence of intergenerational effects. The RIA must present full benefit and cost streams as well as present-value estimates for each relevant group. This approach leaves to policymakers the responsibility for determining the weights that should be explicitly applied to certain groups or to future generations.

Discounting

The draft RIA guidance incorporated the fundamental economic principle that both benefits and costs should be discounted. This practice takes account of the fact that any fixed resource is worth more today than at any future date. Comments were received addressing the appropriate methodology for discounting nonmonetized costs and benefits, the use of "steady-state" approaches instead of discounting, and the selection of the discount rate.

Discounting Effects That Are Not Monetized

One commenter argued that only effects which can be monetized should be subject to discounting. This commenter argued that regulatory effects which are not traded in markets do not exhibit the same value-of-time preference underlying the discounting of monetized commodities.

This argument has three fatal flaws. First, it is based on a misunderstanding of the theory of intertemporal exchange. Second, it can lead to absurd policy implications under certain circumstances. Third, it is refuted by empirical evidence.

The commenter's argument is apparently based on the mistaken belief that nonmonetized effects must be either (a) "directly" tradable across different time periods or (b) amenable to valuation in monetary terms, and that in many instances neither condition holds. This argument is fallacious because neither condition comports with economic theory. The first condition lacks merit because few commodities can be directly traded across time periods without the mediating function of the price system. Any requirement of direct trading imposes an arbitrary constraint that denies the price system's capacity to reduce the transactions costs of exchange. Prices established through the market provide a convenient "scale" that allows individuals to balance one intertemporal consumption path against another based on their particular preferences for current and deferred welfare. This commenter would arbitrarily deny the legitimacy of intertemporal exchange except in cases where there are explicit market prices.

The commenter's second condition (that the commodities in question must be amenable to monetization) is satisfied at least conceptually for all goods of finite value. If it were not satisfied, we would observe individuals devoting their entire wealth to the pursuit of certain infinitely valued goods. Of course, such an

observation is counterfactual. Individuals behave in accordance with real prices where prices exist, and *as if* prices exist in areas where they do not. The relevant distinction between monetizable and nonmonetizable effects is really one of the ease with which one can estimate their value.

Because all commodities are of finite value, analysis requires that they be treated consistently regardless of the ease with which they can be explicitly monetized. To do otherwise would distort the allocation of regulatory resources in favor of nonmonetized goods and services that can be enjoyed in any future time period at the expense of goods and services whose value in that time period is determinate.

Of course, policymakers may wish to weigh certain effects differently than others. However, arbitrarily treating effects differently through the discounting procedure denies decisionmakers that option. As we indicated earlier in our discussion of distributional concerns, the RIA should present the undiscounted streams of costs and benefits as well as their discounted present values in situations where decisionmakers are unusually concerned about nonmonetized effects.

The failure to discount nonmonetized benefits can lead to the absurd result that society will always be better off by deferring an action (and its associated benefits) indefinitely. To argue that a nonmonetized benefit should not be discounted implies that its value is the same whether it occurs today or at any time in the future. Suppose that the resources that would otherwise be used today to achieve a given result could be invested at a positive rate of return (that is, at the discount rate). By forgoing the expense this year and investing the resources at the discount rate, society could spend more next year (by a proportion equal to the discount rate) and achieve a higher level of welfare. As long as society places the same value on a unit of future benefits as a unit of current benefits (i.e., it does not discount), it will be better off by delaying the action ad infinitum.

Finally, there is empirical evidence indicating that individuals behave as if they discount future effects that do not carry explicit prices. In the context of compensating differentials for occupational risks, for example, analysts have estimated a real discount rate of 10 to 12 percent. This implies that the willingness-to-pay today for a 1-year life extension for an individual who expects to live only 5 years is about 40 times as great as that of an individual who expects to live 35 more years. A policy decision based on undiscounted effects in this instance could result in an allocation of resources that is grossly inconsistent with this revealed willingness-to-pay.

While costs and benefits must be compared as if they occurred simultaneously, it is not necessary to discount benefits to accomplish this kind of comparison. As an equivalent alternative to discounting nonmonetized benefits, for example, the RIA may use the discount rate to amortize costs over a period that corresponds to the occurrence of the benefits. Cost estimates will be greater under this method, because they will reflect the forgone investment potential of expenditures that must be made now rather than contemporaneously with the benefit stream.

Estimating Benefits and Costs Based on Steady-State Conditions

Some agencies derive benefit and cost estimates in steady-state equivalents instead of net present value terms. This procedure may be useful for examining regulatory actions when benefits and costs are purely contemporaneous. However, steady-state analysis may obscure the full ramifications of regulatory actions by focusing too much attention on the snapshot view. It is similar in this respect to problems with benefit-cost ratios, which focus attention on relative totals but fail to disclose the magnitude of a contemplated action.

Problems also arise with steady-state analyses when benefits and costs accrue over different time periods. The steady-state outcome may give a distorted impression of the true consequences of a regulatory action. For example, the costs imposed by a particular action may be borne in roughly equal annual increments, whereas the benefits obtained from these expenditures may increase at a declining annual rate until the steady state is achieved many years hence. The net present value of the action will be considerably less than the apparent net benefit in the steady state.

An example of the misuse of steady-state analysis is the practice of "annualizing" health benefits that actually accrue in the latter part of a lifetime. These analyses typically assume that changes in environmental or occupational conditions are instantaneously translated into reduced human health risks. In practice, such changes may take many years to achieve their full protective effect. Analyses that assume instantaneous transmission overstate actual benefits and impart a systematic bias in favor of regulatory action.

Choice of Discount Rates

Rather than specify a single discount rate to be applied in all circumstances, the draft guidance offered two alternatives: (1) a before-tax real rate of 10 percent, consistent with OMB Circular A-94; and (2) an after-tax real rate of 4 percent, consistent with how much consumers must be compensated to defer

consumption. In addition, the draft guidance suggested that departments and agencies might want to develop a regulation-specific discount rate based on the "shadow price of capital" and compare the results against the other two rates, using sensitivity analysis.

Some commenters suggested that the guidelines should provide for the use of other discount rates. As the draft guidance makes clear, however, departments and agencies are free to apply a variety of alternative discount rates in sensitivity analyses and make their best case in favor of an alternative rate. However, the need for consistency across regulations demands that RIAs include at least one common discount rate. In any event, the final RIA guidance has been modified to require departments and agencies to provide the full stream of benefits and costs. This allows for any number of alternative discount rates to be applied by policymakers and independent analysts, thus yielding a more useful document in every respect.

APPENDIX IV

Executive Order No. 12291
Annual Report for 1989

TABLE OF CONTENTS

Exhibits

I. INTRODUCTION

This report provides information on the implementation of Executive Order No. 12291 for the years ending December 31, 1988, and December 31, 1989. It also describes trends in regulatory activity during the past decade.

Executive Order No. 12291, signed on February 17, 1981, established within the Executive Branch a mechanism for improving Federal regulatory activities. The purposes of the Executive Order are to control the growth of Federal regulation and to ensure that individual regulations are well-reasoned, economically sound, and coordinated with the policies of other agencies. In particular, the Order requires that all new regulations, to the extent permitted by law, adhere to the following principles:

- Agencies must base regulations upon adequate information concerning the need for and the consequences of the proposed action.
- Agencies must not issue regulations unless the potential benefits to society outweigh the potential costs to society.
- Of the alternative approaches to a given regulatory objective, an agency must select the alternative involving the least net cost to society.

To ensure compliance with these principles, the President ordered executive agencies to submit all proposed and final regulations to the Office of Management and Budget (OMB) for review before publication.

These review policies and procedures are conducted within statutory authorities. The Executive Order guides Federal regulatory officials in exercising the discretion given them by statute. This statutory discretion is often very broad, and may be ambiguous or contradictory, but may be exercised only to the extent permitted by law. Where statutes clearly exclude economic considerations, by their terms, any Executive Order policies to the contrary are overridden. The Order applies to general policymaking, such as "informal rulemaking" under the Administrative Procedure Act. It does not apply to adjudicatory proceedings.

This is the ninth annual report on the Order's implementation. Section II describes the requirements and procedures of the Order. Section III presents detailed information on the types of rules reviewed and the types of actions taken by OMB in 1988 and 1989. Comparisons are then made between 1989 data and that of 1981 through 1988. Section IV examines the nature and extent of regulatory activity since 1977 by analyzing certain statistics of *Federal Register* activity.

II. IMPLEMENTATION OF THE EXECUTIVE ORDER

The Office of Information and Regulatory Affairs (OIRA) in OMB oversees agency compliance with Executive Order No. 12291. OIRA seeks to ensure, on a day-to-day basis, that agency regulatory activity reflects the President's regulatory policies described in the Order.

OIRA reviews "major" regulations with special attention. Regulations so designated have economic costs of over $100 million annually, or are projected to have significant effects on employment, inflation, or industry viability. A Regulatory Impact Analysis (RIA) must accompany major regulations at both proposed and final rulemaking stages. An RIA assesses the costs and benefits of the action and its alternatives. OMB may waive the RIA requirements in special cases; for example, in order to expedite publication of an emergency regulation. Agencies must submit to OMB major proposed rules at least 60 days before publication, and major final rules at least 30 days before publication.

Executive agencies must transmit nonmajor regulations to OMB at least 10 days prior to planned publication. Executive Order No. 12291 does not require agencies to prepare RIAs for nonmajor actions, but it does require agencies to assure that their rules are consistent with the Executive Order's principles to the extent permitted by law. Many agencies perform an initial analysis of the economic impact of nonmajor rules if they believe the rule will have a significant effect, or if it will be useful in assessing the impact.

III. REVIEW OF REGULATIONS

A. Types of Rules Reviewed in 1989

OMB reviewed 2,220 agency rules in 1989 under Executive Order No. 12291. Exhibit 1 shows that nine agencies accounted for more than 77 percent of the rules reviewed. These agencies were: the Department of Agriculture (405 rules), the Department of Health and Human Services (283 rules), the Department of Transportation (250 rules), the Environmental Protection Agency (201 rules), the Department of Commerce (195 rules), the Department of Justice (100 rules), the Department of the Interior (97 rules), the the Department of Veterans Affairs (95 rules), and the Department of Education (82 rules). Exhibit 1A shows data from 1988.

Exhibit 2 shows the number of rules reviewed during 1989 by each agency. Rules are classified as either proposed or final, and either major or nonmajor. Of the rules OMB reviewed in 1989, 41.5 percent were nonmajor proposed rules and 55.0 percent were nonmajor final rules. Major rules constituted only 3.5 percent of all rules. The Department of Agriculture and the Environmental Protection Agency had the largest number of major proposed rules (9 and 11, respectively). The Department of Agriculture had the largest number of major final rules (22), followed by the the Department of Labor (5). Exhibit 2A shows similar data for 1988. Exhibit 3 lists by name all major proposed and final regulations reviewed in 1989, and Exhibit 3A lists those for 1988.

Exhibit 4 displays changes over the last 9 years in the types of rules reviewed. The total number of rules OMB reviewed in 1989 decreased 6.1 percent over 1988, and was 20.7 percent lower than the number reviewed in 1981. The number of proposed rules in 1989 decreased 28.7 percent from 1988 and 4.2 percent from 1981. The number of final rules reviewed in 1989 increased 23.4 percent from 1988 and dropped 28.4 percent from 1981. The number of major rules in 1989 decreased 4.8 percent from the 1988 level, and rose 31.7 percent from 1981.

Exhibit 5 shows, by agency, the number of rules reviewed during each of the last 9 years. Comparing 1989 with 1981, the greatest percentage decline in the total number of rules reviewed occurred at the

EXHIBIT 1.

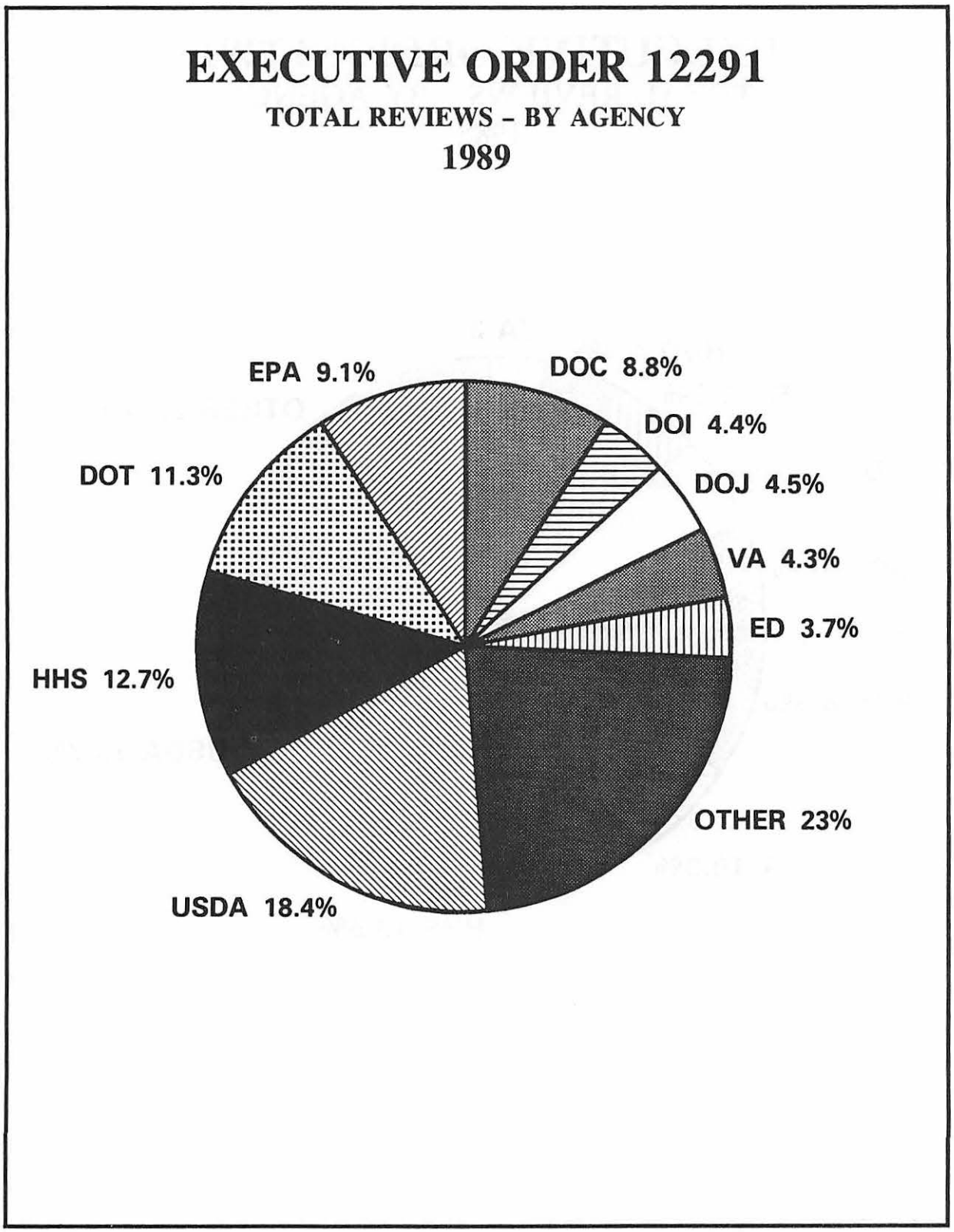
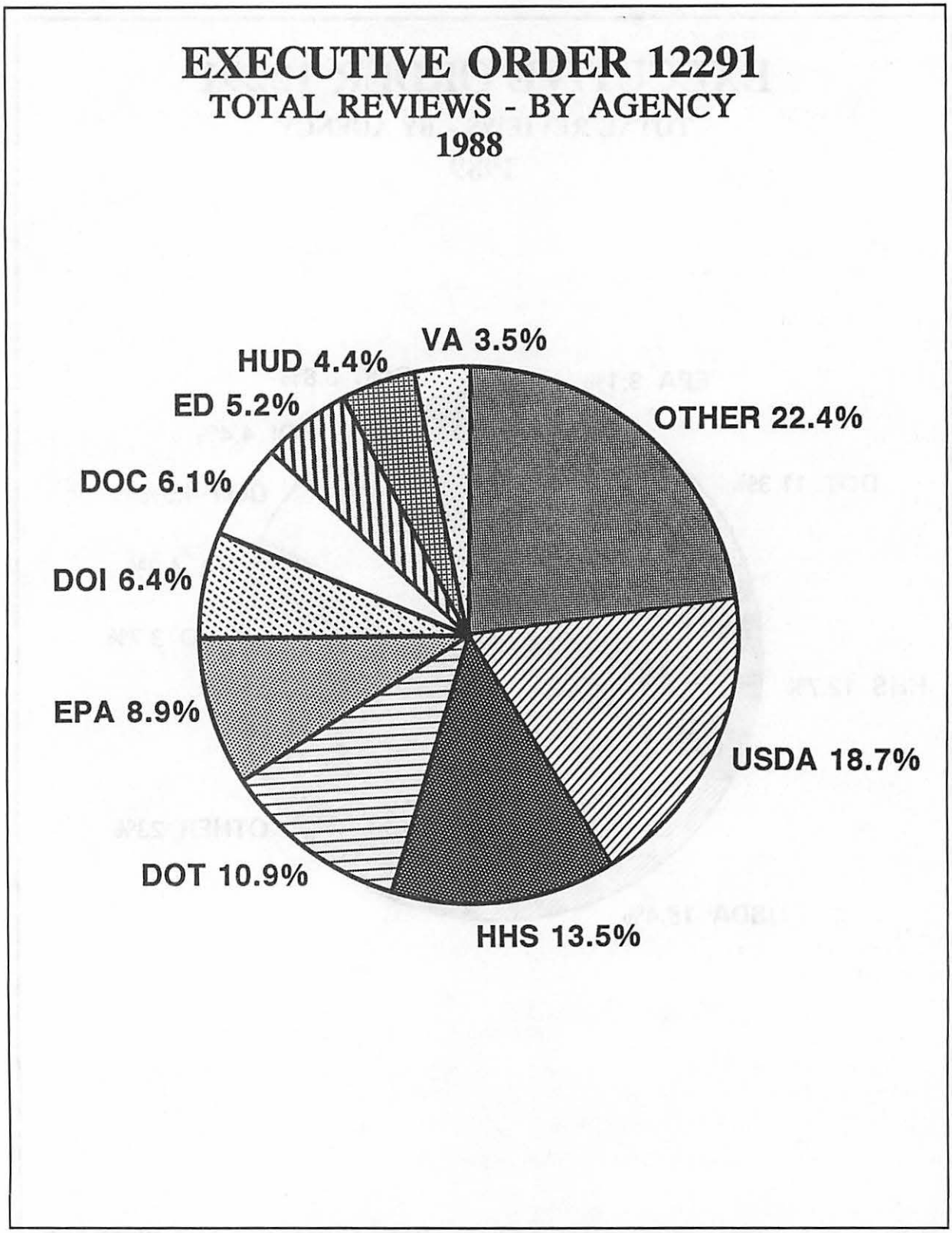

EXECUTIVE ORDER 12291
TOTAL REVIEWS - BY AGENCY
1989
EPA 9.1%
DOC 8.8%
DOI 4.4%
DOJ 4.5%
VA 4.3%
ED 3.7%
OTHER 23%
USDA 18.4%
HHS 12.7%
DOT 11.3%

EXHIBIT 1A.


EXECUTIVE ORDER 12291
TOTAL REVIEWS - BY AGENCY
1988
VA 3.5%
HUD 4.4%
ED 5.2%
OTHER 22.4%
DOC 6.1%
DOI 6.4%
EPA 8.9%
USDA 18.7%
DOT 10.9%
HHS 13.5%

Environmental Protection Agency (–72.6 percent), the Department of Energy (–64.2 percent), the Department of Agriculture (–38.3 percent), and the Department of the Interior (–34.0 percent). The Small Business Adminstration experienced the largest percentage increase since 1981 (290 percent), followed by the Department of Health and Human Services (141.9 percent), the Department of Justice (88.7 percent), the Federal Emergency Management Agency (81.3 percent), and the National Aeronautics and Space Administration (60.0 percent).

EXHIBIT 2. TYPES OF RULES REVIEWED DURING 1989 BY AGENCY

Agency	Total rules	Nonmajor		Major	
		NPRM	Final	NPRM	Final
Agriculture (USDA)	405	154	220	9	22
Health and Human Services (HHS)	283	150	125	4	4
Transportation (DOT)	250	119	127	1	3
Environmental Protection Agency (EPA)	201	87	100	11	3
Commerce (DOC)	195	76	118	0	1
Justice (DOJ)	100	34	66	0	0
Interior (DOI)	97	37	57	1	2
Veterans Affairs (VA)	95	54	41	0	0
Education (ED)	82	28	54	0	0
Housing and Urban Development (HUD)	78	25	50	0	3
General Services Administration (GSA)	61	14	47	0	0
Labor (DOL)	60	21	31	3	5
Office of Personnel Management (OPM)	53	19	34	0	0
Treasury (TREAS)	47	23	24	0	0
Small Business Administration (SBA)	39	11	24	1	3
Federal Emergency Management Agency (FEMA)	29	18	11	0	0
Railroad Retirement Board (RRB)	21	9	12	0	0
Energy (DOE)	19	9	8	2	0
National Aeronautics and Space Administration (NASA)	16	3	13	0	0
State (STATE)	15	3	12	0	0
National Archives and Records Administration (NARA)	8	3	5	0	0
Panama Canal Commission (PCC)	7	5	2	0	0
United States Information Agency (USIA)	7	1	6	0	0
Defense (DOD)	6	1	5	0	0
Equal Opportunity Employment Commission (EEOC)	5	4	1	0	0
National Science Foundation (NSF)	5	1	4	0	0
United States International Development Cooperation Agency (USIDCA)	4	2	2	0	0
Federal Mediation and Conciliation Service (FMCS)	3	2	1	0	0
Other Temporary Commissions	3	1	2	0	0
ACTION	2	1	1	0	0
African Development Foundation (ADF)	2	0	2	0	0
Federal Home Loan Bank Board (FHLBB)	2	0	2	0	0
Institute of Museum Services (IMS)	2	1	1	0	0
Inter-American Foundation	2	0	2	0	0
Peace Corps (PEACE)	2	0	2	0	0
Selective Service System (SSS)	2	1	1	0	0
Architectural and Transportation Barriers Compliance Board (ATBCB)	1	0	1	0	0
Commission on Civil Rights (CCR)	1	1	0	0	0
Federal Acquisition Regulations	1	0	0	0	1

EXHIBIT 2. TYPES OF RULES REVIEWED DURING 1989 BY AGENCY—Continued

Agency	Total rules	Nonmajor		Major	
		NPRM	Final	NPRM	Final
Federal Credit System Assistance Board	1	0	1	0	0
National Endowment for the Arts (NEA)	1	0	1	0	0
National Endowment for the Humanities (HEH)	1	0	1	0	0
Office of Government Ethics (OGE)	1	0	1	0	0
Office of Management and Budget (OMB)	1	0	1	0	0
Office of the United States Trade Representative (USTR)	1	1	0	0	0
Pension Benefit Guaranty Corporation (PBGC)	1	1	0	0	0
Resolution Trust Corporation (RTC)	1	1	0	0	0
United States Office of Special Counsel	1	0	1	0	0
Total	2,220	921	1,220	32	47
Percentage of total	100.0	41.5	55.0	1.4	2.1

EXHIBIT 2A. TYPES OF RULES REVIEWED DURING 1988 BY AGENCY

Agency	Total rules	Nonmajor		Major	
		NPRM	Final	NPRM	Final
Agriculture (USDA)	441	168	249	10	14
Health and Human Services (HHS)	320	162	150	5	3
Transportation (DOT)	257	112	136	5	4
Environmental Protection Agency (EPA)	210	97	97	10	6
Interior (DOI)	152	73	75	2	2
Commerce (DOC)	145	58	86	1	0
Education (ED)	123	55	68	0	0
Housing and Urban Development (HUD)	105	39	61	2	3
Veterans Affairs (VA)	82	35	47	0	0
Labor (DOL)	77	26	42	5	4
Office of Personnel Management (OPM)	74	24	50	0	0
General Services Administration (GSA)	57	17	40	0	0
Justice (DOJ)	52	17	35	0	0
Small Business Administration (SBA)	37	15	19	1	2
Treasury (TREAS)	37	15	22	0	0
Federal Emergency Management Agency (FEMA)	30	15	15	0	0
Energy (DOE)	20	7	12	1	0
National Aeronautics and Space Administration (NASA)	17	4	13	0	0
National Archives and Records Administration (NARA)	17	10	7	0	0
State (STATE)	17	7	10	0	0
Railroad Retirement Board (RRB)	14	7	7	0	0
Defense (DOD)	12	4	8	0	0
United States International Development Cooperation Agency (USIDCA)	9	5	4	0	0
National Science Foundation (NSF)	8	4	4	0	0
Other Temporary Commissions	7	1	6	0	0

EXHIBIT 2A. TYPES OF RULES REVIEWED DURING 1988 BY AGENCY—Continued

Agency	Total rules	Nonmajor		Major	
		NPRM	Final	NPRM	Final
United States Information Agency (USIA)	7	3	4	0	0
Institute of Museum Services (IMS)	6	1	5	0	0
Architectural and Transportation Barriers Compliance Board (ATBCB)	4	0	4	0	0
Federal Mediation and Conciliation Service (FMCS)	4	1	3	0	0
National Endowment for the Arts (NEA)	4	0	4	0	0
ACTION	3	0	3	0	0
National Endowment for the Humanities (NEH)	3	1	2	0	0
Pension Benefit Guaranty Corporation (PBGC)	3	0	1	1	1
African Development Foundation (ADF)	1	1	0	0	0
Commission on Civil Rights (CCR)	1	1	0	0	0
Equal Opportunity Employment Commission (EEOC)	1	0	1	0	0
Office of Management and Budget (OMB)	1	1	0	0	0
Peace Corps (PEACE)	1	0	1	0	0
Pennsylvania Avenue Development Corporation (PADC)	1	1	0	0	0
Selective Service System (SSS)	1	0	1	0	0
Tennessee Valley Authority (TVA)	1	0	1	0	0
Total	2,362	987	1,293	43	39
Percentage of total	100.0	41.8	54.7	1.8	1.7

EXHIBIT 3. MAJOR PROPOSED AND FINAL RULES REVIEWED DURING 1989

1. Major Proposed Rules

UNITED STATES DEPARTMENT OF AGRICULTURE
- 1989 Feed Grain Program
- 1990 Feed Grain Program
- 1990 Upland Cotton Program
- 1990 Pulled Wool and Mohair Support Prices
- 1990 Rice Program Proposed Determinations
- Secondary Market for Guaranteed FHmA Farm Loans
- Disaster Assistance Act of 1988
- Animal Welfare Regulations (Part 1)
- Animal Welfare Regulations (Part 2)

DEPARTMENT OF ENERGY
- Electric Rates, Innovative Low-Emission Technology
- Energy Efficiency Standards for Dishwashers, Clothes Washers, and Clothes Dryers

DEPARTMENT OF HEALTH AND HUMAN SERVICES
- Certification of Respiratory Protective Devices
- Inpatient Hospital Prospective Payment System (Fiscal Year 1990)
- Payment for Home IV Drug Therapy Services
- Determining Disability and Blindness, Substantial Gainful Activity

DEPARTMENT OF THE INTERIOR
- 1989–90 Migratory Game Bird Hunting Regulations

DEPARTMENT OF LABOR
- Respiratory Protection
- Entry Permit Confined Spaces
- Bloodborne Pathogens

DEPARTMENT OF TRANSPORTATION
- Side Impact Protection—Light-Duty Trucks

ENVIRONMENTAL PROTECTION AGENCY
- Use and Disposal of Sewage Sludge
- Drinking Water Standards for 38 Contaminants—Phase II
- Corrective Action for Solid Waste Management Units at Hazardous Waste Management Facilities
- Land Disposal Restrictions for Third Third Scheduled Wastes
- Refueling and Evaporative Emissions
- Evaporative Emissions for Gasoline and Methane Fueled Light-Duty Vehicles and Trucks, and Heavy-Duty Vehicles
- Fuel Quality for Highway Diesel Fuel Sold in 1993 and Later Years
- Organic Air Emissions for Treatment Storage and Disposal Facilities
- New Source Performance Standards—Municipal Waste Combusters
- Chemical Substances Reporting and Exemption Requirements
- Light-Duty Trucks—Emission Standards

SMALL BUSINESS ADMINISTRATION
- Minority Small Business and Capital Ownership Development

EXHIBIT 3. MAJOR PROPOSED AND FINAL RULES REVIEWED DURING 1989—Continued

2. Major Final Rules

UNITED STATES DEPARTMENT OF AGRICULTURE
- 1989 Common Program: Wheat, Feed Grains, Upland Cotton
- Milk Price Support Level and CCC Purchase Prices
- 1989 Upland Cotton Program Final Determination
- 1990 Wheat Program and Common Program Provisions
- 1989 Rice Program
- Milk Price Support Level and CCC Purchase Prices
- Pulled Wool and Mohair for the 1989 Marketing Year
- Price Support and Adjustment Programs, 7 CFR 1434 and 1435
- Price Support Loan Program, 1986—1990 Sugar Beets and Sugarcane
- Milk Price Support Level and CCC Purchase Prices
- Disaster Payment Program for 1989 Crops
- 1989 Crop Sugar Beets and Sugarcane Price Support Loan Rates
- Emergency Livestock Assistance
- Milk Price Support Level and CCC Purchase Prices
- 1989 Crop Soybean Loan and Purchase Rate
- 1990 Feed Grains Program
- Emergency Loan Policies, Procedures and Authorizations
- Operating Loan Policies, Procedures and Authorizations
- Animal Welfare Regulations (Part 2)
- Animal Welfare Regulations (Part 1)
- Food Stamp Program: Maximum Allotments and Income Eligibility Standards
- Debt Settlement—Community and Business Programs

DEPARTMENT OF COMMERCE
- Importation of Yellowfin Tuna

DEPARTMENT OF HEALTH AND HUMAN SERVICES
- Inpatient Hospital Prospective Payment System and Fiscal Year 1990 Rates
- Direct Graduate Medical Education Costs
- Determining Disability and Blindness, Substantial Gainful Activity
- Jobs Program, Child Care and Supportive Services

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT
- Fair Housing Amendments Act of 1988
- Prepayment of a HUD-Insured Mortgage by an Owner of Low-Income Housing
- Prepayment of a HUD-Insured Mortgage by an Owner of Low-Income Housing

DEPARTMENT OF THE INTERIOR
- Final Frameworks for Selecting Early Hunting Seasons on Certain Migratory Game Birds, for 1989–90 Season
- Final Frameworks for Late Season Migratory Bird Hunting Regulations

DEPARTMENT OF LABOR
- Hazardous Waste Operations and Emergency Response
- Permissable Exposure Limits
- Underground Construction
- Occupational Exposure to Lead
- Control of Hazardous Energy (Lockout/Tagout)

DEPARTMENT OF TRANSPORTATION
- Explosives Detection Systems for Checked Baggage
- Passenger Automobile Fuel Economy Standards, 1990
- Cockpit Voice Recorder (CVR)

ENVIRONMENTAL PROTECTION AGENCY
- National Primary Drinking Water Regulations, Filtration, Disinfection, Turbidity
- Clean Water Act, Section 304(M), Effluent Guideline Plan
- Asbestos, Manufacture, Importation, Processing and Distribution in Commerce Prohibitions

SMALL BUSINESS ADMINISTRATION
- Surety Bond Guarantee Regulations—Pilot Preferred
- Small Business Size Standards
- Surety Bond Guarantee Regulations

FEDERAL ACQUISITION REGULATIONS
- Small Business Competitiveness Demonstration Project

EXHIBIT 3A. MAJOR PROPOSED AND FINAL RULES REVIEWED DURING 1988

1. Major Proposed Rules

UNITED STATES DEPARTMENT OF AGRICULTURE
- 1989 Pulled Wool and Mohair Support Prices
- 1989 Upland Cotton Program
- 1989 Rice Program
- Guaranteed Loan Operating Loan Policies, Procedures, and Authorizations of the Farmers Home Administration
- Grains and Similarly Handled Commodities
- 1988 Crop Soybean Preliminary Loan and Purchase Rate
- 1988 Crop Soybean
- Agricultural Credit Act of 1987 Provisions and Farmer Program Regulations Amendments
- 1989 Feed Grain Program
- 1989 Wheat Program and Common Program Provisions

DEPARTMENT OF COMMERCE
- Deep Seabed Mining, Commercial Recovery and Exploration

DEPARTMENT OF ENERGY
- Energy Conservation Standards for Three Types of Consumer Products

DEPARTMENT OF HEALTH AND HUMAN SERVICES
- Referral of Debts to IRS for Tax Refund Offset
- Ambulatory Center Payment Rates
- Clinical Laboratory Regulations
- Payment Policy for Direct Graduate Medical Education Costs
- Changes to Inpatient Hospital Prospective Payment System and Fiscal Year 1989 Rates

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT
- Implementation of the Fair Housing Act of 1988
- Lead-Based Paint Hazard Elimination (FR–2447)

DEPARTMENT OF THE INTERIOR
- 1988–89 Migratory Game Bird Hunting Regulations
- Areas Unsuitable for Mining

EXHIBIT 3A. MAJOR PROPOSED AND FINAL RULES REVIEWED DURING 1988—Continued

1. Major Proposed Rules—Continued

DEPARTMENT OF LABOR
- Operation and Maintenance of Electric Power Generation, Transmission, and Distribution Installations (Part 1910)
- Control of Hazardous Waste Sources (Lockout/Tagout)
- Air Contaminants (Part 1910.1000 Z Tables)
- Shipyard Employment (Subparts B, D, E, I, M, N)
- Hazard Communication

DEPARTMENT OF TRANSPORTATION
- Side Impact Protection
- Anti-Drug Program for Personnel Engaged in Specified Aviation Activities
- Controlled Substances
- Passenger Automobile CAFE
- Side Impact Anthropomorphic Test Dummy

ENVIRONMENTAL PROTECTION AGENCY
- Onboard
- Monitoring for Unregulated Contaminants
- Notification Requirements for Industrial Non-Hazardous Disposal Facilities and Recordkeeping Requirements for Municipal Solid Waste Landfills
- NAAQS—Sulfur Dioxide
- "Soft Hammer" for First Third of Scheduled Wastes
- NPDWR for Lead and Copper
- Emergency Planning and Community Right-to-Know Programs
- National Emissions Standards for Benzene
- Worker Protection Standards for Agricultural Pesticides
- Additional Options for Drinking Water Filtration and Coliform MCLS

PENSION BENEFIT GUARANTY CORPORATION
- Payment of Premiums

SMALL BUSINESS ADMINISTRATION
- Small Business Size Standards for Construction and Surveying Services Industries

2. Major Final Rules

UNITED STATES DEPARTMENT OF AGRICULTURE
- Conservation Reserve Program
- Milk Price Support Program
- Grains and Similarly Handled Commodities
- 1988 Crop Soybean Final Loan and Purchase Rate
- 1988 Crop Program for Wheat, Feed Grains, Rices and Cotton
- Determination of World Price, Upland Cotton
- Disaster Payment Program for 1988 Crops
- Eligible Alien Status
- Thrifty Food Plan and Income Eligibility Standards for 48 States and D.C.
- Emergency Livestock Assistance
- Agricultural Credit Act of 1987
- Guaranteed Loan Policies, Procedures and Authorizations
- 1988 Crop Sugar Beets and Sugarcane
- Operating Loan Policy, Procedures and Authorizations

DEPARTMENT OF HEALTH AND HUMAN SERVICES
- Update of Ambulatory Center Payment Rates
- Payments to Institutions
- 1989 Rates Inpatient Hospital Prospective Payment

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT
- Lead-Based Paint Hazard Elimination
- Housing Voucher Program
- Payment of a HUD-Insured Mortgage by an Owner of Low-Income Housing (FR–2450)

DEPARTMENT OF THE INTERIOR
- Migratory Game Birds 1988–1989 Season
- Late Season Migratory Bird Hunting

DEPARTMENT OF LABOR
- Mechanical Power Press Standard (Part 1910.217)
- Davis-Bacon and Related Acts, Labor Standards Provision
- Occupational Exposure to Asbestos
- Concrete and Masonry Construction

DEPARTMENT OF TRANSPORTATION
- Light Truck Fuel Economy Standards for Model Years 1990 and 1991
- Controlled Substances
- Anti-Drug Program for Personnel Engaged in Specific Aviation Activities
- CAFE Standard for Model Year 1989

ENVIRONMENTAL PROTECTION AGENCY
- NSPS Residential Wood Heaters
- Land Disposal of First Third of Scheduled Wastes ("Second Sixth" Proposal)
- Protection of Stratospheric Ozone
- RCRA Financial Responsibility Requirements for Underground Storage Tanks
- Notification, Recordkeeping, and Reporting Requirements for Underground Storage Tanks
- Toxic Chemical Release Inventory Reporting, Community Right-to-Know

PENSION BENEFIT GUARANTY CORPORATION
- Payment of Premiums

SMALL BUSINESS ADMINISTRATION
- Definition of Small Business for Dredging
- Surety Bond Guarantee

EXHIBIT 4. COMPARISON OF RULES REVIEWED DURING 1981–1989 BY TYPE

Type of rule	Number								
	1981	1982	1983	1984	1985	1986	1987	1988	1989
Nonmajor:									
Proposed	970	1,026	1,045	951	1,050	784	1,056	1,293	921
Final	1,735	1,533	1,377	1,104	1,105	1,150	1,190	987	1,220
Total	2,705	2,559	2,422	2,055	2,155	1,934	2,246	2,280	2,141
Major:									
Proposed	25	29	22	33	21	25	40	43	32
Final	35	50	41	27	39	48	30	40	47
Total	60	79	63	60	60	73	70	83	79
All:									
E.O. Not Applicable	35	1	0	0	0	0	0	0	0
Proposed	995	1,055	1,067	984	1,071	809	1,096	1,336	953
Final	1,770	1,583	1,418	1,131	1,144	1,198	1,220	1,027	1,267
Total	2,800	2,639	2,485	2,115	2,215	2,007	2,316	2,363	2,220
	Percent change								
	1981–82	1982–83	1983–84	1984–85	1985–86	1986–87	1987–88	1988–89	1981–89
Nonmajor:									
Proposed	–5.8	1.9	–9.0	10.4	–25.3	34.7	22.4	–28.8	–5.1
Final	–11.6	–10.2	–19.8	0.1	4.1	3.5	–17.1	23.6	–29.7
Total	–5.4	–5.4	–15.2	4.9	–10.3	16.1	1.5	–6.1	–20.9
Major:									
Proposed	16.0	–24.1	50.0	–36.4	19.0	60.0	7.5	–25.6	28.0
Final	42.9	–18.0	–34.1	44.4	23.1	–37.5	33.3	17.5	34.3
Total	31.7	–20.3	–4.8	0.0	21.7	–4.1	18.6	–4.8	31.7
All:									
E.O. Not Applicable	–97.1	–100.0	NA	NA	NA	NA	NA	NA	–100.0
Proposed	6.0	1.1	–7.8	8.8	–24.5	35.5	21.9	–28.7	–4.2
Final	–10.6	–10.4	–20.2	1.1	4.7	1.8	–15.8	23.4	–28.4
Total	–5.8	–5.8	–14.9	4.7	–9.4	15.4	2.0	–6.1	–20.7

EXHIBIT 5. TWENTY MOST ACTIVE RULE-PRODUCING AGENCIES COMPARISON OF RULES REVIEWED 1981–1989

Agency	Number								
	1981	1982	1983	1984	1985	1986	1987	1988	1989
USDA	656	695	552	483	407	418	420	441	405
HHS	117	272	294	199	212	281	315	320	283
DOT	283	226	225	218	252	196	203	258	250
EPA	734	341	268	303	305	197	205	210	201
DOC	162	147	121	107	113	130	134	145	195
DOJ	53	51	72	46	78	46	84	52	100
DOI	147	249	240	133	161	144	186	152	97
VA	69	70	69	70	65	62	67	82	95
ED	77	53	50	106	108	99	174	123	82
HUD	74	130	112	108	90	68	64	105	78
GSA	56	62	85	63	85	41	59	57	61
DOL	62	49	49	35	38	56	64	77	60
OPM	38	49	65	45	69	72	97	74	53
TREAS	34	32	53	44	26	21	29	37	47
SBA	10	16	20	32	19	30	16	37	39
FEMA	16	6	29	16	26	24	26	30	29
DOE	53	49	34	25	19	16	20	20	19
NASA	10	11	13	15	25	15	15	17	16
NARA	NA	NA	NA	NA	9	13	9	17	8
DOD	4	9	13	7	17	9	17	12	6
	Percent change								
	1981–82	1982–83	1983–84	1984–85	1985–86	1986–87	1987–88	1988–89	1981–89
USDA	6.0	–21.6	–12.5	–15.7	2.7	0.5	5.0	–8.2	–38.3
HHS	132.5	8.1	–32.3	6.5	32.5	12.1	1.6	–11.6	141.9
DOT	–20:1	–0.4	–3.1	15.6	–22.2	3.6	27.1	–3.1	–11.7
EPA	–53.5	–21.4	13.1	0.7	–35.4	4.1	2.4	–4.3	–72.6
DOC	–9.3	–17.7	–11.6	5.6	15.0	3.1	8.2	34.5	20.4
DOJ	–3.8	41.2	–36.1	69.6	–41.0	82.6	–38.1	92.3	88.7
DOI	69.4	–3.6	–44.6	21.1	–10.6	29.2	–18.3	–36.2	–34.0
VA	1.4	–1.4	1.4	–7.1	–4.6	8.1	22.4	15.9	37.7
ED	–31.2	–5.7	112.0	1.9	–8.3	75.8	–29.3	–33.3	6.5
HUD	75.7	–13.8	–3.6	–16.7	–24.4	–5.9	64.1	–25.7	5.4
GSA	10.7	37.1	–25.9	34.9	–51.8	43.9	–3.4	7.0	8.9
DOL	–21.0	0.0	–28.6	8.6	47.4	14.3	20.3	–22.1	–3.2
OPM	28.9	32.7	–30.8	53.3	4.3	34.7	–23.7	–28.4	39.5
TREAS	–5.9	65.6	–17.0	–40.9	–19.2	38.1	27.6	27.0	38.2
SBA	60.0	25.0	60.0	–40.6	57.9	–46.7	131.3	5.4	290.0
FEMA	–62.5	383.3	–44.8	62.5	–7.7	8.3	15.4	–3.3	81.3
DOE	–7.5	–30.6	–26.5	–24.0	–15.8	25.0	0.0	–5.0	–64.2
NASA	10.0	18.2	–15.4	127.3	–40.0	0.0	13.3	–5.9	60.0
NARA	NA	NA	NA	NA	44.4	–30.8	88.9	–52.9	NA
DOD	125.0	44.4	–46.2	142.9	–47.1	88.9	–29.4	–50.0	50.0

B. Types of Actions Taken on Rules

Exhibits 6 through 10 summarize the actions taken on agency rules under Executive Order No. 12291 during 1989. The analogous Exhibits 6A–9A show 1988 data for comparison. Exhibit 11 compares OMB's action during 1989 with actions in previous years.

Exhibit 6 shows the number of rules by type of OMB action during 1989. Of the 2,220 rules reviewed during 1989, OMB found that 73.8 percent were consistent with the principles of the Executive Order as submitted, 19.4 percent were consistent with the Order after the agency adopted changes during the review period, 1.3 percent were inconsistent with the Order and returned to the agency for reconsideration, another 2.7 percent were withdrawn by agencies, and 0.7 percent were suspended. Emergency rules and rules subject to statutory or judicial deadlines constituted 2.0 percent of all 1989 rules, and 0.1 percent were sent improperly or were exempt. Exhibit 6A shows the type of OMB action taken during 1988.

Exhibits 7 and 7A show the percentage of rules in each category for the 21 most active rulemaking agencies in 1988 and 1989.

Exhibit 8 lists by name each of the 29 rules returned for reconsideration in 1989, and Exhibit 8A lists the 29 rules returned for reconsideration in 1988. Exhibit 9 lists by name each of the 61 rules withdrawn by agencies during OMB review in 1989, and Exhibit 9A lists the 57 rules withdrawn by agencies in 1988. OMB may return regulations for reconsideration if it finds them to be inconsistent with the principles of the Executive Order. Agencies may withdraw rules during review because they have concluded that the rules are inconsistent with the Executive Order or for other reasons. An agency may, for example, wish to incorporate newly acquired information into a rule.

Exhibit 10 lists by name each of the 15 rules suspended in 1989. OMB may suspend rules, if agencies have not responded in a timely fashion to requests for information needed to complete a review.

Exhibit 11 compares OMB actions on agency rules during the past 9 years. The percent of rules OMB found consistent with the Executive Order declined rather steadily from 87.3 percent in 1981 to 68.3 percent in 1986, but increased slightly to 70.9 percent in 1988 and 73.8 percent in 1989. At the same time, the percent of rules OMB found consistent after change increased sharply from 4.9 percent in 1981 to 23.7 percent in 1987 and declined to 19.4 percent in 1989. The percent of rules that agencies withdrew through 1985 increased to 3.1 percent from 1.8 percent in 1981, then declined to 2.4 percent in 1988 and increased to 2.8 percent in 1989. The percent of rules that OMB returned for agency reconsideration has fluctuated over the years but reached a low point of 0.4 percent in 1987 compared to a high of 2.7 percent in 1984. In 1989, the number returned for reconsideration increased to 1.3 percent. Only 0.6 percent of rules were suspended in 1989, the first year this type of action was taken. The percent of rules issued by agencies under emergency, statutory, or judicial deadlines has varied from 1.2 percent in 1985 to 4.3 percent the following year; in 1989 it was 1.6 percent.

Exhibit 12 shows OMB's average regulatory review time by agency from 1981 to 1989 for all major and nonmajor rules. Generally, review time for major rules is longer than for nonmajor rules because of their greater complexity and importance. In 1981, OMB's average review time for all major rules was 13 days; in 1989, it was 59 days. OMB's average review time in 1981 for nonmajor rules was 9 days, as compared with an average of 28 days in 1989. The 1989 average review time for all rules was 29 days.

C. Exemptions

Executive Order No. 12291 authorizes the Director of OMB to exempt classes of regulations from any or all of the requirements of the Order. The exemptions granted by OMB fall into four broad categories: (1) rules that are essentially nonregulatory; (2) rules that delegate regulatory authority to States; (3) rules that largely or entirely affect individual entities and that do not involve broader policy issues; and (4) rules for which a delay of even a few days could impose substantial costs and that are unlikely to involve significant policy issues.

At the end of 1989, OMB had granted a total of 29 exemptions (some covering more than one of the categories above) to eight agencies. Exhibit 13 lists these exemptions. Most of the exemptions were established during the initial years of the operation of the Executive Order. In each case, OMB determined that the exempted regulations, as a class, were consistent with the goals and requirements of the Executive Order. OMB continues to review all "major" rules as defined by the Executive Order regardless of class exemptions. OMB may request that agencies submit specific rules within an exempt class and may revoke exemptions at any time.

IV. TRENDS IN REGULATORY ACTIVITY

Because there are no precise or agreed-upon measures of regulatory activity, we cannot measure the precise effect Executive Order No. 12291 has had on regulatory activity. It is useful, however, to compare the number of pages and the number of total rule documents (proposed rule documents plus final rule documents) published in the *Federal Register* during different time periods.

Exhibit 14 shows the number of pages published in the *Federal Register* from its inception in 1936 through 1989. There was little year-to-year change until the 1970s when the size of the *Federal Register* increased dramatically. But in 1981, the year Executive Order No. 12291 went into effect, the growth in the *Federal Register* ended.

In fact, the exhibit shows that from 1981 to 1986 the size of the *Federal Register* has declined steadily on an annual basis. In 1981 through 1984, the number of pages published in the *Federal Register* decreased—there were 41.4 percent fewer pages in the *Federal Register* in 1984 than in 1980. In 1985, the number of pages rose modestly by 4.87 percent over 1984 levels. But in 1986, the number of *Federal Register* pages declined 11.3 percent to its lowest level since 1974. In 1987, the number of published pages increased 4.7 percent above the 1986 level. In 1988, the number of published pages again increased by 7.5 percent, and in 1989 the pages increased modestly by 0.9 percent. Nevertheless, the overall trend of the past 8 years is significantly downward sloping.

Exhibit 15 further depicts the effects of Executive Order No. 12291 on the size of the *Federal Register*. It does this by showing the number of pages published in the *Federal Register* each month since 1977. The dramatic break with the upward trend in the 1970s is clearly evident.

Exhibit 16 depicts the total number of proposed and final rule documents published since 1977. This chart parallels the exhibit for pages published. It also indicates that since Executive Order No. 12291 was issued, Federal regulatory activity as represented by documents issued has decreased.

Exhibits 17, 18, and 19 provide various measures of regulatory activity since 1980.

EXHIBIT 6. TYPES OF ACTIONS TAKEN ON AGENCY RULES DURING 1989

Agency	Total reviews	Consistent without change	Consistent with change	Withdrawn by agency	Returned for reconsideration	Returned, sent improperly	Suspended	Emergency	Statutory or judicial deadline
USDA	405	339	58	4	1	0	1	2	0
HHS	283	187	82	7	5	0	2	0	0
DOT	250	195	48	3	1	0	0	1	2
EPA	201	97	59	5	11	0	4	1	24
DOC	195	177	12	5	0	0	0	1	0
DOJ	100	87	6	2	0	1	0	2	2
DOI	97	82	11	2	2	0	0	0	0
VA	95	85	8	2	0	0	0	0	0
ED	82	51	26	4	0	0	1	0	0
HUD	78	27	30	14	3	0	3	0	1
GSA	61	46	10	3	2	0	0	0	0
DOL	60	22	33	0	2	0	2	0	1
OPM	53	43	5	2	2	0	0	0	1
TREAS	47	37	9	1	0	0	0	0	0
SBA	39	30	8	0	0	0	0	0	1
FEMA	29	16	10	3	0	0	0	0	0
RRB	21	19	2	0	0	0	0	0	0
DOE	19	12	2	2	0	0	0	1	2
NASA	16	11	3	0	0	0	1	0	1
STATE	15	14	1	0	0	0	0	0	0
NARA	8	7	1	0	0	0	0	0	0
USIA	7	6	0	1	0	0	0	0	0
DOD	6	3	1	1	0	0	1	0	0
EEOC	5	4	1	0	0	0	0	0	0
NSF	5	5	0	0	0	0	0	0	0
USIDCA	4	3	1	0	0	0	0	0	0
FMCS	3	2	1	0	0	0	0	0	0
Other Temporary Commissions	3	3	0	0	0	0	0	0	0
ACTION	2	2	0	0	0	0	0	0	0
ADF	2	2	0	0	0	0	0	0	0
IMS	2	2	0	0	0	0	0	0	0
PEACE	2	2	0	0	0	0	0	0	0
SSS	2	2	0	0	0	0	0	0	0
ATBCB	1	0	1	0	0	0	0	0	0
CCR	1	0	1	0	0	0	0	0	0
NEA	1	1	0	0	0	0	0	0	0
NEH	1	1	0	0	0	0	0	0	0
OMB	1	1	0	0	0	0	0	0	0
PBGC	1	1	0	0	0	0	0	0	0
Federal Acquisition Regulations	1	1	0	0	0	0	0	0	0
Federal Credit System Assistance Board	1	1	0	0	0	0	0	0	0
FHLBB	2	0	0	0	0	0	0	1	1
Inter-American Foundation	2	2	0	0	0	0	0	0	0
Office of Government Ethics	1	1	0	0	0	0	0	0	0
PCC	7	7	0	0	0	0	0	0	0
RTC	1	1	0	0	0	0	0	0	0
USTR	1	1	0	0	0	0	0	0	0
U.S. Office of Special Counsel	1	0	1	0	0	0	0	0	0
Total	2,220	1,638	431	61	29	1	15	9	36
Percentage of total	100.0	73.8	19.4	2.7	1.3	0.1	0.7	0.4	1.6

EXHIBIT 6A. TYPES OF ACTIONS TAKEN ON AGENCY RULES DURING 1988

Agency	Total reviews	Consistent without change	Consistent with change	Withdrawn by agency	Returned for reconsider-ation	Returned, sent improperly	Emergency	Statutory or judicial deadline
USDA	441	364	56	5	10	0	5	1
HHS	320	209	101	5	3	1	0	1
DOT	257	169	79	3	2	0	1	3
EPA	210	107	58	6	7	0	1	31
DOI	152	132	14	5	1	0	0	0
DOC	145	96	19	2	1	0	4	23
ED	123	82	39	2	0	0	0	0
HUD	105	57	31	11	0	0	0	6
VA	82	68	12	1	1	0	0	0
DOL	77	37	36	2	1	0	0	1
OPM	74	62	11	0	0	1	0	0
GSA	57	42	12	1	1	0	0	1
DOJ	52	44	8	0	0	0	0	0
SBA	37	20	12	2	1	1	0	1
TREAS	37	32	5	0	0	0	0	0
FEMA	30	18	7	5	0	0	0	0
DOE	20	14	4	0	1	0	0	1
NARA	17	13	0	4	0	0	0	0
NASA	17	16	1	0	0	0	0	0
STATE	17	14	2	0	0	0	0	1
RRB	14	14	0	0	0	0	0	0
DOD	12	10	2	0	0	0	0	0
USIDCA	9	8	1	0	0	0	0	0
NSF	8	7	1	0	0	0	0	0
Other Temporary Commissions	7	6	1	0	0	0	0	0
USIA	7	6	0	1	0	0	0	0
IMS	6	5	0	1	0	0	0	0
ATBCB	4	4	0	0	0	0	0	0
FMCS	4	3	1	0	0	0	0	0
NEA	4	2	1	1	0	0	0	0
ACTION	3	3	0	0	0	0	0	0
NEH	3	1	2	0	0	0	0	0
PBGC	3	3	0	0	0	0	0	0
ADF	1	0	1	0	0	0	0	0
CCR	1	1	0	0	0	0	0	0
EEOC	1	1	0	0	0	0	0	0
OMB	1	0	1	0	0	0	0	0
PADC	1	1	0	0	0	0	0	0
PEACE	1	1	0	0	0	0	0	0
SSS	1	1	0	0	0	0	0	0
TVA	1	1	0	0	0	0	0	0
Total	2,362	1,674	518	57	29	3	11	70
Percentage of total	100.0	70.9	21.9	2.4	1.2	0.1	0.5	3.0

EXHIBIT 7. TYPES OF ACTIONS TAKEN ON AGENCY RULES DURING 1989 BY PERCENTAGE

Agency	Total reviews	Consistent without change	Consistent with change	Withdrawn by agency	Returned for reconsider-ation	Suspended	Emergency	Statutory or judicial deadline
USDA	405	83.7	14.3	1.0	0.2	0.0	0.5	0.2
HHS	283	66.1	29.0	2.5	1.8	0.7	0.0	0.0
DOT	250	78.0	19.2	1.2	0.4	0.0	0.4	0.8
EPA	201	48.3	29.4	2.5	5.5	2.0	0.5	11.9
DOC	195	90.8	6.2	2.6	0.0	0.0	0.5	0.0
DOJ**	100	87.0	6.0	2.0	0.0	0.0	2.0	2.0
DOI	97	84.5	11.3	2.1	2.1	0.0	0.0	0.0
VA	95	89.5	8.4	2.1	0.0	0.0	0.0	0.0
ED	82	62.2	31.7	4.9	0.0	1.2	0.0	0.0
HUD	78	34.6	38.5	17.9	3.8	2.8	0.0	1.3
GSA	61	75.4	16.4	4.9	3.3	0.0	0.0	0.0
DOL*	60	32.3	55.9	1.7	1.7	0.0	0.0	1.7
OPM	53	81.1	9.4	3.8	3.8	0.0	0.0	1.9
TREAS	47	78.7	19.1	2.1	0.0	0.0	0.0	0.0
SBA	39	76.9	20.5	0.0	0.0	0.0	0.0	2.6
FEMA	29	55.2	34.5	10.3	0.0	0.0	0.0	0.0
RRB	21	90.5	9.5	0.0	0.0	0.0	0.0	0.0
DOE	19	63.2	10.5	10.5	0.0	0.0	5.3	10.5
NASA	16	68.8	18.8	0.0	0.0	6.3	0.0	6.3
STATE	15	93.3	6.7	0.0	0.0	0.0	0.0	0.0
NARA	8	87.5	12.5	0.0	0.0	0.0	0.0	0.0
All Other	67	80.6	10.4	1.5	0.0	6.0	1.5	0.0
Total	2,220	73.8	19.4	2.7	1.3	0.7	0.4	1.6

* Includes one returned sent improperly.
** Includes one returned exempt.

EXHIBIT 7A. TYPES OF ACTIONS TAKEN ON AGENCY RULES DURING 1988 BY PERCENTAGE

Agency	Total reviews	Consistent without change	Consistent with change	Withdrawn by agency	Returned for reconsider-ation	Returned, sent improperly	Emergency	Statutory or judicial deadline
USDA	441	82.5	12.7	1.1	2.3	0.0	1.1	0.2
HHS	320	65.3	31.6	1.6	0.9	0.3	0.0	0.3
DOT	257	65.8	30.7	1.2	0.8	0.0	0.4	1.2
EPA	210	51.0	27.6	2.9	3.3	0.0	0.5	14.8
DOI	152	86.8	9.2	3.3	0.7	0.0	0.0	0.0
DOC	145	66.2	13.1	1.4	0.7	0.0	2.8	15.9
ED	123	66.7	31.7	1.6	0.0	0.0	0.0	0.0
HUD	105	54.3	29.5	10.5	0.0	0.0	0.0	5.7
VA	82	82.9	14.6	1.2	1.2	0.0	0.0	0.0
DOL	77	48.1	46.8	2.6	1.3	0.0	0.0	1.3
OPM	74	83.8	14.9	0.0	0.0	1.4	0.0	0.0
GSA	57	73.7	21.1	1.8	1.8	0.0	0.0	1.8
DOJ	52	84.6	15.4	0.0	0.0	0.0	0.0	0.0
SBA	37	54.1	32.4	5.4	2.7	2.7	0.0	2.7
TREAS	37	86.5	13.5	0.0	0.0	0.0	0.0	0.0
FEMA	30	60.0	23.3	16.7	0.0	0.0	0.0	0.0
DOE	20	70.0	20.0	0.0	5.0	0.0	0.0	5.0
NARA	17	76.5	0.0	23.5	0.0	0.0	0.0	0.0
NASA	17	94.1	5.9	0.0	0.0	0.0	0.0	0.0
STATE	17	82.4	11.8	0.0	0.0	0.0	0.0	5.9
RRB	14	100.0	0.0	0.0	0.0	0.0	0.0	0.0
All other	78	82.1	14.1	3.8	0.0	0.0	0.0	0.0
Total	2,362	70.9	21.9	2.4	1.2	0.1	0.5	3.0

EXHIBIT 8. REGULATIONS RETURNED TO AGENCIES FOR RECONSIDERATION DURING 1989

Agency/Title of regulation	Type	Received	Reviewed
UNITED STATES DEPARTMENT OF AGRICULTURE			
Loans, Purchases, and Other Operations	Final	12/22/88	01/13/89
DEPARTMENT OF HEALTH AND HUMAN SERVICES			
Mental Disorders in Children	NPRM	08/08/88	01/11/89
Income Parent to Child Deeming	NPRM	08/23/88	01/11/89
End-Stage Renal Disease Program: Revised Composite Rates	Final	08/31/88	02/27/89
Reciprocal Offset	NPRM	02/29/88	03/16/89
Hospice/Case Management, Medicaid and Medicare	NPRM	03/13/89	05/05/89
DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT			
HUD Procedures for Implementing Executive Orders 11988 and 11990	NPRM	08/23/89	10/06/89
Prepayment of a HUD-Insured Mortgage by an Owner of Low-Income Housing	Final	07/14/89	10/04/89
Deregulation of Mortgagor Income Requirements	Final	01/12/89	03/17/89
DEPARTMENT OF THE INTERIOR			
Valuation Benchmarks in Gas Regulations	NPRM	02/13/89	08/09/89
Dual Accounting Requirement in Gas Valuation Regulations	NPRM	02/16/89	08/09/89
DEPARTMENT OF LABOR			
Ionizing Radiation Standards for Underground Metal and Nommetal Mines	Final	09/07/88	08/22/89
Respiratory Protection	NPRM	05/15/87	07/24/89
DEPARTMENT OF TRANSPORTATION			
Civil Supersonic Aircraft Noise Type Certification Standards	NPRM	09/19/89	10/10/89
ENVIRONMENTAL PROTECTION AGENCY			
CERCLA Manual on Compliance with Other Laws	NPRM	05/16/88	07/24/89
Surface Impoundment Clean Closure Guidance	NPRM	11/02/87	07/24/89
Carbon Monoxide Controls for Hazardous Waste Incinerators	NPRM	07/19/88	02/23/89
Hazardous Waste Incinerator Standards	NPRM	07/20/88	02/23/89
Metals and Hydrogen Chloride Controls for Hazardous Waste Incinerators	NPRM	07/20/88	02/23/89
Liner/Leak Detection Rule	NPRM	04/18/89	11/27/89
Open Burning Permits for Holston Army Ammunition Plant.	NPRM	04/26/89	06/01/89
Refueling and Evaporative Emissions for Gasoline and Menthanol-Fueled Vehicles, Light-Duty Trucks, and Heavy-Duty Vehicles	NPRM	10/28/88	04/18/89
NSPS for SOCMI Reactor Processes	Final	11/10/88	04/13/89
NSPS for SOCMI Distillation Unit Operations	Final	11/10/88	04/13/89
NSPS for SOCMI Air Oxidation Unit Processes	Final	11/10/88	04/13/89
GENERAL SERVICES ADMINISTRATION			
Governmentwide Real Property Asset Management	NPRM	06/07/89	07/31/89
Assignment and Utilization of Space Amendment D	NPRM	06/07/89	07/31/89
OFFICE OF PERSONNEL MANAGEMENT			
Disability Retirement	NPRM	02/01/89	04/25/89
Excepted Service—Schedule A Authority for Employment of Summer Aides	NPRM	08/29/88	03/08/89

EXHIBIT 8A. REGULATIONS RETURNED TO AGENCIES FOR RECONSIDERATION DURING 1988

Agency/Title of regulation	Type	Received	Reviewed
UNITED STATES DEPARTMENT OF AGRICULTURE			
Governmentwide Debarment and Suspension (Nonprocurement)	NPRM	05/13/88	05/25/88
Use of Sodium Lactate and Potassium Lactate as Flavor Enhancers	Final	05/23/88	08/16/88
Use of Certain Binders in Meat and Poultry Products	Final	04/28/88	08/16/88
Labeling of Meat Food Products—Mechanically Separated	NPRM	05/03/88	08/18/88
Confidential Business Information Involving Biotechnical Research	NPRM	02/25/88	08/22/88
Nonprocurement Debarment and Suspension	Final	10/04/88	10/07/88
Addition of Part 1710 and Sections 1710.90 and 1710.94	NPRM	04/19/88	06/29/88
Implementation of the Program Fraud Civil Remedies Act of 1986	NPRM	07/08/88	10/17/88
Rural Telephone Bank Advanced Payments	NPRM	06/29/88	10/21/88
Governmentwide Debarment and Suspension (Nonprocurement)	NPRM	10/04/88	10/06/88
DEPARTMENT OF COMMERCE			
Foreign Fishing Regulations	NPRM	10/04/88	11/15/88
DEPARTMENT OF ENERGY			
Collection of Claims Owed the United States	Final	02/29/88	04/20/88
DEPARTMENT OF HEALTH AND HUMAN SERVICES			
Recordkeeping and Reporting Possible Misconduct in Science	NPRM	04/18/88	04/30/88
Definition of Accrual Basis of Accounting	NPRM	01/27/88	05/26/88
Hospice/Case Management—Medicaid—Medicare	NPRM	10/28/87	06/28/88
DEPARTMENT OF THE INTERIOR			
Oil and Gas Valuation	NPRM	03/09/88	07/05/88
DEPARTMENT OF LABOR			
Employment of Homeworkers in Certain Industries	NPRM	03/16/88	03/30/88
DEPARTMENT OF TRANSPORTATION			
Maintainance and Repair Surveys	NPRM	03/25/88	05/29/88
Antidrug Programs for DOT Contractors	NPRM	09/09/88	11/23/88
VETERANS ADMINISTRATION			
Equal Access to Justice Act, Procedural Rules	NPRM	08/21/87	08/02/88
ENVIRONMENTAL PROTECTION AGENCY			
ATEC Industries—Canfield	NPRM	11/20/87	06/09/88
Astro Shapes	NPRM	11/17/87	06/09/88
Refueling and Evaporative Emissions	NPRM	09/16/88	09/29/88
Georgia-Pacific	NPRM	11/05/87	05/12/88
Printpack	NPRM	11/20/87	05/12/88
NSPS Portland Cement	Final	09/24/86	06/10/88
EASCO Aluminum Corporation	NPRM	12/03/87	06/09/88
GENERAL SERVICES ADMINISTRATION			
Public Voucher for Transportation Charges	Final	04/04/88	04/26/88
SMALL BUSINESS ADMINISTRATION			
Loans to State and Local Development Companies	NPRM	04/08/88	06/14/88

EXHIBIT 9. REGULATIONS WITHDRAWN BY AGENCIES DURING 1989

Agency/Title of regulation	Type	Date received	Date withdrawn
UNITED STATES DEPARTMENT OF AGRICULTURE			
National Commodity Processing Program	Final	04/14/89	04/21/89
Peanut Warehouse Storage 1986–1990 Crops	Final	04/27/89	05/20/89
Secondary Market for Guaranteed FmHA Farm Loans	NPRM	02/17/89	06/03/89
Prepayment of REA Guaranteed Federal Financing Bank Loans	Final	08/31/89	12/28/89
DEPARTMENT OF COMMERCE			
Atlantic Sea Scallop Fishery, Amendment 3	NPRM	05/17/89	06/30/89
Foreign Fishing Regulation	NPRM	07/28/89	09/07/89
Eligibility for Distribution License	Final	07/13/89	07/25/89
Requiring Observers to be Carried on U.S. Fishing Vessels	NPRM	11/18/88	02/08/89
Distribution License for the People's Republic of China	NPRM	03/03/89	03/08/89
DEPARTMENT OF DEFENSE			
Shoreline Management at Civil Works Projects	Final	05/11/89	10/26/89
DEPARTMENT OF EDUCATION			
Secretary's Fund for Innovation in Education	NPRM	03/23/89	04/18/89
Verification of Student Aid Application Information	NPRM	09/29/88	07/26/89
Disposal and Utilization of Surplus Federal Real Property for Educational Purposes	NPRM	03/16/89	06/28/89
Rehabilitation Training Program Funding Priorities for FY 1990	NPRM	07/12/89	07/27/89
DEPARTMENT OF ENERGY			
Electric Rates, Innovative Low-Emission Technologies	NPRM	05/10/89	05/22/89
Life Cycle Cost Analysis Methodology and Procedures	NPRM	06/06/89	11/09/89
DEPARTMENT OF HEALTH AND HUMAN SERVICES			
Pasteurized Process Cheese and Related Products, Standards of Identity	Final	11/17/88	06/01/89
Patient Examination and Surgeon's Gloves, Adulteration	Final	08/16/89	09/08/89
Skim Milk and Skim Milk Cheese, Standards for Identity	Final	11/17/88	06/01/89
Grants for Organ Procurement Organizations	Final	04/20/89	04/27/89
In-Home Respite Care (Medicare)	NPRM	09/18/89	12/05/89
Standards for Program Operations	NPRM	10/14/88	02/06/89
Eligibility, Selection, Enrollment and Attendance in Head Start	NPRM	12/21/88	03/02/89
DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT			
Loans and Housing for the Elderly or Handicapped	Final	05/03/89	05/10/89
Standards of Conduct	NPRM	06/23/89	08/10/89
Prepayment of a HUD-Insured Mortgage by an Owner of Low-Income Housing	Final	08/17/88	01/26/89
Real Estate Settlement Procedures Act—Controlled Business Provisions	Final	12/12/88	01/10/89
Interstate Land Sales Registration	Final	03/15/89	03/30/89
Project-Based Section 8 Assistance	Final	04/20/89	05/12/89
Nehemiah Housing Opportunity	Final	05/02/89	05/10/89
State Agency Amendments—Prohibited Lease Terms	Final	05/18/89	05/28/89
Lead-Based Paint Poisoning Prevention	Final	08/28/89	11/08/89
Fair Housing Accessibility Guidelines	NPRM	09/08/89	11/06/89

EXHIBIT 9. REGULATIONS WITHDRAWN BY AGENCIES DURING 1989—Continued

Agency/Title of regulation	Type	Date received	Date withdrawn
DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT—Continued:			
Additional Types of Mortgages and Loans for Direct Endorsement Processing	Final	11/03/89	11/13/89
Prohibitions on Use of UDAG for Business Relocations	Final	10/14/88	02/07/89
Urban Homesteading Program	Final	04/27/89	05/08/89
Public Housing Child Care Demonstration Program	Final	03/17/89	03/27/89
DEPARTMENT OF THE INTERIOR			
Same-Day Airborne Hunting Regulation	NPRM	05/18/89	05/24/89
Nature and Classes of Mining Claims and Assessment Work	NPRM	12/28/88	02/24/89
DEPARTMENT OF JUSTICE			
Asylum and Withholding of Deportation Procedures	Final	01/25/89	10/23/89
Admission of Adjustment of Status of Replenishment Agricultural Workers	Final	06/02/89	06/28/89
DEPARTMENT OF TRANSPORTATION			
Administration of Contracts	NPRM	02/16/89	05/22/89
Bridge Safety Rules	NPRM	04/27/89	10/18/89
Cargo Preference Requirements Under Food Security Act of 1985	NPRM	05/27/88	06/27/89
DEPARTMENT OF THE TREASURY			
Customs Bond Structure	NPRM	07/21/89	07/25/89
DEPARTMENT OF VETERANS AFFAIRS			
Confidentiality of Tort Claim Peer Review	Final	08/10/89	08/10/89
Grants to States for Construction/Acquisition of State Home Facilities	NPRM	09/21/89	12/11/89
ENVIRONMENTAL PROTECTION AGENCY			
NSPS for Calciners and Dryers in Mineral Industries	Final	01/17/89	07/12/89
Organic Air Emission Standards for Hazardous Waste Treatment, Storage and Disposal Facilities: Process Vents and Equipment Leaks	Final	10/10/89	12/01/89
Organic Air Emission Standards for Hazardous Waste Treatment, Storage and Disposal Facilities: Tanks, Surface Impoundments and Containers	NPRM	10/10/89	12/01/89
Premanufacture Review Reporting and Exemption Requirements for New Chemical Substances—TSCA Biotechnology	NPRM	05/13/88	02/10/89
Experimental Use Permits—FIFRA Biotechnology	NPRM	07/05/88	02/10/89
FEDERAL EMERGENCY MANAGEMENT AGENCY			
Graduated Mobilization Response Guidance—Subchapter E Preparedness	NPRM	03/22/89	04/19/89
Comprehensive Cooperative Agreement Policies	NPRM	06/13/89	08/07/89
National Security Policy Guidance—Scientific and Engineering Workforce	NPRM	08/23/89	10/18/89
GENERAL SERVICES ADMINISTRATION			
Structured Evaluation of All Reporting Requirements	NPRM	01/11/89	02/13/89
Governmentwide Real Property Asset Management	NPRM	09/07/89	10/11/89
Mandatory Federal Telecommunications System (FTS) 2000 Network	Final	10/18/89	11/28/89

EXHIBIT 9. REGULATIONS WITHDRAWN BY AGENCIES DURING 1989—Continued

Agency/Title of regulation	Type	Date received	Date withdrawn
OFFICE OF PERSONNEL MANAGEMENT			
Special Salary Rates for Recruitment and Retention	Final	02/02/88	03/31/89
Debarment, Civil Monetary Penalties and Assessments Imposed on Health Care Practitioners and Providers of Service for Cited Offenses	Final	12/22/88	02/22/89
UNITED STATES INFORMATION AGENCY			
Fee for Processing FOIA Requests and Predisclosure Notification for Business Records	Final	04/19/89	04/27/89

EXHIBIT 9A. REGULATIONS WITHDRAWN BY AGENCIES DURING 1988

Agency/Title of regulation	Type	Date received	Date withdrawn
UNITED STATES DEPARTMENT OF AGRICULTURE			
Ocean Transportation Bidding Procedures	NPRM	07/26/88	12/19/88
Recreation Residence Authorizations	Final	03/22/88	04/05/88
Addition of Sections 1703.90–1703.94	NPRM	03/01/88	03/21/88
Determining Price Quotations for Spot Cotton	NPRM	02/04/88	02/11/88
Pesticide Certification and Fee Schedule for Imported Flue-Cured and Barley Tobacco	NPRM	07/13/88	11/02/88
DEPARTMENT OF COMMERCE			
Amendment 4 to the Fishery Management Plan for the Shrimp Fishery of the Gulf of Mexico	NPRM	10/04/88	10/14/88
Property Management Standards Section 314.6 Mortgages	Final	06/02/87	03/01/88
DEPARTMENT OF EDUCATION			
Priorities for the National Institute on Disability and Rehabilitation Research	NPRM	09/27/88	10/07/88
Debarment and Suspension (Nonprocurement)	NPRM	09/28/87	05/05/88
DEPARTMENT OF HEALTH AND HUMAN SERVICES			
HCFA Availability of Funds for Cooperative Agreements and Grants	Final	09/13/88	12/08/88
Nighttime Sleep-Aid Drug Products for Over-the-Counter Use	Final	05/16/88	05/26/88
Federal Financial Participation in the Cost of a Statewide Mechanized Claims Processing and Information Retrieval System	NPRM	07/10/87	01/29/88
Presumptive Disability and Presumptive Blindness Categories of Impairments—Renal Disease Requiring Dialysis	NPRM	12/09/87	03/14/88
Availability of Funds for Research—Prevention of Unintentional Injuries in Infancy, Childhood and Adolescence	NPRM	12/02/87	01/19/88
DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT			
Lead Standards in Water Piping (FR–2296)	Final	03/09/88	05/05/88
Increase in the Single Person Occupancy Limitation (FR–2063)	NPRM	06/09/88	06/19/88

EXHIBIT 9A. REGULATIONS WITHDRAWN BY AGENCIES DURING 1988—Continued

Agency/Title of regulation	Type	Date received	Date withdrawn
DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT—Continued:			
Authorize Additional Types of Mortgages and Loans for Direct Endorsement Processing	NPRM	08/09/88	10/18/88
Project Based Section 8 Assistance (FR–2502)	Final	05/23/88	10/18/88
Occupant and Investor Mortgagors (FR–2456)	Final	03/08/88	05/04/88
Project Based Section 8 Assistance—Interim Rule	Final	04/28/88	05/03/88
Grade Marking of Plywood (FR–2407)	NPRM	01/21/88	02/03/88
Mat-Formed Particleboard (FR–2322)	NPRM	01/21/88	02/03/88
Loans for Housing for the Elderly or Handicapped (FR–2345)	NPRM	11/18/87	01/07/88
Management and Disposition of HUD-Owned Multifamily Projects	Final	11/20/87	01/12/88
Community Development Block Grants—Relocation Disposition and Acquisition	Final	07/06/88	07/13/88
DEPARTMENT OF THE INTERIOR			
Alluvial Valley Floors	NPRM	12/14/87	02/04/88
Contracts Under the Self-Determination Act	NPRM	09/01/87	04/29/88
Indian School Equalization Program	NPRM	09/01/87	04/29/88
Federal Schools for Indians	NPRM	04/15/88	04/29/88
Tribal Bingo Management Contracts	NPRM	09/23/88	10/18/88
DEPARTMENT OF LABOR			
Claims of Compensation Under the Federal Employees' Compensation Act	Final	11/03/88	11/07/88
Employment of Homeworkers in Certain Industries	Final	06/01/87	02/03/88
DEPARTMENT OF TRANSPORTATION			
Gas Pipelines Operating in Excess of 72 Percent of SMYS	NPRM	08/29/88	12/09/88
Labor and Employment	Final	03/24/86	03/04/88
Truck Size and Weight, Maxi-Cube Vehicle	Final	07/17/87	03/04/88
ENVIRONMENTAL PROTECTION AGENCY			
NSPS Pharmaceutical Manufacturing Point Source Category	Final	05/02/86	06/16/88
Ocean Dumping Regulations Concerning Ocean Incineration	NPRM	08/31/88	11/18/88
Groundwater Classification Guidelines	Final	08/04/88	12/05/88
NESHAPS, Radon-222 Emissions for Licensed Uranium Mill Tailings	NPRM	09/02/88	09/08/88
Automotive Coating—California	NPRM	09/22/88	12/22/88
Phase II Drinking Water MCLs	NPRM	09/09/88	11/08/88
FEDERAL EMERGENCY MANAGEMENT AGENCY			
Elevated Building Coverage	NPRM	02/29/88	03/30/88
State and Local Radiological Emergency Plans and Preparedness	NPRM	02/11/88	04/15/88
Disaster Preparedness Assistance, Subchapter E	NPRM	02/11/88	04/15/88
Comprehensive Cooperative Agreement Policies, Procedures.	NPRM	09/06/88	12/05/88
Hurricane Preparedness Assistance to State and Local Governments	NPRM	06/22/88	09/09/88
GENERAL SERVICES ADMINISTRATION			
Ordering Items from the GSA Supply Catalog	Final	04/25/88	08/01/88

EXHIBIT 9A. REGULATIONS WITHDRAWN BY AGENCIES DURING 1988—Continued

Agency/Title of regulation	Type	Date received	Date withdrawn
INSTITUTE OF MUSEUM SERVICES			
Professional Services Program	Final	03/21/88	05/05/88
NATIONAL ARCHIVES AND RECORDS ADMINISTRATION			
Electronic Records Management	NPRM	08/23/88	12/09/88
Electronic Records Management	NPRM	10/27/88	11/25/88
Presidential Records Act of 1978	NPRM	08/14/87	12/09/88
Presidential Records Act of 1978	NPRM	07/05/88	11/08/88
NATIONAL ENDOWMENT FOR THE ARTS			
Grants and Cooperative Agreements to State and Local Governments	Final	09/01/88	09/19/88
SMALL BUSINESS ADMINISTRATION			
Small Business Size Standards for Industries Without an Established Size Standard	Final	05/31/88	07/29/88
Small Business Size Standards for the Construction Industry	Final	06/13/88	12/02/88
UNITED STATES INFORMATION AGENCY			
Uniform Administrative Requirements for Grants and Cooperative Agreements	NPRM	09/02/88	09/09/88
VETERANS ADMINISTRATION			
Veterans' Benefits Improvement and Health-Care Authorization Act	NPRM	03/30/88	10/24/88

EXHIBIT 10. REGULATIONS SUSPENDED DURING 1989

Agency/Title of regulation	Type	Received	Reviewed
UNITED STATES DEPARTMENT OF AGRICULTURE			
Verified Residue Control Program	NPRM	08/24/89	12/14/89
DEPARTMENT OF DEFENSE			
Protecting Historic Properties—Appendix C	Final	04/08/88	08/17/89
DEPARTMENT OF EDUCATION			
Federal, State, and Local Partnership for Educational Improvement	Final	06/26/89	11/17/89
DEPARTMENT OF HEALTH AND HUMAN SERVICES			
Food Labeling, Health Messages and Label Statements	Final	09/19/88	07/14/89
Respiratory Protective Devices	NPRM	01/10/89	09/19/89
DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT			
HUD Procedures for Implementing Executive Orders 11988 and 11990	NPRM	01/09/89	08/08/89
Project-Based Section 8 Assistance—Interim Rule	Final	05/25/89	08/04/89
Computer Automation of Required Data for Certification	Final	06/16/89	08/04/89
DEPARTMENT OF LABOR			
Occupational Exposures to Hazardous Chemicals in Laboratories	Final	08/25/88	10/06/89
Electrical Safety Standards for Metal and Nonmetal Mines	NPRM	01/06/89	07/14/89

EXHIBIT 10. REGULATIONS SUSPENDED DURING 1989—Continued

Agency/Title of regulation	Type	Received	Reviewed
ENVIRONMENTAL PROTECTION AGENCY			
Reporting Hazardous Waste When Transferring Federal Real Property	Final	07/08/88	03/03/89
Corrective Notice and Reproposed Liner/Leak Detection Rule	NPRM	08/02/88	04/10/89
Corrective Action at Hazardous Waste Management Facilities	NPRM	10/11/88	04/28/89
Low-Level Radioactive Waste	NPRM	08/18/88	03/16/89
NATIONAL AERONAUTICS AND SPACE ADMINISTRATION			
Limited Arrest Authority and Use of Force by NASA Security Personnel	NPRM	11/06/89	12/22/89

EXHIBIT 11. TYPES OF ACTIONS TAKEN ON AGENCY RULES—PERCENTAGE COMPARISON 1981–1989

Action taken	Percentage in								
	1981	1982	1983	1984	1985	1986	1987	1988	1989
Consistent without change	87.3	84.1	82.3	78.0	70.7	68.3	70.5	70.9	73.8
Consistent with change	4.9	10.3	12.7	15.1	23.1	22.9	23.7	21.9	19.4
Withdrawn by agency	1.8	1.2	1.6	2.4	3.1	2.8	2.5	2.4	2.7
Returned for reconsideration	1.6	2.1	1.3	2.7	1.5	1.4	0.4	1.2	1.3
Suspended	NA	NA	NA	NA	NA	NA	NA	NA	0.7
Sent improperly or exempt	3.1	0.9	0.0	0.0	0.3	0.2	0.2	0.1	0.4
Emergency, statutory, or judicial deadline	1.4	1.4	2.0	1.7	1.2	4.3	2.5	3.5	1.6
Total*	100.1	100	99.9	99.9	99.9	99.9	99.8	100.0	99.9
	Percentage change								
	81–82	82–83	83–84	84–85	85–86	86–87	87–88	88–89	81–89
Consistent without change	–3.2	–1.8	–4.3	–7.3	–2.4	2.2	0.4	2.9	–13.5
Consistent with change	5.4	2.4	2.4	8.0	–0.2	0.8	–1.8	–2.5	14.5
Withdrawn by agency	–0.6	0.4	0.8	0.7	–0.3	–0.3	–0.1	0.4	1.0
Returned for reconsideration	0.5	–0.8	1.4	–1.2	–0.1	–1.0	0.8	0.1	–0.3
Suspended	NA	NA	NA	NA	NA	NA	NA	NA	NA
Sent improperly or exempt	–2.2	–0.9	0.0	0.3	–0.1	0.0	–0.1	–0.3	–2.7
Emergency, statutory, or judicial deadline	0.0	0.6	–0.3	–0.5	3.1	–1.8	1.0	–1.9	0.2

* Percentages may not add to 100.0 percent due to rounding.

NA: Not applicable.

EXHIBIT 12. AVERAGE REVIEW TIME OF RULES UNDER EXECUTIVE ORDER NO. 12291
(in days)

	1981–1989			1989			1988			1987			1986		
	Major	Non-major	All	Major	Non-major	All	Major	Non-major	All	Major	Non-major	All	Major	Non-major	All
USDA	19	15	15	31	18	19	13	19	19	19	19	19	13	18	18
DOC	46	15	16	6	15	15	144	35	36	NA	19	19	127	15	15
DOD	11	24	23	NA	92	92	NA	22	22	4	12	11	30	28	28
ED	42	18	19	NA	33	33	NA	32	32	NA	15	15	14	13	13
DOE	41	18	19	52	98	92	125	42	47	NA	24	24	34	15	17
HHS	44	30	30	46	36	36	48	32	33	162	36	37	19	37	36
HUD	30	21	22	83	29	31	21	31	31	35	21	22	44	32	33
DOI	10	16	16	3	30	29	32	22	23	4	20	19	7	11	11
DOJ	2	10	10	1	12	12	NA	17	17	2	6	6	NA	8	8
DOL	114	43	50	179	71	86	133	84	87	132	46	54	76	47	49
STATE	28	13	13	NA	11	11	NA	20	20	NA	12	12	NA	5	5
DOT	41	23	23	71	23	24	58	41	41	21	32	31	32	19	19
TREAS	24	16	16	NA	28	28	NA	17	17	NA	16	16	NA	7	7
VA	NA	22	22	NA	17	17	NA	30	30	NA	38	38	NA	44	44
EPA	64	26	28	104	49	52	51	48	49	49	35	37	41	41	41
Other agencies	47	20	20	28	25	25	66	28	28	42	26	26	74	24	25
All government	40	21	21	59	28	29	44	32	32	29	24	24	29	24	24

	1985			1984			1983			1982			1981		
	Major	Non-major	All	Major	Non-major	All	Major	Non-major	All	Major	Non-major	All	Major	Non-major	All
USDA	15	19	19	11	19	19	15	13	13	17	10	10	22	8	8
DOC	NA	12	12	316	14	17	5	11	11	22	9	10	8	8	8
DOD	NA	30	30	NA	30	30	NA	16	16	NA	6	6	NA	9	9
ED	NA	16	16	39	18	19	NA	11	11	32	12	13	NA	8	8
DOE	30	7	8	77	9	12	45	7	9	26	6	7	7	7	7
HHS	74	46	47	3	33	33	35	18	19	21	10	11	8	7	7
HUD	NA	27	27	10	18	17	12	15	15	NA	11	11	NA	14	14
DOI	5	19	19	7	17	17	12	17	17	13	10	10	6	8	8
DOJ	NA	9	9	NA	10	10	NA	14	14	NA	7	7	NA	6	6
DOL	173	55	61	NA	43	43	121	18	29	37	10	12	26	6	9
STATE	NA	16	16	NA	5	5	28	10	16	NA	7	7	NA	9	9
DOT	80	34	36	42	20	21	24	15	15	37	12	12	8	8	8
TREAS	16	13	13	17	18	18	NA	12	12	60	13	14	1	8	8
VA	NA	23	23	NA	15	15	NA	15	15	NA	11	11	NA	10	10
EPA	78	33	35	58	30	31	14	22	22	88	17	19	12	9	9
Other agencies	105	23	25	26	20	20	35	14	14	40	13	14	5	10	10
All government	64	26	27	31	22	22	28	15	16	28	11	12	13	9	9

EXHIBIT 13. AGENCY RULES EXEMPTED FROM REVIEW PROCEDURES

DEPARTMENT OF AGRICULTURE

Food and Nutrition Service—Special Nutrition program notices that revise reimbursement rates and eligibility criteria for the School Lunch, Child Care Food, and other nutrition programs.

Food and Nutrition Service—Food Stamp program notices that set eligibility criteria and deduction policies.

Agricultural Marketing Service—Regulations that establish voluntary standards for grading the quality of food.

Animal and Plant Health Inspection Service—Rules and notices concerning quarantine actions and related measures to prevent the spread of animal and plant pests and diseases.

Animal and Plant Health Inspection Service—Rules affirming actions taken on an emergency basis if no adverse comments were received.

Rural Electrification Administration—Rules concerning standards and specifications for construction and materials.

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration—Certain time-sensitive preseason and in-season Fishery Management Plan regulatory actions that set restrictions on fishing seasons, catch size, and fishing gear.

DEPARTMENT OF ENERGY

Power Marketing Administrations—Regulations issued by various power administrations relating to the sale of electrical power that they produce or market.

DEPARTMENT OF THE INTERIOR

Office of Surface Mining—Actions to approve, or conditionally approve, State regulatory mining actions or amendments to such actions.

Office of Surface Mining—Approval of State mining reclamation plans or amendments.

Office of Surface Mining—Cooperative agreements between OSM and States.

United States Fish and Wildlife Service—Certain parts of the annual migratory bird hunting regulations.

DEPARTMENT OF TRANSPORTATION

All Offices of DOT—Amendments that postpone the compliance dates of regulations already in effect.

Coast Guard—Regatta regulations, safety zone regulations, and security zone regulations.

Coast Guard—Anchorage, drawbridge operations, and inland waterways navigation regulations.

Coast Guard—Regulations specifying amount of separation required between cargoes containing incompatible chemicals.

Federal Aviation Administration—Standard instrument approach procedure regulations, en route altitude regulations, routine air space actions, and airworthiness directives.

National Highway Traffic Safety Administration—Federal Motor Vehicle Safety Standard 109 table of tire sizes.

DEPARTMENT OF THE TREASURY

Internal Revenue Service, Bureau of Alcohol, Tobacco, and Firearms, and Customs Service—Revenue rulings and procedures, Customs decisions, legal determinations, and other similar ruling documents. Major legislative regulations are covered fully.

ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticides and Toxic Substances—Actions regarding pesticide tolerances, temporary tolerances, tolerance exemptions, and food additives regulations, except those that make an existing tolerance more stringent.

Office of Pesticides and Toxic Substances—Unconditional approvals of TSCA section 5 test marketing exemptions, and of experimental use permits under FIFRA.

Office of Pesticides and Toxic Substances—Decision documents defining and establishing registration standards; decision documents and termination decisions for the RPAR process; and data call-in requests made under section 3(c)(2)(B) of FIFRA.

Office of Air, Noise, and Radiation—Rules that unconditionally approve revisions to State Implementation Plans.

Office of Air, Noise, and Radiation—Unconditional approvals of equivalent methods for ambient air quality monitoring and of NSPS, NESHAPS, and PSD delegations to States; approvals of carbon monoxide and nitrogen oxide waivers; area designations of air quality planning purposes; and deletions from the NSPS source categories list.

Office of Water—Unconditional approvals of State Water Standards.

Office of Water—Unconditional approval of State underground injection control programs; delegations of NPDES authority to States; deletions from the 307(a) list of toxic pollutants; and suspensions of Toxic Testing Requirements under NPDES.

EXHIBIT 13. AGENCY RULES EXEMPTED FROM REVIEW PROCEDURES—Continued

Office of Solid Waste and Emergency Response—Unconditional approvals of State authorization under RCRA of State solid waste management plans and of hazardous waste delisting petitions under RCRA.

PENSION BENEFIT GUARANTY CORPORATION

Interest Rates—Changes in interest rates on late premium payments and delinquent employer liability payments under sections 6601 and 6621 of the Internal Revenue Code as amended by the Tax Equity and Fiscal Responsibility Act of 1982.

GOVERNMENTWIDE

Office of Federal Procurement Policy—All regulations, except those concerning acquisition of automatic data processing and telecommunications equipment; those implementing and supplementing Federal Acquisition Regulation Subparts 15.6 (Source Selection) and 32.5 (Progress Payments Based on Costs); and those implementing and supplementing the Competition in Contracting Act of 1984 (Public Law 98–3691), the Defense Procurement Reform Act of 1984 (Title XII, Public Law 98–525), and the Small Business and Federal Procurement Competition Enforcement Act of 1984 (Public Law 98–577).

EXHIBIT 14

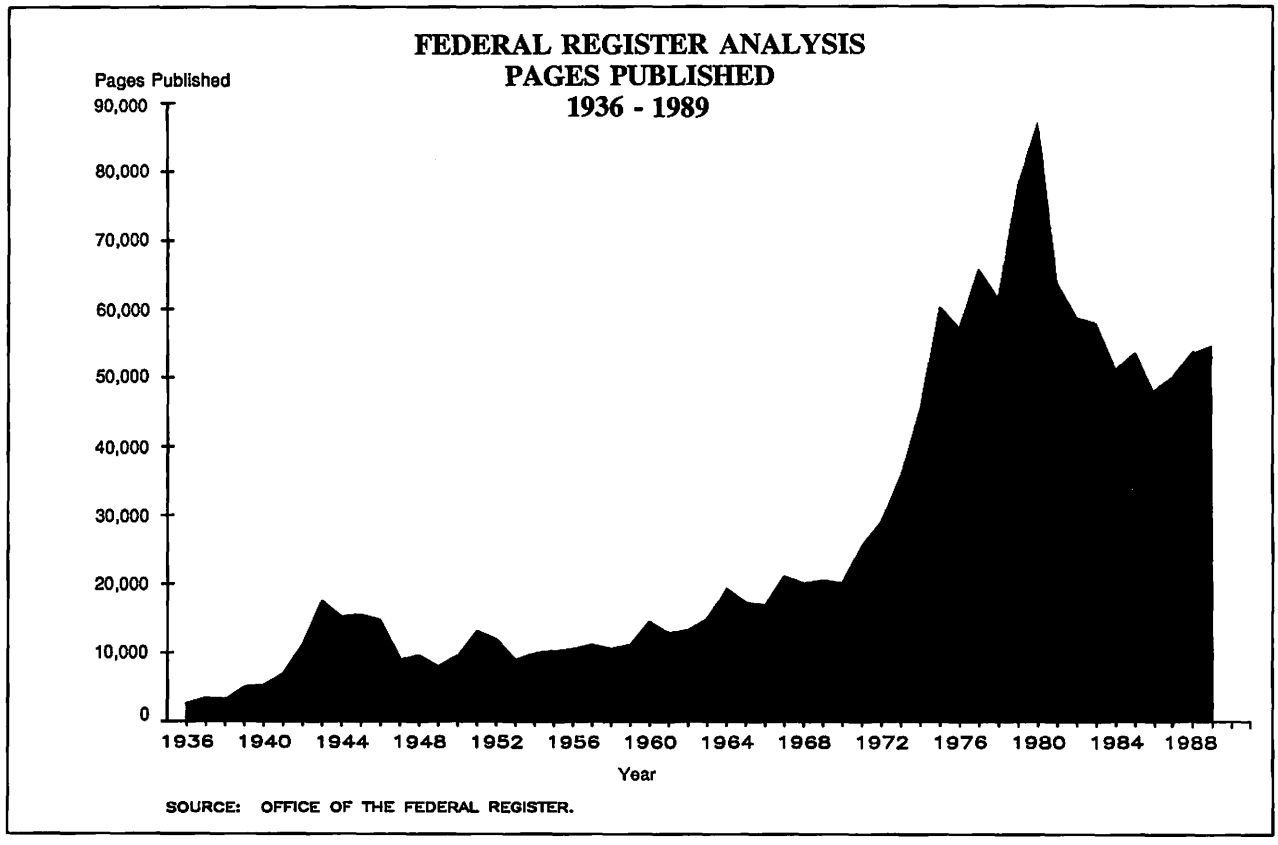


EXHIBIT 15.

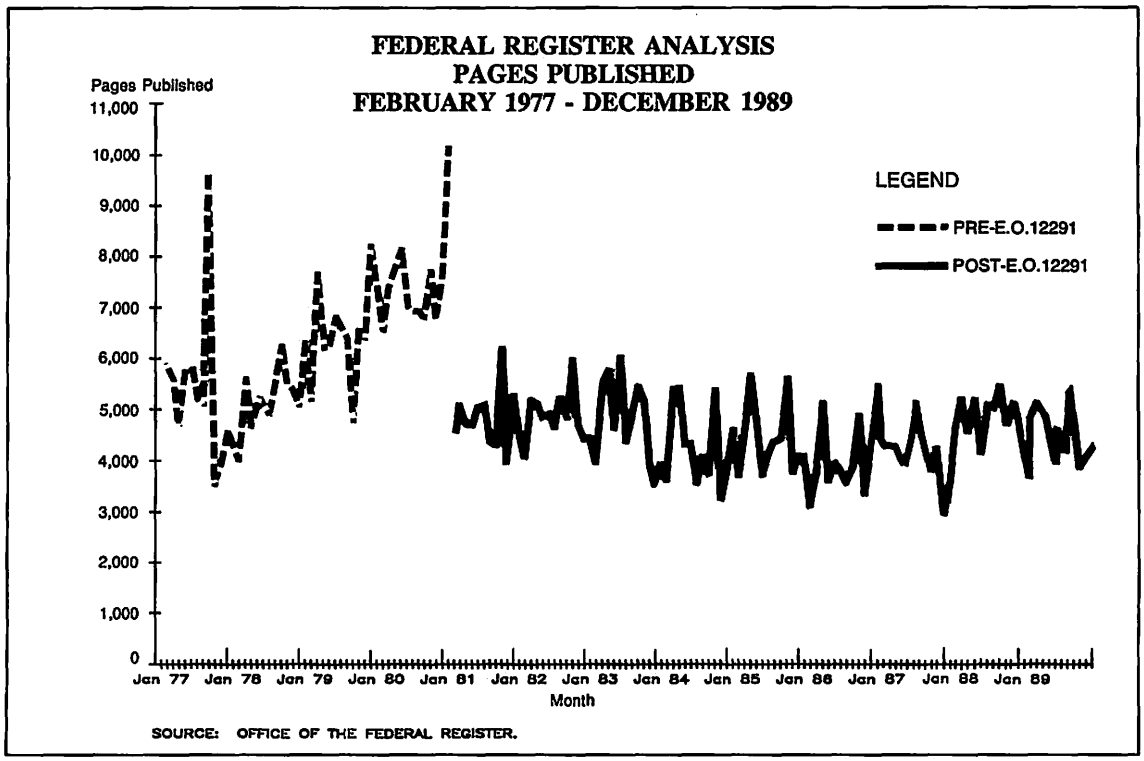


EXHIBIT 16.

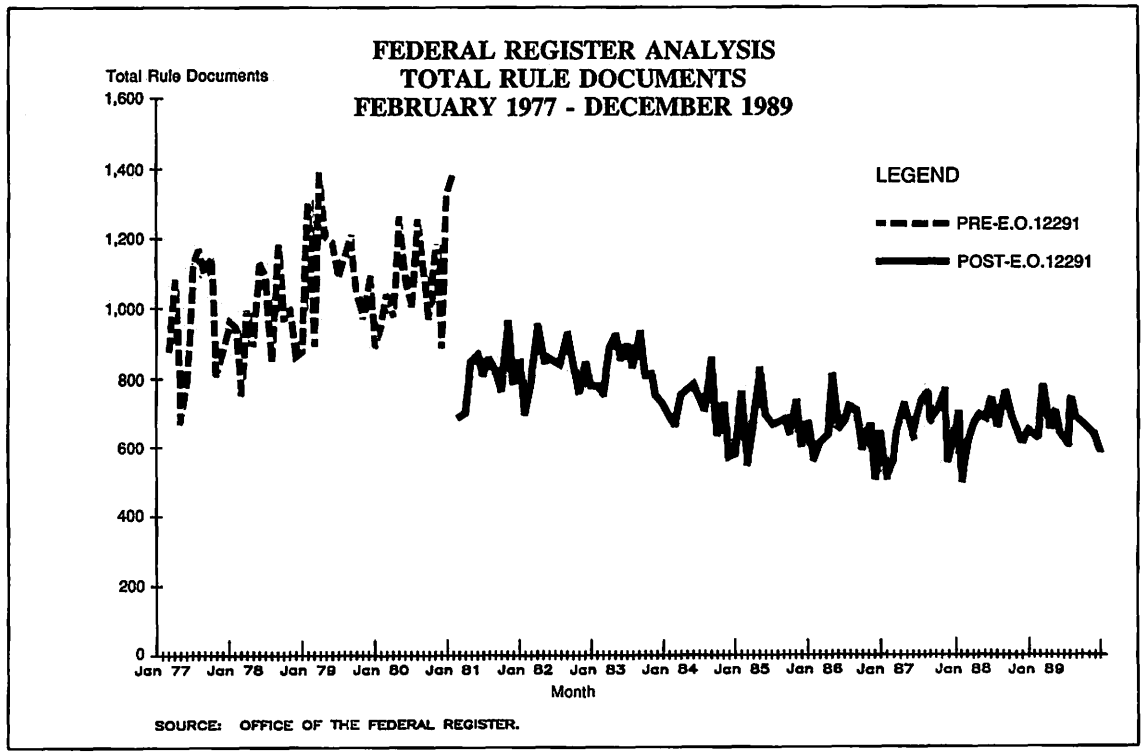


EXHIBIT 17. COMPARISON OF PAGES AND DOCUMENTS PUBLISHED IN THE *FEDERAL REGISTER* 1980–1989

	1980	1981	1982	1983	1984	1985	1986	1987	1988	1989
Total pages published	87,012	63,554	58,494	57,704	50,998	53,480	47,418	49,654	53,376	53,841
Average pages per month	7,251	5,296	4,875	4,809	4,250	4,457	3,952	4,138	4,448	4,487
Percentage change year to year	NA	-27.0	-8.0	-1.4	-11.6	4.9	-11.3	4.7	7.5	0.9
Percentage change from 1980	NA	-27.0	-32.8	-33.7	-41.4	-38.5	-45.5	-42.9	-38.7	-38.1
Proposed rules documents	5,347	3,862	3,729	3,906	3,350	3,381	3,185	3,423	3,277	3,193
Average documents per month	446	322	311	326	279	282	265	285	273	266
Percentage change year to year	NA	-27.8	-3.4	4.7	-14.2	0.9	-5.8	7.5	-4.3	-2.6
Percentage change from 1980	NA	-27.8	-30.3	-26.9	-37.3	-36.8	-40.4	-36.0	-38.7	-40.3
Final rule documents	7,745	6,401	6,288	6,049	5,155	4,843	4,589	4,581	4,697	4,711
Average documents per month	645	533	524	504	430	404	382	382	391	393
Percentage change year to year	NA	-17.4	-1.8	-3.8	-14.8	-6.1	-5.2	-0.2	2.5	0.3
Percentage change from 1980	NA	-17.4	-18.8	-21.9	-33.4	-37.5	-40.7	-40.9	-39.4	-39.2

EXHIBIT 18. ANALYSIS OF FINAL RULE DOCUMENTS PUBLISHED IN THE *FEDERAL REGISTER* 1982–1989

	Final Rules							
	1989	1988	1987	1986	1985	1984	1983	1982
New requirement	367	395	451	366	358	260	248	294
Revision to existing requirements	1,175	1,250	1,241	1,267	1,255	1,350	1,430	1,530
Elimination of existing requirements	51	74	85	142	177	162	217	299
All other	3,118	2,978	2,804	2,814	3,053	3,383	4,154	4,165
Total	4,711	4,697	4,581	4,589	4,843	5,155	6,049	6,288
	Percentage of total							
	1989	1988	1987	1986	1985	1984	1983	1982
New requirement	7.8	8.4	9.8	7.6	7.4	5.0	4.1	4.7
Revision to existing requirements	24.9	26.6	27.1	24.2	25.9	26.2	23.6	24.3
Elimination of existing requirements	1.1	1.6	1.9	3.3	3.7	3.1	3.6	4.8
All other	66.2	63.4	61.2	64.9	63.0	65.6	68.7	66.2
Total	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0

EXHIBIT 19. FINAL RULE DOCUMENTS BY AGENCY PUBLISHED IN THE *FEDERAL REGISTER* 1982–1989

Agency	Number of documents								Percentage of documents							
	1989	1988	1987	1986	1985	1984	1983	1982	1989	1988	1987	1986	1985	1984	1983	1982
USDA	604	625	556	554	611	684	638	674	11.7	12.2	11.3	11.1	11.8	12.9	10.5	10.6
DOC	260	264	285	292	254	202	213	205	5.0	5.1	5.8	5.9	4.9	3.8	3.5	3.2
DOD	155	163	172	198	113	102	109	111	3.0	3.2	3.5	4.0	2.2	1.9	1.8	1.8
ED	69	48	68	51	40	35	25	36	1.3	0.9	1.4	1.0	0.8	0.7	0.4	0.6
DOE	22	23	15	21	14	27	37	52	0.4	0.4	0.3	0.4	0.3	0.5	0.6	0.8
HHS	343	337	380	405	450	422	573	561	6.7	6.6	7.7	8.1	8.7	8.0	9.5	8.9
HUD	80	103	89	95	96	141	128	124	1.6	2.0	1.8	1.9	1.9	2.7	2.1	2.0
DOI	218	254	246	240	258	320	461	477	4.2	4.9	5.0	4.8	5.0	6.0	7.6	7.5
DOJ	105	100	122	116	108	113	159	102	2.0	1.9	2.5	2.3	2.1	2.1	2.6	1.6
DOL	83	75	56	55	68	56	63	63	1.6	1.5	1.1	1.1	1.3	1.1	1.0	1.0
STATE	17	20	18	12	7	7	8	15	0.3	0.4	0.4	0.2	0.1	0.1	0.1	0.2
DOT	1,076	978	859	923	903	748	865	908	20.9	19.0	17.4	18.5	17.4	14.1	14.3	14.3
TREAS	193	204	184	236	219	247	244	180	3.7	4.0	3.7	4.7	4.2	4.7	4.0	2.8
VA	67	69	49	51	49	54	53	54	1.3	1.3	1.0	1.0	0.9	1.0	0.9	0.9
EPA	539	441	438	487	518	624	605	805	10.5	8.6	8.9	9.8	10.0	11.8	10.0	12.7
EEOC	12	5	18	8	13	14	16	7	0.2	0.1	0.4	0.2	0.3	0.3	0.3	0.1
FEMA	95	106	66	71	84	91	261	398	1.8	2.1	1.3	1.4	1.6	1.7	4.3	6.3
GSA	98	77	83	74	107	74	95	80	1.9	1.5	1.7	1.5	2.1	1.4	1.6	1.3
NASA	50	39	33	36	28	15	20	18	1.0	0.8	0.7	0.7	0.5	0.3	0.3	0.3
OMB	0	1	2	0	0	1	2	1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
OPM	34	58	74	44	39	38	43	25	0.7	1.1	1.5	0.9	0.8	0.7	0.7	0.4
SBA	43	28	14	34	26	39	26	26	0.8	0.5	0.3	0.7	0.5	0.7	0.4	0.4
Other	259	273	257	275	241	261	335	337	5.0	5.3	5.2	5.5	4.7	4.9	5.5	5.3
CFTC	23	20	25	19	32	38	51	19	0.4	0.4	0.5	0.4	0.6	0.7	0.8	0.3
CPSC	4	10	8	9	17	30	22	25	0.1	0.2	0.2	0.2	0.3	0.6	0.4	0.4
FCC	420	437	444	306	400	405	359	393	8.1	8.5	9.0	6.1	7.7	7.7	5.9	6.2
FDIC	22	13	16	16	14	20	24	17	0.4	0.3	0.3	0.3	0.3	0.4	0.4	0.3
FERC	40	92	95	82	127	139	156	120	0.8	1.8	1.9	1.6	2.5	2.6	2.6	1.9
FHLBB	28	37	30	29	39	32	41	53	0.5	0.7	0.6	0.6	0.8	0.6	0.7	0.8
FMC	10	14	17	6	9	43	19	26	0.2	0.3	0.3	0.1	0.2	0.8	0.3	0.4
FRS	33	47	32	28	40	37	66	75	0.6	0.9	0.6	0.6	0.8	0.7	1.1	1.2
FTC	38	58	49	77	84	82	116	80	0.6	1.1	1.0	1.5	1.6	1.6	1.9	1.3
ICC	35	35	48	51	59	53	103	127	0.7	0.7	1.0	1.0	1.1	1.0	1.7	2.0
NRC	48	42	47	36	49	42	55	51	0.9	0.8	1.0	0.7	0.9	0.8	0.9	0.8
SEC	34	45	40	54	66	54	65	84	0.7	0.9	0.8	1.1	1.3	1.0	1.1	1.3
Total*	5,157	5,141	4,935	4,991	5,182	5,290	6,056	6,329	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0

* Totals include final rule documents issued jointly by two or more agencies and editorial corrections.