OFFICE OF MANAGEMENT AND BUDGET

Draft Report to Congress on the Costs and Benefits of Federal Regulations

AGENCY: Office of Management and Budget, Executive Office of the President.

ACTION: Notice and request for comments.

SUMMARY: OMB requests comments on the attached Draft Report to Congress on the Costs and Benefits of Federal Regulation. The Draft Report is divided into four chapters. Chapter I discusses regulatory policy during the Administration's first year. It discusses OMB's role in coordinating regulatory policy, its open and transparent approach to regulatory oversight, and its function as overseer of information and quality analysis. Chapter II presents estimates of the costs and benefits of Federal regulation and paperwork with an emphasis on the major regulations issued over the last 30 months. Chapter III discusses developments in regulatory policy governance that have recently taken place in the international arena and its relevance for the U.S. Chapter IV asks for recommendations from the public for the reform of Federal rules.

DATES: To ensure consideration of comments as OMB prepares this Draft Report for submission to Congress, comments must be in writing and received by OMB no later than May 28, 2002.

ADDRESSES: Comments on this Draft Report should be addressed to John Morrall, Office of Information and Regulatory Affairs, Office of Management and Budget, NEOB, Room 10235, 725 17th Street, NW., Washington, DC 20503.

You may also submit comments by facsimile to (202) 395–6974, or by electronic mail to *jmorrall@omb.eop.gov.*

FOR FURTHER INFORMATION CONTACT: John Morrall, Office of Information and Regulatory Affairs, Office of Management and Budget, NEOB, Room 10235, 725 17th Street, NW., Washington, DC 20503. Telephone: (202) 395–7316.

SUPPLEMENTARY INFORMATION: Congress directed the Office of Management and Budget (OMB) to prepare an annual Report to Congress on the Costs and Benefits of Federal Regulations. Specifically, Section 624 of the FY2001 Treasury and General Government Appropriations Act, also known as the ''Regulatory Right-to-Know Act,'' (the Act) requires OMB to submit a report on the costs and benefits of Federal regulations together with recommendations for reform. The Act says that the report should contain estimates of the costs and benefits of regulations in the aggregate, by agency and agency program, and by major rule, as well as an analysis of impacts of Federal regulation on State, local, and tribal government, small business, wages, and economic growth. The Act also states that the report should go through notice and comment and peer review.

John D. Graham,

Administrator, Office of Information and Regulatory Affairs.

Draft Report to Congress on the Costs and Benefits of Federal Regulations; Executive Summary

This Draft Report to Congress on regulatory policy was prepared pursuant to the Regulatory Right-to-Know Act (Section 624 of the Treasury and General Government Appropriations Act, 2001), which requires such an account each year. It provides (a) an overview of the Bush Administration's centralized approach to federal regulatory policy; (b) a statement of the costs and benefits of federal regulations, including assessments of their impact on State, local and tribal governments, small businesses, wages and economic growth; and (c) recommendations for regulatory reforms. The report will be published in final form after revisions to this draft are made based on public comment, external peer review, and interagency review.

Its major features and findings include:

1. In the last six months, OMB has cleared 41 significant federal regulations aimed at responding to the terrorist attacks of September 11th. These rules addressed urgent matters such as homeland security, immigration control, airline safety, and assistance to businesses harmed by the resulting economic disaster experienced in several regions of the country.

2. The Bush Administration's approach to regulatory review, through OMB's Office of Information and Regulatory Affairs (OIRA), is characterized by openness, transparency, analytic rigor, and promptness. OIRA's website puts that perspective on display, with daily updates and an unprecedented amount of information about OIRA's activities. The 20 significant rules that OMB returned to agencies for reconsideration from July 1, 2001 to March 1, 2002 are more than the total number of rules returned to agencies during the Clinton Administration. Inadequate analysis by agencies is the most common reason for returns. The number of OMB reviews consuming more than the allotted 90 days has declined from what had regularly been 15–20 rules to near zero in recent months. OMB has also demonstrated its commitment to necessary federal regulation by clearing numerous well-analyzed rules and prompting agencies to initiate or complete cost-effective rulemaking opportunities. In order to perform its role with greater competence, OIRA is expanding its staffing expertise in several fields of science and engineering that are central to reviewing regulatory proposals.

3. Under the Bush Administration, OIRA is taking a proactive role in suggesting regulatory priorities for agency consideration. In order to play this role constructively, we have devised the ''prompt'' letter as a modest device to bring a regulatory matter to the attention of agencies. OIRA's initial five prompt letters have addressed a range of issues at four different agencies, including the use of lifesaving defibrilators in the workplace, food labeling requirements for trans fatty acids, and better information regarding the environmental performance of industrial facilities.

4. Pursuant to statutory mandate, OIRA has issued government-wide guidelines to enhance the quality of information that federal agencies disseminate to the public. OIRA is now working with agencies to finalize their guidelines by October 1, 2002. These guidelines will offer a new opportunity for affected members of the public to challenge agencies when poor quality information is disseminated. OMB has required each agency to develop an administrative mechanism to resolve these challenges, including an independent appeals mechanism.

5. The report summarizes regulatory reform activities now underway in developed countries throughout the world, with special focus on the European Union.

6. Major federal regulations cleared by OMB from April 1, 1995 to September 30, 2001 were examined to determine their quantifiable benefits and costs. The estimated annual benefits range from $49 billion to $68 billion while the estimated costs range from $51 billion to $54 billion. Estimates of the total benefits and costs of *all* federal regulations currently in effect are found in the Appendix, because they are based substantially on figures that the agencies did not produce and OMB did not review. The estimates of total benefits, which are highly uncertain, range from

about one-half to three times the total costs, which are pegged at $520 billion to $620 billion per year. Total cost figures are roughly comparable to the federal government's total discretionary budget authority in FY 2001.

Finally, OMB seeks public comment on all aspects of this Draft Report. OMB is also calling for public nominations of regulatory reforms in the following three areas:

- Reforms to specific existing regulations that, if adopted, would increase overall net benefits to the public, considering both qualitative and quantitative factors. These reforms might include (1) extending or expanding existing regulatory programs; (2) simplifying or modifying existing rules or (3) or rescinding outmoded or unnecessary rules.
- Identification of specific regulations, guidance documents, and paperwork requirements that impose especially large burdens on small businesses and other small entities without an adequate benefit justification.
- Reviews of problematic agency ''guidance'' documents of national or international significance that should be reformed through notice and comment rulemaking, peer review, interagency review, or rescission.

Nominations should be presented in the format provided in the report to facilitate orderly consideration by OMB, agencies, and the public. OMB will consider the nominations, provide a preliminary evaluation, and report these evaluations in the final draft of this report. OMB will request that agencies consider all nominations but especially those that OMB's preliminary evaluation suggest merit ''high priority.''

In addition, OMB would welcome: (1) Comments on any cases where consultations under the Unfunded Mandates Reform Act between federal agencies and State, local, and tribal governments were not sufficient or timely enough to have a meaningful impact on the rulemaking process; and (2) suggestions of analytical issues needing refinement or development to improve OMB's analytic guidance document.

Chapter I: Regulatory Policy Under the Bush Administration: The First Year

Federal regulation is a fundamental instrument of national policy. It is one of the three major tools—besides spending and taxing—used to implement policy. It is used to advance numerous public objectives, from homeland security to privacy, environmental protection, food safety, transportation safety, delivery of quality health care, equal employment opportunity, energy security, educational quality, immigration control and consumer protection. Yet regulation also is costly. While the exact cost of regulation is uncertain, the total cost is comparable to discretionary spending—about $640 billion in 2001. Regulation can increase the cost of producing goods and services in the economy, thereby raising prices to the consumer, creating potential competitive problems for U.S. firms in a global economy, exacerbating fiscal challenges to State and local governments, and placing jobs and wages at risk. Regulatory policy does not lend itself to simple answers because the underlying scientific and economic issues often are complex, there may be tradeoffs between laudable social objectives, and success often hinges on the details about how a rule is designed, implemented and enforced.

The Bush Administration supports federal regulations that are sensible and based on sound science, economics, and the law. Through OMB's Office of Information and Regulatory Affairs (OIRA), the Administration is stimulating development of a regulatory process that adopts new rules when markets fail, simplifies and modifies existing rules to make them more effective and/or less costly or intrusive, and rescinds outmoded rules whose benefits do not justify their costs. In pursuing this agenda, OIRA has pursued an approach based on the principles of regulatory analysis and policy espoused in Executive Order 12866, signed into law by President Clinton in 1993.

The regulatory reforms now being implemented and described below, while modest, incremental and generally procedural in nature, promise to have a powerful positive long run effect on the quality of federal regulation. With regard to federal regulation, the Bush Administration's objective is quality, not quantity. Those rules that are adopted promise to be more effective, less intrusive, and more cost-effective in achieving national objectives while demonstrating greater durability in the face of political and legal attack.

One of OIRA's most important functions is coordinating the President's regulatory policy. As discussed in last's year's annual report to Congress, the first regulatory action taken by the Bush Administration was issuance of the ''Card Memorandum,'' a January 20, 2001 directive from the President's Chief of Staff, Andrew H. Card, Jr., to agency heads to take steps to ensure that policy officials in the incoming Administration had the opportunity to review any new or pending regulations. In last year's report, we provided a summary of actions taken by agencies pursuant to rules targeted for scrutiny by the Card memo, and by a subsequent OMB memorandum to agencies. In Appendix A of this report, we provide an update of these actions. In the next section, we discuss another coordinating role OMB is playing—one that was unexpected.

A. The Regulatory Response to September 11th

After the shocking terrorist attacks of September 11, 2001, the American public looked to the federal government to take action not only to prevent future security threats but also to provide relief for individuals affected by the tragedies. In response, the federal government revisited its current practices and procedures, and sought solutions to address these concerns. Also in response to the attacks, several agencies including Departments of Justice, Transportation, Labor, Health and Human Services, and Commerce and the Office of Personnel Management, Small Business Administration, and Office of Management and Budget issued new regulations. Table 1 lists the 41 significant federal regulations issued in response to the terrorist attacks.

TABLE 1.—THE 41 REGULATIONS RESPONDING TO THE TERRORIST ATTACKS OF SEPT. 11, 2001

Agency	Sub agency	Title	Rulemaking stage
DOC	BXA	India and Pakistan: Lifting of Sanctions, Removal of Indian and Pakistani Entities, and Revision in License Review Policy.	Final Rule.
DOJ	BOP	National Security: Prevention of Acts of Rule Violence and Terrorism.	Interim Final Rule.
DOJ	LA	September 11th Victim Compensation Fund of 2001	Pre-rule.
DOJ	LA	September 11th Victims Compensation Fund of 2001	Final Rule.

TABLE 1.—THE 41 REGULATIONS RESPONDING TO THE TERRORIST ATTACKS OF SEPT. 11, 2001—Continued

Agency	Sub agency	Title	Rulemaking stage
DOJ	INS	Custody Procedures	Interim Final Rule.
DOJ	INS	Review of Custody Determinations	Interim Final Rule.
DOJ	LA	September 11th Victim Compensation Fund of Rule 2001	Interim Final Rule.
DOL	ETA	Disaster Unemployment Assistance Program Amendment	Interim Final Rule.
DOT	FAA	Screening of Checked Baggage on Flights within the United States.	Final Rule.
DOT	FAA	Aircraft Security under General Operating and Flights Rules	Final Rule.
DOT	FAA	Flight Crew Compartment Access and Door Design	Final Rule.
DOT	OST	Procedures for Compensation of Air Carriers	Final Rule.
DOT	FRA	Locational Requirement for Dispatching of U.S. Rail Operations.	Interim Final Rule.
DOT	FAA	Flight Crew Compartment Access and Door Designs	Final Rule.
DOT	FAA	Criminal History Background Checks	Final Rule.
DOT	FAA	Security Screeners: Qualifications, Training and Testing	Other.
DOT	FAA	Security Considerations in the Design of the Flight Deck on Transport Category Airplanes.	Other.
DOT	TSA*	Imposition and Collection of Passenger Civil Aviation Security Fees in the Wake of September 11, 2001.	Other.
DOT	TSA	Aviation Security Infrastructure Fees	Interim Final Rule.
DOT	TSA	Security Programs for Aircraft with a Maximum Certificated Takeoff Weight of 12,500 Pounds or More.	Interim Final Rule.
DOT	TSA	Civil Aviation Security Rules	Interim Final Rule.
DOT	FAA	Airspace and Flight Operations Requirements for the 2002 Winter Olympic Games, Salt Lake City, UT.	Final Rule.
DOT	FAA	Procedures for Reimbursement of Proposed Airports, On-Airport Parking Lots and Vendors of On-Airfield Direct Services to Air Carriers for Security Mandates.	Notice of Proposed Rulemaking.
DOT	FAA	Firearms, Less-Than-Lethal Weapons, and Emergency Services on Commercial Air Flights.	Request for comments.
DOT	FAA	Temporary Extension of Time Allowed for Certain Training and Testing.	Final Rule.
DOT	FAA	Security control of Air Traffic	Final Rule; request for comments.
DOT	FAA	Temporary Flight Restrictions	Final Rule.
HHS	SAMHSA	Substance Abuse and Mental Health Services Administration Mental Health and Substance Abuse Emergency Response Criteria.	Interim Final Rule.
OMB		Regulation for Air Carrier Guarantee Loan Program	Final Rule.
OPM		Absence and Leave Use of Restored Annual Leave	Interim Final Rule.
OPM		Absence and Leave Use of Restored Annual Leave	Final Rule.
OPM		Administratively Uncontrollable Overtime Pay	Interim Final Rule.
SBA**		Size Standards; Inflation Adjustment	Interim Final Rule.
SBA		Disaster Loan Program	Interim Final Rule
SBA		Small Business Size Standards: Travel Agencies	Interim Final Rule.
Treasury	FinCEN	Amendment to the Bank Secrecy Act Regulations Rule	Interim Final Rule.
Treasury	FinCEN	Proposed Amendment to the Bank Secrecy Act Regulations	Notice of Proposed Rulemaking.
Treasury	FinCEN	Cooperative Efforts to Deter Terrorist Rule and Financing and Money Notice of Laundering.	Temporary Rule and Notice of Proposed Rulemaking.
Treasury	Departmental Offices	Counter Money Laundering Requirements—Correspondent Accounts with Foreign Shell Banks; Rulemaking Recordkeeping Related to Foreign Banks with Correspondent Accounts.	Temporary Rule and Notice of Proposed Rulemaking.
Treasury	IRS	Special Form 720 Filing Rule	Final Rule Rule without Notice of Proposed Rulemaking.
Treasury and other Financial Institutions***		Identity Verification Program	Notice of Proposed Rulemaking.

* Traffic Safety Administration.
** Small Business Administration.
*** Office of Comptroller of the Currency, Board of Governors of the Federal Reserve System, Federal Deposit Insurance Corporation, Office of Thrift Supervision, and National Credit Union.

As an integral part of the expedited issuance of these rules, OIRA conducted its full regulatory review and coordination function under Executive Order 12866. OIRA ensured that all affected agencies were aware of what other agencies were proposing and facilitated their timely comments on the proposed actions. These efforts made sure that all September 11th related rules received priority attention from the appropriate reviewers and that the Administration's best solutions to the circumstances caused by the terrorist attacks were implemented.

The Administration issued two types of rules in response to the events of September 11th. The first improves and strengthens national security. The

second directs relief to the individuals affected by the attacks.

The Department of Justice promulgated several rules that addressed the need for heightened security at home and compensation for victims of the attacks. Shortly after the September 11th, 2001 terrorist attack, the President signed the ''September 11th Victim Compensation Fund of 2001'' into law as Title IV of the Air Transportation Safety and System Stabilization Act. The Act authorizes compensation to any individual (or the personal representative of a deceased individual) who was physically injured or killed as a result of the terrorist-related aircraft crashes on that day. The Victims Compensation Fund is designed to provide a no-fault alternative to tort litigation for individuals who were physically injured or killed as a result of the aircraft hijackings and crashes on September 11th. This regulation established procedural rules for administration of the Victims Compensation Fund.

A second Justice rule involved the monitoring of communications between an inmates and their attorneys or their agents, where the Attorney General has determined that such actions are reasonably necessary in order to deter future acts of violence or terrorism, and upon a specific notification to the inmate and attorneys involved. Under the rule, a privilege team of individuals not involved in the underlying investigation would sift through the attorney-client communications. The privilege team would disclose information to the investigators and prosecutors only upon approval of a federal judge, unless the team leader determined that acts of violence or terrorism are imminent.

On the immigration side, the Department of Justice and the Immigration and Naturalization Service issued two rules signaling the need for tighter security. INS established an automatic stay of the judge's decision in cases where the individual is ordered to be released, allowing INS to continue to detain the alien while it appeals the decision. An additional INS rule extended the period an individual can be held in custody after his or her initial arrest. This rule afforded the INS additional time to run background security clearances on individuals to determine whether they were security risks.

The Department of Transportation and the Federal Aviation Administration issued over a dozen rules in four key areas: flight-deck security requirements, airline compensation, background checks, and flight rules. In order to improve security on aircrafts, the FAA issued a series of rules to strengthen cockpit doors and locks to protect against unauthorized access to the cockpit. FAA also issued an interim final rule to require more permanent measures such as the replacement of cockpit doors. In addition, to fund enhanced security measures, such as airport screener services, a rule was promulgated that allowed for a $2.50 security fee per segment traveled, with a maximum of $10.00 per round trip. The fee is to be used for enhanced security protections.

In compensation, FAA issued a rule which set forth procedures for the allocation for approximately $5 billion to air carriers affected by the events of September 11th. In the final two categories of rules, the FAA promulgated several regulations regarding criminal history background checks, security procedures, screening of passengers, and screening of checked baggage.

The Treasury Department issued a series of rules to tighten the security of financial banking and establish procedures to identify suspicious transactions as part of the counter money-laundering program. With the need to deter the financing of terrorist acts, the Treasury also issued a rule permitting information sharing among financial institutions and the federal government.

The second category of rules promulgated seeks to provide assistance to individuals affected by the September 11th attacks. The Department of Labor issued a rule regarding disaster relief for individuals unemployed as a result of the attacks, clarifying eligibility requirements. In addition, the Office of Personnel Management set forth a rule to assist agencies dealing with individuals who were forced to take leave during the national emergency and risked losing annual leave time. A second OPM regulation clarified technical procedures on compensation of individuals whose work is now related to the September 11th tragedy and recent security concerns. This would include law enforcement officials who have been temporarily reassigned work in response to recent national emergency declaration.

The Department of Health and Human Services issued a rule regarding mental health and substance abuse that was drafted prior to the 11th. After the events, the Department added language to the preamble discussing the attacks, though no changes to the regulation itself were made. Finally, the Small Business Administration set forth rules on disaster loan programs and inflation that may occur as a result of the terrorist attacks and economic downturns.

Since the events of September 11, the Administration has sought to address the need for heightened national security in addition to assistance for disaster victims. OIRA has collaborated with the agencies on 41 significant regulatory actions made necessary by the events of September 11th. The regulatory actions summarized above occurred in the months soon after the attacks in order to implement solutions expeditiously.

B. An Open Approach to Centralized Regulatory Oversight

The Bush Administration supports strong, centralized oversight by OMB's Office of Information and Regulatory Affairs (OIRA) to stimulate development of a smarter regulatory process. To best achieve this goal, OIRA has developed a more transparent and open approach to centralized regulatory oversight. This policy of openness reflects the preferences of the current OMB Director and OIRA Administrator but also responds to past complaints that OMB decision making was secretive and rooted more in interest-group politics than professional analysis. Although some critics continue to perceive OIRA as a mysterious organization, the long-term, cumulative impact of the steps described below should demystify the process of regulatory oversight.

OMB has taken the following specific steps to enhance the openness of the regulatory review process:

- OIRA is improving implementation of the public disclosure provisions in E.O. 12866, including both the letter and spirit of the provisions relating to communications with outside parties interested in regulations under review by OIRA. The Administrator's relevant guidance to OIRA staff is available on OIRA's website: < *http://www.whitehouse.gov/omb/inforeg/regpol.html*>.
- For meetings subject to the disclosure provisions of E.O. 12866, OIRA maintains a log (which notes the meeting date, topic, lead agency, and participants) on OIRA's website and docket room. We also invite the relevant agency and file any documents submitted at EO 12866 meetings in our docket room with copies provided to the agency.
- Under the E.O. 12866 disclosure procedures, we are posting information about written correspondence from outside parties on regulations under review by OIRA. Information on this correspondence—including the date of the letter, the sender and his or her organizational affiliation, and the

subject matter—is available on the OIRA website. Copies of these letters are also available in the docket room.[1]

• OIRA has increased the amount of information available on the OIRA website. In addition to the information on meetings and correspondence noted above, OIRA makes available communications from the OIRA Administrator to agencies, including ''prompt,'' ''return,'' and ''post clearance'' letters, as well as the Administrator's memorandum to the President's Management Council (September 20, 2001) on ''Presidential Review of Agency Rulemaking by OIRA.''

• OIRA has adopted an open-door approach to meetings with outside parties, leading to meetings with more than 100 outside groups from July 2001 to December 2001 on matters of general regulatory policy or specific rules.

• OIRA has initiated a multi-year process aimed at linking up to the Administration's E-government initiative, thereby allowing outside parties electronic access to the information now contained in OIRA's docket room while giving the public greater opportunity to provide and view the electronic input of others on OIRA decision-making.

Openness does not necessarily reduce controversy. In pursuit of the policies and priorities of the Bush Administration, OIRA is already establishing procedures and making decisions that are controversial. That is the nature of regulatory policy. However, the objective of openness is to transform controversy from a dispute about decision process (who was able to speak with OMB officials before the decision was made?) to a dispute about the substance of regulatory analysis or policy (e.g., do the benefits of this rule justify the costs?). Indeed, explicitness about the grounds for regulatory decision making will in some cases sharpen public controversy by making differences of opinion more apparent to everyone interested in regulatory outcomes. Thus, OIRA does not regard absence of public controversy as a measure of success of regulatory oversight.

C. Gatekeeper for New Rulemakings

Presidential Executive Order 12866 provides OIRA with substantial authority to review rulemaking proposals from agencies. During the Clinton Administration, concerns were raised that the sound principles and procedures in this Order were not always implemented and enforced by OIRA.

An average of 600 significant rulemaking actions were approved per year during the Clinton Administration. During the last three years of the Clinton Administration, there were exactly zero rules returned to agencies by OMB for reconsideration. [2] The absence of returns could indicate either that the agency-OIRA relationship was tilted too heavily in favor of the agencies or that the agencies were meeting OIRA's expectations. Although it is often better for OIRA to work with an agency to resolve a problem rather than simply return a rule, the degree of OIRA's actual effectiveness can be questioned when it declines to use its authority to return rules.

Under the Bush Administration, OIRA has revived the ''return letter,'' making clear that OMB is serious about the quality of new rulemakings. From July 2001 to December 2001, there were 18 significant rulemakings returned to agencies for reconsideration.[3] As the data in Table 2 illustrate, this represents a significant rate of return when measured against recent history. The technical and policy rationales for these returns are stated in letters to agency officials that are made public and posted on OIRA's web site. In five cases, after modifications and later submission for review under E.O. 12866, OIRA approved the rule. More importantly, agencies are beginning to invite OIRA staff into earlier phases of regulatory development in order to prevent returns late in the rulemaking process. It is at these early stages where OIRA's analytic approach can most improve on the quality of regulatory analyses and the substance of rules.

TABLE 2.—EXECUTIVE ORDER REVIEWS 1981–2001

Year	Total reviews	Returns	Percent
All	35,111	414	1.2
2001	700	18	2.6
2000	579	0	0.0
1999	583	0	0.0
1998	486	0	0.0
1997	507	4	0.8
1996	503	0	0.0
1995	619	3	0.5
1994	861	0	0.0
1993	2,167	9	0.4
1992	2,286	9	0.4
1991	2,525	28	1.1
1990	2,138	21	1.0
1989	2,220	29	1.3
1988	2,362	29	1.2
1987	2,315	10	0.4
1986	2,011	29	1.4
1985	2,213	34	1.5
1984	2,113	58	2.7
1983	2,484	32	1.3
1982	2,641	56	2.1
1981	2,798	45	1.6

[1] Please call (202) 395 -6880 for access to the docket room located in Room 10102, the New Executive Office Building, 725 17th St., NW., Washington DC 20503.

[2] During the full eight years of the Clinton Administration, OMB returned for reconsideration approximately one rule in 500.

[3] A detailed table of the number of regulations reviewed by OMB by agency and type of action taken from January 1, 2001 to the present is maintained on our website at <*http://www.whitehouse.gov/library/omb/OMBRCYTD–2001.html*>.

In a September 20, 2001 memorandum to the President's Management Council, the OIRA Administrator summarized for top agency officials the supporting information that must accompany a draft significant regulatory action. The six specific elements are described below.

• First, the agency should articulate how the draft regulatory action is consistent with the principles and procedures of E.O. 12866 and the underlying statute(s). An important aspect of OIRA's review of a draft rule is an evaluation of the possible impact on the programs of other Federal agencies. OIRA will make an assessment, in collaboration with policy officials from interested agencies, as to whether the draft action is consistent with the policies and priorities of the Administration.

• Second, the agency must prepare a formal regulatory impact analysis for rulemaking actions deemed economically significant. This analysis should include an assessment of benefits and costs (quantitative and qualitative) and a rigorous analysis of several regulatory alternatives. The RIAs should be timely and prepared in a way consistent with OMB's government-wide guidance, as explained by OMB on March 22, 2000 and June 19, 2001. An RIA is necessary regardless of whether the underlying statute governing agency action requires, authorizes or prohibits cost-benefit analysis as an input to decisionmaking. The public and Congress have an interest in benefit and cost information, regardless of whether it plays a central role in decisionmaking under the agency's statute. Congress has mandated that OMB provide this information in this annual report to Congress on the costs and benefits of regulation.

• Third, for draft regulatory actions that are supported by risk assessments of health, safety and environmental hazards, OIRA recommends that agencies adopt the basic informational quality and dissemination standards that Congress adopted in the Safe Drinking Water Act Amendments of 1996. These standards were recently codified in OMB's government-wide guidelines on information quality.

• Fourth, OIRA recommends that draft RIAs, including supporting technical documents (*e.g.,* risk assessments), be subjected to formal, independent external peer review by qualified specialists. Given the growing public interest in peer review at agencies, OIRA recommends that (a) peer reviewers be selected primarily on the basis of necessary technical expertise; (b) peer reviewers be expected to disclose to agencies prior technical/policy positions they may have taken on the issues at hand; (c) peer reviewers be expected to disclose to agencies their sources of personal and institutional funding (public and private); and (d) peer reviews be conducted in an open and rigorous manner. OIRA will give a measure of deference to agency analysis that has been developed in conjunction with such peer review procedures. EPA's recent decision to affirm an arsenic standard in drinking water of 10 parts per billion is a good illustration of a recent regulatory decision that was supported by rigorous external peer reviews.

• Fifth, for regulatory actions with impacts on State, local, and tribal governments, OIRA staff will insist on agency certification of compliance with Executive Orders 13132 and 13175 and compliance with the Unfunded Mandates Reform Act. The OMB Director has pledged to Congress that OIRA will return any rulemaking proposal to agencies that has not been subjected to adequate consultation with affected State, local, and tribal officials.

• Sixth, the Regulatory Flexibility Act as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA) requires that OIRA ensure that impacts on small businesses and other small entities are taken into account in the regulatory process. This work is done in part in collaboration with the Small Business Administration's Chief Counsel for Advocacy. OIRA looks to see that an appropriate analysis of small business impacts has been performed, including an evaluation of regulatory alternatives designed to reduce the burden on small businesses without compromising the statutory objective. In the cases of OSHA and EPA rulemakings under SBREFA that are expected to have economically significant impacts on a substantial number of small entities, OIRA staff participate in Small Business Advocacy Panels prior to publication of a rulemaking proposal.

In addition, under E.O. 13045, OIRA reviews proposed regulatory actions that may pose disproportionate environmental or safety risks to children. [4] E.O. 13045 requires agencies to prepare an evaluation of the risks to children of planned regulations including an explanation of why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the agency.

Finally, OIRA administers the provisions of Executive Order 13211, especially the required ''Statements of Energy Effects,'' in situations where a rule may have significant impacts on energy supply, distribution or use. OIRA published guidance for implementing the new energy executive order on July 13, 2001.

Despite the apparent complexity of these analytical and procedural requirements, OIRA is committed to performing its regulatory reviews within the 90-day period set out in E.O. 12866. As Table 3 reveals, OIRA has already made substantial progress in reducing the number of reviews that consume more than the allotted 90 days. The OIRA Administrator has informed OIRA staff that no review will be permitted to extend beyond 90 days without the explicit permission of the OIRA Administrator.

TABLE 3.—EO 12866 REVIEWS OVER 90 DAYS BY DATE

Month	Year	Pending Over 90 Days	Pending	Percent Over 90 days
January	1999	15	77	19.5
April	1999	10	84	11.9
July	1999	11	84	13.1
October	1999	16	76	21.1
January	2000	15	83	18.1
April	2000	19	124	15.3

[4] See E.O. 13045, Protection of Children From Environmental Health Risks and Safety Risks, April 21, 1997.

TABLE 3.—EO 12866 REVIEWS OVER 90 DAYS BY DATE—Continued

Month	Year	Pending Over 90 Days	Pending	Percent Over 90 days
July	2000	24	101	23.8
October	2000	42	154	27.3
January	2001	50	117	42.7
April	2001	4	72	5.6
July	2001	25	97	25.8
October	2001	1	62	1.6
January	2002	0	86	0.0

OIRA regards the 90-day review limit as a performance indicator for a strong regulatory gatekeeper. In previous Administrations there were cases where OIRA reviews consumed more than six months or even more than a year without any conclusion for the agency. OIRA intends to provide agencies with prompt and explicit responses to its draft rulemaking actions.

D. Proactive Role in Establishing Regulatory Priorities

Historically, OIRA has been a reactive force in the regulatory process, responding to proposed and final rulemakings generated by federal agencies. Under the Bush Administration, OIRA is taking a proactive role in suggesting regulatory priorities for agency consideration. In order to play this role constructively, we have devised the ''prompt'' letter as a modest device to bring a regulatory matter to the attention of agencies.

OIRA's initial five prompt letters have addressed a range of issues at four different agencies:

- A letter to FDA requested that a consumer labeling rule involving the trans fatty-acid content of foods be finalized in order to reduce an established risk factor for coronary artery disease;
- A letter to OSHA urged that actions be taken to promote the availability and proper use of automated external defibrilators, a technology that can save lives among people suffering from sudden cardiac arrest;
- A letter to NHTSA urged initiation of a new rulemaking that would require vehicle manufacturers to test cars and light trucks for occupant protection in what are called ''offset'' frontal collisions, a crash mode responsible for a significant number of lower extremity injuries to occupants;
- A letter to EPA urged administrative and legislative action to reduce public exposure to fine particles in outdoor air emissions, coupled with a targeted, multi-year research program aimed at discovering which sources of particles are most responsible for the adverse health impacts of breathing fine particulate matter; and
- A letter to EPA encouraged steps to improve the utility of the data available on the environmental performance of industrial facilities. Better environmental information plays an essential role in advancing our objectives of protecting public health and the environment. The letter suggested that EPA explore several steps to enhance the practical utility of the information available to the public by establishing a single facility identification number, setting up an integrated system for reporting and access of data across multiple programs, and improving the timeliness of the availability of Toxic Release Inventory data.

Prompt letters do not have the mandatory implication of a Presidential directive. Unlike a ''return letter,'' which is authorized by E.O. 12866, the prompt letter simply constitutes an OIRA request that an agency elevate a matter in priority, recognizing that agencies have limited resources and many conflicting demands for priority attention. The ultimate decision about priority setting remains in the hands of the regulatory agency.

An important feature of the prompt letter can be its public nature, aimed at stimulating agency, public and congressional interest in a potential regulatory priority. Although prompt letters could be treated as confidential pre-decisional communications, OIRA believes that it was wiser to make these prompt letters publicly available in order to focus congressional and public scrutiny on the important underlying issues.

OIRA's experience with the first five prompt letters suggests that (a) preliminary dialogue between OIRA and agency staff is advisable; (b) touching base with OMB budget officials and interested EOP staff is wise; and (c) informal communication with policy officials at agencies is necessary, though it is important for OIRA to send some prompt letters that policy officials at agencies would prefer not to receive.

The original ideas for the initial five prompt letters came from OIRA personnel but there is no reason why members of the public should not suggest ideas for prompt letters to the OIRA Administrator. These suggestions can be faxed to the OIRA Administrator at (202) 395–3047 (note OIRA is still not receiving first-class mail due to the anthrax threat) or submitted in the public comment process leading to the publication of this annual report. Agencies are still responding to the first five prompt letters, but the original letters and initial agency responses are posted on OIRA's web site.

E. Overseer of Analysis and Information Quality

The public image of OIRA, insofar as one exists, is an office that concentrates on clearing, modifying, or returning specific rulemaking proposals by agencies. OIRA also plays an important role, as a result of its broad-based responsibility, for ensuring the quality of information used and disseminated by agencies, including the information posted on agency web sites, issued in routine, yet important statistical reports, and used in regulatory impact analyses.

In the Bush Administration, OIRA has taken a strong interest in improving the quality of information and analysis used and disseminated by agencies. This initiative complements a variety of the initiatives in the President's Management Agenda.

The Paperwork Reduction Act of 1980, as amended in 1995, provides OMB broad authority in the field of information policy. OMB Circular A–130, ''Management of Federal Information Resources,'' provides structure and content to the executive branch's commitment to information dissemination.

During the Clinton Administration, concerns were raised that scientific information produced with federal financial support and used to support binding agency actions were not always available for public scrutiny and reanalysis. With new authority from Congress, OMB played an important

role, through OMB Circular A–110, in clarifying the degree of public access to such information required through the Freedom of Information Act.

In Section 515 of the Treasury and General Government Appropriations Act for Fiscal Year 2001 (Public Law 106–554), Congress further directed OMB to issue government-wide guidelines to ensure and maximize the quality of information disseminated by federal agencies. After two rounds of public and interagency comment, OMB issued these final guidelines on September 28, 2001 and January 3, 2002.[5] Each federal agency, including the independent agencies, must now issue tailored information-quality guidelines that are compatible with OMB's general guidelines. Section 515 reflects a concern by Congress that some agencies are distributing information to the public that is of questionable quality, objectivity, usefulness and security.

The OMB guidelines provide affected parties concerned about poor quality information with the opportunity to seek administrative corrections to agency information, with assurances that their complaints will be addressed in a timely manner. Although some agencies already have well-developed information quality management procedures, OMB believes agency practices are uneven and relatively little thought has been devoted to assuring the objectivity of agency responses to complaints from the public.

Improving information quality is costly and thus it is important that the value of better information to the public be considered. In this regard, the OMB guidelines draw a consequential distinction between ''influential'' and ordinary information, where ''influential'' is defined, when used in the context of ''scientific, financial and statistical information,'' as information that the agency ''can reasonably determine * * * will have or does have a clear and substantial impact on important public policies or important private sector decisions.'' Influential information is subject to higher quality standards by the OMB guidelines.

With several important exceptions and qualifications, the OMB guidelines require that influential information disseminated by agencies be reproducible by qualified third parties. If influential information is to be disseminated without the capability of reproduction, it is subject to some special robustness and transparency requirements. The OMB guidelines provide agencies a measure of flexibility in the interpretation and implementation of these expectations.

In order to facilitate better public and scientific input into the process of information-quality improvement, OMB has encouraged agencies to commission the National Research Council of the National Academy of Sciences to undertake several workshops aimed at assisting agencies in the development of their information quality guidelines. OMB is also organizing several interagency committees to address information quality issues that are likely to be common across two or more federal agencies. OMB will review the proposed and final information guidelines prepared by agencies pursuant to statutory mandate.

OMB's new information quality guidelines establish stricter standards for agency analyses of original data than for the data themselves. OMB believes that agencies are in a better position than OMB to establish specific quality standards for the generation of original and supporting data.

With regard to the quality of regulatory impact analyses prepared by agencies, OIRA has initiated a process of refinement to its formal analytic guidance documents. This activity, to be co-chaired by the OIRA Administrator and a member of the Council of Economic Advisors (CEA), will be supported by public comment, agency comments, and external peer review. In this draft report, OMB is seeking comment on the particular analytic issues that should be addressed in the refinement of OMB's analytic guidelines. At a minimum, OMB–CEA intend to address the following issues

- The practice of applying a 7% real discount rate to future costs and benefits;
- The methods employed to account for latency periods between exposure to toxic agents and development of chronic diseases;
- The methods employed to evaluate the risk of premature death, particularly the relative advantages and disadvantages of differing statistical approaches including the quality-adjusted-life year (QALY) approach; [6]
- The need for use of methods of risk assessment that supply central estimates of risk as well as upper and lower bounds on the true yet unknown risks;
- The need for methods of risk assessment to account for the vulnerabilities of specific subpopulations such as the children, the elderly, and the infirm; and
- Methods for valuing improvements in the health of children.

We urge public commentators and agencies to nominate additional analytic issues for consideration in this process. The ultimate guidance that emerges from this process will be used by OIRA when evaluating the regulatory proposals and analyses submitted by agencies.

F. Expanded and Diversified Professional Staff

In Supreme Court Justice Stephen Breyer's book *Breaking the Vicious Circle,* centralized regulatory oversight is viewed as a predominantly professional activity rooted in the analytical insights gleaned from tools that are taught in professional schools throughout the United States. OIRA's history and structure is based on this professional model. If OIRA were strictly a political review mechanism, there might be no need for career civil servants at OIRA. Yet the Bush Administration supports the development of a strong professional staff at OIRA to support Presidential management of the regulatory state. OMB has reviewed the situation and determined that additional allocations of staff are necessary at OIRA.

As Table 4 shows, staffing at OIRA declined steadily from a peak of 90 FTEs in 1981, when the Office was first created, to a low of 47 FTEs from 1997 to 2000. The decline occurred continuously for 20 years, through both Republican and Democratic Administrations. The decline in OIRA staffing has been steeper than the general decline experienced throughout the Office of Management and Budget. These staffing declines have occurred at the same time that OIRA has assumed new statutory responsibilities from the Congress on issues concerning unfunded mandates, paperwork reduction, small business, regulatory accounting, and information policy.

TABLE 4.—OIRA STAFF CEILING

Fiscal year	Full time equivalents ceiling
1981	90
1982	79
1983	77
1984	80
1985	75

[5] A final corrected version was published on February 22, 2002 (67 FR 8452). It is also available on our web site at <*http://www.whitehouse.gov/omb/*>.

[6] The quality-adjusted-life-year or QALY approach weights life-years extended based on criteria established by medical experts, patients, and community residents to allow comparisons of different health outcomes. See M.R. Gold, J.E. Siegel, L.B. Russell, and M.C. Weinstein, (eds.) *Cost-Effectiveness in Health and Medicine.* New York, NY, Oxford University Press, 1996.

TABLE 4.—OIRA STAFF CEILING—Continued

Fiscal year	Full time equivalents ceiling
1986	*75/69
1987	69
1988	69
1989	62
1990	65
1991	*65/60
1992	60
1993	57
1994	52
1995	50
1996	49
1997	47
1998	47
1999	47
2000	47
2001	49
2002	54

*Indicates a ceiling was reduced in mid-year.

The Bush Administration has begun to reverse the 20-year decline in OIRA staffing, adding a total of seven new OIRA positions for a total of about 54 FTEs. Four of these positions will provide new science and engineering expertise to OIRA. This will enable us to develop a more diversified pool of expertise to ask penetrating technical questions about agency proposals. It will also enable us to collaborate more effectively with our colleagues in the Office of Science and Technology Policy. The remaining positions will buttress OIRA's staffing in information technology and policy for the E-Government initiative. The new staffing will complement OIRA's historical staffing strengths in economics, policy analysis, statistics and law.

G. Facilitator of Targeted Agency Reviews of Existing Rules

There are so many federal regulations now on the books that there has never been an accurate, up-to-date count of their exact number. Since many of these rules are quite old, it is logical to suggest that existing rules be reviewed to determine whether they remain appropriate. Yet regulated entities often adapt creatively to federal rules in ways that reduce or minimize their adverse impact while fulfilling the social objective. The dynamics of post-regulation behaviors call into question the validity of efforts to simply add up the costs and benefits of existing rules based on analyses done prior to the original promulgation of rules.

Thus, any comprehensive effort to look at existing rules requires original data collection and evaluation, a resource-intensive exercise for agencies and regulated entities. Across-the-board reviews of all existing rules have been attempted in the past but have not always been particularly successful and have induced a questionable allocation of limited agency and OIRA resources. The Bush Administration believes that a targeted review process for existing rules, pursuant to public comment and new statutory authority provided to OIRA, is the best available mechanism to facilitate review of existing rules outside of the authority under the Regulatory Flexibility Act. [7]

Last year's version of this report to Congress represented OIRA's first effort to facilitate reviews of existing rules under unique statutory authority provided to OIRA. We requested that public commentators nominate specific existing rules that should be rescinded or changed to increase net benefits by either reducing costs or increasing benefits. We called for such nominations in a **Federal Register** notice that also requested public comment on a draft version of the year 2001 report to Congress. We provided a suggested format for nominations in order to facilitate organized public comment and both OIRA and agency consideration of nominations.

We believe that OIRA's first effort at targeted reviews of existing rules was partially successful but can be improved. There were a total of 71 specific nominations covering 17 agencies suggested by 33 commentators. A particularly diligent commentator, the Mercatus Center at George Mason University, submitted 44 nominations based on public filings before agencies they had been doing for several years.

OIRA evaluated these nominations and assigned each nomination to one of three categories: (1) High priority, indicating that OIRA is inclined to agree with the comment and look into the suggestion, (2) medium priority, meaning that OIRA needs more information before it can give a clear indication of priority, and (3) low priority, meaning that OIRA is not convinced of the merits of the suggestion. There were a total of 23 nominations rated by OIRA as ''high priority.'' Appendix B to this report provides preliminary information about what agencies are doing about these 23 regulations. We intend to update this accounting of the outcome of reform nominations in our final report.

Eight of the 23 nominations address EPA rules while another five address rules that might be considered environmental in nature (i.e., those concerning DOI, DOE and USDA rules). However, a closer examination of OIRA's decision making process reveals no implicit or explicit intent to target environmental rules for scrutiny.

The distribution of nominated rules by agency reflects the concerns raised by public comments, not the interests of OIRA. Of the 71 nominations, over half (43) might be considered ''environmental'' regulations, a pattern that is unsurprising since federal environmental regulation is of broad public interest and a source of persistent public controversy. OIRA was quite critical in its internal evaluation of all nominations, including those in the environmental arena. Only 13 of the 33 ''environmental'' rule nominations were rated as ''high priority'' for agency reconsideration. A review of these 13 nominations reveals that some had already been established as an Administration priority for review. Few comments suggested repeal or loosening of environmental standards. The new reform ideas (*e.g.,* regarding rules under Toxic Substances Control Act (TSCA) and Resource Conservation and Recovery Act (RCRA) were modest in nature. OIRA welcomes nominations from all interested parties, including regulated entities.

Indeed OIRA desires the broadest possible public participation in the nomination process including input from environmental advocacy groups, consumer groups, and public health and safety groups. We will be taking several aggressive steps to broaden participation by these groups in coming years. OIRA will not rely exclusively on the **Federal Register** as a vehicle to publicize the request for public nominations. OIRA's website will also this opportunity. A press release will be issued to increase public awareness of nomination opportunities. OIRA welcomes all good ideas, regardless of whether or not statutory change is required, though suggestions that do not entail legislative action may receive more near-term priority.

H. Formation of a Scientific Advisory Panel to OIRA

At the suggestion of the OMB Director, OIRA is in the process of forming a scientific advisory panel that will suggest initiatives to OIRA, evaluate OIRA's ongoing activities, comment on national and international policy developments of interest to OIRA, and act as a resource and recruitment mechanism for OIRA staff. OIRA envisions that the panel will be comprised of academics with

[7] Section 610 of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) requires agencies to review rules that have a significant economic impact on a substantial number of small entities within 10 years of their publication.

specialized expertise in economics, administrative law, regulatory analysis, risk assessment, engineering, statistics, and health and medical science. The composition and formation of the panel will comply with the guidance on competent and credible peer review mechanisms espoused by the OIRA Administrator in his September 20, 2001, memorandum to the President's Management Council.

OIRA envisions that the panel will meet twice each year in Washington, DC. Panel meetings will be open to the public. OIRA expects that the first meeting of this panel will occur this summer.

I. Agency Compliance With the Unfunded Mandates Reform Act

In last year's report to Congress ''Making Sense of Regulation,'' OMB included its annual report to Congress on agency compliance with the Unfunded Mandates Reform Act in addition to OIRA's report on the costs and benefits of regulations. This was done because the two reports together address many of the same issues and both highlight the need for regulating in a responsible manner that both accounts for the costs and benefits of rules and takes into consideration the interests of our intergovernmental partners.

OIRA intends to continue to publish these two reports together. We are currently working with the agencies to gather data on the extent of consultations with State, local, and tribal governments through September 2001. The results of this work will appear along with a discussion of any rules that imposed and unfunded mandate (defined in the Act as expenditures of $100 million or greater) between May 2001 and October 2001 in the final report.

However, as noted in last year's report, many of our intergovernmental partners feel that they are not being consulted sufficiently on those issues that matter most to them. The Office of Management and Budget is particularly interested in what State, local, and tribal governments perceive as failures in the consultation process. We invite public comment on the two questions listed below:

1. In the examples of federal consultation described in last year's report (available at *http://www.whitehouse.gov/omb/inforeg/costbenefitreport.pdf*), was the consultation sufficient? Was it conducted at a time in the decisionmaking process when it was meaningful? Were the views of States, local governments and tribes sufficiently solicited by the agencies?

2. Are there instances other than those described in last year's report where consultation should have taken place between an agency and a State, local, or tribal government where it did not?

Responses to these two questions will be very valuable as the Administration develops policies to further the rights of State, local and tribal governments under the Unfunded Mandates Reform Act.

J. Summary Statistics on the Bush Administration's Regulatory Record

Basic statistics about regulatory transactions provide a crude indicator of the dynamics of regulatory activity at federal agencies and OIRA. In Table 15 in Appendix E, we provide a statistical comparison of regulatory transactions (total and by agency) for calendar years 1998, 1999, 2000, and 2001.

These data indicate that out of the roughly 4,500 regulatory actions that occur on average each year, about 500 are judged to be significant and a far smaller number, about 70, are judged to be economically significant. Only ''significant'' actions are subject to OIRA review under E.O. 12866, and only the ''economically significant'' rules are required to be supported by a regulatory impact analysis. Ranked by the number of E.O. reviews at OIRA, the busiest 11 regulatory agencies over the last four years are, in order: HHS, USDA, EPA, DOT, DOI, DOC, HUD, OPM, VA, DOJ, ED. Three agencies—HHS, EPA, and USDA—accounted for about 70 percent of the economically significant rules.

Chapter II: The Costs and Benefits of Federal Regulations

Section 624 of the FY 2001 Treasury and General Government Appropriations Act, the ''Regulatory Right-to-Know Act,'' [8] requires OMB to submit ''an accounting statement and associated report'' including:

''(1) An estimate of the total annual costs and benefits (including quantifiable and nonquantifiable effects) of Federal rules and paperwork, to the extent feasible:

(A) In the aggregate;

(B) by agency and agency program; and

(C) by major rule;

''(2) an analysis of impacts of Federal regulation on State, local, and tribal government, small business, wages, and economic growth; and

''(3) recommendations for reform.[9]

This report revises the estimates in last year's report by updating the estimates to the end of fiscal year 2001 (September 30, 2001). We make three types of revisions. First, we include the costs and benefits of the economically significant rules reviewed by OMB between April 1, 1999 and September 30, 2001. Second, we revised our estimates and discussion of estimates based on studies and data that became available since the last report was written. Third, we updated our estimates to 2001 dollars from the 1996 dollars used in the four previous reports.

Estimates of the Total Costs and Benefits of Regulations Reviewed by OMB [10]

Table 5 presents estimates by agency of the costs and benefits of major rules reviewed by OMB over the period April 1, 1999 to September 30, 2001.[11] We reviewed 117 final major rules over that period. Of the 117 rules, 72 implemented federal budgetary programs, which caused income transfers from one group to another, and 45 imposed mandates on state and local entities or the private sector.[12] Of the 45 social regulations, we are able to present estimates of both monetized costs and benefits for 19 rules.[13] Seven agencies issued major regulations adding from $32 billion to $53 billion annual benefits and from $15 billion to $18 billion annual costs over the 30 month period. About 80% of the benefits and 70% of the costs were from one agency, EPA. Table 6 presents estimates for six and a half years by expanding the period covered by Table 5 back by four years to April 1, 1995.[14] Before April 1, 1995, OMB did not systematically

[8] 31 U.S.C. 1105 note, Pub. L. 106–554, § 1(a)(3) [Title VI, § 624], Dec. 21, 2000, 114 Stat. 2763, 2763A–161. (See Appendix F).

[9] Recommendations for reform are discussed in Chapter IV.

[10] In our previous four reports, we presented detailed discussions about the difficulty of estimating and aggregating the costs and benefits of different regulations over long time periods and across many agencies. We do not repeat those discussions here. Our previous reports are on our website at <*http://www.whitehouse.gov/omb/inforeg/regpol.html*>.

[11] The list of major rules and their individual cost and benefit estimates and discussion of the assumptions and calculations used to derive the estimates are in Appendix D.

[12] Rules that transfer Federal dollars among parties are not included because transfers are not social costs or benefits. If included, they would add equal amounts to benefits and costs.

[13] We used agency estimates where available. If an agency quantified estimates but did not monetize, we used standard assumptions to monetize as explained in Appendix D.

[14] Table 6 is the sum of Table 5 in this report and Table 5 from the 2000 report (OMB 2000) after converting to 2001 dollars and excluded three regulations to prevent double counting: emission standards for heavy duty engines and the NAAQS ozone and particulate matter rules. These calculations are explained in Appendix D. Two other rules reviewed by OMB are not included: OSHA's ergonomics rule that was overturned under the Congressional Review Act and FDA's tobacco rule that was overturned by the Supreme Court.

estimate and sum the benefits of major rules.

TABLE 5.—ESTIMATES OF THE ANNUAL COSTS AND BENEFITS OF MAJOR RULES, APRIL 1, 1999 TO SEPTEMBER 30, 2001

[Millions of 2001 dollars]

Agency	Costs	Benefits
Agriculture	814	<1.
DOE	1,520	3,110.
HHS	2,400	5,792.
HUD	150	190.
DOL	78	167.
DOT	400 to 1,600	140 to 2,000.
EPA	10,742 to 12,302	23,738 to 43,491.
Total	16,104 to 19,264	33,137 to 54,350.

TABLE 6.—ESTIMATES OF THE ANNUAL COSTS AND BENEFITS OF MAJOR RULES, APRIL 1, 1995 TO SEPTEMBER 30, 2001

[Millions of 2001 dollars]

Agency	Costs	Benefits
Agriculture	2,249 to 2,271	2,938 to 5,989.
Ed	362 to 610	655 to 814.
DOE	1,836	3,991 to 4,059.
HHS	2,988 to 3,067	8,165 to 9,182.
HUD	150	190.
DOL	361	1,173 to 3,557.
DOT	1,756 to 3,808	2,400 to 4,312.
EPA	41,523 to 42,326	29,140 to 66,092.
Total	51,225 to 54,429	48,652 to 67,602.

We provide revised estimates of the aggregate costs and benefits of social regulation (health, safety and environmental regulation) in the aggregate and by major program as of September 30, 2001, in Appendix C.[15] We also include estimates of the aggregate costs of economic and process regulation in Appendix C.[16] We include these aggregate estimates in the appendix rather than the text to emphasize the quality differences in the two sets of estimates. The estimates of the costs and benefits of Federal regulations over the period April 1, 1995 to March 31, 2001, are based on agency analyses subject to public notice and comments and OMB review under E.O. 12866. The estimates in the Appendix for earlier regulations are based on studies of varying quality. Some are first-rate studies published in peer reviewed journals. Others are non random surveys of questionable methodology. And some estimates are based on studies completed 20 years ago for regulations issued over 30 years ago, whose precise cost and benefit estimates today are unknown.

Also included in Appendix C is an analysis of impacts of Federal regulation on State, local, and tribal governments, small business, wages, and economic growth, as required by Section 624(a)(2) of the Act.

Estimates of Benefits and Costs of This Year's ''Major'' Rules

In this section, we examine the benefits and costs of each ''major rule,'' as required by section 624(a)(1)(C). We have included in our review those final regulations on which OMB concluded review during the 18-month period April 1, 2000, through September 30, 2001. We used an 18 month period this year to transition to a fiscal year reporting period. The four previous reports used a ''regulatory year,'' ending on March 31st.

The statutory language categorizing the rules we consider for this report differs from the definition of ''economically significant'' in Executive Order 12866 (section 3(f)(1)). It also differs from similar statutory definitions in the Unfunded Mandates Reform Act and subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996—Congressional Review of Agency Rulemaking. Given these varying definitions, we interpreted section 624(a)(1)(C) broadly to include all final rules promulgated by an Executive branch agency that meet any one of the following three measures:

- Rules designated as ''economically significant'' under section 3(f)(1) of Executive Order 12866
- Rules designated as ''major'' under 5 U.S.C. 804(2) (Congressional Review Act)
- Rules designated as meeting the threshold under Title II of the Unfunded Mandates Reform Act (2 U.S.C. 1531–1538)

We also include a discussion of major rules issued by independent regulatory agencies, although OMB does not review these rules under Executive Order 12866. This discussion is based on data provided by these agencies to the General Accounting Office (GAO) under the Congressional Review Act that met the criteria noted above. Of these rules, USDA submitted nineteen; the DOC, DOE, Social Security Administration, and Federal Emergency Management Administration, each submitted three; HHS twenty-two; DOL eight; Treasury, DOJ, Architectural and Transportation Barriers Compliance Board (ATBCB), DoD, the Office Federal Housing Enterprise Oversight, Veterans Administration, Office of Personnel Management each submitted one; DOI five; DOT four; EPA seven; SBA and

[15] We calculated these estimates by adding the estimates in Table 5 above to Table 4 of the 2000 OMB report and updating Table 4's 1996 dollars to 2001 dollars using the CPI.

[16] Economic regulation restricts the price or quantity of a product or service that firms produce including whether firms can enter or exit specific industries.

FAR two. One of these rules was a common rule issued by three agencies-DOL, HHS and Treasury. These 86 rules represent less than 20 percent of the final rules reviewed by OMB during this period.

Social Regulation

Of the 86 economically significant rules reviewed by OMB, 34 are regulations requiring substantial additional private expenditures and/or providing new social benefits as described in Table 7. EPA submitted seven; DOI, DOL and HHS each submitted five; USDA, DOC, DOE each submitted three; DOT two; DOJ, Treasury and ATBCB each submitted one. Agency estimates and discussion are presented in a variety of ways, ranging from a mostly qualitative discussion, for example, the USDA's National Organic Program rule where all of the benefits and costs except for the recordkeeping component were discussed qualitatively, to a more complete benefit-cost analysis such as the EPA's heavy-duty engine and vehicle rule.

TABLE 7.—SUMMARY OF AGENCY ESTIMATES FOR FINAL RULES 4/1/00–9/30/01
[As of date of completion of OMB review]

Agency	Rule	Benefits	Costs	Other information
USDA	Roadless Area Conservation	Estimated $219,000/year cost savings from reduced road maintenance activities.	Loss of $56.9 million (direct) and $164 million (total) per year in the short term, with an additional impact of $12.4 million (direct) and $20.2 million (total) per year in the long term.	Monetized costs include an estimated 1,054 direct and 4,032 total jobs lost related to road construction, timber harvesting, and mining in the short term, with an additional 308 direct and 509 total jobs lost in the long term. [66 FR 3268—3269] Other costs include the following: ''about 873 million tons of phosphate and 308—1,371 million tons of coal would likely be unavailable for development. About 11.3 trillion cubic feet of undiscovered gas and 550 million barrels of undiscovered oil resources may be unavailable.'' [66 FR 3269] A variety of other nonquantified benefits were mentioned in the preamble to the final rule.
USDA	National Organic Program	Not estimated	$13 million/yr for recordkeeping; others not estimated.	Because basic market data on the prices and quantities of organic goods and the costs of organic production are limited, it is not possible to provide quantitative estimates of all benefits and costs of the final rule. Consequently, the analysis does not estimate the magnitude or the direction (positive or negative) of net benefits.'' [65 FR 80663]
USDA	Retained Water in Raw Meat and Poultry Products.	Not estimated	$110 million	''Consumers will benefit from the additional information on retained water that will be provided as a result of the labeling requirement. The information on retained water should contribute to a sounder basis for purchasing decisions. Consumers are currently not being informed about the amount of retained water. Consumers will benefit from having improved knowledge of product quantity in terms of meat or poultry meat content.'' [66 FR 1768]
DOC	Annual Framework Adjustment (framework 14) for the Atlantic sea scallop fishery management plan for 2001.	Not estimated	Not estimated.	
DOC	Closure of Critical Habitat Pursuant to a Court Order.	Not estimated	Up to $88 million	''NMFS estimates that the potential economic losses in closing critical habitat to pollock trawling from June through December 2000 could be as high as $88 million. Industry has estimated that if the injunction remains in place through the A/B seasons, loses could be as high as $250 million.'' [65 FR 49769]
DOC	Steller Sea Lion Protection Measures for the Groundfish Fisheries Off Alaska.	Not estimated	Not estimated	''NMFS issues an emergency interim rule to implement Steller sea lion protection measures to avoid the likelihood that the groundfish fisheries off Alaska will jeopardize the continued existence of the western population of Steller sea lions or adversely modify its critical habitat. These management measures will disperse fishing effort over time and area and provide protection from fisheries competition for prey in waters adjacent to rookeries and important haulouts''.[66 FR 7276]
DOE	Energy Conservation Standards for Fluorescent Lamp Ballasts.	$3.51 billion (present value) in energy savings between 2005 and 2030.	$.9 billion (present value) for purchases between 2005 and 2030.	DOE projects a cumulative reduction in nitrogen oxide emissions of 59.6 thousand metric tons (undiscounted) over the period 2005–2030 and a cumulative reduction in carbon dioxide equivalent emissions of 19 million metric tons (undiscounted) over the period 2005–2020.
DOE	Energy Conservation Standards for Water Heaters.	$8.6 billion (present value) in energy savings between 2004 and 2030.	$6.4 billion (present value) for purchases between 2004 and 2030.	DOE projects a cumulative reduction in nitrogen oxide emissions of 90 thousands metric tons discounted over the period 2004–2030 and a cumulative reduction in carbon dioxide equivalent emissions of 50 million metric tons discounted over the period 2004–2020.
DOE	Energy Conservation Standards for Clothes Washers.	$27.2 billion (present value) in energy and water savings between 2004 and 2030.	$11.9 billion (present value) for purchases between 2004 and 2030.	DOE projects a cumulative reduction in nitrogen oxide emissions of 70.8 thousand metric tons discounted over the period 2004–2030 and a cumulative reduction in carbon dioxide equivalent emissions of 24.1 million metric tons discounted over the period 2004–2020.
HHS	Health Insurance Reform: Standards for Electronic Transactions.	$36.9 billion over 10 years	$7 billion over 10 years	''The costs of implementing the standards specified in the statute are primarily one-time or short-term costs related to conversion. These costs include system conversion/upgrade costs, start-up costs of automation, training costs, and costs associated with implementation problems. These costs will be incurred during the first three years of implementation * * * The benefits of EDI include reduction in manual data entry, elimination of postal service delays, elimination of the costs associated with the use of paper forms, and the enhanced ability of participants in the market to interact with each other.'' [65 FR 50351] The discounted present value of the savings is $19.1 billion over ten years. Furthermore, the updated impact analysis still produces a conservative estimate of the impact of administrative simplification. For example, the new impact analysis assumes that over the ten-year post-implementation period, only 11.2% of the growth in electronic claims will be attributable to HIPAA.'' [65 FR 50355]
HHS	Safe and Santiary Processing and Importing of Juice.	$151 monthly/yr	$44 million to $55 million in the first year and $23 million/yr thereafter.	''The quantified benefits (discounted annually over an infinite time horizon at 7 percent) are expected to be about $2 billion ($151 million/7 percent) and the quantified costs (discounted annually over an infinite time horizon at 7 percent) are expected to be about $400 million.'' [66 FR 6190]

TABLE 7.—SUMMARY OF AGENCY ESTIMATES FOR FINAL RULES 4/1/00–9/30/01—Continued
[As of date of completion of OMB review]

Agency	Rule	Benefits	Costs	Other information
HHS	Standards for Privacy of Individually Identifiable Health Information.	Net present value savings of $19 billion.	Net present value costs of $11.8 billion.	The Rule shows a net savings of $29.9 billion over 10 years (2002–2011), or a net present value savings of $19 billion. This estimate does not include the growth in ''e-health'' and ''e-commerce'' that may be spurred by the adoption of uniform codes and standards. This final Privacy Rule is estimated to produce net costs of $18.0 billion, with net present value costs of $11.8 billion (2003 dollars) over ten years (2003–2012). This estimate is based on some costs already having been incurred due to the requirements of the Transactions Rule, which included an estimate of a net savings to the health care system of $29.9 billion over 10 years (2002 dollars) and a net present value of $19.1 billion. The Department expects that the savings and costs generated by all administrative simplification standards should result in a net savings to the health care system. [65 FR 82761]
HHS	Labeling of Shell Eggs	$261 million/yr	$56 million in the first year. $10 million/yr. thereafter.	''Although there were no comments directly on the estimated benefits, several comments argued that FDA used too high a baseline number of SE illnesses. In addition, some comments cited new data from CDC on SE. In the economic analysis in the proposal, FDA used the results of the USDA SE risk assessment for one estimate of the baseline risk and the CDC Salmonella surveillance data for another estimate of the baseline.'' [65 FR 76105] ''The agency estimated the median benefits attributable to labeling alone to be $261 million using the USDA SE risk assessment baseline and $103 million using the CDC surveillance baseline.'' [65 FR 76106]
HHS/DOL/Treasury.	Nondiscrimination in Health Coverage in the Group Market.	Not estimated	A one time cost of $19 million the first year for affected businesses, plus $10.2 million annually for government enforcement.	''The premium and claims cost incurred by group health plans to provide coverage under HIPAA's statutory nondiscrimination provisions to individuals previously denied coverage or offered restricted coverage based on health factors are offset by the commensurate or greater benefits realized by the newly eligible participants on whose behalf the premiums or claims are paid.'' [66 FR 1389]
DOI	Early-Season Migratory Bird Hunting Regulations 2000–2001.	$50 million to $192 million/yr.	Not estimated	The analysis was based on the 1996 National Hunting and Fishing Survey and the U.S. Department of Commerce's County Business Patterns, from which it was estimated that migratory bird hunters would spend between $429 million and $1,084 million at small businesses [66 FR 49485]. The listed benefits represent estimated consumer surplus.
DOI	Late Season Migratory Game Bird Hunting regulations 2000–2001.	$50 million to $192 million/yr.	Not estimated	The analysis was based on the 1996 National Hunting and Fishing Survey and the U.S. Department of Commerce's County Business Patterns, from which it was estimated that migratory bird hunters would spend between $429 million and $1,084 million at small businesses [66 FR 49485]. The listed benefits represent estimated consumer surplus.
DOI	Early-Season Migratory Bird Hunting Regulations 2001–2002.	$50million to $192 million/yr.	Not estimated	The analysis was based on the 1996 National Hunting and Fishing Survey and the U.S. Department of Commerce's County Business Patterns, from which it was estimated that migratory bird hunters would spend between $429 million and 1,084 million at small businesses [66 FR 49485]. The listed benefits represent estimated consumer surplus.
DOI	Late season Migratory Game Bird Hunting regulations 2001–2002.	$50 million to $192 million/yr.	Not estimated	The analysis was based on the 1996 National Hunting and Fishing Survey and the U.S. Department of Commerce's County Business Patterns, from which it was estimated that migratory bird hunters would spend between $429 million and $1,084 million at small businesses [66 FR 49485]. The listed benefits represent estimated consumer surplus.
DOI	Mining Claims under the General Mining Law; Surface Management.	Not estimated	Enforcement and administrative costs of $15.6 million annually ($1999); foregone production between 0 and $133 million per year.	''* * * these values may overstate actual losses because a number of factors will act to mitigate any production losses and because they are calculated using a base of total U.S. gold production, not production originating from public lands. Simply adjusting for production originating on public lands could reduce the value of forgone production by half.'' [65 FR 70101]
DOJ	Adjustment of Status to That Person Admitted for Permanent Residence.	Not estimated	$178 million in 2001, $99.2 million in 2002, and 91.9 million in 2003.	''This rule adds the new sunset date of April 30, 2001, for the filing of qualifying petitions or applications that enable the applicant to apply to adjust status using section 245(i) of the Act, clarifies the effect of the new sunset date on eligibility, and discusses motions to reopen.'' [66 FR 16383]
DOL	Ergonomics Program	$9.1 billion/yr. (1996 dollars)	$4.5 billion/yr (1996 dollars)	''The cost analysis does not account for any changes in the economy over time, or for possible adjustments in the demand and supply of goods, changes in production methods, investment effects, or macroeconomic effects of the standard.'' [65 FR 68773]
DOL	Occupational Injury and Illness Recording and Reporting Requirements.	Not Estimated	$38.6 million	Qualitative benefits of the rule include: (1) Enhanced ability of employers and employees to prevent injuries and illnesses, and (2) Increased utility of and data to OSHA.
DOL	Safety Standards for Steel Erection.	22 fatalities and 1,142 injuries per year.	$78.4 million/year	OSHA estimates that, of the 35 annual steel erection fatalities, 8 fatalities will be averted by full compliance with the existing standard and that an additional 22 fatalities will be averted by compliance with the final standard. Additionally, of the 2,279 lost-workday steel erection injuries occurring annually, OSHA estimates that 1,142 injuries will be averted by full compliance with the existing and final standards [66 FR 5199] OSHA projects that full compliance with the final standard will, after deducting costs incurred to achieve compliance with the existing standard, result in net (or incremental) annualized costs of $78.4 million for affected establishments. [66 FR 5251]

TABLE 7.—SUMMARY OF AGENCY ESTIMATES FOR FINAL RULES 4/1/00–9/30/01—Continued
[As of date of completion of OMB review]

Agency	Rule	Benefits	Costs	Other information
DOL	Amendments to Summary Plan Description Regulations.	Not estimated	$47 million in 2001, $208 million in 2002, $24 million/yr. thereafter.	''The regulation will ensure that participants have better access to more complete information about their benefit plans. Such information is important to participants' ability to understand and secure their rights under their plans at critical decision points, such as when illness arises, when they must decide whether to participate in a plan, or when they must determine which benefit package option might be most suitable to individual or family needs.'' ''Improved information is expected to promote efficiency by fostering competition based on considerations beyond pricing alone, and by encouraging providers to enhance quality and reduce costs for value-conscious consumers. Complete disclosure will limit competitive disadvantages that arise when, for example, incomplete or inaccurate information on different benefit option packages is used for decision making purposes. Information disclosure also promotes accountability by ensuring adherence to standards. Equally importantly, information disclosure under the SPD regulation, if combined with additional disclosures pertaining to plan and provider performance, and with other health system reforms that promote efficient, competitive choices in the health care market, could yield even greater benefits.'' [65 FR 70234]
DOT	Light Truck Average Fuel Economy Standard, Model Year 2003.	Not estimated	Not estimated.	
DOT	Advanced Airbags	-233 to 215 fatalities and 1,966 to 2,388 nonfatal injuries prevented and $.2 billion to $1.3 billion in reduced property damage/yr..	$400 million to $2 billion/yr	Benefit estimates are undiscounted.
ATBCB	Electronic Information Technology Accessibility Standards.	Not estimated	$177–1,068 million/yr. in $2000.	The federal proportion of the costs will range from $85 million to $691 million.
EPA	Identification of Dangerous Levels of Lead.	$45 billion to 176 billion (present value over 50 years).	$70 billion (present value over 50 years).	''The upper benefit estimate is obtained using the IEUBK model while the lower benefit estimate is obtained using the empirical model.'' [66 FR 1235] EPA calculated present values using a 3 percent discount rate.
EPA	Lead and Lead Compounds: Lowering of Reporting Thresholds; Community Right-to-Know Toxic Chemical Release Reporting.	Not Estimated	$80 million in first year; $40 million in subsequent years.	Benefits include more information about environmental releases of lead and lead compounds and promotion of pollution prevention.
EPA	Revisions to the Water Quality Planning and Management Regulation.	Not estimated	$23 million/yr ($2000) annualized over 10 yrs.	EPA believes that these regulations will benefit human health and the environment by establishing clear goals for identification of impaired waterbodies and establishment of TMDLs and establishing priorities for clean-up. [65 FR 43586]
EPA	Arsenic and Clarifications to Compliance and New Source Contaminants Monitoring.	$140–198 million/yr	$206 million/yr	''EPA was not able to quantify many of the health effects potentially associated with arsenic due to data limitations. These health effects include other cancers such as skin and prostate cancer and non-cancer endpoints such as cardiovascular, pulmonary, and neurological impacts.'' [66 FR 7012] The benefit estimates do not account for significant time lags between reduced exposure and reduced incidence of disease.
EPA	Control of emissions of air pollution from 2004 and later model year highway heavy-duty engines; revision of light-duty truck definition.	Reduced emissions of 2.5 million tons/year nitrogen oxides, 167,000 tons/year nonmethane hydrocarbons, 11160 tons/year air toxics (benzene, formaldehyde, acetaldehyde, 1,3-butadiene).	$479 million/yr.	
EPA	Heavy-Duty Engine and Vehicle Standards.	$70.4 billion in 2030 (1999$)	$4.3 billion in 2030 (1999$)	Benefit and cost estimates are annualized to the year 2030.
EPA	National emission Standards for Hazardous Air Pollutants for Chemical Recovery Combustion Sources.	$280 million to $370 million/yr ($1999).	$240 million in capital costs and then $30 million annually ($1999).	''Implementation is expected to reduce emissions of HAP, PM, VOC, CO, and SO2, while it is expected to slightly increase emissions of NOX. Such pollutants can potentially cause adverse health effects and can have welfare effects, such as impaired visibility and reduced crop yields. (In the benefits analysis, we have not conducted detailed air quality modeling to evaluate the magnitude and extent of the potential impacts from individual pulp and paper facilities. Nevertheless, to the extent that emissions from these facilities cause adverse effects, this final rule would mitigate such impacts''. [66 FR 3189])

TRANSFER RULES

Dept. of Agriculture (USDA)

Agricultural Disaster and Market Assistance
2000 Crop Agricultural Disaster and Market Assistance
Market Assistance for Cottonseed, Tobacco, and Wool and Mohair
Bioenergy Program
Farm Storage Facility Loan Program
Wool, Mohair, and Apple Market Loss Assistance Programs
Dairy, Honey, and Cranberry Market Loss Assistance and Sugar Programs
Livestock Assistance, American Indian Livestock Feed, Pasture Recovery, and Dairy Price Support Programs
2000 Crop Disaster Program
Catastrophic Risk Protection Endorsement
Food Stamp Program: Recipient Claim Establishment and Collection Standards
National School Lunch and School Breakfast Program: Additional menu Planning Approaches
Requirements for and Evaluation of WIC Program Bid Solicitations for Infant Formula Rebate Contracts
Non-Discretionary Provisions of the Personal Responsibility and Work Opportunity Reconciliation Act of 1996
Non-Citizen Eligibility and Certification Provisions of Public Law 104–193
Food Stamp Program: Personal Responsibility Provisions of the Personal Responsibility and Work Opportunity Reconciliation Act of 1996

Dept. of Defense

Tricare: Civilian Health and Medical Program of the Uniformed Services (CHAMPUS), NDAA for FY 2001 and Pharmacy Benefits Program
Dept. of Health and Human Services (HHS)

TABLE 7.—SUMMARY OF AGENCY ESTIMATES FOR FINAL RULES 4/1/00–9/30/01—Continued
[As of date of completion of OMB review]

Agency	Rule	Benefits	Costs	Other information
	Medicare Program: Medicare + Choice			
	Prospective Payment System for Home Health Agencies			
	Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities			
	Medicare Program: Hospital Inpatient Payments and Rates and Costs of Graduate Medical Education (1999)			
	Medicare Program: Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2001 Rates			
	Medicare Program: Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2001			
	Medicare Program: Expanded Coverage for Outpatient Diabetes			
	Prospective Payment System for Hospital Outpatient Services			
	Revision to Medicaid Upper Payment Limit Requirements for Inpatient Hospital Services			
	Medicaid Program: Medicaid Managed Care			
	Medicaid Program: Change in Application of Federal Financial Participation Limits			
	Medicare Program: Inpatient Payments and Rates and Costs fo Graduate Medical Education (2000)			
	Medicare Program: Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities—Update			
	Medicare Program: Prospective Payment System for Inpatient Rehabilitation Hospital Services			
	Medicare Program: Changes to the Hospital Inpatient Prospective Payment Systems and Rates and Costs fo Graduate Medical Education for Fiscal Year 2002			
	Modification of the Medicaid Upper Payment Limit Transition Period for Hospitals, Nursing Facilities, and Clinic Services			
	State Child Health; Implementing Regulations for the State Children's Health Insurance Programs			
Social Security Administration				
	Supplemental Security Income: Determining Disability for a Child Under Age 18			
	Revised Medical Criteria for Determination of Disability, Musculoskeletal System and Related Criteria			
	Collection of the Title XVI Cross-Program Recovery			
The Office of Federal Housing Enterprise Oversight				
	Risk-based Capital			
Department of Labor				
	Government Contractors, Affirmative Action Requirements			
	Claims for Compensation Under the Energy Employees Occupational Illness Compensation Program Act			
	Procedures for Predetermination of Wage Rates; Labor Standards Provisions Applicable to Contracts Covering Federally Financed and Assisted Construction and to Certain Nonconstruction Contracts (''Helpers'')			
	Birth and Adoption Unemployment Compensation			
Dept. of Transportation				
	Safety Incentive Grants for the Use of Seatbelts			
	Amendment of Regulations Governing Railroad Rehabilitation and Improvement Financing Program			
Veterans Administration				
	Disease Associated with Exposure to Certain Herbicide Agents: Type 2 diabetes			
Federal Emergency Management Administration				
	Supplemental Property Acquisition and Elevation Assistance			
	Disaster Assistance: Cerro Grande Fire Assistance			
	Supplemental Property Acquisition and Elevation Assistance			
Small Business Administration				
	Small Business Size Standards: General Building Contractors, etc.			
	New Market Venture Capital Program			
Office of Personnel Management				
	Health Insurance Premium Conversion			
Federal Acquisition Regulation (FAR)				
	Electronic Commerce in Federal Procurement: FAR case 1997–304			
	Electronic Commerce and Information Technology Accessibility: FAR case 1999–607			
Securities and Exchange Commission (SEC)				
	Disclosure of Mutual Fund After-Tax Returns			
	Privacy of Consumer Financial Information (Regulation S–P)			
	Selective Disclosure and Insider Trading			
	Unlisted Trading Privileges			
	Disclosure of Order Execution and Routing Practices			
	Revision of the Commission's Auditor Independence Requirements			
Federal Trade Commission (FTC)				
	Privacy of Consumer Financial Information			
Federal Communications Commission (FCC)				
	Promotion of Competitive Networks in Local Telecommunications Markets			
	Competitive Bidding Procedures			
	Installment Payment Financing for Personal Communications Services (PCS) Licensees			
	Assessment and Collection of Regulatory Fees for Fiscal Year 2000			
	Narrowband Personal Communications Services; Competitive Bidding			
	24 Ghz Service; Licensing and Operation			
	Extending Wireless Telecommunications Services to Tribal Lands			
	Assessment and Collection of Regulatory Fees for Fiscal Year 2001			
Nuclear Regulatory Commission				
	Revision of Fee Schedules; 100% Fee Recovery			
	Emergency Core Cooling System Evaluation Models			
	Revision of Fee Schedules; Fee Recovery for FY 2001			
Federal Reserve System				
	Privacy of Consumer Financial Information			

1. Benefits Analysis

Agencies monetized at least some benefit estimates for 19 of the 34 rules including: (1) EPA's estimate of $70.4 billion in 2030 primarily from reduced PM exposure from diesel fuel; (2) DOE's present value estimate of $8.6 billion from 2004 through 2030 in energy savings from water heater energy conservation; and (3) DOI's estimate of $50 million to $192 million per year in benefits from its migratory bird hunting

regulations. In one case, the agency provides some of the benefit estimates in monetized and quantified for, but discusses other benefits qualitatively. Namely, USDA estimated that the Roadless Area Conservation rule will save $219,000 per year from reduced road maintenance but did not quantify the benefits associated with projected increases in air and water quality and biodiversity. In three cases, the agencies did not monetize all of the quantified benefits. For example, DOE quantified and monetized the energy saving benefits from its three energy conservation standards, but did not monetize the projected reductions in nitrogen oxide emissions. In 14 cases, agencies did not report any quantified or monetized benefit estimates.

2. Cost Analysis

For 26 of the 34 rules, agencies provided monetized cost estimates. These include such items as HHS's estimate of $56 million in the first year and $10 million annually thereafter as the cost of labeling shell eggs. For the remaining seven rules, DOI's four migratory bird hunting rules, DOC's two emergency fishery management rules, and DOT's light truck fuel economy rule, the agencies did not estimate costs

3. Net Monetized Benefits

Twelve of the 34 rules provided at least some monetized estimates of both benefits and costs. Of these, the estimated monetized benefits of nine of the rules unambiguously exceed the estimated monetized costs. The magnitude of the net benefits vary from less than $100 million per year to $66 billion per year. Two rules have negative net monetized benefits with variation ranging from approximately $10 million per year to $70 million per year. One rule yielded an estimate that included the possibility of positive or negative net benefits. EPA estimated that the expected benefits from identifying dangerous levels of lead range from $45 billion to $176 billion over 50 years depending on the underlying model, resulting in the net benefit estimates ranging from -$25 billion to $106 billion.

The presentation of the monetized benefits and costs varied. Five rules presented both benefits and costs in present value terms, whereas two rules used annualized forms. Four rules presented the estimated benefits in annualized forms and the costs in annual form. This distinction is important since annualized form smooths the projected streams of benefits and costs evenly over a period of time while the annual form does not. The annual form allows the reader to glean information on not only how much benefits and costs are likely to accrue but when.

4. Rules Without Quantified Effects

Three of the rules in Table 7 are classified as economically significant even though the agency did not provide any quantified estimates their effects.

DOC—Steller Sea Lion Protection Measures for the Groundfish Fisheries Off Alaska: Based upon publicly available information, OMB determined that rules covering these species were major.

DOC—Annual Framework Adjustment (framework 14) for the Atlantic Sea Scallop Fishery Management Plan for 2001: Based upon publicly available information, OMB determined that rules covering these species were major.

DOT—Light Truck CAFÉ: For each model year, DOT must establish a corporate average fuel economy (CAFÉ) standard for light trucks, including sport-utility vehicles and minivans. (DOT also sets a separate standard for passenger cars, but is not required to revisit the standard each year.) For the past five years, however, appropriations language has prohibited NHTSA from spending any funds to change the standards. In effect, it has frozen the light truck standard at its existing level of 20.7 miles per gallon (mpg) and has prohibited NHTSA from analyzing effects at either that or alternative levels. Although DOT did not estimate the benefits and costs of the standards, the agency's experience in previous years indicates that they may be substantial. Over 5 million new light trucks are subject to these standards each year, and the 20.7 mpg standard is binding on several manufacturers. In view of these likely, substantial effects, we designated the rule as economically significant even though consideration of the effects was prohibited by law.

Transfer Regulations

Of the 86 rules listed in Table 7, 53 implement Federal budgetary programs. The budget outlays associated with these rules are ''transfers'' to program beneficiaries. Of the 53, 16 are USDA rules in which 10 are crop assistance and disaster aids for farmers and 6 are food stamp program rules. HHS promulgated 17 rules implementing Medicare and Medicaid policy. The Social Security Administration and Federal Emergency Management Agency each promulgated three rules. DOL promulgated four rules including two on compensation programs on occupational illness and paid leave for birth and adoption. DOT, SBA and FAR each finalized two rules, one of which promotes safety incentive grants for seatbelt use. DoD, the Office of Federal Housing Enterprise Oversight, Veterans Administration, and the Office of Personnel Management each finalized one rule.

Major Rules for Independent Agencies

The congressional review provisions of the Small Business Regulatory Enforcement Fairness Act (SBREFA) require the General Accounting Office (GAO) to submit reports on major rules to the committees of jurisdiction, including rules issued by agencies not subject to Executive Order 12866 (the ''independent'' agencies). We reviewed the information on the costs and benefits of major rules contained in GAO reports for the period of April 1, 2000 to September 30, 2001.

GAO reported that five independent agencies issued nineteen major rules during this period. Two agencies did not conduct benefit-cost analyses. Three agencies considered benefits and costs of the rules. OIRA lists the agencies and the type of information provided by them (as summarized by GAO) in Table 8. Securities and Exchange Commission and Federal Trade Commission consistently considered benefits and costs in their rulemaking processes while Federal Communications Commission did not prepare benefit-cost analyses.

In comparison to the agencies subject to E.O. 12866, the independent agencies provided relatively little quantitative information on the costs and benefits of the major rules. As Table 8 indicates, eight of the 19 rules included some discussion of benefits and costs. Six of the 19 regulations had monetized cost information; three regulations monetized benefits. However, it is difficult to discern whether the rigor and the extent of the analyses conducted by the independent agencies are similar to those agencies subject to the Executive Order.

Chapter III: Regulatory Governance Abroad

As a special feature, this year's Annual Report to Congress on the Costs and Benefits of Regulation includes information on regulatory governance developments in other developed countries. The information is drawn from reports from the Organisation for Economic Co-operation and Development (OECD), Asian Pacific Economic Cooperation, (APEC) and the European Commission (EC) and supplemented by insights drawn from

OIRA discussions with OECD, APEC, and EC officials.

TABLE 8.—RULES FOR INDEPENDENT AGENCIES (APRIL, 2000–SEPTEMBER, 2001)

Agency	Rule	Information on costs or benefits	Monetized costs	Monetized benefits
Federal Communications Commission	Narrowband personal communications services.	No	No	No.
Federal Communications Commission	Assessment and collection of regulatory fees for fiscal year 2000.	No	No	No.
Federal Communications Commission	Extending wireless telecommunications services to tribal lands.	No	No	No.
Federal Communications Commission	Installment payment financing for personal communications services (PCS) licensees.	No	No	No.
Federal Communications Commission	Competitive bidding procedures	No	No	No.
Federal Communications Commission	24 Ghz Service; Licensing and operation	No	No	No.
Federal Communications Commission	Promotion of competitive networks in local telecommunications markets.	No	No	No.
Federal Communications Commission	Assessment and collection of regulatory fees for fiscal year 2001.	No	No	No.
Federal Reserve System	Privacy of consumer financial information	No	No	No.
Federal Trade Commission	Privacy of consumer financial information	Yes	No	No.
Nuclear Regulatory Commission	Emergency core cooling system evaluation models.	Yes	Yes	Yes.
Nuclear Regulatory Commission	Revision of fee schedules; 100% fee recovery, FY 2000.	No	No	No.
Nuclear Regulatory Commission	Revision of fee schedules; Fee recovery for FY 2001.	No	No	No.
Securities and Exchange Commission	Privacy of consumer financial information	Yes	Yes	No.
Securities and Exchange Commission	Selective disclosure and insider trading	Yes	Yes	No.
Securities and Exchange Commission	Unlisted trading privileges	Yes	No	No.
Securities and Exchange Commission	Disclosure of order execution and routing practices.	Yes	Yes	Yes.
Securities and Exchange Commission	Revision of the commission's auditor independence requirements.	Yes	Yes	Yes.
Securities and Exchange Commission	Disclosure of mutual fund after-tax returns	Yes	Yes	No.

OECD Activities

The OECD consists of 30 democracies with advanced, market economies, in Western Europe, North America, Australia, New Zealand, Japan, and Korea. As an integral part of its mission, OECD's Public Management program (PUMA) assists governments with the ''tools'' and ''rules'' of good governance to build and strengthen effective, efficient and transparent government structures.

The OECD countries have developed, through OECD's PUMA activities, a systematic approach to evaluating the quality of national regulatory management programs. In its 1997 report, OECD reported that the number of countries with such programs has grown from three or four in 1980 to almost all 30 OECD countries today. The international public debate about regulatory improvement has been transformed from a discussion about whether regulatory reform programs should be adopted to a debate about what specific measures should be implemented to improve regulatory performance.

In 1995 the OECD published the first internationally accepted set of principles on ensuring regulatory quality: the Recommendation of the Council of the OECD on Improving the Quality of Government Regulation. We have reproduced these principles in Box 1. OECD reports that experience in member countries reveals that an effective regulatory management system requires three basic components: a regulatory policy adopted at the highest political level; explicit and measurable standards for regulatory quality; and a continuing regulatory management capacity. Countries vary in how well they provide these components, which OECD considers as mutually reinforcing in their impact on the quality of regulatory governance.

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Box 1. The OECD Reference Checklist for Regulatory Decision-making

- **Is the problem correctly defined?**

The problem to be solved should be precisely stated, giving evidence of its nature and magnitude, and explaining why it has arisen (identifying the incentives of affected entities).

- **Is government action justified?**

Government intervention should be based on explicit evidence that government action is justified, given the nature of the problem, the likely benefits and costs of actions (based on a realistic assessment of government effectiveness), and alternative mechanisms for addressing the problem.

- **Is regulation the best form of government action?**

Regulators should carry out, early in the regulatory process, an informed comparison of a variety of regulatory and non-regulatory policy instruments, considering relevant issues such as costs, benefits, distributional effects and administrative requirements.

- **Is there a legal basis for regulation?**

Regulatory processes should be structured so that all regulatory decisions rigorously respect the "rule of law; that is responsibility should be explicit for ensuring that all regulations are authorized by higher level regulations and consistent with treaty obligations, and comply with relevant legal principles such as certainty, proportionality and applicable procedural requirements.

- **What is the appropriate level (or levels) of government for this action?**

Regulators should choose the most appropriate level of government to take action, or if multiple levels are involved, should design effective systems of co-ordination between levels of government.

- **Do the benefits of regulation justify the costs?**

Regulators should estimate the total expected costs and benefits of each regulatory proposal and of feasible alternatives, and should make the estimates available in accessible format to decision-makers. The costs of government action should be justified by its benefits before action is taken.

- **Is the distribution of effects across society transparent?**

To the extent that distributive and equity values are affected by government intervention, regulators should make transparent the distribution of regulatory costs and benefits across social groups.

- **Is the regulation clear, consistent, comprehensible and accessible to users?**

Regulators should assess whether rules will be understood by likely users, and to that end should take steps to ensure that the text and structure of rules are as clear as possible.

- **Have all interested parties had the opportunity to present their views?**

Regulations should be developed in an open and transparent fashion, with appropriate procedures for effective and timely input from interested parties such as affected businesses and trade unions, other interested groups, or other levels of government.

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In light of these OECD principles, the Secretariat of the OECD has been sponsoring, since 1998, detailed reviews of the regulatory governance programs in member countries. Sixteen country reviews have been completed from 1998 to 2001 and several more are now underway. OECD also commissioned a regulatory survey of member countries in 2000, convened a meeting of senior risk management officials from governments in October 2001, and sponsored an international meeting in December 2001.

Taken as a whole, the country-specific reviews, the 2000 OECD survey and recent international meetings reveal that the most common feature of regulatory management programs is that affected parties be consulted prior to regulation. A requirement for regulatory impact analysis prior to regulation has also been adopted in a majority of OECD countries. About half have some general requirement that regulatory alternatives be considered. Formal evaluation requirements for existing rules are less widespread. Some countries (*e.g.*, Japan and Korea) have focused on the need to reduce overregulation while in other countries (*e.g.*, the United States) the recent focus has been on improving regulatory quality through better analysis of benefits, costs and alternatives.

APEC Activities

The Asia-Pacific Economic forum was established by President George H.W. Bush in 1989. It is the primary international organization for promoting open trade and international cooperation among the 21 Pacific Rim countries. In addition to the seven OECD Pacific Rim countries, APEC includes Russia, China, Hong Kong, Chinese Taipei, Singapore, and Chile, among others. The APEC economies account for almost 50 percent of world trade. APEC is promoting increased transparency, openness and predictability based on the rule of law for both trade and regulation. It seeks to eliminate impediments to trade and investment by encouraging member economies to reduce barriers, adopt transparent, market-oriented policies and address such issues as outdated telecommunications regulatory practices. APEC requires its member countries to post on its web site individual action plans (IAPs) that set out how they plan to meet the APEC goals and to update them each year. One of the IAPs is a deregulation initiative based on the USG's and other countries' experiences. The main focus of the deregulation initiative is to promote information sharing and dialogue, and increase the transparency of existing regulatory regimes and regulatory reform processes. OIRA has been helping USTR and the State Department promote this effort by highlighting our open, transparent, and analytically based regulatory development and oversight program.

EC Activities

The European Union has been criticized on the grounds that its approach to governance is too disconnected from the concerns of ordinary residents of the member states. To address these concerns, the European Commission prepared in early 2001 a white paper entitled ''European Governance,'' which describes major areas of concern and promising directions for reform of governance in the EU. Public consultation on the contents of the white paper is scheduled to extend until March 2002, with conclusions drawn by the EC prior to the next Intergovernmental Conference, where European governance will be debated.

The white paper addressed broad concerns about good governance and the need for increased openness, participation, accountability, effectiveness and coherence. These five principles are designed to reinforce the overriding principles of proportionality and subsidiarity. Before launching an initiative, applying these principles means checking systematically to determine (a) if public action is really necessary; (b) if the European level is the most appropriate one; and (c) if the measures chosen are proportionate to the objectives.

Concern about regulatory policy—both the EC's and the member states roles—is featured in the white paper. As the executive arm of the European Union, the EC was granted the exclusive power to propose or initiate legislation and policy for Europe. The European Parliament (elected representatives of the people) and the European Council (comprised of representative ministers from member states) can modify EC proposals but do not have the power to initiate proposals. The EC has the initiating role in both ''regulations,'' which become law throughout Europe after Council and Parliament approval, and ''directives'', which must be ''transposed'' (i.e., tailored and implemented) by the Member States before they are legally enforceable.

The white paper calls for attention to ''improving the quality, effectiveness and simplicity of regulatory acts''. The mechanisms cited include formal regulatory analysis, consideration of various policy instruments, choice of the right type of instrument, consideration of ''co-regulation'' involving cooperation among regulated entities, more cooperation among member states on practices and targets, evaluation and feedback once rules are established, discouraging over complicated proposals, and faster legislative processes. The white paper, recognizing the extent of existing regulation but the absence of credible regulatory agencies in some areas, calls for both a comprehensive program of simplification of existing regulations as well as the creation of some new independent regulatory agencies (*e.g.*, in airline and food safety where public confidence in Europe is low). The white paper also notes that a stronger regulatory system in Europe will allow the EU to be a more effective advocate of regulatory management in international settings.

Soon after the Commission adopted the white paper in July 2001, a more specific ''communication'' was issued by the EC on ''Simplifying and Improving the Regulatory Environment.'' This document calls for at least a 25 percent reduction in the overall volume of European regulation (measured as the number of printed pages of laws) and the withdrawal of 100 or so pending yet outmoded proposals from before 1999. With regard to new actions, the communication calls for enhancement of consultation, especially electronic, on-line consultation, and impact analysis. The latter, defined as ''pre-assessments'' of draft proposals to determine which proposals merit detailed impact analysis, including assessments covering economic, social and environmental consequences.

A far more detailed report on ''better regulation'' was prepared by an authoritative group chaired by the distinguished Frenchman Dieudonne Mandelkern. Known as the Mandelkern Report. As published in November 2001, this report emphasized the economic significance of regulatory policy, suggesting that regulatory expenditures comprise perhaps 2 percent to 5 percent of the European gross domestic product. The report rejects unthinking deregulation but recognizes that better regulation is necessary to enhance public confidence in government and assure that the public-welfare benefits of regulatory policy are attained in the future.

The Mandelkern Report provides a detailed action plan on the themes of impact assessment, consultation, simplification, institutional structures to promote better regulation, alternatives to regulation, public access to the texts

of regulations and ''transposition'' (or the tailoring and implementation of EC directives by the member states of Europe). Annex A of the Mandelkern Report draws from the recent OECD regulatory work to define the crucial steps in achieving better regulation.

Late in 2001 the Economic and Social Committee of the European Parliament issued an ''Opinion'' on regulatory simplification by a vote of 62 votes in favor, 5 votes against and 5 abstentions. The Committee concluded as follows:

—The over-regulation of business is primarily a national problem but it also has a European dimension that needs to be addressed;
—There is a manifest need for a fundamental overhaul of the regulatory framework within the European Union, accompanied by a streamlining and simplification of the existing body of legislation;
—This regulatory review must focus not just on the future but also on the existing body of legislation and must be oriented not only towards simplification and improved methods but towards quantitative reductions;
—The regulatory environment should establish a level playing field for businesses operating throughout Europe, which means a reduction in the variability in the requirements on businesses established by the member states;
—A regulatory review body should be set up to review existing legislation and set out the guidelines for introducing new legislation. It should also conduct ex-post evaluations of the effects of legislation. This body should comprise representatives of the Commission, the national agencies and business.

The stage is obviously set for a vigorous public debate about which steps should actually be taken to accomplish better regulation throughout the European Union. It is too early to assess what actions will be taken, but the next steps taken by the European Commission may be critical in determining whether meaningful regulatory improvements will occur. Even if the EC does take concrete steps, supportive steps will also be required by the other EU institutions as well as the member states.

Chapter IV. Recommendations for Reform

In addition to estimates of the costs and benefits of Federal rules and paperwork, the Regulatory Right-to-Know Act also requires OMB to submit ''recommendations for reform.'' Below we highlight for comment two reform initiatives. First, we repeat our solicitation of public comments on regulations or regulatory programs in need of reform. Second, we invite a review of agency practice regarding guidance documents.

Review of Regulations and Regulatory Programs

Efforts to improve regulation should not be prospective only. Agencies also should look back and review existing rules to streamline and modernize those that are outdated, duplicative, ineffective, or unnecessary. With the passage of time, outmoded agency decisions need review and revision.

OMB is calling for public nominations of regulatory reforms to specific existing regulations that, if adopted, would increase overall net benefits to the public, considering both qualitative and quantitative factors. These reforms might include (1) extending or expanding existing regulatory programs; (2) simplifying or modifying existing rules or (3) rescinding outmoded or unnecessary rules.

The Administration recognizes that agencies should be particularly sensitive to the burden of their rules on small business. The Regulatory Right-to-Know Act directs that analysis of the impacts of Federal rules should give special consideration to small business impacts. As Congress stated in the findings for the Small Business Regulatory Enforcement Fairness Act of 1996, ''small businesses bear a disproportionate share of regulatory costs and burdens.'' A recent empirical study sponsored by the Small Business Administration Office of Advocacy supports this finding. The study shows that the average regulatory costs per employee were about 60 percent higher for small businesses than for large businesses: the average regulatory cost was about $7,000 for firms with less than 20 employees compared to about $4,500 for firms with over 500 employees.[17] This is a significant finding since small firms accounted for about three-quarters of the employment growth and 90 percent of the new business growth in the 1990s.[18] Small business ownership is a critical vehicle for all Americans—and increasingly for women and minorities—to achieve greater economic opportunity.[19] Accordingly, OMB requests comments on needed reforms of regulations unnecessarily impacting small businesses and identification of specific regulations and paperwork requirements that impose especially large burdens on small businesses and other small entities without an adequate benefit justification. OMB also requests comments from the small business community on problematic guidance documents discussed in the following section. OMB will coordinate with the Office of Advocacy of the Small Business Administration on this initiative.

While broad reviews of existing regulations have been required since 1981 under Executive Orders 12291, 12498, and 12866, they have met with limited success. Clearly, achieving broad agency review of existing rules is much easier said than done. In the first annual report on Executive Order 12866 released in November 1994, OIRA Administrator Sally Katzen noted that bureaucratic incentives make such review a difficult undertaking. While the ''lookback'' process had begun under E.O. 12866, she said, ''it had proven more difficult to institute than we had anticipated.* * * [A]gencies are focused on meeting obligations for new rules, often under statutory or court deadlines, at a time when staff and budgets are being reduced; under these circumstances, it is hard to muster resources for the generally thankless task of rethinking and rewriting current regulatory programs'' (p. 36). Past efforts at broad reviews of existing regulations, including reviews under Executive Order 12866 and the National Performance Review, were largely unsuccessful.[20] Beyond bureaucratic disincentives, resource constraints, and the complexity of the task, reviewing old rules may be hampered by unfounded fears that any attempt to modernize or streamline old rules is a veiled attempt to ''rollback'' needed safeguards. The difficulties and concerns surrounding this task do not mean it should be abandoned; they do counsel that an across-the-board review of all existing rules could be a poor use

[17] See W. Mark Crain & Thomas D. Hopkins, ''The Impact of Regulatory Costs for Small Firms,'' a report for the U.S. Small Business Administration, Office of Advocacy, RFP No. SBAHQ–00–R–0027 (2001).

[18] *Small Business Economic Indicators 2000* (SBA, Office of Advocacy 2001).

[19] The number of women-owned businesses increased by 16 percent between 1992 and 1997 (*Women in Business,* 2001: SBA, Office of Advocacy, October 2001) while the while the percent of minority-owned businesses increased from 6.8 percent in 1982 to 14.6 percent in 1997 (*Minorities in Business, 2001:* SBA,Office of Advocacy, November 2001) .

[20] See, *e.g.,* General Accounting Office, *Regulatory Reform: Agencies' Efforts to Eliminate and Revise Rules Yield Mixed Results* (Oct. 1997); Statement of L. Nye Stevens, Director, Federal Management and Workforce Issues, General Government Division, General Accounting Office, before the Senate Committee on Governmental Affairs, February 24, 1998.

of OMB and agency resources, and that a review of old rules should be done carefully and openly . Accordingly, OMB has established a modest process to review and improve old rules based on a public comment process.

With respect to improving existing rules or eliminating outmoded ones, OIRA would like to receive comments that are as specific as possible. In addition to supplying documentation and supporting materials (including citations to published studies), OIRA would appreciate use of the following format to summarize the suggestions:

FORMAT FOR SUGGESTED REGULATORY REFORM IMPROVEMENTS

Name of regulation	
Regulating Agency	(Include any subagency).
Citation	(Code of Federal Regulations).
Authority	(Statute).
Description of Problem	(Harmful impact and on whom).
Proposed Solution	(Both the fix and the procedure to fix it).
Estimate of Economic Impacts	(Quantified benefits and costs if possible. Qualitative descriptions if needed).

In selecting which rules or regulatory programs to propose for review, commenters should consider the extent to which (1) the rule or program could be revised to be more efficient or effective; (2) the agency has discretion under the statute authorizing the rule to modify the rule or program; and (3) the rule or program is important relative to other rules or programs being considered for review.

Review of Problematic Agency Guidance

As the scope and complexity of regulation and the problems it addresses have grown, so too has the need for government agencies to inform the public and provide direction to their staffs. To meet these challenges, agencies have relied increasingly on issuing guidance documents. The use of guidance documents is widespread, and often for good reasons. Agencies may properly provide guidance to interpret existing law, through an interpretative rule, or to clarify how the agency will treat or enforce a governing legal norm, through a policy statement. In some cases, Congress has directly expressed the need for guidance, such as the small business compliance guides mandated by Section 212 of the Small Business Regulatory Enforcement Fairness Act.[21] Guidance documents, used properly, can channel the discretion of agency employees, increase efficiency by simplifying and expediting agency enforcement efforts, and enhance fairness by providing the public clear notice of the line between permissible and impermissible conduct while ensuring equal treatment of similarly situated parties.

Experience has shown, however, that guidance documents also may be used improperly. Problematic guidance documents have received increasing scrutiny by the courts, the Congress and scholars.[22] While recognizing the enormous value of agency guidance in general, in this section OMB requests public comment on problematic agency guidance documents.

To promulgate regulations, an agency must ordinarily comply with the notice-and-comment procedures specified in the Administrative Procedure Act (APA), 5 U.S.C. 553. Section 553 requires that agencies must, in many cases, publish a notice of proposed rulemaking in the **Federal Register**. 5 U.S.C. 553(b). When notice is given, agencies also generally give interested persons an opportunity to comment on the proposal in writing. Agencies also may invite the public to present their views in person. 5 U.S.C. 553(c). Unless otherwise required by statute, notice and opportunity for comment are not required when an agency issues rules of agency organization, procedure, or practice; or where the agency finds for good cause that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest. 5 U.S.C. 553(b)(A)–(B).

Generally speaking, guidance (as opposed to regulations) is issued without notice and comment in order to clarify or explain an agency interpretation of a statute or regulation. These guidance documents may have many formats and names, including guidance documents, manuals, interpretive memoranda, staff instructions, policy statements, circulars, bulletins, and so on.

Beyond being exempt from notice-and-comment procedures, guidance documents may not normally be subject to judicial review or the kind of careful OMB and interagency review required by Executive Order 12866, as amended. Finally, some guidance documents may not be subjected to the rigorous expert peer review conducted on some complex legislative rulemakings. Because it is procedurally easier to issue guidance documents, there may be an incentive for regulators to issue guidance documents rather than conduct notice and comment rulemakings. As the D.C. Circuit recently observed in *Appalachian Power:*

> The phenomenon we see in this case is familiar. Congress passes a broadly worded statute. The agency follows with regulations containing broad language, open-ended phrases, ambiguous standards and the like. Then as years pass, the agency issues circulars or guidance or memoranda, explaining, interpreting, defining and often expanding the commands in regulations. One guidance document may yield another and then another and so on. Several words in a regulation may spawn hundreds of pages of text as the agency offers more and more detail regarding what its regulations demand of regulated entities. Law is made, without notice and comment, without public participation, and without publication in the **Federal Register** or the Code of Federal Regulations.

208 F.2d at 1019. Through guidance documents, agencies sometimes have issued or extended their ''real rules,'' *i.e.,* interpretative rules and policy statements, quickly and inexpensively—particularly with the use of the Internet—and without following procedures prescribed under statutes or Executive orders.

[21] 5 U.S.C. 601 note, Title II of Pub. L. 104–121, Mar. 29, 1996.

[22] E.g., *United States* v. *Mead,* 533 U.S. 218 (2001); *Appalachian Power Company* v. *Environmental Protection Agency,* 208 F.3d 1015 (D.C. Cir. 2000); ''Non-Binding Legal Effect of Agency Guidance Documents,'' H. Rep. 106–1009 (106th Cong., 2d Sess. 2000); H.R. 3521, the ''Congressional Accountability for Regulatory Information Act of 2000,'' Section 4; Robert A. Anthony ''Interpretative Rules, Policy Statements, Guidances, Manuals and the Like—Should Federal Agencies Use Them to Bind the Public?,'' 41 Duke L.J. 1311 (1992); Richard J. Pierce, Jr., ''Seven Ways to Deossify Agency Rulemaking,'' 47 Admin. L. Rev. 59 (1995); Peter L. Strauss, ''Comment, the Rulemaking Continuum,'' 41 Duke L.J. 1463 (1992); Administrative Conference of the United States, Rec. 92–2, 1 CFR 305.92–2 (1992); Carnegie Commission, *Risk and the Environment: Improving Regulatory Decisionmaking* (1993).

The failure to comply with the APA's notice-and-comment requirements or observe other procedural review mechanisms can undermine the lawfulness, quality, fairness, and political accountability of agency policymaking. The misuse of agency guidance also can impose significant costs on or limit the freedom of regulated parties without affording an opportunity for public participation.

Problematic guidance may take a variety of forms. An agency publication that is characterized as some kind of ''guidance'' document or ''policy statement'' may directly or indirectly seek to alter rights or impose obligations and costs not fairly discernible from the underlying statute or legislative rule that the document purports to interpret or implement. Such documents are occasionally treated by the agency as having legally binding effect on private parties. When that occurs, substantial question can arise regarding the propriety of the guidance itself—specifically whether it should be considered a regulation subject to APA procedures. Some guidance documents also may be founded on complex technical or scientific analyses or conclusions, which would be improved not only by public comment but also by expert, independent peer review. Finally, problematic guidance might be improved by interagency review.

The benefits of these procedural safeguards are well established. Notice-and-comment procedures can benefit agency policymaking in several ways. Potentially affected parties may improve the quality of a rule by supplying helpful information or alerting the agency to unintended consequences of a proposal. Notice-and-comment procedures also increase fairness by allowing potentially affected parties to participate in the decisionmaking process, and enhance political accountability by providing the public and its elected representatives advance notice of its policy decisions and an opportunity to shape them. As the Supreme Court recently confirmed in the *Mead* decision, the rule of law supports the use of regulations over guidance to bind the public, and guidance will receive less deference by the courts than properly implemented agency rules. Legislative rulemaking may also increase efficiency by allowing an agency to resolve recurring issues of legislative fact once instead of addressing such issues repeatedly on a case-by-case basis. Moreover, independent and expert peer review of highly technical or scientific agency guidance can enhance its objectivity and reliability and lead to better-informed decisionmaking. Finally, interagency review can ensure that agency action is consistent with Administration policy and is beneficial from a broader, societal perspective.

Under its obligation to promote recommendations for reforming the regulatory process and agency rules under the ''Regulatory Right-to-Know Act'' as well as its general duties to manage the efficiency and integrity of the regulatory process, OMB requests public comment on problematic Federal agency guidance. Specifically, OMB seeks public comment on the nature and extent of problematic guidance documents in agency policymaking, the adverse impacts, the benefits of proper guidance documents, criteria to identify problematic guidance, current examples of problematic guidance documents, and suggestions on how problematic guidance can be curtailed without undermining the typically appropriate use of guidance by Federal agencies.

OMB asks commenters to identify examples of problematic agency ''guidance'' documents of national or international significance. Commenters should submit to OMB a copy of the problematic guidance, with any relevant portions identified. They also should submit recommendations for remedying the problem, such as reissuance through notice and comment rulemaking, peer review, interagency review or rescission. Where guidance elaborates on an existing legislative rule or statute, OMB requests that commenters provide a copy of the relevant rule or statute and a concise explanation of how the guidance alters rights or imposes costs and obligations on the public that are not fairly discernible from the text of the statute or legislative rule, as well as, to the extent feasible, an estimate of such costs. In such cases, commenters also should explain whether the agency has provided reasonably sufficient detail in the legislative rule before resorting to guidance, considering the importance of the relevant issues, competing demands on the agency, available resources, and the need for resolution of the issues. In addition to supplying documentation and supporting materials (including citations to published studies), OIRA would appreciate use of the following format to summarize the suggestions.

FORMAT FOR SUGGESTED GUIDANCE DOCUMENT IMPROVEMENTS

Name of guidance document	
Regulating Agency	(Include any subagency).
Citation	(E.g. FEDERAL REGISTER).
Authority	(Statute or Legislative Rule).
Description of Problem	(Harmful impact and on whom).
Proposed Solution	(Both the fix and the procedure to fix it).
Estimate of Economic Impacts	(Quantified benefits and costs if possible. Qualitative descriptions if needed).

Appendix A. Update of Impact of the Card Memorandum

On January 20, 2001, the President's Chief of Staff issued a directive to agency heads to take steps to ensure that policy officials in the incoming Administration had the opportunity to review any new or pending regulations. This followed similar practices adopted at the beginning of previous administrations.

In last year's annual report to Congress, we provided a summary of actions taken by agencies pursuant to rules identified by the directive, and by a subsequent OMB memorandum to agencies. These actions, subject to certain exceptions, included withdrawing unpublished regulations from the **Federal Register** and from OMB's Office of Information and Regulatory Affairs, and delaying the effective date of final rules published in the **Federal Register** but not yet in effect. As noted in last year's annual report, by the end of May 2001, agencies had conducted reviews and taken appropriate action on most of the regulations subject to the directive and to subsequent OMB guidance. The final disposition of many of these rules, however, had not been decided.

The directives issued by Chief of Staff Card and OMB Director Mitchell E. Daniels, Jr. to Federal agencies to review and, if necessary and appropriate, withdraw unpublished regulations and delay the effective date of certain published regulations allowed newly appointed political officials to ensure that regulations published and implemented after January 20, 2001, reflected the priorities and policies of the Bush Administration. Given the deliberative (and often lengthy) nature of the rulemaking process, some of the regulations subject to the reviews and procedures required by the directives remain under active consideration by agencies.

Agency heads also had to review published final rules that had not yet become effective to decide which ones should go into effect as scheduled and which ones should be delayed to allow for the proper policy review. According to a recent General Accounting Office (GAO) report, a total of 371 published final rules were potentially subject to the directives' requirements that effective dates be delayed by agencies.[23] GAO found that, as of January 20, 2002, agencies had allowed 281 of these 371 rules to go into effect without delay. Agencies decided to delay the effective dates of the remaining 90 regulations. Table 9 lays out an agency-by-agency accounting of these rules. GAO's review of the 90 rules delayed by agencies determined that 75 went into effect after one or more delays. GAO reported that 13 of the delayed regulations were modified, withdrawn, and/or replaced by agencies. Other delayed rules were the subject of pending litigation including some of the 15 rules that remained delayed as of January 20, 2002.[24]

TABLE 9.—NUMBER OF REGULATIONS DELAYED AND NOT DELAYED

Department/Agency	Delayed	Not delayed	Total
Agriculture	10	6	16
Commerce	2	12	14
Education	3	10	13
Energy	8	6	14
Health and Human Services	16	13	29
Housing and Urban Development	4	1	5
Interior	6	2	8
Justice	4	4	8
Labor	5	3	8
Transportation	15	117	132
Treasury	0	12	12
Environmental Protection Agency	8	52	60
Independents and Other	9	43	52
Total	90	281	371

Source: General Accounting Office, ''Delay of Effective Dates of Final Rules Subject to the Administration's January 20, 2001, Memorandum'' (GAO–02–370R) [forthcoming].

Following the issuance of the directives, OMB instructed agencies to withdraw from OMB review regulations that they had submitted prior to January 20th. Except for those rules that met the exemptions provided for by the Card Memorandum, agencies formally withdrew 130 regulations. By the end of 2001, OMB subsequently cleared 61 after they were reviewed and resubmitted to OMB. Table 10 presents the numbers of regulations that agencies withdrew from OMB and those that agencies then submitted to OMB for Executive Order 12866 review and approval.

TABLE 10.—NUMBER OF REGULATIONS WITHDRAWN FROM AND SUBSEQUENTLY CLEARED BY OMB

Department/Agency	Withdrawn (as of 5/18/01)	Cleared (as of 12/31/01)
Agriculture	13	7
Commerce	5	3
Defense	2	1
Education	1	0
Health and Human Services	13	5
Housing and Urban Development	11	5
Interior	3	0
Justice	13	7
Labor	2	0
Transportation	12	5
Veterans Affairs	18	12
Environmental Protection Agency	21	10
Office of Personnel Management	6	3
Small Business Administration	3	1
Social Security Administration	2	1
Other	5	1
Total	130	61

Source: General Services Administration, Regulatory Information Service Center.

Appendix B. Proposals for Reform of Regulations

In the draft version of last year's annual report, OMB asked for suggestions from the public about specific regulations that should be modified or rescinded in order to increase net benefits to the public. We received suggestions regarding 71 regulations from 33 commenters involving 17 agencies. In an initial review of the comments, OIRA placed the suggestions into three categories: high priority, medium priority, and low priority.

Twenty-three agency actions were rated Category 1, those suggestions OIRA agreed

[23] General Accounting Office, ''Delay of Effective Dates of Final Rules Subject to the Administration's January 20, 2001, Memorandum'' (GAO–02–370R) [forthcoming].

[24] General Accounting Office, ibid., p. x. GAO's report provides a detailed discussion of specific actions taken by agencies on regulations delayed pursuant to the Card Memorandum.

were ''high priority review'' candidates. Since the publication of last year's report, OIRA has discussed these regulations with the agencies to better understand where they fit with agency priorities. As detailed below, agencies have already taken action on a number of these suggestions. On others, agencies have agreed to consider the need for reform and will be evaluating specific actions. Finally for some, agencies have convinced us that reform is unnecessary. A status report on the high priority reviews is provided below.

USDA: Forest Service Planning Rules and Roadless Area Conservation Regulations (2 rules)—On May 10, 2001, a federal judge issued an injunction blocking implementation of the roadless rule and a portion of the forest planning rule. In July, the Forest Service issued an advanced notice soliciting comments on possible changes to the roadless rule in light of the court action. Further action awaits the Forest Service's consideration of comments.

Department of Education: Regulations Related to Financial Aid.—These regulations are the subject of annual regulatory negotiations. For this year the Department has made clear its commitment to streamlining the regulations consistent with statutory requirements.

Department of Energy: Central Air Conditioning and Heat Pump Energy Conservation Standards—On January 3, 2002, DOE submitted a revision to this rule to OMB for review. OMB completed review on February 1, 2002.

Department of Health and Human Services: Standards for Privacy of Individually Identifiable Health Information—HHS has issued guidance clarifying the requirements of this rule and has publicly committed to making regulatory changes to certain aspects of the rule.

Department of Health and Human Services: Food Labeling: Trans Fatty Acids in Nutrition Labeling, Nutrient Content and Health Claims—OIRA Administrator John D. Graham sent a prompt letter to FDA on September 18, 2001 urging the agency to finalize this rulemaking. Secretary Thompson responded on November 26, 2001, agreeing that finalization was a high priority. FDA is currently awaiting the results of a National Academy of Science's study on this subject prior to proceeding with the final rule.

Department of the Interior: Amendments to National Park Service Snowmobile Regulations—The snowmobile industry filed a lawsuit against this rule, and this Administration reached a settlement with the plaintiffs on June 29, 2001 to revise the January 22, 2001 final rule. Public comments are now being solicited on several alternatives.

Department of the Interior: Regulations Governing Hardrock Mining Operations—DOI completed a revision of these regulations on October 31, 2001.

Department of Labor: Procedures for Certification of Employment-Based Immigration and Guest Worker Applications—On November 21, 2001, DOL submitted a proposed regulation on this subject to OMB for review. We completed review on February 19, 2002.

Department of Labor: Proposal Governing ''Helpers'' on Davis-Bacon Act Projects—DOL has decided that changes in the Davis-Bacon regulations are not appropriate at this time.

Department of Labor: Overtime Compensation Regulations Under the Fair Labor Standards Act—DOL is considering whether revisions to these regulation would be appropriate.

Department of Labor: Recordkeeping and Notification Requirements Under the Family and Medical Leave Act—DOL is considering whether revisions to these regulations would be appropriate.

Department of Labor: Equal Opportunity Survey—DOL is considering whether modifications to the survey would be appropriate.

Department of Transportation: Hours of Service of Drivers—DOT is considering revisions to these regulations which were proposed in 2000. Any final rule will reflect public comments in response to the notice of proposed rulemaking.

Equal Employment Opportunity Commission: Uniform Guidelines for Employee Selection Procedures—EEOC has requested and received an extension of clearance of these guidelines under the Paperwork Reduction Act to allow further consideration of changes.

Environmental Protection Agency: ''Mixture and Derived From'' Rule—EPA is considering whether revisions to these regulations would be appropriate.

Environmental Protection Agency: Proposed Changes to the Total Maximum Daily Load Program—EPA is considering whether revisions to these regulations would be appropriate.

Environmental Protection Agency: Drinking Water Regulations: Cost Benefit Analyses—OIRA will address these issues in its forthcoming analytical guidance project.

Environmental Protection Agency: Economic Incentive Program Guidance—EPA issued guidance in January 2001, and the States are now using the guidance in developing economic incentive programs. OIRA will consider further review of the guidance after the States have further experience with the current guidelines.

Environmental Protection Agency: New Source Review—EPA is considering whether revisions to these regulations and guidance documents are appropriate.

Environmental Protection Agency: Concentrated Animal Feeding Operations Effluent Guidelines—This rule was proposed in December 2000. EPA is currently examining comments and will consider all of these comments and those raised in the last report in producing a final rule.

Environmental Protection Agency: Arsenic in Drinking Water—EPA has decided not to modify this final rule.

Environmental Protection Agency: Notice of Substantial Risk: TSCA—EPA is considering several options to address the issues raised in its last report.

Appendix C. Estimates of the Aggregate Costs and Benefits of Regulation

Since there are so many different types of Federal regulation, it is useful to break rules down into categories. Three main categories of regulations are widely used: social, economic and process. The discussions in earlier reports provide examples for each of these categories.

A. Social Regulation

Table 11 presents the estimate of the total annual costs and benefits of social regulation (health, safety, and the environmental regulation) in the aggregate and by major program as of September 30, 2001. We calculated it by adding the estimates from table 1 in Chapter II to Table 4 from the 2000 OMB report, updated to 2001 dollars.

TABLE 11.—ESTIMATES OF TOTAL ANNUAL MONETIZED COSTS AND MONETIZED BENEFITS OF SOCIAL REGULATIONS

[Billions of 2001 dollars as of 2001, Q3]

	Environmental	Transportation	Labor	Other	Total
Costs	$120 to 203	$17 to 22	$20 to 22	$24 to 30	$181 to 277.
Benefits	$120 to 1,783	$95 to 126	$32 to 34	$61 to 66	$308 to 2,009.
Net Benefits [a]	$−83 to 1,663	$73 to 109	$10 to 14	$31 to 42	$31 to 1,828.

Source: Table 6, Ch.II and Table 4 from (OMB 2000) as adjusted per fn. 6 updated to 2001 dollars.

[a] Lower estimate calculated by subtracting high cost from low benefit. Higher estimate calculated by subtracting low cost from high benefit.

Note: The dollar figures in this table do not reflect benefits that were quantified but not monetized. They also do not reflect benefits and costs (including indirect costs) that were not quantified.

B. Economic Regulation

Economic regulation restricts the price or quantity of a product or service that firms produce, including whether firms can enter or exit specific industries. In previous reports, OIRA presented an estimate that the efficiency costs of economic regulation amounted to $80 billion (updated to 2001 dollars). In a 1999 comprehensive report on regulatory reform in the United States by a panel of experts from around the world, the OECD estimated that additional reforms in

the transportation, energy and telecommunications sectors would lead to an increase in GDP of 1 percent (OECD, 1999). One percent of the 2001 GDP of $10.15 trillion is about $100 billion. This estimate does not include the costs of international trade protection, which Hopkins included in his estimate of the cost of economic regulation.

According to a recent study, the potential consumer gains from removing trade barriers existing in 1990 would be about 1.3 percent of GDP (Council of Economic Advisers 1998) or about $130 billion for the 2001, assuming trade barriers have not changed.[25] These estimates taken together suggest that Hopkins' 1992 estimate may be too low. Crain and Hopkins (2001) in a report for the Small Business Administration recently estimated the efficiency costs of economic regulation at $150 billion (updated to 2001 dollars).[26] Crain and Hopkins state that they reestimated the earlier Hopkins estimate based on OMB's 2000 report which also discussed the CEA (1998) estimate cited above. Economic theory predicts that regulation that restricts competitive prices and establishes entry barriers produces no social benefits except in the case of natural monopoly, a phenomenon becoming rare in a world of rapid technological progress.

C. Process Regulation

The main burden of process regulation consist of the paperwork costs imposed on the public. Section 624(a)(1)(A) of the FY 2001 Treasury and General Government Appropriations Act (the Act), also known as the ''Regulatory Right to Know Act,'' calls on OMB to examine the costs and benefits of paperwork. OMB has worked in the past with IRS on this issue. Currently, IRS is developing a new model that will estimate the amount of burden incurred by wage and investment taxpayers as a result of complying with the tax system. IRS has undertaken this study to improve understanding of taxpayer burdens, to enable us to measure both current and future levels of burden, and to help isolate the burden of particular tax provisions, regulations, or procedures. To help provide input into reporting of monetized burdens, the IRS paperwork burden study included the development of a white paper, ''Revealed and Stated Preference Estimation of the Value of Time Spent for Tax Compliance'' (Cameron 2000).

In the annual *Information Collection Budgets*, OIRA calculates paperwork burden imposed on the public, using information that agencies give us with their information collection requests. Table 12 presents estimates of paperwork burden in terms of the hours the public devotes annually to gathering and providing information for the Federal government. At a future point, OIRA hopes to be able to provide information on the dollar cost of paperwork burden imposed by Federal agencies. At present, it is not feasible to estimate the value of annual societal benefits of the information the government collects from the public.

Table 12 shows total burden hours by agency of the paperwork approved by OMB under the Paperwork Reduction Act as of September 30, 2001. The total burden of 7,651 million hours is made up of 6,416 million hours for the Treasury Department (84 percent) and 1,235 million hours for the rest of the Federal government. Using the estimate of average value of time from our previous four reports ($30 in 2001 dollars) per hour for individuals and entities that provide information to the government, we derive a cost estimate of public paperwork of $230 billion. Note, however, that (1) this is a rough average and should not be applied to individual agencies or agency collections: and (2) this estimate should not be added to our estimates of the costs of regulation because it would result in some double counting. Our estimates of regulatory costs already include some paperwork costs. Many paperwork costs arise from regulations, often for enforcement and disclosure purposes. One way to eliminate this overlap is to focus on tax compliance costs by using the burden estimate for the Treasury Department. This produces an estimate of $190 billion. The basis for our complex tax system is presumably related to considerations of equity and fairness. The changes in the distribution of income that our tax system produces are transfers and not counted as social benefits.

TABLE 12.—SUMMARY OF ACTIVE INFORMATION COLLECTIONS APPROVED UNDER THE PAPERWORK REDUCTION ACT AS OF 09/30/2001

[Millions of hours]

Department/Agency	Total hour burden
Agriculture	86.72
Commerce	10.29
Defense	92.05
Education	40.50
Energy	3.84
Health and Human Services	186.61
Housing and Urban Development	12.05
Interior	7.55
Justice	40.52
Labor	186.10
State	16.57
Transportation	80.33
Treasury	6,415.84
Veterans Affairs	5.30
EPA	130.78
FAR	23.74
FCC	40.10
FDIC	10.53
FEMA	5.50
FERC	3.95
FTC	72.59
NASA	6.87
NSF	4.72
NRC	8.17
SEC	144.28
SBA	1.93
SSA	24.26
Government Total	7,651.42

Table 13 presents an estimate of the total annual costs and benefits of Federal rules and paperwork to the extent feasible in the aggregate, as required by Section 624 (a)(1)(A) of the Act.

TABLE 13.—TOTAL ANNUAL COST AND BENEFITS OF REGULATIONS AS OF SEPTEMBER 30, 2001

[Billions of 2001 dollars]

Type of regulation	Costs	Benefits
Social	181 to 277	308 to 2,009.
Economic (efficiency Loss)	150	0.
Process	190	0 .
Total	521 to 617	308 to 2,009.
Economic (transfer)	337	337

Source: Table 11 and text.

[25] The CEA report also went on to state that studies of this type only capture static costs, fail to capture value of foregone varieties of products, quality improvements, and productivity enhancements that would take place in the absence of trade barriers, and thus understate the benefits from trade (CEA 1998, p. 238). The Michigan Model of World Production and Trade, a computational general equilibrium model that takes into account some of these considerations, predicts that the elimination of all global trade restrictions (not just U.S.) would increase U.S. GDP by 5.92 percent. (Brown, Deardorff, and Stern, 2001).

[26] Crain and Hopkins also include an alternative estimate of the cost of economic regulation of $435 billion by including transfer costs, which are equal shifts of income from one group of citizens to another. Since transfers are not net costs to society (one person's loss is another's gain), transfers should not be added to our other cost estimates. Nevertheless, transfers may affect economic incentives and produce indirect costs to society.

Sec. 638 (a)(2) of the Act calls on OMB to present an analysis of the impacts of Federal regulation on State, local, and tribal governments, small business, wages, and economic growth.

Impact on State, Local, and Tribal Government

Over the past five years, five rules have imposed costs of more than $100 million on State, local, and Tribal governments (and thus have been classified as public sector mandates under the Unfunded Mandates Act of 1995).[27] All five of these rules were issued by the Environmental Protection Agency. These rules are described in greater detail below.

• *EPA's Rule on Standards of Performance for Municipal Waste Combustors and Emissions Guidelines* (1995): This rule set standards of performance for new municipal waste combustor (MWC) units and emission guidelines for existing MWCs under sections 111 and 129 of the Clean Air Act [42 U.S.C. 7411, 42 U.S.C. 7429]. The standards and guidelines apply to MWC units at plants with aggregate capacities to combust greater than 35 megagrams per day (Mg/day) (approximately 40 tons per day) of municipal solid waste (MSW). The standards require sources to achieve the maximum degree of reduction in emissions of air pollutants that the Administrator determined is achievable, taking into consideration the cost of achieving such emission reduction, and any non-air quality health and environmental impacts and energy requirements.

EPA estimated the national total annualized cost for the emissions standards and guidelines to be $320 million per year (in constant 1990 dollars) over existing regulations. EPA estimated the cost of the emissions standards for new sources to be $43 million per year. EPA estimated the cost of the emissions guidelines for existing sources to be $277 million per year. The annual emissions reductions achieved through this regulatory actions include, for example, 21,000 Mg. of SO2; 2,800 Mg. of particulate matter (PM); 19,200 Mg of NOX; 54 Mg. of mercury; and 41 Kg. of dioxin/furans.

• *EPA's Standards of Performance for New Stationary Sources and Guidelines for Control of Existing Sources: Municipal Solid Waste Landfills* (1996): This rule set performance standards for new municipal solid waste landfills and emission guidelines for existing municipal solid waste landfills to implement section 111 of the Clean Air Act. The rule addressed non-methane organic compounds (NMOC) and methane emissions. NMOC include volatile organic compounds (VOC), hazardous air pollutants (HAPs), and odorous compounds. Of the landfills required to install controls, about 30 percent of the existing landfills and 20 percent of the new landfills are privately owned. The remainder are publicly owned. The total nationwide annualized costs for collection and control of air emissions from new and existing MSW landfills are estimated to be $94 million per year annualized over five years, and $110 million per year annualized over 15 years.

• *National Primary Drinking Water Regulations: Disinfectants and Disinfection Byproducts* (1998): This rule promulgates health-based maximum contaminant level goals (MCLGs) and enforceable maximum contaminant levels (MCLs) for about a dozen disinfectants and byproducts that result from the interaction of these disinfectants with organic compounds in drinking water. The rule will require additional treatment at about 14,000 of the estimated 75,000 water systems nationwide affected by this rule. The costs of the rule are estimated at $700 million annually. The quantified benefits estimates range from zero to 9,300 avoided bladder cancer cases annually, with an estimated monetized value of $0 to $4 billion. Possible reductions in rectal and colon cancer and adverse reproductive and developmental effects were not quantified.

• *National Primary Drinking Water Regulations: Interim Enhanced Surface Water Treatment* (1998): This rule establishes new treatment and monitoring requirements (primarily related to filtration) for drinking water systems that use surface water as their source and serve more than 10,000 people. The purpose of the rule is to enhance protection against potentially harmful microbial contaminants. EPA estimated that the rule will impose total annual costs of $300 million per year. The rule is expected to require treatment changes at about half of the 1,400 large surface water systems, at an annual cost of $190 million. Monitoring requirements add $96 million per year in additional costs. All systems will also have to perform enhanced monitoring of filter performance. The estimated benefits include mean reductions of from 110,000 to 338,000 cases of cryptosporidiosis annually, with an estimated monetized value of $0.5 to $1.5 billion, and possible reductions in the incidence of other waterborne diseases.

• *National Pollutant Discharge Elimination System—Regulations for Revision of the Water Pollution Control Program Addressing Storm Water Discharges* (1999): This rule would expand the existing National Pollutant Discharge Elimination System program for storm water to cover smaller municipal storm sewer systems and construction sites that disturb one to five acres. The rule allows for the exclusion of certain of these sources from the program based on a demonstration of the lack of impact on water quality. EPA estimates that the total cost of the rule on Federal and State levels of government, and on the private sector, is $803.1 million annually. EPA considered alternatives to the rule, including the option of not regulating, but found that the rule was the option that was, ''most cost effective or least burdensome, but also protective of the water quality.''

While these five EPA rules were the only ones over the past five years to require expenditures by State, local and Tribal governments exceeding $100 million, they were not the only rules with impacts on other levels of governments. For example, 15 percent, 10 percent, and 6 percent of rules listed in the April 2000 Unified Regulatory Agenda cited some impact on State, local or Tribal governments, respectively. In general, OMB works with the agencies to ensure that the selection of the regulatory option for all final rules complies fully with the Unfunded Mandates Reform Act. For proposed rules, OMB works with the agencies to ensure that they also solicited comment on alternatives that would reduce costs to all regulated parties, including State, local and Tribal governments.

Agencies have also significantly increased their consultation with State, local, and Tribal governments on all regulatory actions that impact them. For example, EPA and the Department of Health and Human Services have engaged in particularly extensive consultation efforts over a wide variety of programs, on both formal unfunded mandates as defined by the Unfunded Mandates Reform Act and other rules with intergovernmental impacts. Agencies have also made real progress in improving their internal systems to manage consultations better. This has helped them analyze specific rules in ways that reduce costs and increase flexibility for all levels of government and for the private sector, while implementing important national priorities.

This Administration will bring more uniformity to the consultation process to help both agencies and intergovernmental partners know when, how and with whom to communicate. States and localities should have a clear point of contact in each agency, and agencies must understand that ''consultation'' means more than making a telephone call the day before a rulemaking action is published in the **Federal Register**. Finally, this Administration intends to enforce the Unfunded Mandates Reform Act to ensure that agencies are complying with both the letter and the spirit of the law. If an agency is unsure whether a rule contains a significant mandate, it should err on the side of caution and prepare an impact statement prior to issuing the regulation.

Clearly, more still needs to be done to ensure that this consultation takes place in all instances where it is needed and early in the federal decisionmaking process. Toward that end, the President established an Interagency Working Group on Federalism. Devolving authority and responsibility to State and local governments, and to the people, is a central tenet of the President's management of the Executive Branch. This working group is striving to turn this principle into policy.

In Chapter I above we ask for comments from the public for suggestions to help improve the consultation process. We intend to include a discussion of those comments in the final report. We also intend to include in our final report a full discussion of agency

[27] EPA's proposed rules setting air quality standards for ozone and particulate matter may ultimately lead to expenditures by State, local or tribal governments of $100 million or more. However, Title II of the Unfunded Mandates Reform Act provides that agency statements on compliance with Section 202 must be conducted ''unless otherwise prohibited by law.'' The conference report to this legislation indicates that this language means that the section ''does not require the preparation of any estimate or analysis if the agency is prohibited by law from considering the estimate or analysis in adopting the rule.'' EPA has stated, and the courts have affirmed, that under the Clean Air Act, the air quality standards are health-based and EPA is not to consider costs.

compliance with the Unfunded Mandates Reform Act.

Impact on Small Business

The Administration explicitly recognizes the need to be sensitive to the impact of regulations and paperwork on small business with Executive Order 12866, ''Regulatory Planning and Review.'' The Executive Order calls on the agencies to tailor their regulations by business size in order to impose the least burden on society, consistent with obtaining the regulatory objectives. It also calls for the development of short forms and other streamlined regulatory approaches for small businesses and other entities. Moreover, in the findings section of the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), Congress stated that ''. . . small businesses bear a disproportionate share of regulatory costs and burdens.'' This is largely attributable to fixed costs—costs that all firms must bear regardless of size. Each firm has to determine whether a regulation applies, how to comply, and whether it is in compliance. As firms increase in size, fixed costs are spread over a larger revenue and employee base resulting in lower unit costs.

This observation is supported by empirical information from a study sponsored by the Office of Advocacy of the Small Business Administration (Crain and Hopkins 2001). That study found that regulatory costs per employee decline as firm size—as measured by the number of employees per firm—increases. Crain and Hopkins (2001) estimate that the total cost of regulation (environmental, workplace, economic, and tax compliance regulation) was 60 percent greater per employee for firms with under 20 employees compared to firms with over 500 employees. [28]

These results do not indicate, however, the extent to which reducing regulatory requirements on small firms would affect net benefits. That depends upon the differences between relative benefits per dollar of cost by firm size, not on differences in costs per employee. If benefits per dollar of cost are smaller for small firms than large firms, then decreasing requirements for small firms while increasing them for large firms should increase net benefits. The reverse may be true in some cases.

Impact on Wages

The impact of Federal regulations on wages depends upon how ''wages'' are defined and on the types of regulations involved. If we define ''wages'' narrowly as workers' take-home pay, social regulation usually decreases average wage rates, while economic regulation often increases them, especially for specific groups of workers. If we define ''wages'' more broadly as the real value or utility of workers' income, the directions of the effects of the two types of regulation can be reversed.

1. Social Regulation

By broad measures of welfare, social regulation, regulation directed at improving health, safety, and the environment is intended to create benefits for workers and consumers that outweigh the costs. Compliance costs, however, must be paid for by some combination of workers, business owners, and/or consumers through adjustments in wages, profits, and/or prices. This effect is most clearly recognized for occupational health and safety standards. As one leading text book in labor economics suggests: ''Thus, whether in the form of smaller wage increases, more difficult working conditions, or inability to obtain or retain one's first choice in a job, the costs of compliance with health standards will fall on employees.'' [29]

Viewed in terms of overall welfare, the regulatory benefits of improved health, safety, and environmental improvements for workers can outweigh their costs assuming the regulation produces net benefits. In the occupational health standards case, where the benefits of regulation accrue mostly to workers, workers are likely to be better off if health benefits exceed compliance costs. [30] Although wages may reflect the cost of compliance with health and safety rules, the job safety and other benefits of such regulation can compensate for the monetary loss. Workers as consumers benefitting from safer products and a cleaner environment may also come out ahead if regulation produces significant net benefits for society.

2. Economic Regulation

For economic regulation, designed to set prices or conditions of entry for specific sectors, these effects may at times be reversed to some degree. Economic regulation can result in increases in income narrowly defined for workers in the regulated industries, but decreases in broader measures of income based on utility or overall welfare, especially for workers in general. Economic regulation is often used to protect industries and their workers from competition. Examples include the airline and trucking industries in the 1970s and trade protection, today. These wage gains come at a cost in inefficiency from reduced competition, however, which consumers must bear. Moreover, growth in real wages, which are limited generally by productivity increases, will not grow as fast without the stimulation of outside competition. [31]

These statements are generalizations for the impact of regulation in the aggregate or by broad categories. Specific regulations can increase or decrease the overall level of benefits accruing to workers depending upon the actual circumstances and whether net benefits are produced.

Economic Growth

The conventional measurement of GDP does not take into account the market value of improvements in health, safety, and the environment. It does incorporate the direct compliance costs of social regulation. Accordingly, conventional measurement of GDP can suggest that regulation reduces economic growth. [32] In fact, sensible regulation and economic growth are not inconsistent once all benefits are taken into account. By the same token, inefficient regulation reduces true economic growth.

The OECD (1999) estimates that the economic deregulation that occurred in the U.S. over the last 20 years permanently increased GDP by 2 percent. The OECD also estimates that further deregulation of the transportation, energy, and telecommunication sectors would increase U.S. GDP by another 1 percent. Jaffe, Peterson, Portney, and Stavins (1995) summarize their findings after surveying the evidence of the effects of environmental regulation on economic growth as follows: ''Empirical analysis of the productivity effects have found modest adverse impacts of environmental regulation.'' Based on the studies that tried to explain the decline in productivity that occurred in the US during the 1970s, they placed the range attributable to environmental regulation from 8 percent to 16 percent (p. 151).

As indicated above, conventionally measured GDP growth does not take into account the market value of the improvements in health, safety, and the environment that social regulation has brought us. If even our lower range estimate of the benefits of social regulation ($266 billion) were added to GDP, then the more comprehensive measure of GDP, one that includes the value of nonmarket goods and services provided by regulation, would be about 3 percent greater. [33] Focusing on the effect of social regulation on economic growth is misleading if it does not take into account the full benefits of regulation.

More important than knowing the impact of regulation in general on growth is the impact of specific regulations and alternative regulatory designs on economic growth. As Jaffe et al put it: ''Any discussion of the productivity impacts of environmental protection efforts should recognize that not all environmental regulations are created equal in terms of their costs or their benefits.'' (p 152).

[28] The average per employee regulatory costs were $6,975 for firms with under 20 employees compared to $4,463 for firms with over 500 employees. These findings are based on their overall estimate of the cost of Federal regulation for 2000 of $843 billion. (*See* Crain and Hopkins, ''The Impact of Regulatory Costs for Small Firms'' SBA, Office of Advocacy, 2001).

[29] From Ehrenberg and Smith's *Modern Labor Economics,* p. 279.

[30] Based on a cost benefit analysis of OSHA's 1972 Asbestos regulation by Settle (1975), which found large net benefits, Ehrenberg and Smith cite this regulation as a case where workers' wages were reduced, but they were made better off because of improved health (p. 281).

[31] Winston (1998) estimates that real operating costs declined between 25 and 75 percent in the sectors that were deregulated over the last 20 years—transportation, energy, and telecommunications.

[32] Social regulation reduces measured growth by diverting resources from the production of goods and services that are counted in GDP to the production or enhancement of ''goods and services'' such as longevity, health, and environmental quality that generally are not counted in GDP.

[33] Including the value of increasing life expectancy in the GDP accounts to come up with a more comprehensive measure of the full output of the economy is not as far fetched as it sounds. It was first proposed and estimated in 1973 by D. Usher in ''An Imputation to the Measure of Economic Growth for Changes in Life Expectancy'' *NBER Conference on Research in Income and Wealth.*

In this regard, market-based or economic-incentive regulations will tend to be more cost-effective than those requiring specific technologies or engineering solutions. Under market-based regulation, profit-maximizing firms have strong incentives to find the cheapest way to produce the social benefits called for by regulation. How you regulate can go a long way toward reducing any negative impacts on economic growth and increasing the overall long run benefits to society.

Appendix D. Explanation of Calculations for Costs and Benefits Tables

Chapter II presents estimates of the annual costs and benefits of major regulations reviewed by OMB between April 1, 1995 and September 30, 2001, for which we had quantified costs and benefits. The explanation for the calculations of the major rules reviewed by OMB between April 1, 1995 and March 31, 1999, is in Chapter IV of our 2000 report (OMB 2000). Table 14 presents OIRA's estimates of the benefits and costs of the 19 individual rules reviewed between April 1, 1999 and September 30, 2001 which were included in Table 5. As mentioned in Chapter II, we adjusted these estimates to update the estimates to 2001 dollars and removed three EPA regulations to prevent double counting. First, we decided to exclude the benefit and cost estimates for the Ozone and fine Particulate Matter NAAQS. EPA has adopted a number of key rules in the ensuing five years—for example, the NO_X SIP Call, the Regional Haze rule, the Tier II rule setting stringent emission limits for light duty vehicles, and the Heavy Diesel Engine rules setting stringent emission limits for on-highway diesel engines. These rules can achieve emission reductions and impose costs that were also included in the EPA benefit and cost estimates developed for the O_3 and PM NAAQS rules. Second, EPA issued a 1998 rule limiting Heavy Duty Diesel Engine emissions beginning in 2004 and ''reaffirmed'' the 1998 rule in a final rule issued last year. OIRA has used the benefit and cost estimates from EPA's 2001 rulemaking because we believe it provides a better estimate of the likely emission reductions and costs of these emission standards.

In assembling estimates of benefits and costs, OIRA has:

(1) Applied a uniform format for the presentation of benefit and cost estimates in order to make agency estimates more closely comparable with each other (for example, providing the benefit and cost streams over time and annualizing benefit and cost estimates); and

(2) monetized quantitative estimates where the agency has not done so (for example, converting some projections of tons of pollutant per year to dollars).

Adopting a format that presents agency estimates so that they are more closely comparable also allows, at least for purposes of illustration, the aggregation of benefit and cost estimates across rules. While OIRA has attempted to be faithful to the respective agency approaches, the reader should be cautioned that agencies have used different methodologies and valuations in quantifying and monetizing effects.

Valuation Estimates for Regulatory Effects [34]

Agencies continue to take different approaches in monetizing benefits for rules that affect small risks of premature death. As a general matter, we have deferred to the individual agencies' judgment in this area. In cases where the agency both quantified and monetized fatality risks, we have made no adjustments to the agency's estimate. In cases where the agency provided only a quantified estimate of fatality risk, but did not monetize it, we have monetized these estimates in order to convert these effects into a common unit. For example, in the case of HHS's organ donor rule, the agency estimated, but did not monetize, statistical life-years saved (although it has discussed its use of $116,500 per life-year in other contexts). OIRA valued those life-years at $116,500 each. For NHTSA's child restraint rule, OIRA used NHTSA's approach to valuing life saving benefits.

In cases where agencies have not adopted estimates of the value of reducing these risks, OIRA used estimates supported by the relevant academic literature.[35] OIRA did not attempt to quantify or monetize fatality risk reductions in cases where the agency did not at least quantify them. As a practical matter, the aggregate benefit and cost estimates are relatively insensitive to the values we have assigned for these rules because the aggregate benefit estimates are dominated by EPA's rules.

The following is a brief discussion of OIRA's valuation estimates for other types of effects that agencies identified and quantified, but did not monetize.

- *Injury.* For the child restraint rule, the Department of Transportation approach of converting injuries to ''equivalent fatalities'' was adopted. These ratios are based on DOT's estimates of the value individuals place on reducing the risk of injury of varying severity relative to that of reducing risk of death. For the OSHA industrial truck operator rule, OIRA did not monetize injury benefits beyond OSHA's estimate of the direct cost of lost workday injuries. For the OSHA safety standards for steel erection, OIRA monetized injury benefits using a value of $50,000 per injury averted.
- *Change in Gasoline Fuel Consumption.* We valued reduced gasoline consumption at $.80 per gallon pre-tax.
- *Reduction in Barrels of Crude Oil Spilled.* OIRA valued each barrel prevented from being spilled at $2,000. This is double the sum of the most likely estimates of environmental damages plus cleanup costs contained in a recently published journal article (Brown and Savage, 1996).
- *Change in Emissions of Air Pollutants.* Estimates of the benefits per ton for reductions in hydrocarbon, nitrogen oxide (NO_X), sulfur dioxide (SO_2), and fine particulate matter (PM) were derived from EPA's pulp and paper cluster rule (October, 1997). These estimates were obtained from the RIA prepared for EPA's July, 1997 rules revising the primary NAAQS for ozone and fine PM. In this area, as in others, the academic literature offers a number of methodologies and underlying studies to quantify the benefits. There remain considerable uncertainties with each of these approaches. In particular, the derivation and application of per-ton coefficients to value reductions in these pollutants requires significant simplifying assumptions. This is particularly true with respect to the relationship between changes in emitted precursors pollutants and changes in the ambient pollutant concentrations which yield actual benefits. As a result of these simplifying assumptions, the monetary benefit estimates obtained by multiplying tons reduced by benefit estimates per-ton, which we derive from analyses of other rules, should be considered highly uncertain. For each of these pollutants, the following values (all in 1996$) were used for changes in emissions: [36]

Hydrocarbons: $519 to $2,360/ton;
Nitrogen Oxides: $519 to $2,360/ton;
Particulate Matter: $11,539/ton; and
Sulfur Dioxide: $3,768 to $11,539/ton.

The NO_X benefit estimate is based on benefit transfer values ranging from $519 to $2,360 per ton derived from a 1997 benefit analysis of VOC emission reductions, as noted above. This analysis required two key assumptions: (1) That NO_X reductions have no effect on particulate matter concentrations; and (2) that NO_X and VOC reductions contribute proportionately to ozone reductions. While reductions in VOC and NO_X emissions both lead to reductions in ambient concentrations of ozone, reductions in NO_X emissions also lead to reductions in particulate matter. In addition, reductions in NO_X may have a disproportionate impact on reductions in ozone. For these reasons, estimates of benefits based on the VOC transfer coefficients should be viewed with caution. All else equal, they are likely to underestimate actual NO_X -related benefits.

Analysis of other recent EPA rules yield a range of estimates for the NO_X benefits per ton. Each of these analyses is arguably methodologically superior to the 1997 benefit analysis. For example, the OTAG SIP and the Section 126 rules limiting NO_X emissions from electric utilities yielded estimates of $960 to $2500 per ton and $1350 to $2100 per ton in 2007, respectively, and the recent Tier 2 rule limiting NO_X emissions from cars and light trucks yielded estimates of $4500 to $7900 per ton in 2030. Finally, a recent EPA memo on the benefits of the NSR program provided an estimate based on previous EPA analyses that the average mortality-related benefits estimate is around $1300 per ton of NO_X reduced. The

[34] The following discussion updates the monetization approach used in previous reports and draws on examples from this and previous years.

[35] As a result of OSHA's interpretation of the Supreme Court's decision in the ''Cotton Dust'' case, *American Textile Manufacturers Institute* v. *Donovan,* 452 U.S. 491 (1981), OSHA does not conduct cost-benefit analysis or assign monetary values to human lives and suffering.

[36] Where applicable, the lower (higher) end of the value ranges in all of the tables throughout this report reflect the lower (higher) values in these ranges.

corresponding benefits estimate for SO_2 reductions is $7300 per ton. In these studies, the mortality-related benefits generally accounted for over 90 percent of monetary benefits. Currently, we recognize that there are potential problems and significant uncertainties that are inherent in any benefits analysis based on $/ton benefit transfer techniques. The extent of these problems and the degree of uncertainty depends on the divergence between the policy situation being studied and the basic scenario providing the benefits transfer estimate.

Several factors may be responsible for uncertainty and variability in the benefits transfer values. These factors include sources of emissions, meteorology, transport of emissions, initial pollutant concentrations, population density, and population demographics, such as proportion of elderly and children and baseline incidence rates for health effects. In order to minimize the uncertainty associated with benefits transfer, benefit transfer values should be taken from situations that are similar to the rule being evaluated. For example, where possible, benefit transfer values for individual pollutants should be based on primary benefits analyses for rules where the pollutant of interest, e.g. NO_X, is the primary pollutant controlled by the rule.

These additional issues are particularly relevant for the NO_X benefits transfer conducted for this report. Alternative benefits transfer analyses are available, as outlined above, including a benefits transfer estimate offered by EPA based on its recent analysis of the Tier 2 rule and the EPA staff estimate recently included in the New Source Review docket. Relative to the 1997 VOC rule, the benefits transfer based on these alternative analyses are (a) more focused on NO_X emissions, (b) based on more up-to-date data and methods, and (c) focused on sources more similar in character to the sources being evaluated in this report. The EPA staff estimate for the NSR docket is within the $520 to $2,360 per ton estimate used in this report.

In order to make agency estimates more consistent, we developed benefit and cost time streams for each of the rules. Where agency analyses provide annual or annualized estimates of benefits and costs, we used these estimates in developing streams of benefits and costs over time. Where the agency estimate only provided annual benefits and costs for specific years, we used a linear interpolation to represent benefits and costs in the intervening years.[37] For the Tier 2 rule and the Heavy Duty Diesel Engine rules, EPA only developed benefit estimates for a single year (2030) because of the difficulty of doing the air quality modeling necessary to support development of benefits estimates over multiple years. However, EPA did develop estimates of the expected emission reductions for intermediate years. We used these emission reduction estimates to scale the 2030 benefit estimate to provide a benefit stream over the relevant time period. For the Regional Haze rule, EPA provided only an estimate of benefits and costs in 2015. To develop benefit and cost streams, we used a linear extrapolation of benefits and costs beginning in 2009 and scaling up to the reported 2015 estimates.

Agency estimates of benefits and costs cover widely varying time periods. While HHS analyzed the effects of providing transplant-related data from 1999 through 2004, other agencies generally examined the effects of their regulations over longer time periods. HHS used a 10-year period for its over-the counter drug labeling rule; DOL also used a 10-year period for its truck operator training rule. EPA's analyses on disinfection and enhanced water treatment rules evaluated the effects over a twenty-year period. The differences in the time frames used for the various rules evaluated generally reflect the specific characteristics of individual rules such as expected capital depreciation periods or time to full realization of benefits.

In order for comparisons or aggregation to be meaningful, benefit and cost estimates should correctly account for all substantial effects of regulatory actions, including potentially offsetting effects, which may or may not be reflected in the available data. We have not made any changes to agency monetized estimates. To the extent that agencies have adopted different monetized values for effects—for example, different values for a statistical life or different discounting methods—these differences remain embedded in the tables. Any comparison or aggregation across rules should also consider a number of factors which our presentation does not address. For example, these analyses may adopt different baselines in terms of the regulations and controls already in place. In addition, the analyses for these rules may well treat uncertainty in different ways. In some cases, agencies may have developed alternative estimates reflecting upper- and lower-bound estimates. In other cases, the agencies may offer a midpoint estimate of benefits and costs. In still other cases the agency estimates may reflect only upper-bound estimates of the likely benefits and costs.

While we have relied in many instances on agency practices in monetizing costs and benefits, we believe that it may be critical in the coming year to take a more precise look at the variety of agency practices in use. Accordingly, our citation of or reliance on agency data in this report should not be taken as an OIRA endorsement of all of the varied methodologies used to derive benefit and cost estimates.

TABLE 14.—ESTIMATE OF BENEFITS AND COSTS OF 19 MAJOR RULES, APRIL 1, 1999 TO SEPTEMBER 30, 2001

[Annualized 2001 dollars in millions]

Regulation	Agency	Benefits	Costs	Explanation
1999–2000:				
Lead-Based Paint Hazards	HUD	190	150	Both costs and benefits come from Table 4 of the 2001 report. The present value estimates are amortized over five years.
Storm Water Discharges Phase II.	EPA	700–1,700	900–1,100	From Table 4 of 2001 report.
Tier 2 Motor Vehicle Emission Standards.	EPA	7,300–13,400	4,000	EPA provided a monetized benefit estimate only for the year 2030. EPA also estimated reductions for various individual years between 2004 and 2030. We assumed that the monetized benefits were directly correlated with emission reductions. We developed an annualized stream of emission reductions by interpolating between years for which EPA provided estimates. We then prorated the monetized benefits annually in proportion to the annual emission reductions. Finally, we annualized the resulting stream of monetized benefits. We used EPA's annual cost estimates to develop the annualized cost estimates.

[37] In other words, if hypothetically we had costs of $200 million in 2000 and $400 million in 2020, we would assume costs would be $250 million in 2005, $300 million in 2010, and so forth.

TABLE 14.—ESTIMATE OF BENEFITS AND COSTS OF 19 MAJOR RULES, APRIL 1, 1999 TO SEPTEMBER 30, 2001—Continued

[Annualized 2001 dollars in millions]

Regulation	Agency	Benefits	Costs	Explanation
Regional Haze	EPA	300–7,000	300–1,600	EPA provided a monetized benefit and cost range of estimates only for the year 2015. EPA also estimated emission reductions targeted for improving visibility for various individual years between 2010 and 2105, We assumed that the monetized benefits were directly correlated with emission reductions. We developed an annualized stream of emission reductions by assuming a linear improvement in haze from 2010 to 2015. We than prorated the monetized benefits annually in proportion to the annual emission reductions. Finally, we annualized the resulting stream of monetized benefits. We used EPA's annual cost estimates to develop the annualized cost estimates.
Handheld Engines	EPA	250–860	190–250	For benefits, we valued EPA's annualized emission reductions at $1,000—$2500 per ton. Costs and benefits are taken directly from table 4: Summary of Agency Estimates for Final Rules 4/1/99–3/31/00, converted to 2001$.
Total		8,740–23,150	5,540–7,100	
2000–2001:				
Roadless Area Conservation	USDA	0.219	184	Both costs and benefits come from Table 7: summary of Agency Estimates for Final Rules, 4/1/00–9/30/01. The benefits are taken as given. Costs aggregate the total short-term and long term per year costs provided.
Energy Conservation Standards for Fluorescent Lamp Ballasts.	DOE	280	70	Benefits and costs are estimated by amortizing the estimated present value of $3.51 billion in benefits and $.9 billion in costs over the next 30 years.
Energy Conservation Standards for Water Heaters.	DOE	680	510	Benefits and costs are estimated by amortizing the estimated present value of $8.6 billion in benefits and $6.4 billion in costs over the next 30 years.
Energy Conservation Standards for Clothes Washers.	DOE	2,150	940	Benefits and costs are estimated by amortizing the estimated present value of $27.2 billion in benefits and $11.9 billion in costs over the next 30 years.
Health Insurance Reform: Standards for Electric Transactions.	HHS	2,720	700	Benefits are estimated by annualizing the $19.1 billion present value of benefits estimated to accrue in the next 10 years. Costs are estimated by assuming that the estimated $7 billion of costs occur evenly over the next 10 years.
Safe and Sanitary Processing and Importing of Juice.	HHS	150	30	Benefits above are identical to what is listed in Table 7; the costs are estimated as $23 million per year with an up-front costs of $44–$55 million in the first year. The first year costs are amortized over the next 30 years.
Standards for Privacy of Individually Identifiable Health Information.	HHS	2,700	1,680	Amortized the net present value of benefits and costs of $19 billion and $11.8 billion respectively.
Labeling of Shell Eggs	HHS	261	15	Benefits above are identical to what is listed in Table 7; the costs are estimated as $10 million per year with an up-front costs of $56 million in the first year. The first year costs are amortized over the next 30 years.
Safety Standards for Steel Erection.	DOL	167	78	Benefits are estimated at 22 fatalities averted and 1,142 injuries averted per year. Each fatality averted is valued at $5 million, and each injury averted is valued at $50,000. Costs are what was estimated by the agency.
Advanced Airbags	DOT	140–1,600	400–2000	Based on methodology in NHTSA's ''The Economic Cost of Motor Vehicle Crashes, 1994.''
Identification of Dangerous Levels of Lead.	EPA	1,750–6,840	2,700	Calculated by amortizing the estimated present value of benefits of $45–$176 billion as well as the estimated present value of benefits of $70 billion using a discount rate of 3%, a rate explicitly specified the EPA in this rule.
Arsenic and Clarifications	EPA	140–198	206	Both costs and benefits taken directly from Table 7.

TABLE 14.—ESTIMATE OF BENEFITS AND COSTS OF 19 MAJOR RULES, APRIL 1, 1999 TO SEPTEMBER 30, 2001—Continued

[Annualized 2001 dollars in millions]

Regulation	Agency	Benefits	Costs	Explanation
National Emission Standards for Hazardous Air Pollutants for Chemical Recovery.	EPA	293–393	32	Both costs and benefits taken directly from Table 7.
Heavy-Duty Engine and Vehicle Standards.	EPA	13,000	2,400	We estimated the present value of the stream of costs and benefits generated until 2030, deflated the present value to 2001$'s, and then annualized the streams.
Total		24,435–31,139	9,965–11,565	

Note: Assumptions: 7% discount rate unless another rate explicitly identified by the agency. For DOL: $5 million VSL assumed for deaths averted when not already quantified. Injuries averted valued at 50,000 both of the above from Viscusi. All values converted to 2001 dollars. All costs and benefits stated on a yearly basis.

Appendix E.

TABLE 15.—REGULATIONS REVIEWED BY AGENCY, 1998—2001

	Total	2001	2000	1999	1998
USDA:					
S	225	53	56	69	47
ES	46	8	24	10	4
HHS:					
S	334	66	89	88	91
ES	101	28	26	22	25
EPA:					
S	201	52	51	42	56
ES	56	9	18	15	14
DOT:					
S	129	48	29	26	26
ES	38	14	7	8	9
DOC:					
S	139	20	47	46	26
ES	11	2	4	4	1
DOI:					
S	142	32	63	28	19
ES	16	3	6	4	3
ED:					
S	58	9	29	23	6
ES	1	0	0	1	0
HUD:					
S	126	35	29	36	26
ES	6	0	2	3	1
VA:					
S	113	68	12	20	13
ES	5	4	1	0	0
DOJ:					
S	108	39	29	13	27
ES	4	2	0	1	1
OPM:					
S	121	32	37	28	24
ES	0	0	0	0	0
Sum:					
S	1,696	445	471	419	361
ES	284	70	88	68	58

*Data are all for years beginning 2/1 and extending through 1/31 the next year.
S = Significant rulemaking.
ES = Economically significant rulemaking.

Appendix F. The "Regulatory Right-to-Know Act" [38]

SEC. 624. (a) IN GENERAL.—For calendar year 2002 and each year thereafter, the Director of the Office of Management and Budget shall prepare and submit to Congress, with the budget submitted under section 1105 of title 31, United States Code, an accounting statement and associated report containing—

(1) an estimate of the total annual costs and benefits (including quantifiable and nonquantifiable effects) of Federal rules and paperwork, to the extent feasible—

(A) in the aggregate;

(B) by agency and agency program; and

(C) by major rule;

(2) an analysis of impacts of Federal regulation on State, local, and tribal government, small business, wages, and economic growth; and

(3) recommendations for reform.

(b) NOTICE.—The Director of the Office of Management and Budget shall provide public notice and an opportunity to comment on the statement and report under subsection (a)

[38] Section 624 of the Treasury and General Government Appropriations Act, 2001, 31 U.S.C. 1105 note, Pub. L. 106–554, sec. 1(a)(3) [Title VI, sec. 624], Dec. 21, 2000, 114 Stat. 2763, 2763A–161.

before the statement and report are submitted to Congress.

(c) GUIDELINES.—To implement this section, the Director of the Office of Management and Budget shall issue guidelines to agencies to standardize—

(1) measures of costs and benefits; and

(2) the format of accounting statements.

(d) PEER REVIEW.—The Director of the Office of Management and Budget shall provide for independent and external peer review of the guidelines and each accounting statement and associated report under this section. Such peer review shall not be subject to the Federal Advisory Committee Act (5 U.S.C. App.).

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