Stimulating Smarter Regulation:

2002 Report to Congress on the Costs and Benefits of Regulations and Unfunded Mandates on State, Local, and Tribal Entities

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Office of Management and Budget
Office of Information and Regulatory Affairs

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EXECUTIVE SUMMARY

This Final Report to Congress on regulatory policy was prepared in response to the Regulatory Right-to-Know Act[1] and the Unfunded Mandates Reform Act[2]. The Report provides: (a) a summary of Federal regulatory actions taken due to the tragic events of September 11th and their aftermath, (b) an overview of the Office of Information and Regulatory Affairs' (OIRA) activities; (c) an accounting 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; (d) a summary of regulatory reform activities in other developed countries, with a particular focus on the European Union; and (e) a discussion of nominations of regulatory improvements from approximately 1,700 public comments. This Final Report reflects revisions made to a Draft Report that was subjected to public comment, external peer review, and interagency review.

The major features and findings of the Report include:

1. Since September 11th, OIRA has cleared 58 significant Federal regulations aimed at responding to the terrorist attacks. These rules addressed urgent matters such as homeland security, immigration control, airline safety, and the need for assistance to businesses harmed by the resulting economic disaster.

2. OIRA's goals in regulatory oversight include openness, promptness, and analytic rigor. OIRA's website has regular updates on rules under review, meetings with outside parties, and key letters and memoranda to agencies. The number of OIRA reviews consuming more than the allotted 90 days has declined from what had regularly been 15-20 rules at any given time to near zero in recent months. From July 1, 2001, to March 1, 2002, OIRA returned more than 20 rules to agencies for reconsideration, more than the total number of rules returned to agencies during the entire Clinton Administration. Inadequate analysis by agencies was the most common reason for returns. The absence of returns in recent months (March 2002 to September 2002) reflects better communication between OMB and agencies and increased quality in rulemaking packages.

3. OIRA has developed the "prompt letter" for suggesting promising regulatory and informational priorities for agency consideration. OIRA's initial six prompt letters have addressed a range of issues at five different agencies, including the use of lifesaving defibrillators in the workplace, food labeling requirements for trans-fatty acids, and better

[1]31 U.S.C. § 1105 note, Pub. L. 106-554, § 1(a) (3) [Title VI, § 624], Dec. 21, 2000, 114 Stat. 2763, 2763A-161
[2]P.L. 104-4, Title II

information regarding the environmental performance of industrial facilities. Agencies have performed independent assessments of each of these suggestions and adopted reasonable responses.

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 worked with agencies to finalize their guidelines prior to the October 1, 2002, statutory deadline. These guidelines offer a new opportunity for affected members of the public to request corrections when poor quality information is disseminated or used to justify new regulations or other policies. OMB has directed each agency to develop an administrative mechanism to resolve these requests, 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. The European Commission has recently issued an Action Plan for Better Regulation that includes expanded transparency, consultation with stakeholders, and more rigorous regulatory impact analysis.

6. OIRA examined major Federal regulations cleared from April 1, 1995 to September 30, 2001 to determine their quantifiable benefits and costs. The estimated annual benefits range from $48 billion to $102 billion, while the estimated costs range from $50 billion to $53 billion. Based on the information released in previous reports, the total costs and benefits of all Federal rules now in effect (major and non-major, including those adopted more than 10 years ago) could easily be a factor of ten or more larger than the sum of the costs and benefits reported here. More research is necessary to provide a stronger analytic foundation for comprehensive estimates of total costs and benefits by agency and program. OMB's examination of the benefits and costs of Federal regulation supports the need for a common-sense approach to modernizing Federal regulation that involves the expansion, modification, and rescission of regulatory programs, as appropriate.

7. In response to an open, invitational process of regulatory reform proposals, OIRA received public suggestions on 316 regulations and guidance documents covering 26 Federal agencies. This number of public nominations is over four times larger than the 71 nominations received in 2001 and covers a broader range of topics. This year's commenters are also more diverse in organizational affiliation. As requested, this year's public reform nominations include suggestions to review existing paperwork requirements and guidance documents, as well as to add, modify, or rescind regulations. This report provides a summary of these nominations and describes a review process in which agencies should consider the nominations and identify those that are worthy reforms. This year's review process is different from last year's process, when OIRA identified high priority reform candidates. Rather than suggest any specific agency priorities, OIRA is forwarding all of the public's suggestions, with the expectation that agencies will make decisions about which, if any, reforms to pursue based on their assessment of the prospects and practicality of achieving regulatory improvements.

8. The Bush Administration is concerned about unfunded mandates that impact State and local governments. The scope of consultation activities undertaken by Federal agencies such as Agriculture and Justice demonstrate the Bush Administration's commitment to building strong relationships with our governmental partners. Federal agencies are now actively consulting with States, localities, and tribal governments.

9. Small businesses play a vital role in creating jobs and stimulating growth despite their disproportionate share of regulatory costs and burdens. The report contains numerous constructive suggestions on how agencies can reduce unnecessary regulations and paperwork requirements that impose especially large burdens on small business.

OMB has already begun to prepare the 2003 Report to Congress on the Costs and Benefits of Regulation. Our objective is to publish the draft 2003 Report to Congress with the new Federal budget, thereby starting earlier the annual processes of public comment, external peer review, and interagency review.

PART 1: Report to Congress on the Costs and Benefits of Federal Regulations

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—in addition to spending and taxing—used to implement policy. It is used to advance numerous public objectives, including homeland security, environmental protection, food safety, transportation safety, quality health care, equal employment opportunity, energy security, educational quality, immigration control and consumer protection. Yet, regulation also is costly. The exact cost of regulation is uncertain, but the total cost is large—yet often hidden—from public view. To the extent regulation increases the cost of producing goods and services in the economy, it raises prices to the consumer. In addition to diminishing the purchasing power of consumers, regulation can create potential competitive problems for U.S. firms in a global economy, exacerbate fiscal challenges to State and local governments, and place small businesses, jobs, and wages at risk.

Regulatory policy does not lend itself to simple answers. The underlying scientific and economic issues often are complex. There may be difficult tradeoffs between laudable social objectives. 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 striving for a regulatory process that adopts new rules when necessary to serve the public interest, simplifies and modifies existing rules to make them more effective and/or less costly or less 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 by President Clinton in 1993.[3]

The regulatory process improvements described below, while generally procedural in nature, promise to have a powerful positive long term 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 year's annual report to Congress, the first regulatory action taken by the Bush Administration was the issuance of the "Card Memorandum," a January 20, 2001

[3]Regulatory Planning and Review, September 30, 1993 (58 FR 51735, October 4, 1993), as amended, E.O. 13258, Amending Executive Order 12866 on Regulatory Planning and Review, February 26, 2002 (67 FR 9385, February 28, 2002).

directive from the President's Chief of Staff, Andrew H. Card, Jr., to agency heads. The memorandum directed the agencies 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 the review called for in the Card memo, and by a subsequent OMB memorandum to agencies. In Appendix A of this report, we provide an update of these actions.

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. Several agencies, including the Departments of Justice, Transportation, Labor, Health and Human Services, Commerce, the Office of Personnel Management, the Small Business Administration, and the Office of Management and Budget issued new regulations. In the year following September 11th, Federal agencies issued 58 significant new regulations in response to the attacks (see Table 1).

Table 1. Regulations Responding to the Terrorist Attacks of September 11, 2001
(As of September 11, 2002.)

Agency	Title	Rulemaking Stage
DOC	India and Pakistan: Lifting of Sanctions, Removal of Indian and Pakistani Entities, and Revision in License Review Policy	Final Rule
DOJ	National Security: Prevention of Acts of Violence and Terrorism	Interim Final Rule
DOJ	September 11th Victim Compensation Fund of 2001	Prerule
DOJ	September 11th Victim Compensation Fund of 2001	Interim Final Rule
DOJ	September 11th Victim Compensation Fund of 2001	Final Rule
DOJ	Screening of Aliens and Other Designated Individuals Seeking Flight Training	Interim Final Rule
DOJ	Screening of Aliens and Other Designated Individuals Seeking Flight Training	Proposed Rule
DOJ/INS	Custody Procedures	Interim Final Rule
DOJ/INS	Review of Custody Determinations	Interim Final Rule
DOJ/INS	Limiting the Period of Admission for B Nonimmigrant Aliens (Section 610 Review)	Proposed Rule
DOJ/INS	Requiring Change of Status from B to F-1 or M-1 Nonimmigrant Prior to Pursuing a Course of Study	Interim Final Rule
DOJ/INS	Requiring Aliens Ordered Removed from the United States to Surrender to the INS for Removal	Proposed Rule
DOJ/INS	Retention and Reporting of Information for F, J, and M Nonimmigrants; SEVIS	Proposed Rule
DOJ/INS	Release of Information Regarding INS Detainees in Non-Federal Facilities	Interim Final Rule
DOJ/INS	Registration and Monitoring of Certain Nonimmigrants	Proposed Rule

Table 1. Regulations Responding to the Terrorist Attacks of September 11, 2001 (As of September 11, 2002.)		
Agency	**Title**	**Rulemaking Stage**
DOJ/INS	Allowing Eligible Schools to Apply for Preliminary Enrollment in the Student and Exchange Visitor Information System (SEVIS)	Interim Final Rule
DOJ/INS	Registration and Monitoring of Certain Nonimmigrants	Final Rule
DOJ/INS	Reduced Course Load for Certain F and M Nonimmigrant Students in Border Communities	Interim Final Rule
DOJ	Protective Orders in Immigration Administrative Proceedings	Interim Final Rule
DOL	Disaster Unemployment Assistance Program Amendment	Interim Final Rule
DOT/FAA	Screening of Checked Baggage on Flights within the U.S.	Final Rule
DOT/FAA	Aircraft Security under General Operating and Flights Rules	Final Rule
DOT/FAA	Flight Crew Compartment Access and Door Designer	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/FRA	U.S. Locations Requirement for Dispatching of United States Rail Operations	Interim Final Rule
DOT	Procedures for Compensation of Air Carriers (Emergency Rule)	Final Rule
DOT	Procedures for Compensation of Air Carriers	Final Rule
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/TSA	Private Charter Security Rules	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 Airports, On-Airport Parking Lots and Vendors of On-Airfield Direct Services to Air Carriers for Security Mandates	NPRM
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/SAMSA	Substance Abuse and Mental Health Services Administration Mental Health and Substance 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

Table 1. Regulations Responding to the Terrorist Attacks of September 11, 2001 (As of September 11, 2002.)		
Agency	**Title**	**Rulemaking Stage**
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; Economic Injury Disaster Loan Program	Interim Final Rule
SBA	Small Business Size Standards; Travel Agencies	Interim Final Rule
SBA	Small Business Size Standards; Travel Agencies; Economic Injury Disaster Loan Program	Final Rule (N/C)
Treasury/FinCEN	Amendment to the Bank Secrecy Act Regulations	Interim Final Rule
Treasury/FinCEN	Proposed Amendment to the Bank Secrecy Act Regulations	NPRM
Treasury/FinCEN	Cooperative Efforts to Deter Terrorist Financing and Money Laundering	Temporary Rule and NPRM
Treasury	Counter Money Laundering Requirements -- Correspondent Accounts with Foreign Shell Banks; Recordkeeping Related to Foreign Banks with Correspondent Accounts	Temporary Rule and NPRM
Treasury/IRS	Special Form 720 Filing Rule	Final Rule without NPRM
Treasury and Banking Agencies**	Identity Verification Program	NPRM
VA	Exceptions to Definition of Date of Receipt Based on Special or Unforeseen Circumstances	Final Rule

*Transportation Security Agency
** 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 rules related to September 11th 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 and businesses affected by the attacks.

Protecting National Security

The Department of Justice promulgated several rules that addressed the need for heightened security at home. One new Justice rule involved the monitoring of communications between 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 (INS) issued rules signaling the need for tighter security when handling aliens. 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. Other immigration rules issued seek to provide the INS with greater control of the flow of and greater information regarding nonimmigrant aliens in and out of the United States.

Within the Department of Transportation, the Federal Aviation Administration (FAA) and the Transportation Security Administration issued over a dozen rules in three key areas: flight-deck security requirements, background checks, and flight rules. In order to improve security on aircrafts, the FAA issued a series of rules to facilitate the strengthening of 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, in order 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 the other two categories of rules, the FAA promulgated several regulations regarding criminal history background checks, security procedures and screening of passengers, and screening of checked baggage.

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

Post-Attack Assistance

The second category of rules promulgated seeks to provide assistance to individuals and businesses affected by the September 11th attacks. 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) that 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 these individuals. This regulation established procedural rules for administration of the Victims Compensation Fund.

FAA issued a rule that set forth procedures for the allocation of approximately $5 billion in compensation to air carriers affected by the events of September 11th. 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 (OPM) 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. 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.

The Federal government has sought, since the events of September 11th, to address the need for heightened national security in addition to assistance for disaster victims. Regulatory action summarized above occurred in the months soon after the attacks, allowing for solutions to be implemented expeditiously. Coordination of the Federal government is necessary to ensure consistency, efficiency, and effectiveness in our efforts to protect the nation's security.

Response to Public Comment[4]

One commenter (79) expressed concern that some of the rules responding to the events of September 11th may have been adopted under duress, and that these rules therefore deserve special priority for *ex post* review to make sure they are economically reasonable. Another commenter (85) requested more information on the economic impact of anti-terrorism rules. Since many of these rules were not judged to be "economically significant" (e.g., costing the economy more than $100 million per year), agencies did not support them with a formal regulatory impact analysis described in Executive Order 12866. OIRA reviewed these 58 rules carefully but will be open in future years to public nominations of one or more of these rules for review.

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 based on professional analysis. Although some critics perceive OIRA as a mysterious organization, the long-term, cumulative impact of the steps described below should help demystify the process of regulatory oversight.

[4]Numbers in parenthesis identify the commenters. Appendix B contains the key to their identity. Identical commenters (about 1,500) are not listed separately.

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/oira_disclosure_memo-b.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 in the public docket room. We also invite the relevant agency to the meetings with outside parties, and we file any documents submitted at E.O. 12866 meetings in our docket room, with copies provided to the agency. Substantive phone calls on rules under review are logged and disclosed as described under E.O. 12866.

- Under the E.O. 12866 disclosure procedures, we are posting on the OIRA website information about 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.[5]

- 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 letters," "return letters," 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 during 2001 on matters of general regulatory policy or specific rules.

- OIRA has initiated a multi-year process to place OIRA at the forefront of the Administration's E-government initiative. When fully implemented, OIRA's electronic system will permit outside parties ready access to the information now contained only in OIRA's public 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. Indeed, explicitness about the grounds for regulatory decision making will in some cases sharpen public controversy by making differences of opinion more apparent. Thus, OIRA does not regard absence of public controversy as a measure of success of regulatory oversight. Indeed, OIRA hopes a full debate of the

[5]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 D.C. 20503.

relative merits of regulation will strengthen regulatory oversight.

Response to Public Comments

A large number of commenters supported OIRA's more open approach to regulatory oversight, and no commenters opposed the more open approach. A variety of suggestions were made to clarify, refine or expand OIRA's policy of openness. One commenter (70) suggested that OIRA take steps to respond directly to each comment on this Report submitted by the public. Although it is not feasible for OIRA to respond to each point made in the roughly 2,000 comments that have been received, this report does respond to each major category of comments that have not caused a revision.

A number of commenters (70, 77, 79, 80, 93, and 104) urged OIRA to be more explicit in this Report about the criteria it uses to rate regulatory reforms as high, medium, or low priority. OIRA has decided, however, to use an agency-initiated process for identifying regulatory reform candidates, so we are not rating nominations as we did last year. As described in Chapter 4, OIRA has developed criteria to help guide agency consideration of potential reforms.

One commenter (77) expressed concern that OIRA's policy of early analytic involvement with agencies, which is typically done informally, needs to be subjected to a greater degree of openness. OIRA believes that its interactions with agencies prior to formal regulatory review are pre-decisional communications that should generally be insulated from public disclosure in order to facilitate valuable deliberative exchanges.

One commenter (77) urged more transparency about what it means when OIRA clears a rule that is coded by OIRA as "consistent with change". This phrase generally indicates that the draft rule OIRA cleared differs in some manner from the original draft submitted to OIRA for formal review. OIRA cautions readers that changes from the original draft were not necessarily suggested or favored by OIRA. In fact, the cleared rule represents the decision of the rulemaking agency.

One commenter (93) expressed concern that OIRA does not publicly disclose meetings with outside parties that occur at times when a matter is not under formal or informal OIRA review. OIRA's non-disclosure practice in this regard is consistent with E.O. 12866. The same commenter expressed concern that, in the meetings with outside parties that OIRA discloses on OMB's website, some of the attorneys present are listed with respect to their law firm affiliation rather than the client they represent. OIRA believes that this point has merit. Thus, OIRA staff have been instructed to request that attorneys participating in future E.O. meetings indicate, where applicable, the client they are representing.

One commenter (73), while supporting OIRA's new policy of openness, cautioned that a policy of openness can be taken too far, thereby inducing and exacerbating public disagreements between officials within the executive branch. OIRA agrees that a balance needs to be struck in order to foster valuable deliberative communications among executive branch agencies.

C. Gatekeeper for New Rulemakings

Presidential Executive Order 12866 provides OIRA with substantial authority to review rulemaking proposals from agencies. An average of 600 significant rulemaking actions were approved per year from 1993 to 2000. During the period of 1997 to 2000, OIRA did not return any rules to agencies for reconsideration. 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.

Recently, OIRA has revived the "return letter," making clear that OMB is serious about the quality of new rulemakings. From July 1, 2001 to October 15, 2002, there were 22 significant rulemakings returned to agencies for reconsideration. As the data in Table 2 illustrate, this represents a significant rate of return when measured against OIRA's 20-year history.

Table 2. Executive Order Reviews and Returns 1981 – 2001

Year	Total Reviews	Returns	Percent
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%
Total	**35,111**	**414**	**1.2%**

The technical and policy rationales for OIRA's returns are stated in letters to agency officials that are made public and posted on OIRA's website. In ten cases, after modifications and later submission for review under E.O. 12866, OIRA approved the rule. Table 3 provides the status of the rules that OIRA has returned to agencies.

Table 3. Status of Draft Rules Returned for Reconsideration as of 10/8/02

Agency	Rule	Returned	Resubmitted	OMB Review Ended
USDA	Environment Enhancement for Nonhuman Primates	1/29/02	Not Resubmitted	–
HUD	Public Housing Capital Fund Program	11/21/01	Not Resubmitted	–
HUD	Establishment of a Demonstration Risk-Sharing Program	9/26/01	Not Resubmitted	–
DOT	Tire Pressure Monitoring Systems	2/12/02	5/28/02	5/29/02
DOT	U.S. Locational Requirement for Dispatching the U.S. Rail Operations	9/20/01	11/13/01	11/20/01
DOT	Digital Flight Data Recorder Regulations	9/14/01	Not Resubmitted	–
DOT	Corrosion Prevention and Control Program	9/14/01	6/18/02	9/16/02
DOT	Aging Aircraft Safety	9/14/01	6/18/02	9/24/02
DOT	Certification of Pilots, Aircraft, and Repairmen for Light Sport Aircraft	8/8/01	12/17/01	1/3/02
DOT	Safety Requirements for External Product Piping on Cargo Tanks Transporting Flammable Liquid	8/8/01	Not Resubmitted	–
DOT	Part 145 Review: Repair Stations	7/20/01	7/20/01	7/30/01
VA	Evidence of Permanent and Total Disability	9/14/01	Not Resubmitted	–
VA	Medical Care and Treatment for which VA Will Not Seek Reimbursement	10/3/01	Not Resubmitted	–
VA	Exclusions from Income	11/28/01	Not Resubmitted	–
VA	Availability of Vendee Financing for VA-Acquired Properties	10/8/02	Not Resubmitted	–
EPA	Water Quality Standards for Indian County	10/2/01	Not Resubmitted	–

Table 3. Status of Draft Rules Returned for Reconsideration as of 10/8/02				
Agency	**Rule**	**Returned**	**Resubmitted**	**OMB Review Ended**
SBA	Small Business Size Standards: Economic Injury Disaster Loan Payment	2/11/02	5/15/02	5/23/02
SSA	Clarification of Rules	9/27/01	4/3/02	5/28/02
SSA	Filing Claims under the Federal Tort Claims Act and the Military Personnel and Civilian Employees Claims Act	9/27/01	Not Resubmitted	–
SSA	Revised Medical Criteria for Evaluating Hematologic Disorders and Malignant Neoplastic Diseases	9/27/01	11/9/01	11/14/01
SSA	Representative Payment Under the Title II and Title XVI of the Social Security Act	9/27/01	Not Resubmitted	–
SSA	Ticket to Work and Self-Sufficiency Program	11/15/01	11/20/01	12/17/01

The quality of regulatory packages seems to be improving, as reflected in the recent decline in the number of returns (i.e., only one return since February 2002). More importantly, there is earlier interaction between OIRA and agency staffs during 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 the quality of regulatory analyses and the substance of rules. For example, OIRA and EPA recently announced an initiative to fashion jointly a major rule to reduce pollution from off-road diesel engines used in mining, agriculture, construction and airport service.

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 seven 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 (RIA) for rulemaking actions deemed economically significant. This analysis should include an assessment of benefits and costs (quantitative and qualitative) and a rigorous analysis of potentially effective and reasonably feasible 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.[6] 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 such information in this annual report to Congress on the costs and benefits of regulation.

- Third, for draft regulatory actions that are supported by influential risk assessments of health, safety and environmental hazards, OIRA recommends that agencies adopt or adapt the basic informational quality and dissemination standards that Congress adopted in the Safe Drinking Water Act Amendments of 1996.[7] These standards were recently included in OMB's government-wide guidelines on information quality.[8]

- Fourth, 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,[9] 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.

- Fifth, under the Regulatory Flexibility Act, as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA),[10] OIRA ensures 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 for an appropriate analysis of small business impacts, 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 significant economic impacts on a substantial number of small entities, OIRA staff participate in Small Business Advocacy Panels prior to publication of a rulemaking proposal. In a recent Memorandum of Understanding between OIRA and SBA Advocacy Office, OIRA pledged to return for reconsideration any rulemaking package that had not adequately considered impacts on small businesses and other small entities.[11] In addition, on August 13, 2002, President Bush issued E.O. 13272, which requires agencies to notify the Chief Council for Advocacy of any draft rules that might have a significant economic impact on a substantial number of small entities when they submit them to OIRA for E.O. 12866

[6]OMB Memorandum M-01-23, Improving Regulatory Impact Analyses, June 19, 2001.
[7]42 U.S.C. 300g-1(b)(3)(A) & (B)
[8]OMB, "Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies," (67 FR 8452, February 22, 2002).
[9]E.O., 13132, Federalism, August 4, 1999 (64 FR 43255, August 10, 1999); E.O. 13175, Consultation and Coordination with Indian Tribal Governments, November 6, 2000 (65 FR 67249, November 9, 2000),
[10]5 U.S.C. Chapter 6
[11]See http://www.whitehouse.gov/omb/inforeg/oira.pdf

review, authorized Advocacy to comment to the agency and OIRA on the draft rule, and directed agencies to give every appropriate consideration to the comments.[12]

- Sixth, under E.O. 13045, OIRA reviews proposed regulatory actions that may pose disproportionate environmental or safety risks to children.[13] 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.[14] OIRA published guidance for implementing the new energy executive order on July 13, 2001.[15]

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 4 reveals, OIRA has already made substantial progress in reducing the number of reviews that consume more than the allotted 90 days.

Table 4. E.O. 12866 Reviews Over 90 Days by Date

Month	Year	Pending Over 90 Days	Total Pending	% 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%
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	83	0.0%

[12]See http://www.sba.gov/advo/laws/eo13272.pdf
[13]See E.O. 13045, Protection of Children From Environmental Health Risks and Safety Risks, April 21, 1997.
[14]Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use, May 18, 2001 (66 FR 28355, May 22, 2001).
[15]OMB Memorandum M-01-27, Guidance for Implementing E.O. 13211, July 13, 2001.

Table 4. E.O. 12866 Reviews Over 90 Days by Date				
Month	**Year**	**Pending Over 90 Days**	**Total Pending**	**% Over 90 Days**
April	2002	0	72	0.0%
July	2002	1	73	1.4%
October	2002	0	105	0%

OIRA regards the 90-day review limit as a performance indicator for a strong regulatory gatekeeper. In previous Administrations, some 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 their draft rulemaking actions.

Response to Public Comments

Public commenters were divided as to whether OIRA's revitalized role as regulatory gatekeeper is a good or bad development. Supporters of OIRA's revitalized role welcomed the enhanced analytic discipline in the rulemaking process, particularly the renewed emphasis given to cost-benefit considerations (12, 24, 30, 32, 37, 73, 78, 79, and 85). One commenter (79) welcomed the effect that returns have had on increasing the willingness of agencies to consult with OIRA about rules under development. OIRA believes the increasing willingness of agencies to collaborate with OIRA may partly explain the absence of return letters from OIRA during the March-October 2002 period. Yet one commentator (106) cautioned that early OIRA-agency collaboration in rule development should not cause OIRA to relax its "arms-length" relationship with regulators. Several commenters (79, 85, and 104) urged OIRA to provide more information about what happens to returned rules, including agency responses and final outcomes. OIRA believes this comment has merit and is considering how to best respond to this request, beyond the information provided in this report (see Table 3). Other critics argued that OIRA's approach was confrontational with respect to agencies (70, 93), that OIRA was giving too much emphasis to cost-benefit considerations in reviewing agency submissions (70, 77, 80, 94), that returns rarely promote health and safety (77), and that OIRA may be exceeding its legal authority when it returns rules (70, 93).

E.O. 12866 provides careful and explicit authority for the return of rules to agencies for reconsideration and OIRA has been explicit about the general criteria for returns. [16] Each return has a written technical and/or policy rationale that is disclosed to the public. With various degrees of frequency, this authority to return rules has been used by OIRA and respected by agencies for more than 20 years. Of course, OIRA respects all laws relevant to a particular rulemaking. No commenter has provided any clear example where OIRA's decision to return a rule for reconsideration had violated any statute.

[16]Memorandum for the President's Management Council from John D. Graham, "Presidential Review of Agency Rulemaking by OIRA," September 20, 2001.

D. Greater Use of Formal, Independent, External Peer Review

In a September 20, 2001 memorandum to the President's Management Council, OIRA recommended that draft RIAs, including supporting technical documents (e.g., risk assessments and engineering feasibility studies) be subjected to formal, independent, external peer review. Given the growing public interest in peer review practices, OIRA recommended a four-point plan of competent and credible peer review: (a) peer reviewers should be selected primarily on the basis of necessary technical expertise; (b) peer reviewers should be expected to disclose to the agency any prior technical/policy positions they have taken on the issues at hand; (c) peer reviewers should be expected to disclose to the agency their sources of personal and institutional funding (public sector and private sector sources); and (d) peer reviews should be conducted in an open and rigorous manner.

OIRA did not require greater use of peer review. Instead, OIRA has offered each agency an extra measure of deference during OMB review if a regulatory package has been subjected to competent and credible peer review. EPA's recent decision to affirm an arsenic standard in drinking water of 10 parts per billion was supported by substantial peer review, including reports from the National Research Council of the National Academy of Sciences and the Agency's Science Advisory Board. Although this is a relatively intensive amount of peer review, OIRA expects that agencies will tailor the intensity of peer review—which can be costly and time-consuming—to the importance of the issue.

Response to Public Comments

There were numerous public comments on OIRA's encouragement of agencies to make greater use of formal, independent external peer review. One commenter (79) noted that many peer review efforts sponsored by agencies do not satisfy OIRA's four-point program of competent and credible peer review. Another commenter (37) is concerned that peer review is only valuable if agencies use the technical suggestions of peer reviewers (37). In the eyes of one commenter (106), peer review of agency science is a more promising strategy than judicial review of agency science (except for procedural matters). OIRA generally shares these views.

Several commenters (77, 93) argued that OIRA's vision of peer review does not go far enough in preventing or minimizing conflicts of interest due to commercial interests (77, 93). They argued that disclosure of potential conflicts to the agency is not sufficient; they sought disclosure of financial information and other potential conflicts to the public. If scientists have conflicts, some argue, they should be replaced by scientists who have no conflicts, assuming such expertise exists. OIRA expects that the most knowledgeable and well-respected scientists will be in the highest demand from the private and public sectors and thus are likely to have the most potential conflicts. Moreover, OIRA is concerned that some public-disclosure suggestions (e.g., those involving public disclosure of sources and amounts of personal income to scientists) might be perceived as an invasion of privacy and thereby reduce the rate of scientific participation in agency work. This area certainly deserves further consideration, and OIRA is aware that both FDA and EPA are refining their approach to selection of scientists for service on peer review panels. OIRA is also tracking the conflict-of-interest practices of leading scientific

journals and the National Research Council of the National Academy of Sciences. OIRA shares the view that more care needs to be given to addressing conflict-of-interest concerns.

Several commenters (99, 100, and 104) raised cost-benefit concerns about greater agency use of formal, independent external peer review. OIRA shares these concerns and has therefore suggested that agencies tailor the intensity of peer review to the importance of the issue. EPA has already prepared a document on different types of peer review and has considerable experience to offer in this area (99). Reviews conducted by electronic communication, for example, may be more cost-effective than multi-day meetings in Washington, DC. OIRA is also exploring whether it would be adequate, at least in some cases, to have RIAs peer-reviewed by specialists within the Federal government who do not work for the agency that has produced the RIA under review.

E. 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" to bring a policy matter to the attention of agencies.

OIRA's initial six prompt letters have addressed a range of issues at five 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 defibrillators, 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;

- 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; and

- a letter to request that the Office of Federal Housing Enterprise Oversight (OFHEO) consider a rulemaking to strengthen the corporate governance of Fannie Mae and Freddie Mac and require the two publicly traded firms to make certain public disclosures. These steps would advance the President's Ten Point Plan for Corporate Responsibility and Protecting America's Shareholders by providing better information to investors and making corporate officers more accountable. Currently, the two firms are exempt from direct SEC oversight but are within the purview of OFHEO's regulatory mission to extend generally applicable principles of governance and disclosure to them.

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 or informational 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.

Suggestions for possible prompt letters can be submitted in the public comment process leading to the publication of this annual report or faxed to the OIRA Administrator at (202) 395-3047 (note OIRA is still not receiving first-class mail). Agencies are still responding to the first six prompt letters, but the original letters and initial agency responses are posted on OIRA's website. Table 5 provides a brief summary of agency responses to the original six prompt letters and related OMB and agency follow-up activities.

Table 5. AGENCY RESPONSES TO PROMPT LETTERS

Agency	Prompt Letter Subject	Agency Response
OSHA	Promoting use of automated external defibrillators.	OSHA has issued a technical information bulletin and is contemplating further action.
FDA	Labeling for trans-fatty acids.	FDA has committed to publishing a final rule by the conclusion of calendar year 2002.

Table 5. AGENCY RESPONSES TO PROMPT LETTERS		
Agency	**Prompt Letter Subject**	**Agency Response**
EPA	Researching fine particulate matter.	OIRA will soon be meeting with EPA on this topic. No rulemaking is required.
NHTSA	Modifying its frontal occupant protection standard by establishing a high-speed, frontal offset crash test.	NHTSA plans to issue an NPRM by June 2003.
EPA	Improving the utility of the data available on the environmental performance of industrial facilities.	EPA is actively working on projects in this area. No rulemaking is required.
OFHEO	Strengthening the corporate governance of Fannie Mae and Freddie Mac	OFHEO is currently working on an NPRM.

Response to Public Comments

With some exceptions (69, 77, 93, 105), commenters were generally supportive of OIRA's innovative use of prompt letters to suggest promising regulatory and information-policy priorities to agencies. The public nature of prompt letters was particularly appreciated. Commenters submitted a variety of possible ideas for prompt letters, and we have merged these suggestions with the public nominations for regulatory reform

Another commenter (77) expressed concern about whether OIRA, by issuing prompt letters to agencies, may be usurping the priority-setting role of agencies. Yet OIRA defines prompt letters as a request for agency consideration, not a directive or dictate. Agencies are entitled to protect their priority-setting discretion by declining a request made in the form of a prompt letter from OIRA. The record shows that agencies have been careful about considering OIRA's prompt letters and making independent decisions as to whether OIRA's ideas are worth pursuing. The same commenter (77) acknowledged that an OIRA prompt letter may be appropriate as a device to accelerate a worthy rulemaking that an agency has already initiated but not completed.

Another commenter (105) suggested some possible disadvantages to the use of OMB prompt letters. The prompt might undercut (rather than assist) an agency's efforts to bring closure to a contentious issue. Moreover, a formal prompt letter may be less effective than an informal suggestion to agency officials, though such informality is less transparent.

OIRA agrees with the following cautionary remarks about prompt letters made by commenters. First, prompt letters should be used judiciously (32). Second, prompt letters should not be used if they become an invitation for agencies to propose regulations without rigorous analysis (79). Finally, there is need for a more systematic, governmentwide approach to helping agencies set wise rulemaking priorities (106).

F. Overseer of the Quality of Information and Analysis

In addition to clearing, modifying, or returning specific rulemaking proposals by agencies, OIRA also plays an important role in promoting the quality of the information used and disseminated by agencies. This includes the information posted on agency websites, 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,[17] 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, some argued that scientific information produced with Federal financial support and used to support binding agency actions was 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.

Information Quality Guidelines

In Section 515 of the Treasury and General Government Appropriations Act for Fiscal Year 2001 (Public Law 106-554; H.R. 5658), 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 guidelines in interim final form on September 28, 2001 and in final form on February 22, 2002.[18] Each Federal agency subject to the Paperwork Reduction Act, 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 programs and agencies are distributing information to the public that is of questionable quality, objectivity, usefulness and security.

The OMB guidelines direct all Federal agencies to 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 that agency practices are uneven and that insufficient thought has been devoted to assuring the objectivity of agency responses to complaints from the public.

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[17] 44 U.S.C., chapter 35.

[18] A January 3, 2002, final version was reissued in corrected form on February 22, 2002 (67 FR 8452). It is also available on our web site at <http://www.whitehouse.gov/omb/>.

Improving information quality can be costly. Therefore, it is important that the costs and benefits of better information to the public be considered. In this regard, the OMB guidelines draw an important distinction between "influential" and ordinary information. "Influential" is defined 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." OMB's government-wide guidelines subject influential information to higher quality standards than ordinary information.

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 standards.

In order to facilitate better public and scientific input into the process of information-quality improvement, OMB encouraged agencies to commission the National Research Council of the National Academy of Sciences (NAS) to undertake several workshops aimed at assisting agencies in the development of their information quality guidelines. These workshops took place in the spring of 2002 and were each attended by several hundred participants.[19] OMB also organized several interagency committees to address information quality issues that are likely to be shared by two or more Federal agencies. In a June 10, 2002, memorandum to the President's Management Council (PMC), OMB also suggested various improvements to draft agency guidelines. OMB reviewed the final information guidelines prepared by agencies prior to the effective date of October 1, 2002. As part of this review, OMB sent a memorandum to the PMC on September 5, 2002, that identified a few process issues for which cross-agency uniformity would help improve agency implementation of their guidelines.

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.

Guidelines for Regulatory Impact Analyses

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.[20] 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

[19]The workshops took place on March 21-22, 2002, and on May 30, 2002. The workshop transcripts are available on the NAS website at < http://www7.nationalacademies.org/stl/Data_Dissemination_Meeting.html> and at <http://www7.nationalacademies.org/stl/DQ_Workshop.html>.

[20]See Economic Analysis of Federal Regulations Under Executive Order 12866 ("Best Practices Guidance") (January 11, 1996).

this draft report, OMB sought comment on the particular analytic issues that should be addressed in the refinement of OMB's analytic guidelines. At a minimum, OMB-CEA will address the following issues:

- the practice of applying a 7 percent real discount rate to future costs and benefits in both intragenerational and intergenerational applications;

- the methods employed to account for latency periods between exposure to toxic agents and development of chronic diseases; the methods employed to value in monetary units reductions in the risk of premature death, illness and health impairment as well as cost-effectiveness methods that forgo monetization of health gains and instead express health benefits through metrics such as the number of quality-adjusted-life years (QALY) saved or the number of disability-adjusted life years (DALYs) saved;[21]

- 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 urged public commenters and agencies to nominate additional analytic issues for OIRA-CEA consideration. The ultimate guidance that emerges from this process will be used by OIRA when evaluating the regulatory proposals and analyses submitted by agencies.

Response to Public Comments

OIRA's growing role as promoter of information and analysis quality stimulated a wide range of comments that are difficult to summarize. The major themes are discussed below as they relate to information and analysis quality.

Information Quality

One commenter (77) expressed concern that OIRA has interpreted the information-quality statute too broadly. The commenter believes that the statute addresses only factual errors, not a general concern for the quality of data or data interpretation. OIRA has a different view. The key terms objectivity, utility and integrity—key dimensions of quality—convey an interest in information quality that goes beyond prevention and correction of factual errors. The statute emphasizes the quality of information, and does so in the context of the Paperwork

[21]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.

Reduction Act,[22] with its emphasis on ensuring the greatest possible benefit from and maximizing the utility of information created, collected, maintained, and disseminated by Federal agencies.

Another commenter (93) questioned OIRA's view that the information-quality law covers independent agencies. However, as the law directed OMB to issue its guidelines under authority provided by the Paperwork Reduction Act, OMB interpreted the information quality law to apply to those covered by the Paperwork Reduction Act.

Another commenter (37) supported OIRA's policy of expanding use of the risk assessment principles found in the Safe Drinking Water Act Amendments of 1996. However, the same commenter noted that EPA, while moving in the right direction, has been somewhat slow to implement these principles. One commenter (77) expressed concern about taking information quality principles about risk assessment, those found in the Safe Drinking Water Act Amendments, and applying them throughout the entire risk assessment process of the Federal government. OIRA believes that the OMB guidelines provide agencies with the flexibility to adapt rather than adopt the Safe Drinking Water Act principles, if adaptation is appropriate for a particular agency context.

Two commenters (12, 79) recommended that OIRA use the new information-quality guidelines as a basis for disapproval of agency information-collection requests under the Paperwork Reduction Act. OIRA believes that this suggestion has merit and will incorporate the guidelines' principles into our PRA reviews.

One commenter (106) expressed concern that information-quality challenges may spawn a new wave of litigation, thereby exacerbating the highly legalistic tendencies of the U.S. regulatory system. Another commenter (104) expressed concern that OIRA has not given adequate cost-benefit consideration to the net value of stricter information-quality requirements. OIRA believes that OMB's information quality guidelines do reflect cost-benefit considerations and are not likely to give rise to a new wave of litigation.

Several commenters (12, 77, 79, 80) stressed that OIRA should make sure that this Final Report to Congress satisfies OMB's new information-quality guidelines. OIRA has complied with the OMB guidelines in issuing this report.

Analysis Quality

There was substantial support for—and no general opposition to—the OMB-CEA initiative to refine OIRA's guidance document on regulatory analysis. However, two commenters (73, 79) expressed the view that enforcement of guidance deserved more priority than refinement of the existing OIRA guidance to agencies. OIRA agrees that refinement of guidance is not very useful if the guidance is not enforced.

[22] 44 U.S.C. Chapter 35.

One commenter (85) expressed the view that Congress should pass a law or the President should issue an executive order that requires agencies to comply with OIRA's analytic guidance to agencies. Another commenter (78) recommended that such a law be focused on independent agencies while other commentators concurred that OIRA should give more priority to independent agencies (83, 52). OIRA believes that a new legal requirement that agencies adhere to OIRA's guidance is worthy of serious consideration. The appropriate roles for peer review and OIRA review (as opposed to congressional and judicial review) of such a requirement also merit consideration.

One commenter (71) expressed support for use of both cost-effectiveness analysis (CEA) and cost-benefit analysis (CBA) in the evaluation of health and safety as well as medical programs. With regard to improving the quality of CEA, the same commenter referred to the report of analytic guidelines issued by an expert panel commissioned by the Department of Health and Human Services. A summary of the guidelines was published in the *Journal of the American Medical Association* in 1996. OIRA is reviewing that report and the larger book (Oxford University Press, 1996) upon which it is based.[23] This report recommends a standard set of analytic practices, including use of quality-adjusted life years as the standard effectiveness metric.

Several commenters (70, 77, 80, and 93) expressed opposition—on ethical, legal and/or technical grounds—to the exercise of placing monetary values on human health, safety and environmental consequences of regulations. OIRA observes that these concerns help explain why many health economists and decision scientists have supported the development of cost-effectiveness analysis as a supplement or alternative to cost-benefit analysis of health and safety regulations.

OIRA shares the views of commenters that full monetization of costs and benefits is not always necessary or recommended (104) and that decision makers need to consider carefully how much weight to give to unquantified versus quantified considerations (37). One commenter (80) made a plausible case that the Roadless Area Conservation rule is an example where the considerations that the agency has not yet been able to quantify are more important than the few costs and benefits that have been quantified.

Another commenter (100) cited references to "devastating" critiques of CBA as applied to health, safety and environmental regulation. OIRA notes that these critiques are authored primarily by legal specialists and are not published in the peer-reviewed journals where technical experts in CBA and CEA publish. Nevertheless, OIRA believes that some of these criticisms are valid and they will be addressed in OIRA's refined analytic guidance to agencies.

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[23]See Weinstein MC, Siegel JE, Gold MR, Kamlet MS, and Russell LB. Recommendations of the Panel on Cost-Effectiveness in Health and Medicine. *JAMA* 1996;276: 1253-1258 and 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.

In order to support cost-effectiveness analysis in the health arena, measures of effectiveness such as lives saved, life-years saved, quality-adjusted life years (QALYs) saved and disability-adjusted life years (DALYs) saved have been used. The principal advantage of QALYs and DALYs over the older measures is that they permit morbidity and lifesaving benefits to be combined into a single numerical index. Otherwise, the benefits of health policies in terms of reduced nonfatal illness and functional impairment cannot be considered in cost-effectiveness analysis. Commenters raised a variety of legal, ethical and technical concerns about QALY-like measures (70, 80, 82, and 99). Some commenters (37, 73) recommended use of life-years saved while QALYs are further developed, but these commenters did not address how analysts should account for reductions in non-fatal conditions and functional impairments. OIRA will address these issues in more detail in its forthcoming public comment process on OIRA's refined guidance to agencies on how to conduct regulatory analysis.

Two commenters (80, 93) expressed particular concerns about the current technical inability to place dollar values on ecological values such as wilderness protection and species diversity. Another commenter (99) noted that there is a spectrum of qualitative and quantitative information on benefits and costs of environmental policies that can inform decision makers. OIRA acknowledges that, given the current state of the art of environmental economics, some environmental values—important as they are—must be treated qualitatively or only semi-quantitatively in regulatory analysis.

The following issues were recommended for inclusion in OIRA's refined analytic guidance document:

- the role of stakeholders in supplying data, suggesting alternatives and offering criticisms in the development of RIAs (12);

- the use of formal analytic tools from decision science in RIAs, such as quantitative uncertainty analysis and value-of-information analysis (12, 71) and the use of best estimates for costs and benefits, not just ranges for uncertain figures (78);

- the standardization of analytic identification and quantification of costs and benefits (12, 24);

- the disclosure of sources of overestimation of the costs of industrial regulation, including analytic strategies to reduce overestimation or protocols to compensate for anticipated overestimation (72, 77, 80, 99);

- the role of willingness to pay versus willingness to accept in benefit estimation (77);

- the role of distributional effects and fairness considerations in RIA (106);

- more focus on the non-economic costs of regulation, such as adverse effects on human health, safety, the environment and intrusions into privacy and freedom (78);

- more focus on generic uncertainties in the application of CBA to environmental decisions, including the distinction between CBA as an information tool and CBA as a decision criterion for policy making (80, 93); and

- the analytic treatment of latency periods, the discounting of future health effects, and the valuation of effects on future generations (80, 82).

OIRA and CEA are now considering which of these issues to address in OIRA's refined analytic guidance to agencies.

G. 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 insights gleaned from the analytic tools taught in professional schools throughout the United States. OIRA's history and structure is based on this professional model. 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 6 shows, staffing at OIRA declined steadily from a peak of 90 full time equivalents (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. Some decline beginning in 1993 may have been expected by the decision to reduce the number of new Federal rules subject to the review requirements of E.O. 12866. Yet the more recent staffing declines 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. During the same twenty- year period that OIRA's staff declined by 48 percent (1981-2000), the constant dollar budgets at Federal regulatory agencies increased by 71 percent while staffing increased by ten percent. [24]

Table 6. OIRA Staff Ceiling

Fiscal Year	Full Time Equivalents Ceiling
1981	90
1982	79
1983	77
1984	80

[24]See Susan Dudley and Melinda Warren, Regulatory Response: An Analysis of the Shifting Priorities of the U.S. Budget for Fiscal Years 2002 and 2003 (Regulatory Budget Report No 24, Weidenbaum Center, Washington University in St. Louis and Mercatus Center, George Mason University (June 2002) pp. 25 and 26).

Table 6. OIRA Staff Ceiling	
Fiscal Year	**Full Time Equivalents Ceiling**
1985	75
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	55
2003	55

* Indicates a ceiling was reduced in mid-year.

The Bush Administration has reversed the 20-year decline in OIRA staffing, adding a total of eight new professionals for a total of 55 FTEs (FY 2002). Five 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.

Response to Public Comments

One commenter (70) expressed concern that OIRA staff training and experience are predominantly in economics. OIRA has always had a multidisciplinary staff and the recent hires at OIRA have further increased the diversity in OIRA's expertise mix. Yet some commenters opposed OIRA's efforts to add more science staff (74, 77, and 93). Two commenters (12, 32) expressed the view that OIRA needs more staffing resources, especially given the growing

statutory obligations that Congress has imposed on OIRA's declining resource base (73). OMB does regularly evaluate OIRA's staffing needs in relationship to the rest of OMB's needs.

H. Facilitator of 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 old 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 with limited success and have induced a questionable allocation of limited agency and OIRA resources. The Bush Administration believes that a selective review process for existing rules, pursuant to public comment and new statutory authority provided to OIRA under the Regulatory Right-to-Know Act, is the best available mechanism to facilitate review of existing rules outside of the authority under the Regulatory Flexibility Act.[25]

Last year's version of this report to Congress represented OIRA's first effort to facilitate reviews of existing rules under the new statutory authority provided to OIRA. We requested that public commenters nominate specific existing rules that should be rescinded or changed to increase net benefits by reducing costs and/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 selected 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.

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 C to this report provides updated information about what agencies are doing about these 23 regulations.

[25]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.

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). An examination of OIRA's decisionmaking process reveals no implicit or explicit intent to target environmental rules for scrutiny. In fact, 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.

Response to Public Comments

OIRA has referred to the Regulatory Right-to-Know Act as a statutory basis for eliciting public comment on recommended reforms to existing regulations. Several commenters questioned whether this statute provides this authority or whether Congress intended this particular use of the authority when the statute was adopted (77, 93). OIRA is confident that a plain reading of the statute authorizes what OIRA has done, but OIRA also notes that OMB has other executive and statutory authorities that could support an initiative to seek public comment about existing rules that need to be extended, modified or rescinded. One commenter (32) suggested that new legislation be adopted authorizing OIRA to force agencies to change existing rules. OIRA is not convinced that such legislation is necessary or appropriate at this time.

Several commenters (69, 77, and 93) questioned last year's public comment process because the Mercatus Center supplied a majority of the specific nominations for regulatory reform. OIRA believes this line of criticism is misplaced. If there was a problem in last year's comment process, it was not that the Mercatus Center was too active but that other potential commenters were silent. OIRA expanded outreach considerably this year, and we are pleased that the number of commenters has exploded from 33 last year to roughly 1,700 this year. The organizational affiliations of the commenters and the topics of the reform nominations are also quite diverse.

Several commenters suggested that OIRA's discussion of regulatory reform go beyond improvement of specific regulations and include overarching reforms of the current system. Suggestions for consideration include enactment of a formal regulatory budget, better use of the annual Federal Regulatory Plan to analyze regulatory priorities (106), creation of task forces to analyze the impacts of multiple rules on a specific sector of the economy (106), and replacement of formal notice-and-comment procedures with participation mechanisms that promote citizen dialogue and cooperation (106). OIRA is considering whether to seek public comment on broad-based regulatory reforms.

I. Formation of a Scientific Advisory Panel to OIRA

OIRA considered forming a scientific advisory panel to 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 envisioned that the panel would be comprised of academics with specialized expertise in economics, administrative law, regulatory analysis, risk assessment, engineering, statistics, and health and medical science. The composition and formation of the panel would have complied 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. For a variety of reasons, some mentioned in the comments and some related to limited resources, OIRA has decided not to proceed with a formal Scientific Advisory Panel at this time.

Response to Public Comments

Although several commenters endorsed the idea of a Scientific Advisory Panel to OIRA (12, 106), concerns were also raised (99) and there was opposition to the idea (74, 77). OIRA believes that its extensive use of public comment and expert peer review on this Report will provide OIRA with adequate input from the relevant scientific and technical communities.

J. Agency Compliance with the Unfunded Mandates Reform Act

In the 2001 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. This year's report contains information on the extent of consultations with State, local, and tribal governments through September 2001. The results of this work appear along with a discussion of any rules that imposed an unfunded mandate (defined in the Act as expenditures of $100 million or greater) between May 2001 and October 2001 in part 2 of this report.

As noted in last year's report, many of our intergovernmental partners felt that they were 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 invited public comment on these issues. The comments we received from states and localities on specific suggestions for regulatory reforms are discussed in Chapter 4.

K. 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 Appendix D, 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,"[26] 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.[27]

This chapter presents the accounting statement. It revises the benefit-cost estimates in last year's report by updating the estimates to the end of fiscal year 2001 (September 30, 2001). Since last year, 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 update our estimates to 2001 dollars from the 1996 dollars used in the four previous reports. Third, we revise our estimates (and the discussion of estimates) based on the public comments and peer reviews received on the draft report published on March 28, 2002. All of the estimates presented in this chapter are based on agency information or transparent modifications of agency information performed by OIRA.

A. Estimates of the Total Costs and Benefits of Regulations Reviewed by OMB[28]

Table 7 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.[29] We reviewed 118 final major rules over that period. Of the 118 rules, 72 implemented Federal budgetary programs, which caused income transfers from one group to another, and 46 imposed mandates on State and local entities or the private sector.[30] Of these 46 "social regulations," we are able to present estimates of both

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[26]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).

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

[28]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>.

[29]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 E.

[30]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.

monetized costs and benefits for 20 rules.[31] Seven agencies issued major regulations adding from $33 billion to $54 billion annual benefits and from $16 billion to $19 billion annual costs over the 30-month period. About 75 percent of the benefits and 65 percent of the costs were attributed to the actions of one agency: EPA.

Table 8 presents estimates for six-and-a-half years by expanding the period covered by Table 7 by four years to April 1, 1995, the first year that OMB began to accumulate this information.[32] Table 8 contains an estimate of the total costs and benefits of all regulations reviewed by OMB over this period that met two conditions. Each rule generated costs or benefits of at least $100 million annually and its costs and benefits were quantified and monetized by the agency or, in some cases, by OMB. The estimates are therefore not a complete accounting of all the costs and benefits of all regulations issued by the Federal government during this period.

Based on the information released in previous reports, the total costs and benefits of all Federal rules now in effect (major and non-major, including those adopted more than 10 years ago) could easily be a factor of ten or more larger than the sum of the costs and benefits reported in Table 8. More research is necessary to provide a stronger analytic foundation for comprehensive estimates of total costs and benefits by agency and program. OMB's examination of the benefits and costs of Federal regulation supports the need for a common-sense approach to modernizing Federal regulation that involves the expansion, modification, and rescission of regulatory programs, as appropriate.

Response to Public Comments on Estimates for Major Rules (April 1, 1995 to September 30, 2001)

Several commenters questioned the quality, completeness, and transparency of these estimates (70, 79, 80, 93, 99, and 104). Some commenters stated that cost-benefit analysis is inherently biased because costs are systematically overstated and benefits undervalued (70, 80). OMB believes that both benefit and costs estimates are subject to unknown biases. OMB's guidelines are dedicated to reducing biases through promotion of consistent and well-grounded practices. A key provision of the Regulatory Right-to-Know Act authorizes OMB to issue guidelines to agencies to standardize measures of costs and benefits. Elsewhere in this report we describe our efforts to improve the quality of information, including information about the costs and benefits of regulations.

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[31]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 E. The 26 rules that we did not include are rules that did not have monetized estimates for either costs or benefits or both.

[32]Table 8 is the sum of Table 7 in this report and Table 5 from the 2000 report (OMB 2000) after converting to 2001 dollars and excluding four regulations to prevent double counting: emission standards for heavy duty engines, voluntary standards for light-duty vehicles, and the NAAQS ozone and particulate matter rules. The reasons for excluding the four rules are explained in Appendix E. The calculations for Tables 5 and 6 from the draft report are explained in Appendix E and in previous reports. Two other rules reviewed by OMB are not included: OSHA's ergonomics rule that was overturned by Congress under the Congressional Review Act and FDA's tobacco rule that was overturned by the Supreme Court.

Other commenters pointed out that the cost and benefit estimates present only a partial picture of the impact of Federal regulations over this period (73, 78, 104). This is correct. We have added further explanation and disclaimers to the text and tables to make this clear. Table 8 is based on the 67 major regulations (1995-2001) for which the agencies and OMB had sufficient information on both costs and benefit to enable us to present dollar estimates. These 67 regulations are about half of the major social regulations and about four percent of the total final regulations that OMB reviewed over this six-and-one-half-year period. In addition, not all of the costs and benefits of the 67 regulations could be quantified and monetized. OMB does not review regulations of the independent agencies or any regulations that are not determined to be "significant" under the E.O. 12866 definition. These 67 regulations make up only one percent of all final regulations issued during the last six years. OMB believes that major (economically significant) rules account for the vast majority of the total costs of Federal regulation, even though most Federal rules are not considered major.

Finally, some commenters criticized the tables because of the difficulty of reproducing them (99, 104). Part of the problem is that the discussions of the calculations for the 67 regulations are contained in five OMB reports issued since 1997. Most of the input data were extracted from the 67 individual regulatory impact analyses produced by the agencies and reviewed by OMB. The five OMB reports, which are all on our website, provide the necessary information to reproduce our calculations. The 67 RIAs issued over the last six-and-a-half years are more difficult to access, because they must be obtained from numerous Federal agencies, but they are all publicly available documents. Looking forward, we intend to work with agencies to make more RIAs readily available over the Internet.

Table 7: Estimates of the Annual Costs and Benefits of Major Federal Rules, April 1, 1999 to September 30, 2001
(millions of 2001 dollars)

Agency	Costs	Benefits
Agriculture	814	< 1
Energy	1,520	3,110
Health &Human Services	2,400	5,792
Housing & Urban Development	150	190
Labor	78	167
Transportation	400 to 2,000	140 to 1,600
Environmental Protection Agency	11,380 to 12,812	25,338 to 56,141
Total	**16,744 to 19,774**	**34,737 to 67,000**

Table 8: Estimates of the Annual Costs and Benefits of Major Federal 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
Education	362 to 610	655 to 814
Energy	1,836	3,991 to 4,059
Health &Human Services	2,988 to 3,067	8,165 to 9,182
Housing & Urban Development	150	190
Labor	361	1,173 to 3,557
Transportation	1,756 to 3,808	2,400 to 4,312
Environmental Protection Agency	40,683 to 41,356	28,540 to 73,892
Total	**50,385 to 53,459**	**48,052 to 101,975**

In Appendix C of the draft report, published in the *Federal Register* on March 28, 2002, we provided revised estimates of the costs and benefits of social regulation (health, safety and environmental regulation) in the aggregate and by agency as of September 30, 2001.[33] We also included estimates of the aggregate costs of economic and process regulation in Appendix C.[34] We included 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 draft report for earlier regulations were 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 costs and benefits today are unknown.

Response to Public Comments on Aggregate Estimates

Our decision to de-emphasize older (pre-1995) benefit-cost information struck a responsive cord with commenters. The majority of comments from differing perspectives that opined on this change agreed that the differences in the quality of the data merited different treatment (12, 72, 77, 79, 80, 82, 85, 93, 99, and 104). One commenter, a peer reviewer (85), described our change this way: "OMB dramatically changed its approach to estimating the aggregate costs and benefits of regulation in this report. Instead of combining estimates from other published work, it relied on its own database of regulations from April 1, 1995 through September 30, 2001." The commenter than expressed the opinion: "We think this approach is preferable for OMB. … This simplified and less ambitious handling of aggregates makes the

[33]We calculated these estimates by adding the estimates in Table 7 above to Table 5 of the 2000 OMB report and updating Table 4's 1996 dollars to 2001 dollars using the Consumer Price Index.

[34]Economic regulation restricts the price or quantity of a product or service that firms produce and/or restrict whether firms can enter or exit specific industries. Process regulations impose paperwork burdens on the public by establishing and verifying conditions for participation in government programs or payment of taxes.

information in this year's report more credible and useful." Other commenters went further. Another peer reviewer (104) stated: "In spite of its breadth and imagination, however, the technical analysis and quantitative aggregations on the draft report are generally of poor quality and in my view do not meet the standards for publication in the peer reviewed journals with which I am familiar." Our accounting statement in this final report is responsive to such concerns.

Several commenters expressed the opinion that the aggregate estimates in the draft report would not meet OMB's data quality guidelines for reproducibility and transparency (12, 79, 80, 93, and 99) but recommended different courses of action. One suggested we should attempt to improve our efforts at consistency and standardization (12), others that we should provide strong disclaimers in all of the tables (79, 104) and still others that we should not report aggregate estimates based on existing inadequate studies (72, 77, 80, 93). One commenter, an agency (99), suggested that OMB's estimates in the draft report differed from its own estimates and do not meet OMB's data quality guidelines.

Part of the reproducibility and transparency problem with the aggregate estimates reported in the draft report is that this is the fifth report in a series that builds on the estimates in the previous reports. One needs all five volumes to trace back the estimates to the original underlying studies. A second part of the problem, as the draft and previous four reports point out, is that many of the underlying studies are old and may no longer be reliable indicators of today's regulatory costs and benefits.

A researcher in the field (82) pointed out that aggregate estimates are not the simple sum of individual estimates and that major distortions can occur when estimates are simply added together. A basic assumption of economic analysis is that the changes analyzed must be marginal (small)—relative to average household income—for the estimates to have economic validity. For example, benefit estimates are based on the willingness of households to pay for the policy changes. Yet the "willingness" is constrained by a household's ability to pay. Table 13 in the draft report indicates that the benefits of social regulation may be as high as $2 trillion, which is about $20,000 per household. This implies that the average household is willing and able to pay—every year—about half of its after-tax income for health, safety and environmental regulation--an implausible implication.[35] On the other hand several commenters urged us to keep and improve our aggregate estimates (73, 107). They emphasized the importance of understanding the magnitude of the costs and benefits of regulations for the overall conduct of economic policy. We find both viewpoints about the value of these estimates to be persuasive.

In our future annual reports, we plan to improve the estimates by focusing on the last ten years of major Federal regulations. We plan to expand the number of years covered by our estimates of the costs and benefits of major rules to ten from the six-and-a-half currently included in Table 8. We do not believe that the estimates of the costs and benefits of regulations issued over ten years ago are reliable or very useful for informing current policy decisions.

[35]Data are from page 435 of the *Statistical Abstract of the United States*: 2001.

Some observers see a complete "accounting statement"—one that includes all existing rules on the books—as a necessary condition for enactment of a "regulatory budget." The idea is that Congress might be expected to authorize each year a total regulatory budget, much like Congress now passes an appropriation for an agency's "on-budget" expenses. Although the idea of a regulatory budget is worthy of consideration, we do not believe that a complete accounting statement is necessary to move forward with the idea. A regulatory budget need only be incremental to the current baseline. One does not need to know full costs and benefits of all regulations to decide that regulatory costs should be held to an increase (or decrease) of a specified amount over the next year. In fact, most Federal budgeting is incremental in nature.

In keeping with the spirit of OMB's new information-quality guidelines, we have decided not to reproduce the aggregate estimates that were contained in Appendix C of the draft report. As suggested, we have also moved the analysis of the impacts of Federal regulation on State, local, and tribal governments, small business, wages, and economic growth that was in Appendix C of the draft report into this chapter, as presented below.

B. Impacts of Federal Regulations

Sec. 638 (a)(2) of the Regulatory Right-to-Know 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. We summarize the limited additional information that has become available since publication of last year's report.

Impacts on State, Local, and Tribal Governments

Over the past six years, six rules have imposed costs of more than $100 million per year on State, local, and tribal governments (and thus have been classified as public sector mandates under the Unfunded Mandates Act of 1995).[36] The Environmental Protection Agency issued all five of these rules, which are described in some 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 combustion capacities greater than 35 mega grams per day (Mg/day) (approximately 40 tons per day) of municipal solid waste (MSW). The EPA standards require sources to achieve the maximum degree of reduction in emissions of air pollutants that the Administrator

[36]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 of 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 primary air quality standards are health-based and EPA is not to consider costs.

determined is achievable, taking into consideration the cost of achieving such emissions reduction, and any non-air quality health and environmental impacts and energy requirements.

EPA estimated the annualized costs of the emissions standards and guidelines to be $320 million per year (in constant 1990 dollars) over existing regulations. While EPA estimated the cost of such standards for new sources to be $43 million per year, the cost existing sources was $277 million per year. The annual emissions reductions achieved through this regulatory action include, for example, 21,000 Mg. of sulfur dioxide; 2,800 Mg. of particulate matter (PM); 19,200 Mg of nitrogen oxides; 54 Mg. of mercury; and 41 Kg. of dioxins/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 under 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 remaining landfills are publicly owned. The total annualized costs for collection and control of air emissions from new and existing MSW landfills are estimated to be $100.

- *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 covered water systems nationwide. 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 per year. 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 health 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 average reductions of 110,000 to 338,000

cases of cryptosporidiosis annually, with an estimated monetized value of $0.5 to $1.5 billions, and possible reductions in the incidence of other waterborne diseases.

- *National Pollutant Discharge Elimination: System B Regulations for Revision of the Water Pollution Control Program Addressing Storm Water Discharges* (1999): This rule expands the existing National Pollutant Discharge Elimination System program for storm water control. It covers smaller municipal storm sewer systems and construction sites that disturb one to five acres. The rule allows for the exclusion of certain 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."

- *National Primary Drinking Water Regulations; Arsenic and Clarifications to Compliance and New Source Contaminants Monitoring* (2001): This rule reduces the amount of arsenic that is allowed to be in drinking water from 50 ppb to 10 ppb. It also revises current monitoring requirements and requires non-transient, non-community water systems to come into compliance with the standard. This rule may affect either State, local or tribal governments or the private sector at an approximate annualized cost of $206 million. The monetized benefits of the rule range from $140 to $198 million per year. The EPA selected a standard of 10 ppb because it determined that this was the level that best maximizes health risk reduction benefits at a cost that is justified by the benefits, as required by the Safe Drinking Water Act.

Although these six EPA rules were the only ones over the past six 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, 14 percent, 9 percent, and 6 percent of rules listed in the April 2001 Unified Regulatory Agenda cited some impact on State, local or tribal governments, respectively.

In Part 2 of the report, we present a full discussion of agency compliance with the Unfunded Mandates Reform Act.

Impact on Small Business

The need to be sensitive to the impact of regulations and paperwork on small business was recognized in 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 efficient 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 Federal 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. The average per employee regulatory costs were $6,975 for firms with fewer than 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.[37]

These results do not indicate whether reducing regulatory requirements on small firms would produce net positive 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—defined as rules designed to improve health, safety, and the environment—create benefits for workers and consumers. 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 textbook 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."[38]

Viewed in terms of overall welfare, the regulatory benefits of health, safety, and environmental improvements for workers can outweigh their costs, assuming the regulation

[37]See Crain and Hopkins, "The Impact of Regulatory Costs for Small Firms," SBA, Office of Advocacy, 2001.
[38]From Ehrenberg and Smith's *Modern Labor Economics*, p. 279.

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 and such costs are not borne primarily by workers.[39] 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 benefiting 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, defined as rules designed to set prices or conditions of entry for specific sectors, the effects on wages may be positive or negative. 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.[40]

These statements are generalizations of 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 gross domestic product (GDP) does not take into account fully 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.[41] 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 United States over the last 20 years permanently increased measured GDP by 2 percent. The OECD

[39]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).

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

[41]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 fully counted in GDP.

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) surveyed the evidence of the effects of environmental regulation on economic growth and concluded as follows: "Empirical analyses 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, measured GDP growth does not take into account fully the market value of improvements in health, safety, and the environment that social regulation has brought us. If even lower-range estimates of the benefits of social regulation are added to GDP, then a more comprehensive measure of GDP, one that includes the value of nonmarket goods and services provided by regulation, would be about 3 percent greater.[42] Focusing on the effect of social regulation on measured economic growth is misleading since 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).

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. Choosing the right regulatory instrument can go a long way toward reducing any negative impacts on economic growth while increasing the overall long-run benefits to society.

C. 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

[42]Including the value of increasing life expectancy in the GDP 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.*

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); and

- 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 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 87 economically significant rules reviewed by OMB, 34 are regulations requiring substantial additional private expenditures and/or providing new social benefits. Table 9 summarizes the costs and benefits of these rules and provides "other information" taken from rule preambles and agency RIAs. 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.

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 form, 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 varies 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 negative $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 smoothes 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—but when—benefits and costs are likely to accrue.

4. Rules without Quantified Effects.

Three of the rules in Table 9 are classified as economically significant even though the agency did not provide any quantified estimates of 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 CAFE: For each model year, DOT must establish a corporate average fuel economy (CAFE) 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 DOT was prohibited by law from changing the standards.

Table 9. 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, such as maintenance of air and water quality, recreational opportunities, wildlife habitat, and livestock grazing.
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." [65FR80663]
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." [66FR1768]
DOC	Annual Framework Adjustment (framework 14) for the Atlantic sea scallop fishery management plan for 2001	Not estimated	Not estimated	

Table 9. 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**
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." [65FR 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".[66FR7276]
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 thousand 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.

Table 9. 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**
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." [65FR50351] 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." [65FR50355]
HHS	Safe and Sanitary Processing and Importing of Juice	$151 million/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." [66FR6190]
HHS	Standards for Privacy of Individually Identifiable Heath 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. [65FR82761]

Table 9. 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**
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." [65FR76105] "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." [65FR76106]
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." [66FR1389]
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 [66FR49485]. 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 [66FR49485]. 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 [66FR49485]. The listed benefits represent estimated consumer surplus.

Table 9. 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**
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 [66FR49485]. 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	"[T]hese 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." [65FR70101]
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." [66FR16383]
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." [65FR68773]
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 data to OSHA.

Table 9. 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**
DOL	Safety Standards for Steel Erection	22 fatalities and 1,142 injuries averted 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 [66FR5199] 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. [66FR5251]
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." [65FR70234]
DOT	Light Truck Average Fuel Economy Standard, Model Year 2003	Not estimated	Not estimated	

Table 9. 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**
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 and 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." [66FR1235] 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. [65FR43586]

Table 9. 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**
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." [66FR7012] 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".[66FR3189])

Transfer Regulations

Of the 87 economically significant rules, Table 10 lists those that implement Federal budgetary programs. The budget outlays associated with these rules are "transfers" to program beneficiaries. Of the transfer rules, 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.

Table 10. Agency Transfer Rules: 4/1/00 to 9/30/01 (As of date of completion of OMB review.)
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)
Medicare Program: Medicare + Choice
Prospective Payment System for Home Health Agencies

Table 10. Agency Transfer Rules: 4/1/00 to 9/30/01 (As of date of completion of OMB review.)
Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities
Medicare Program: Hospital Inpatient Payments and Rates and Costs for 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 for 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 of 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

Table 10. Agency Transfer Rules: 4/1/00 to 9/30/01 (As of date of completion of OMB review.)
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

Table 10. Agency Transfer Rules: 4/1/00 to 9/30/01 (As of date of completion of OMB review.)
Emergency Core Cooling System Evaluation Models
Revision of Fee Schedules; Fee Recovery for FY 2001
Federal Reserve System
Privacy of Consumer Financial Information

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 11. 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 that are subject to E.O. 12866, the independent agencies provided relatively little quantitative information on the costs and benefits of the major rules. As Table 11 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.

Table 11. Rules for Independent Agencies (April, 2000 - September, 2001)				
Agency	**Rule**	**Information on Costs or Benefits**	**Monetized Costs**	**Monetized Benefits**
FCC	Narrowband personal communications services	No	No	No
FCC	Assessment and collection of regulatory fees for fiscal year 2000	No	No	No
FCC	Extending wireless telecommunications services to tribal lands	No	No	No
FCC	Installment payment financing for personal communications services (PCS) licensees	No	No	No
FCC	Competitive bidding procedures	No	No	No

Table 11. Rules for Independent Agencies (April, 2000 - September, 2001)				
Agency	**Rule**	**Information on Costs or Benefits**	**Monetized Costs**	**Monetized Benefits**
FCC	24 GHz Service; Licensing and operation	No	No	No
FCC	Promotion of competitive networks in local telecommunications markets	No	No	No
FCC	Assessment and collection of regulatory fees for fiscal year 2001	No	No	No
Federal Reserve	Privacy of consumer financial information	No	No	No
FTC	Privacy of consumer financial information	Yes	No	No
NRC	Emergency core cooling system evaluation models	Yes	Yes	Yes
NRC	Revision of fee schedules; 100% fee recovery, FY 2000	No	No	No
NRC	Revision of fee schedules; Fee recovery for FY 2001	No	No	No
SEC	Privacy of consumer financial information	Yes	Yes	No
SEC	Selective disclosure and insider trading	Yes	Yes	No
SEC	Unlisted trading privileges	Yes	No	No
SEC	Disclosure of order execution and routing practices	Yes	Yes	Yes
SEC	Revision of the Commission's auditor independence requirements	Yes	Yes	Yes
SEC	Disclosure of mutual fund after-tax returns	Yes	Yes	No

Response to Public Comments

One commenter (105) suggested that OIRA meet with international counterparts to develop a common reporting framework for costs and benefits that could be used internationally. OIRA believes that OECD might be an appropriate sponsor of this kind of activity.

The Federal Communications Commission (98) stated that, although it was not subject to E.O. 12866 and reported to GAO that the requirement to propose a formal cost-benefit analysis "is not applicable" to the FCC, it did use cost-benefit analysis in its decision making in the FCC rules mentioned.

The Nuclear Regulatory Commission (95) also stated that the draft report gave a misleading impression of its use of cost-benefit analysis in its regulatory decision making. The NRC stated that it "routinely" prepares detailed, quantitative, monetized information concerning the costs and benefits of its regulatory actions, including its rulemaking actions not classified by OMB as "major rules."

OIRA admits that a simple analysis of the GAO reports required by SBREFA may not present the full picture of agency use of cost-benefit analysis.

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 Organization 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.

A. 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.

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

1. 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).

2. 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.

3. 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.

4. 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.

5. 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.

6. 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.

7. 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.

8. 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.

9. 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.

10. How will compliance be achieved?

Regulations should assess the incentives and institutions through which the regulation will take effect, and should design responsive implementation strategies that make the best use of them.

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.

B. 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 and adopt transparent, market-oriented policies, and addresses such issues as outdated telecommunications regulatory practices. APEC requires its member countries to post on its website 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.

C. 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 overly 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 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 the business community.

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.

Response to Public Comments

Several commenters welcomed this new chapter to the report (73, 105, 106). One commenter emphasized the usefulness of identifying best practices among international regulatory authorities and cited the OECD checklist as a good example. Another thought that the chapter was a good first step in international understanding and that next step should be coordination in reporting results of regulatory policy in a consistent framework on an international scale (105). A third commenter suggested that U.S. support for better European regulation could produce major gains (106). This commenter urged more communication between the United States and the rest of the world about U.S. regulatory practices in order to counteract the belief by some that the U.S. economy is an unregulated "jungle economy." The commenter suggested that the true picture is more complicated than that with the United States being both underregulated and overregulated at the same time.

One commenter criticized the chapter for not emphasizing the importance of environmental protection and the precautionary principle in particular (99). The commenter suggested that we reference Environmental Issue Report No. 22 (2001) "Late Lessons from Early Warnings: The Precautionary Principle 1896-2000."

CHAPTER IV. RECOMMENDATIONS FOR REFORM

The Regulatory Right-to-Know Act requires OMB to publish "recommendations for reform." In response to this requirement, OMB considered ways to involve the public in identifying candidates for reform. Accordingly, OMB sought public comment in its March 2002 draft report on two reform initiatives. First, we solicited public comments on specific rules or regulatory programs in need of reform. As part of this first initiative, OMB specifically invited comments on regulatory and paperwork burdens imposed on small businesses. Second, we invited a review of agency practice regarding guidance documents, a first-time endeavor by OMB.

In response to our request for regulatory reform proposals, we received suggestions on 316 unique regulations and guidance documents covering 26 Federal agencies. This number of nominations is over four times larger than the 71 nominations received in 2001 and covers a broader range of topics.

Last year, we used an OIRA-initiated process for selecting potential reforms in which we identified 23 of the 71 public nominations as "high priority review" candidates. As described in greater detail later in this chapter, this year we have decided to evaluate the nominations through an agency-initiated process.

We have instituted this change for two reasons. First, the large volume of nominations (316 this year compared to 71 last year) strains OIRA's ability to develop an informed list of priority nominations for consideration by agencies. Second, OIRA expects that agencies will perform the evaluation of the nominations bringing to bear on the candidates their extensive knowledge and resources, which will provide a basis for selecting reform priorities in consultation with OIRA. While the agencies are the final decisionmakers as to which reforms are undertaken, OIRA will share its views on reform opportunities during the inter-agency consultation process.

Since this is OIRA's second experience with a public-comment process on regulatory reform, much can be learned for the future about how the process can be improved. OIRA intends to compare the experience this year to last year when it decides in the future how to stimulate reforms of specific rules, paperwork requirements, and guidance documents.

A. Review of Regulations, Paperwork, and Regulatory Programs

In the March 2002 draft report, OMB called for public nominations of reforms that, if adopted, would increase overall net benefits to the public, considering both qualitative and quantitative factors. In doing so, OMB acknowledged that, 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.[43] 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 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 of OMB and agency resources, and that any review of old rules should be done carefully and openly.

Accordingly, OMB established a modest process to review and improve agency rules. In selecting which rules or regulatory programs to propose for review, OMB directed commenters to 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. OMB indicated that recommended reforms might include extending or expanding regulatory programs; simplifying or modifying existing rules; or rescinding outmoded or unnecessary rules.

OMB sought to ensure that this public comment process reflected the Administration's goal of ensuring that agencies 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 per employee for firms with less than 20 employees compared to about $4,500 for firms with over 500 employees.[44] 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.[45] Small business ownership is a critical vehicle for all Americans—and increasingly for women and minorities—to achieve greater economic opportunity.[46]

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[43] 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.

[44] 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).

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

[46] The number of women-owned businesses increased by 16 percent between 1992 and 1997.

OMB therefore specifically requested 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 requested comments from the small business community on problematic guidance documents discussed in the following section. OIRA is coordinating with the Office of Advocacy of the Small Business Administration on this initiative.

B. 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. In recognition of this trend, OIRA decided to add a new feature of this report: a specific request for public comments on problematic agency 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.[47] 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.[48] While acknowledging the enormous value of agency guidance in general, OMB sought 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.

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[47] 5 U.S.C. 601 note, Title II of Pub. L. 104–121, Mar. 29, 1996.

[48] 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).

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, or to clarify how the agency will treat or enforce a governing legal norm. 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 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.

The failure to comply with the APA's notice-and-comment requirements or to 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 the public 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 questions 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, 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, leading 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 requested public comment on problematic Federal agency guidance. Specifically, OMB sought 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.

C. Responses to OMB's Request for Regulatory Reforms

Based on our prior experience with regulatory-reform processes, OIRA sought to improve this year's process and increase the usefulness of public comments. In the March 2002 draft report, for example, OIRA provided more specific direction to commenters, requesting that they use a standard format to summarize their nominations. OIRA also actively encouraged diverse segments of the public to provide comments in an effort to increase the number and breadth of nominations. Among the comments that OIRA received were responses to a speech made by President Bush on March 19, 2002, at the Women's Entrepreneurship Summit, in which he asked participants to e-mail OMB suggestions to reduce unnecessary regulatory burdens on small businesses.

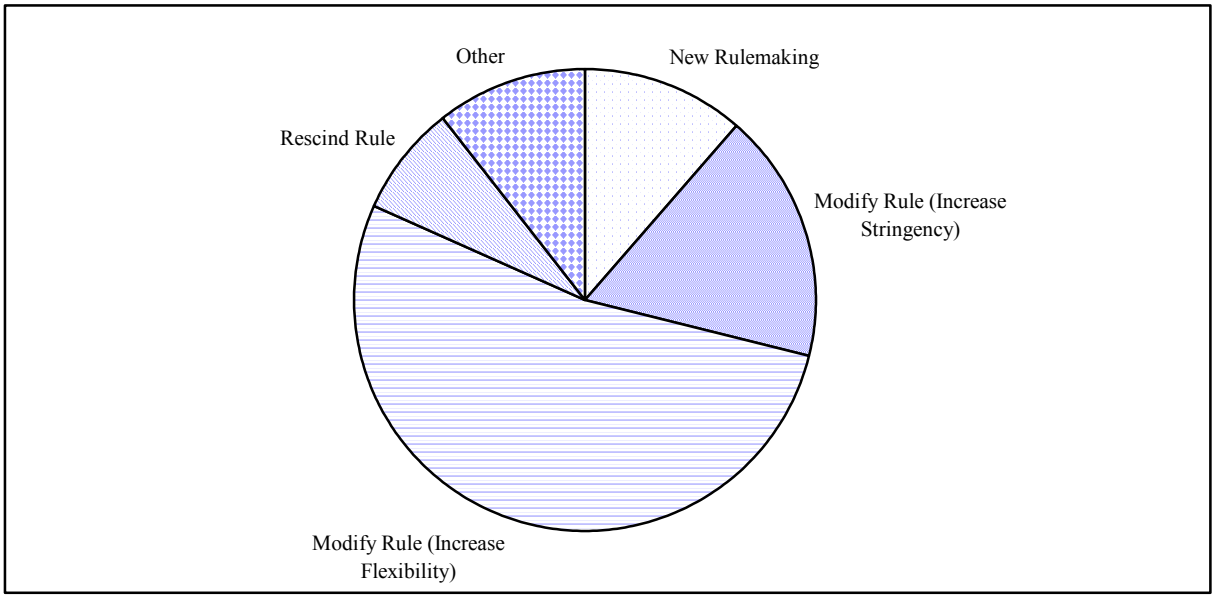
OMB received comments on 267 regulations and 49 guidance documents from approximately 1,700 individuals, firms, trade associations, non-profit organizations, academics, and government agencies.[49] Two commenters (80 and 93) did not submit specific nominations, but did provide useful reports that OIRA staff were able to transform into specific nominations. As noted earlier, OMB received suggestions on only 71 regulations from 33 commenters last year. Of this year's 267 regulatory nominations, 26 directly involved paperwork and recordkeeping requirements.

The commenters who participated in this year's initiatives represented a broad range of interests and perspectives. Approximately 26.5 percent of the commenters were individuals, 26.5 percent were firms, 32.9 percent were trade associations, 9 percent were non-profit groups and academics, and 5.2 percent were government agencies.

The diversity of the commenters was reflected in the issues they raised and the types of solutions they proposed. For example, excluding the regulatory nominations concerning independent agencies, 52.8 percent of the regulatory nominations sought modifications to existing or proposed rules that would increase flexibility and 7.8 percent recommended rescissions of existing rules. Over a quarter of the nominations advocated extending regulation, either by making existing and proposed rules more stringent (17.4 percent) or by promulgating new regulations (11.5 percent). Other nominations did not fall into these four categories for several reasons: (1) no solution was proposed, (2) the nature of the proposed solution was not clear, or (3) they had more than one commenter recommending different types of solutions (see Chart 1).

[49]Over a thousand of this year's comments were submitted as part of a coordinated effort relating to the Department of Labor's rules implementing the Family and Medical Leave Act. A similar campaign concerning the National Archives and Records Administration's rules on the Disposition of Federal Records involved almost 500 commenters.

Chart 1. Commenters' Proposed Regulatory Solutions



OIRA's first step in processing the public nominations was to prepare summaries of each of the rules and guidance documents that were nominated by one or more commenters. The summaries were based largely on information provided by commenters using OMB's suggested formats. Summaries of the nominations of rules and guidance documents can be found in a separate background document entitled "Stimulating Smarter Regulation: Summaries of Public Suggestions for Reform of Regulations and Guidance Documents," which is available on OMB's website at www.whitehouse.gov/omb/inforeg/regpol-reports_congress.html. These summaries provide identifying information about the regulations and guidance documents and describe what the existing regulations or guidance documents do (or what the new regulations or guidances would do). In addition, the summaries outline the commenters' descriptions of harmful or beneficial impacts and their proposed solutions. The identity of each commenter is also disclosed.

OMB also requested that commenters provide an estimate of economic impacts, including quantified costs and benefits. If quantified estimates were not available, commenters could provide qualitative descriptions. OIRA did not supplement these estimates in the summaries, which indicate whether commenters provided this information.

As noted above, consistent with a Presidential priority, the March 2002 draft report highlighted the regulatory burden imposed on small business. OIRA's summaries therefore indicate whether or not a nominated rule or guidance document might unnecessarily impact small businesses and/or impose especially large burdens on small businesses without a justifiable benefit. In most cases this information was provided by commenters, although OIRA occasionally added relevant information.

D. Process for Evaluating Reform Nominations

During our preliminary review of the public comments—when we identified the 267 rules and 49 guidance documents nominated for reform by one or more commenters—we excluded from consideration comments that did not provide specific information on regulations or guidance documents. In our review of the 316 nominations, OIRA found that the rules and guidance documents fell into several categories. This review was based on information available to OIRA at the time we processed the public nominations.

The first category includes 92 rules and 12 guidance documents that were under agency consideration or were recently the subject of agency consideration. This category also includes nominations designated by OIRA in last year's report as "high priority review" candidates.[50] The second category includes 49 rules and two guidance documents that raised issues concerning independent agencies, which are outside the purview of OIRA's regulatory-review responsibilities.[51] The remaining 126 rules and 35 guidance documents make up a third category of nominations that OIRA is referring to agencies for their evaluation (see Table 12).

Table 12. Categorization of Public Nominations

Category	Rules	Guidance Documents	Total
Issues Under Review/Completed	92	12	104
Issues Concern Independent Agency	49	2	51
Issues Referred to Agency for Evaluation	126	35	161
Total	267	49	316

While OIRA is forwarding to the agencies all of the public nominations for their review, we are specifically requesting that the responsible agencies consider the nominations in the third category as potential candidates for reform. The regulations and guidance documents that we are referring to agencies for their evaluation are listed in Tables 13 and 14, respectively. It is OIRA's intention that this agency review of nominations be a merit-based process in which the consideration of nominations is objective, consistent, and grounded in the regulatory principles codified in Executive Order 12866 and the statutory authority of the agencies.

To help guide agency review of the public nominations, OIRA suggests that agencies rely on three criteria: efficiency, fairness, and practicality. These criteria are defined as follows:

[50]Appendix C provides a status report for each of the 23 high-priority rules that OIRA suggested for reform in 2001.
[51]The following independent agencies are responsible for issues raised by public commenters: the Equal Employment Opportunity Commission, the Federal Communications Commission, the Federal Reserve Board, the Federal Trade Commission, and the Securities and Exchange Commission.

- **Efficiency.** Agencies should give consideration to reforms that present an opportunity to increase regulatory efficiency by maximizing net benefits, including potential quantitative and qualitative improvements to the economy, environment, and public health and safety.
- **Fairness**. In addition to assessing overall costs and benefits, agencies should take into consideration nominations with the potential to increase fairness through desirable distributive impacts and process considerations.
- **Practicality**. Agencies should give greater weight to nominations that (1) they have discretion to implement under existing statutory authority (although potential reforms should not be eliminated simply because implementing them would require new statutory authority) and (2) are judged to be important relative to other regulations and programs under consideration for review. OIRA is sensitive to the practicalities (including agency resources) of pursing certain nominations at this time.

OIRA understands that agency assessments of reform nominations will necessarily take into account budgetary considerations, statutory mandates, and other relevant factors. OIRA also does not expect agencies to necessarily agree with the analysis or solutions presented by commenters, even for those nominations they identify as reform candidates.

Table 13. Nominations Referred to Agencies for Evaluation – Regulations

Agency	Regulation	Ref. Number*
Agriculture	Child Nutrition Program	1
Agriculture	Animal Identification	3
Agriculture	Salmonella Performance Standards	6
Agriculture	National Organic Program	7
Agriculture	Badge as Identification of Inspectors	10
Agriculture	Phytosanitary Certificates for Seeds	12
Agriculture	Swine Production Contract Library	13
Agriculture	National Forests Land Use: Special Uses	14
Agriculture	Low Cost Timber Sales and Grazing Fees	16
Education	Title IX and Collegiate Sports Participation	18
Energy	Energy Conservation Standards for Clothes Washers	21
HHS	Special Treatment: Direct Graduate Medical Education Payments	23
HHS	Medicare Secondary Payer Provision	24
HHS	Physician Certification for Non-Emergency Ambulance Services	25
HHS	75% Rule	26
HHS	Converted Bed Rule	27
HHS	Exemption Date Rule	28

Table 13. Nominations Referred to Agencies for Evaluation – Regulations		
Agency	**Regulation**	**Ref. Number***
HHS	Medical Director Rule	29
HHS	Minimum Staffing Standards for Nursing Homes	30
HHS	One-Hour Restraint Rule	31
HHS	Revisions to Medicare Payment Policies	32
HHS	Certificates of Medical Necessity	33
HHS	Use of the OASIS for Home Health Agencies	35
HHS	Clinical Laboratory Improvement Act Rules	36
HHS/FDA	Standard of Chemical Quality – Arsenic	38
HHS/FDA	Standard of Chemical Quality – Uranium	39
HHS/FDA	Labeling Genetically Modified Foods	41
HHS/FDA	Hormones in the Food Supply	42
HHS/FDA	Antibiotics in Food Supply	43
HHS/FDA	Food Identity Standards	44
HHS/FDA	Medical Drug and Device Regulations	45
HHS/FDA	Labeling of Carmine	47
HHS/FDA	Labeling of Sorbitol	48
HHS/FDA	Labeling of Caffeine Content	49
HHS/FDA	Labeling of Food Allergens	50
HHS/FDA	Investigational New Drug (IND) Regulations	51
HUD	Predatory Lending	55
HUD	Insured Ten-Year Protection Plans	56
Interior	National Landscape Conservation System	62
Justice	Hemp Food Products	68
Justice/INS	Driver's Privacy Protection Act	70
Justice/INS	Electronic Storage of I-9 Forms	71
Justice/INS	Forms I-140 and I-485	73
Labor	Medical Certification	77
Labor	Computer Professional Exemption under FLSA	78
Labor	FLSA Administrative Exception	80
Labor	SCA/Wage Determination Process/Wage Surveys	82
Labor	SCA Wage Increases and Benefit Improvements	84
Labor	FLSA Medical Leave	85
Labor	Explosives	88
Labor/OSHA	Explosives and Process Safety Management	90
Labor/OSHA	Hazard Communication	92

Table 13. Nominations Referred to Agencies for Evaluation – Regulations		
Agency	**Regulation**	**Ref. Number***
Labor/OSHA	Lead in Construction	93
Labor/OSHA	Sling Standard	96
Labor/OSHA	Process Safety Management/Highly Hazardous Chemicals	99
Labor/OSHA	Bloodborne Pathogens Standard	100
Labor/OSHA	Metalworking Fluids	101
Labor/PWBA	Claims Procedures	104
State	Flight Simulators	105
DOT	Disadvantaged Business Enterprise Program	106
DOT/FAA	General Definitions	107
DOT/FAA	Design and Construction	108
DOT/FAA	Seats, Berths, Safety Belts, and Harnesses	110
DOT/FAA	Improved Flammability Standards for Thermal/Acoustic Material	112
DOT/FHWA	Contract Requirements for Minor Transportation Projects	113
DOT/FHWA	Historic Preservation Regulations	114
DOT/FHWA	Outdoor Advertising Control	115
DOT/FHWA	Highway Design	116
DOT/FHWA	Traffic Operations	117
DOT/FHWA	Highway Work Zone Safety	118
DOT/FHWA	Commercial Size and Weight	119
DOT/FMCSA	Inspection, Repair, and Maintenance	121
DOT/FTA	Buy America Pre-Award and Post Delivery Certification	125
DOT/FTA	Set-Aside for Intercity Bus	126
DOT/MARAD	Vessel Financing Assistance	127
DOT/NHTSA	Lower Interior Front Impact Protection	134
DOT/NHTSA	Passenger Vehicle Compatibility	135
DOT/NHTSA	Roof Crush	137
DOT/NHTSA	Passenger Vehicle Brakes	138
DOT/NHTSA	Door Locks	139
DOT/NHTSA	Glazing Materials and Crash Avoidance	142
DOT/NHTSA	Lamps, Reflective Devices, and Assoc. Equipment	143
DOT/NHTSA	Commercial Vehicle Operator Visibility	144
DOT/NHTSA	On-Board Crash Recorders	145
DOT/NHTSA	Driver Distractions	146
DOT/NHTSA	Pedestrian Crash Protection	147
DOT/NHTSA	Bumper Strength	148

Table 13. Nominations Referred to Agencies for Evaluation – Regulations		
Agency	**Regulation**	**Ref. Number***
DOT/NHTSA	Commercial Vehicle Brakes	149
DOT/NHTSA	Consumer Information	150
DOT	Commercial Vehicle Rollover	151
DOT/NHTSA	Side-Impact Protection	152
DOT	Emergency Response and Auto Crash Notification	154
DOT	Commercial Vehicle Design Compatibility	155
DOT/RSPA	Emergency Preparedness Grants	157
DOT/RSPA	Hazardous Materials Training	158
Treasury	Currency and Foreign Financial Accounts	159
Treasury/IRS	Employer Identification Numbers	161
Treasury/IRS	Flexible Spending Accounts	162
Treasury/IRS	Monthly Tax Deposits	166
Treasury/IRS	Mortgage Revenue Bond Purchase Price Limits	167
Treasury/IRS	Partnership Investments in Small Business Stock	168
Treasury/IRS	Business Use of Home	169
EPA	Regulatory Reform for Handling Refrigerants	170
EPA	Chemical Plant Safety Standards	171
EPA	Protections for Farm Children from Pesticide Exposures	178
EPA	Definition of Volatile Organic Compound	179
EPA	Motor Vehicle Emission Standards for Greenhouse Gases	180
EPA	Withdrawal of State Delegations	184
EPA	TRI Alternate Reporting Threshold (Form A)	188
EPA	Collection of Health Screening Data	189
EPA	Export Notification Requirements	190
EPA	PCB Spill Cleanup Policy	191
EPA	Storage for Reuse	192
EPA	Spill Prevention Plans	194
EPA	NPDES and Sewage Sludge Monitoring Reports	195
EPA	Stormwater Phase I	201
EPA	Stormwater Phase II	202
EPA	Removal Credits for POTWs	203
EPA	Drinking Water Standards for Radionuclides	207
EPA	TRI Form R Reporting	209
EPA	TRI: Lowering Reporting Thresholds for PBT Chemicals	210
NARA	Disposition of Federal Records	253

Table 13. Nominations Referred to Agencies for Evaluation – Regulations		
Agency	**Regulation**	**Ref. Number***
OPM	Federal Employees Health Benefits	254
US Army Corps	Nationwide Permits	265
US Corps, EPA	Definition of Fill Material	266
USPS	Commercial Mail Receiving Agencies	267

*Refers to numbers assigned to nominations in Section I of "Summaries of Public Suggestions for Reform of Regulations and Guidance Documents," which is available at www.whitehouse.gov/omb/inforeg/regpol-reports_congress.html.

Table 14. Nominations Referred to Agencies for Evaluation – Guidance Documents		
Agency	**Guidance Document**	**Ref. Number***
HHS	Medicare Carrier Manual/Medicare Intermediary Manual	2
HHS	Signature on File Requirement for Ambulance Services	3
HHS	Payment to Health Care Delivery System	4
HHS	Individual Health Insurance Rules	5
HHS	Guidance to Surveyors - Long Term Care	6
HHS	Discrimination Against Persons with LEP	7
HHS/FDA	Nine-Compounds Monitoring	8
HHS/FDA	Coverage of Personal Importations	9
Interior	Endangered Species Act Survey Protocols	10
Justice	Guidance on Federal Prison Industries	11
Labor	Coordination of FMLA with other Leave Policies	12
Labor/OSHA	Multi-Employer Citation Policy	16
DOT/FAA	General Operating and Flight Rules	17
DOT/Coast Guard	Marine Safety Manual	18
Treasury/IRS	Low-Income Housing Tax Credit	19
Access Board	ADA/ABA Guidelines	20
EPA	EPA Index of Applicability Decisions	21
EPA	"Once In, Always In" Policy	23
EPA	Improving Air Quality Through Land Use Activities	24
EPA	TRI Reporting Forms and Instructions	26
EPA	TRI Reporting Questions and Answers	27
EPA	Waterborne Diseases	28
EPA	Food Quality Protection Act Policy Papers	29
EPA	Integrated Risk Information System	30

Table 14. Nominations Referred to Agencies for Evaluation – Guidance Documents		
Agency	**Guidance Document**	**Ref. Number***
EPA	Investigating Title VI Administrative Complaints	31
EPA	Economic Benefit of Noncompliance in Civil Penalty Cases	32
EPA	TRI Lead Reporting	33
EPA	Pesticide Registration Notices	34
EPA	Site-Specific Risk Assessments in RCRA	35
EPA	RCRA Spent Catalyst Policy	37
EPA	Superfund Indirect Costs	38
EPA	Ecoregional Nutrient Criteria Documents	39
EPA	Submetering Water Systems	40
OMB	Cost Accounting Standards for Educational Institutions	47
SBA	Guidance on Credit Unions	48

*Refers to numbers assigned to nominations in Section II of "Summaries of Public Suggestions for Reform of Regulations and Guidance Documents," which is available at www.whitehouse.gov/omb/inforeg/regpol-reports_congress.html.

The counts of rule nominations by agency generally reflect the relative size of the agencies' regulatory programs. The 267 regulations that commenters nominated for reform are the responsibility of 24 regulating agencies. Five of these agencies—the Departments of Health and Human Services, Labor, and Transportation, EPA, and the Federal Communications Commission (FCC)—accounted for over two-thirds of the total nominated regulations. Commenters nominated for reform 49 guidance documents from 14 agencies. EPA accounted for almost half of these nominations (see Table 15).

Table 15. Total Public Nominations by Agency			
Agency	**Regulations**	**Guidance Documents**	**Total**
Agriculture	16	1	17
Commerce	1	0	1
Education	3	0	3
Energy	2	0	2
HHS	32	8	40
HUD	2	0	2
Interior	11	1	12
Justice	7	1	8

Table 15. Total Public Nominations by Agency			
Agency	**Regulations**	**Guidance Documents**	**Total**
DOL	30	5	35
State	1	0	1
DOT	53	2	55
Treasury	11	1	12
Access Board	0	1	1
EEOC	3	1	4
EPA	43	22	65
FERC	1	0	1
Federal Reserve	8	0	8
FCC	24	0	24
FTC	4	1	5
NARA	1	0	1
OMB	0	3	3
OPM	1	0	1
SBA	1	1	2
SEC	9	0	9
U.S. Army Corps	2	1	3
U.S. Postal Service	1	0	1
Total	267	49	316

E. Next Steps

OIRA is requesting that agencies review all of the public nominations. The process of selecting candidates for reform will involve consultations between the agencies and OIRA. Specifically, OIRA is asking that agencies complete their initial review of the nominations for which they are responsible and discuss them with OIRA by February 28, 2003. Final decisions about which reforms to undertake will be made by the agencies.

During these consultations, the 92 rules and 12 guidance documents that are under current or recent agency consideration will also be discussed. Where appropriate, OIRA may request agencies to provide brief status reports about their recent or ongoing activities concerning the issue(s) raised by the public commenter(s). The type of status report will depend on the status of the issues raised. In some cases, the status report will indicate that no further action is needed. In cases where a final decision has not been made and agency activities are

underway, OIRA is encouraging agencies to consider the public comment and, where appropriate, place it in the rulemaking docket. For the 49 rules and two guidance documents that raised issues concerning independent agencies, OIRA is requesting that these agencies evaluate these nominations, as well.

Finally, OIRA is asking SBA's Office of Advocacy to review all of the public nominations and identify for agencies those that it thinks offer the potential to reduce unjustified regulatory burdens on small businesses. OIRA is requesting that SBA consult with OIRA to develop a process for addressing these issues.

APPENDIX A. 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. The directive issued by Chief of Staff Andrew Card, and subsequent instructions from OMB Director Mitchell Daniels, 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 that were subject to the reviews and procedures required by the Card and OMB directives remain under active consideration by agencies.

In last year's annual Report to Congress, 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. These actions, subject to certain exceptions, included withdrawing unpublished regulations from the *Federal Register* and from review by 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. By the end of May 2001, agencies had conducted reviews and taken appropriate action on most of the regulations subject to the Card Memo and to subsequent OMB guidance. The final disposition of many of these rules, however, had not been decided.

Agency heads were also instructed to review published final rules that had not yet become effective to decide which ones should be permitted to go into effect as scheduled and which ones should be delayed to allow for proper policy review. According to a January 2002 General Accounting Office (GAO) report, there were a total of 371 published final rules potentially subject the Card Memorandum's requirement that effective dates be delayed by agencies.[52] 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 16 provides an agency-by-agency status report on these rules.

[52]General Accounting Office, "Delay of Effective Dates of Final Rules Subject to the Administration's January 20, 2001, Memorandum" (GAO-02-370R), p. 3.

Table 16. 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).

GAO's review of the 90 rules delayed by agencies pursuant to the Card Memorandum determined that 75 went into effect after one or more delays. Table 17 provides descriptions of the 15 regulations that remained delayed as of January 20, 2002, their current status, and (where applicable) the reason why they remain under review. This information is based on GAO's findings and more recent information obtained by OIRA.

Table 17. Status of 15 Rules Subject to the Card Memorandum That Had Not Become Effective as of January 20, 2002			
Agency	**Rule**	**Description**	**Current Status**
USDA	Roadless Area Conservation	Would prohibit road construction, road reconstruction, and timber harvesting in inventoried roadless areas on National Forest Service land.	On May 10, 2001, the Idaho District Court enjoined the Forest Service from implementing the rule. On July 10, 2001, the Forest Service issued an ANPRM seeking public comment on key issues raised by the court's ruling. The May 2001 injunction is now under appeal in the Ninth Circuit Court.

Table 17. Status of 15 Rules Subject to the Card Memorandum That Had Not Become Effective as of January 20, 2002			
Agency	**Rule**	**Description**	**Current Status**
Energy	Central Air Conditioners and Heat Pump Energy Conservation Standards	Would have set energy conservation standards for air conditioners and heat pumps approximately 30 percent higher than existing standards.	On April 20, 2001, DOE delayed the effective date pending a decision by the Fourth Circuit Court of Appeals regarding a petition for judicial review of the original, January 2001 final rule. DOE indicated that it would likely resolve the issues raised by the petition through forthcoming rulemaking. On May 23, 2002, DOE withdrew the original rule and issued a final rule raising the minimum energy efficiency levels by 20 percent.
HHS/FDA	Prescription Drug Policies, Requirements and Administrative Procedures	Sets forth requirements for importation and wholesale distribution of prescription drugs; sale, purchase or trade of prescription drugs by hospitals or health care entities; and distribution of drug samples.	On March 1, 2001, FDA delayed to April 1, 2002, the effective date of pending provisions, noting that the extension satisfied the Card Memo requirement. The rule went into effect on April 1, 2002.
HHS/FDA	Aluminum in Large and Small Volume Parenterals Used in Total Parenteral Nutrition	Adds certain labeling requirements, specifies upper limit, and requires applicant to submit methods for detecting aluminum content.	On January 26, 2001, FDA extended this rule's effective date to January 26, 2003. FDA stated that some of the affected products were medically necessary and without alternatives, and could not be reformulated by the existing effective date.
HHS/CMS	Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships	Restricts the ability of physicians to make referrals for designated health services to health care entities with which the physician has a financial relationship. Protects the Medicare program from potential abuse.	On February 2, 2001, CMS delayed the effective date of section 424.22(d) of the original January 2001 final rule until April 6, 2001. That portion of the rule took effect on that date. Except for one provision (see below), the remainder of the final rule went into effect on January 4, 2002, as scheduled. On December 3, 2001, CMS delayed the effective date of the last sentence of section 411.354(d)(1) until January 6, 2003, to allow CMS to reconsider a key definition.

Table 17. Status of 15 Rules Subject to the Card Memorandum That Had Not Become Effective as of January 20, 2002			
Agency	**Rule**	**Description**	**Current Status**
HHS/CMS	Anesthesia Services	Permits States to determine which professionals are permitted to administer anesthesia services and the level of supervision required.	On July 5, 2001, CMS published a proposed rule to permit States to set supervision requirements for anesthesia services. On November 13, 2001, CMS published a final rule finalizing this change and withdrawing the original rule.
HHS/CMS	Medicaid Managed Care	Allows States greater flexibility to amend their plans to require certain categories of Medicaid beneficiaries to enroll in managed care without obtaining waivers and establishes new beneficiary protections.	On August 20, 2001, CMS published a proposed rule "to address some of the concerns that were expressed to the Department during our review, as well as to allow additional opportunity for public comment." On June 14, 2002, CMS withdrew the January 2001 final rule and finalized the August 2001 proposal.
HHS	Protection of Human Research Subjects	Provides additional protections for pregnant women and human fetuses involved in research and pertains to human in vitro fertilization.	On November 13, 2001, HHS published a final rule that withdrew and replaced the original January 2001 rule. The new rule clarified provisions for paternal consent when research is conducted involving fetuses and clarifies language that applies to research on newborns of uncertain viability.
Interior	Acquisition of Title to Land in Trust	Sets procedures used by Indian tribes and individuals to acquire title land in trust.	On November 9, 2001, the Department withdrew the final rule to address "specific areas of concern in a new rule."
Labor	Diesel Particulate Matter Exposure of Metal and Nonmetal Miners	Establishes new health standards for underground metal and nonmetal miners working at mines that use equipment powered by diesel engines.	On August 28, 2001, Labor issued a bulletin explaining its plan to enforce this standard. The bulletin stated that some provisions of the rule would not go into effect until after July 19, 2002, or January 19, 2006.

Table 17. Status of 15 Rules Subject to the Card Memorandum That Had Not Become Effective as of January 20, 2002			
Agency	**Rule**	**Description**	**Current Status**
DOT/NHTSA	School Bus Body Joint Strength	Extends the application of standard on school bus body joint strength to lighter school buses and narrows exclusions for maintenance access panels.	NHTSA first issued this rule on November 5, 1998, with an original effective date of May 5, 2000. NHTSA subsequently received petitions for reconsideration from industry. On March 6, 2000, NHTSA delayed the effective date to May 5, 2001; on April 20, 2001, NHTSA delayed it again to June 1, 2002. NHTSA issued a new final rule on December 13, 2001, that amended the November 1998 rule and delayed the effective date to January 1, 2003. NHTSA stated that it wanted "to ensure that the school bus industry has adequate notice of the changes in this document, and can make the die and tooling and other manufacturing changes necessary to meet this final rule."
DOT/FAA	Grand Canyon National Park Special Flight Rules: Area and Flight Free Zones	Modifies the airspace in the special flight rules area for aircraft flight operations over the Grand Canyon National Park.	On December 5, 2001, FAA extended the effective date for portions of the rule to February 20, 2003 to allow for an evaluation of "new safety concerns raised by the air tour operators."
DOT/FAA	Service Difficulty Reports	Amends reporting requirements for air carriers and repair station operators concerning failures, malfunctions, and defects of aircraft engines, systems, and components.	On November 23, 2001, FAA published a final rule that delayed the effective date until January 16, 2003. FAA expects to issue a new proposed rulemaking.
EPA	Arsenic in Drinking Water	Set goals and maximum contaminant levels for arsenic in community water systems and non-transient non-community water systems.	A final rule published February 22, 2002 effectively reinstated the level of protection reflected in the original January 2001 rule.
SBA	New Markets Venture Capital Program	Establishes the requirements for venture capital companies to make developmental investments in smaller enterprises located in low-income geographic areas and provide operational assistance to such enterprises.	On May 23, 2001, SBA published a final rule withdrawing the original rule and finalizing new regulations that reflected technical changes based on public comments on the original interim final rule.

Following the issuance of the Card Memo, OMB instructed agencies to withdraw from OMB review regulations that they had submitted prior to January 20, 2001. Except for those rules that met the exemptions provided for by the Card Memo, agencies formally withdrew 130 regulations from OMB. Since then, agencies have been resubmitting these rules to OMB. As of June 30, 2002, OMB has cleared 87 of the 130 regulations that were withdrawn by agencies. Table 18 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 18. Number of Rules Withdrawn From and Subsequently Cleared by OMB

Agency	Withdrawn (as of 5/18/01)	Cleared (as of 6/30/02)
Agriculture	13	9
Commerce	5	4
Defense	2	2
Education	1	0
Health and Human Services	13	9
Housing and Urban Development	11	10
Interior	3	0
Justice	13	8
Labor	2	0
Transportation	12	9
Veterans Affairs	18	14
Environmental Protection Agency	21	13
Office of Personnel Management	6	4
Small Business Administration	3	1
Social Security Agency	2	3
Other	5	1
Total	130	87

Source: General Services Administration, Regulatory Information Service Center

APPENDIX B. KEY TO PUBLIC COMMENTS

OMB appreciates all of the comments we received in response to the draft report. In particular, we would like to thank our invited peer reviewers: Robert Hahn and Robert Litan of the AEI-Brookings Joint Center for Regulatory Studies, Scott Jacobs of Jacobs and Associates and formerly of the OECD, Richard Morgenstern of Resources for the Future, and Wendy Wagner of the University of Texas School of Law. Below is a listing of all the commenters and the numbers we assigned to their comments.

1. T. Peter Ruane
President
American Road & Transportation Builders Association

2. Jeffrey A. Norris
President
Equal Employment Advisory Council

3. Mark A. de Bernardo
General Counsel
Council for Employment Law Equity

4. Patrick Donoho
Vice President, Government Relations
International Bottled Water Association

5. Andrew T. O'Hare, P.G.
Vice President, Regulatory Affairs
American Portland Cement Alliance

6. Laura Tague
Director of Regulatory Policy
Petroleum Marketers Association of America

7. Sandra J. Boyd
Assistant Vice President, Human Resource Policy
National Association of Manufacturers

8. Robert R. Rich, M.D.
President
Federation of American Societies for Experimental Biology
Jordan J. Cohen, M.D.
President
Association of American Medical Colleges

9. Mark B. Roberts
COO & General Counsel
National Association of Computer Consultant Businesses

10. Valley Employer Association

11. Bill Hammond
President
Texas Association of Business

12. Joe J. Mayhem
Vice President, Regulatory & Technical Affairs
American Chemistry Council

13. Tim Hammonds
President and CEO
Food Marketing Institute

14. Glen P. Kedzie
Assistant General Counsel &
Environmental Counsel
American Trucking Association, Inc.

15. Leslie Sue Ritts
Counsel to National Environmental
Development Association/Clean
Air Regulatory Project

16. John Arnett
Government Affairs Counsel
Copper and Brass Fabricators
Council, Inc.

17. Neil A. Mac Vicar
Senior Director
Unemployment Compensation Program
Michigan Health & Hospital Association
Service Corporation

18. Robert J. Schreiber, Jr. P.E.
Region 7 BIF Work Group
Schreiber & Yonley Associates

19. Jeff Gunnulfsen
Manager, Government Relations
Synthetic Organic Chemical Manufacturers
Association

20. Andrew Bopp
Executive Director
Society of Glass and Ceramic
Decorators

21. Frank A. White
Vice President
Organization Resources Counselors, Inc.

22. Howard J. Feldman
Director
Regulatory Analysis and Scientific
Affairs
American Petroleum Institute

23. S. Lawrence Kocot
Senior Vice President and General Counsel
National Association of Chain Drug Stores

24. Richard W. Newpher
Executive Director
Washington Office
American Farm Bureau Federation

25. Deanna R. Gelak, SPHR
Executive Director
FMLA Technical Corrections Coalition

26. Deron Zeppelin, PHR
Director, Governmental Affairs
Society for Human Resource
Management

27. Cory Siansky
Director, Administration and Public
Affairs
LPA, Inc.

28. Michel R. Benoit
Executive Director
Cement Kiln Recycling Coalition

29. Wendy Lechner
Senior Director
Federal Employment Policy
Printing Industries of America, Inc.

30. Dan Danner
Senior Vice-President
Federal Public Policy
National Federation of Independent Business

31. David Kushner, CMP, CAE
President and CEO
Community Hospital Medical Education Alliance

32. William L. Kovacs
Vice President
Environment, Technology & Regulatory Affairs
US Chamber of Commerce

33. Harold P. Coxson
Ogletree, Deakins, Nash, Smoak & Stewart, P.C.

34. Darrel J. Grinstead
Counsel to the American Ambulance Association
American Ambulance Association

35. Barry Epperson
Associated Wire Rope Fabricators

36. Lynn L. Bergeson, Esquire
Eileen Salathe Gernhard, Esquire
Rodenticide Registrants Task Force
Bergeson & Campbell, P.C.

37. Thomas W. Curtis
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38. W. Fred McGuire
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American Osteopathic Association

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Director, Public Policy
Washington Business Group on Health

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NATSO, Inc.

42. Sandy J. Boyd
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National Association of Manufacturers

43. Fern Abrams
Director of Environmental Policy
IPC - The Association Connecting Electronic Industries

44. Mike Keegan
Analyst
National Rural Water Association

45. Joan Claybrook
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46. Lynn Shotwell
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American Council on International Personnel

47. Mark D. Dopp
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American Meat Institute

48. Gerald M. Howard
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President
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National Association of Federal Credit Unions

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Policies and Labor Relations
The Sherwin-Williams Company

68. Henry I. Miller, MD
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132. James F. Boland
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165. Samantha Curto

166. Angela Townley
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167. High Mountain Heli-Skiing, Inc.
Teton Village WY

168. Nicole Gartzke

169. Mary Curtin

170. Bob G. Shupe
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172. Renee Pearison
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177. Dennis L. Costello, MD

178. Jerry W. Plant, CFA, CPA
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179. Michael H. Levin

180. Ralph H. Smith
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181. Marjorie A. O'Connell
O'Connell & Associates

182. Lynn Martin

183. Heather M. Stewart
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184. Cynthia Hilton
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185. Daniel J. Popeo
Chairman and General Counsel
Paul D. Kamenar
Senior Executive Counsel
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186. Angela Logomasini
Director of Risk and Environmental Policy
Competitive Enterprise Institute

187. Patrick Bennett
Director of Environmental Affairs
Indiana Manufacturers Association

188. Larry Alexander
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189. Earl Bouse
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190. Roxanne L. Scott
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192. Hal Hawk
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193. Patrick Bennett
Director of Environmental Affairs
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194. Jennifer Young

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Vice President
Corporate Communications and Government Affairs
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196. Ajay Kumar
Manager, Env. Affairs

197. Lee Deierling
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198. Paul Sarbanes
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199. Ed Pastor
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200. Ann Gosier
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Guidant Corporation

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202. Charles O. Howarth
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CAHHS Unemployment Insurance Division

203. Henry J. Hood
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APPENDIX C. STATUS OF THE 23 HIGH-PRIORITY RULES OIRA SUGGESTED FOR REFORM IN 2001

In the draft version of the 2001 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, "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. Commenters responding to the March 2002 draft report also nominated some of these rules again this year. 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 or not appropriate at this time. A status report on the high priority reviews is provided below.

USDA: Forest Service Planning Rules and Roadless Area Conservation Regulations (Two 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 2001, 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. The Forest Service plans to submit revisions to the Forest Service Planning Rule to OMB.

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. The Department published NPRM's in August and will finalize the rules this fall. The Federal Family Education Loan Program was nominated for reform by the public again this year.

Department of Energy: Central Air Conditioning and Heat Pump Energy Conservation Standards—On January 22, 2001, DOE promulgated a regulation that would have raised the energy efficiency of new central air conditioners by 30 percent. On May 23, 2002, DOE withdrew this rule and issued a final rule raising the minimum energy efficiency levels by 20 percent. This rule was nominated for reform by the public again this year.

Department of Health and Human Services: Standards for Privacy of Individually Identifiable Health Information—On August 14, 2002, HHS published final revisions to this rule clarifying some aspects and modifying others. The rule as amended goes into effect on April 12, 2003. This rule was nominated for reform by the public again this year.

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 has recently announced that it plans to finalize this rule by the end of calendar year 2002.

Department of the Interior: Amendments to National Park Service Snowmobile Regulations (Rocky Mountain)—Interior had issued a proposed rule on January 5, 2001, and a draft environmental impact statement in December 2000. Interior has not issued a final rule. Currently, the proposed rule is under internal departmental review. This rule was nominated for reform by the public again this year.

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. DOL published the proposed rule in April 2002. DOL is currently in the process of addressing comments and finalizing the rule.

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 regulations would be appropriate.

Department of Labor: Recordkeeping and Notification Requirements Under the Family and Medical Leave Act (FMLA)—DOL is considering whether revisions to these regulations would be appropriate. Additional aspects of the FMLA rules were nominated for reform by the public again this year.

Department of Labor: Affirmative Action and E.O. Survey—DOL is considering whether modifications to the survey would be appropriate. The Survey was nominated for reform by the public again this year.

Department of Transportation: Hours of Service of Drivers—DOT proposed changes to these regulations in 2000 and continues to consider revisions. Any final rule will reflect public comments in response to the notice of proposed rulemaking. This rule was nominated for reform by the public again this year.

Equal Employment Opportunity Commission: Uniform Guidelines for Employee Selection Procedures—EEOC has requested and received several extensions 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. EPA plans to submit revisions to this rule to OMB for review this fall.

Environmental Protection Agency: Proposed Changes to the Total Maximum Daily Load Program—EPA published a notice in October 2001 delaying the effective date of the new TMDL rule for 18 months, in order to allow time to consider possible revisions to the rule. The agency then conducted extensive "listening sessions" with stakeholders and has now prepared a draft proposed rule that addresses many of the concerns raised. EPA expects to publish the proposed rule for public comment this fall. This rule was nominated for reform by the public again this year.

Environmental Protection Agency: Drinking Water Regulations: Cost Benefit Analyses—OIRA is addressing these issues in its forthcoming analytic guidance. This guidance was nominated for reform by the public this year.

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. This guidance was nominated for reform by the public again this year.

Environmental Protection Agency: New Source Review—EPA has submitted these regulations for OMB review. This rule was nominated for reform by the public this year.

Environmental Protection Agency: Concentrated Animal Feeding Operations Effluent Guidelines—This rule was proposed in December 15, 2000. EPA has a court deadline to promulgate a final rule by December 2002. During the past year, EPA has issued two Notices of Data Availability providing additional information and soliciting public comment on additional, more flexible regulatory options. The draft final rule will be submitted for E.O. 12866 review later this calendar year. This rule was nominated for reform by the public again this year.

Environmental Protection Agency: Arsenic in Drinking Water—EPA has decided not to modify this final rule. This rule was nominated for reform by the public again this year.

Environmental Protection Agency: Notice of Substantial Risk: TSCA—EPA is considering several options to address the issues raised in its last report. EPA has established a new TSCA 8(e) web page that contains guidance, previous 8(e) submissions, and new submissions posted within two weeks of receipt. EPA is also working on a package that would make policy clarifications.

APPENDIX D. REGULATIONS REVIEWED BY AGENCY: 1998 TO 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	0	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 E. CALCULATIONS OF COSTS AND BENEFITS: EXPLANATION

Chapter II presents estimates of the annual costs and benefits of selected final major regulations reviewed by OMB between April 1, 1995 and September 30, 2001. The explanation of the calculations for the major rules reviewed by OMB between April 1, 1995 and March 31, 1999, can be found in Chapter IV of our 2000 report (OMB 2000). Table 19 of this 2002 Report presents OIRA's estimates of the benefits and costs of the 20 individual rules reviewed between April 1, 1999 and September 30, 2001 which were included in Table 7. All benefit and cost estimates were adjusted to 2001 dollars.

Four EPA regulations were removed to prevent double counting. We decided to exclude the benefit and cost estimates for the new National Ambient Air Quality Standards (NAAQS) for ozone and fine particulate matter. 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 2" rule setting emission limits for light duty vehicles, and the Heavy Diesel Engine rules setting emission limits for on-highway diesel engines. These rules will achieve emission reductions and impose costs that were also included in the EPA benefit and cost estimates developed for the NAAQS rules. EPA issued its Tier 2 rule in 1999 setting emission standards for light duty cars and trucks beginning in 2004. The Tier 2 rule will largely supercede EPA's 1996 rule establishing Voluntary Standards for Light-Duty Vehicles beginning in 2002. EPA also issued a 1998 rule limiting Heavy Duty Diesel Engine emissions beginning in 2004 and "reaffirmed" this rule in a final rule issued in 2001. OIRA has used the benefit and cost estimates from EPA's 2001 rulemaking (instead of the 1998 rulemaking) because we believe the 2001 analysis 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, annualizing benefit and cost estimates); and

(2) monetized quantitative estimates where the agency has not done so (for example, converting Agency projections of quantified benefits, such as, estimated injuries avoided per year or tons of pollutant reductions per year to dollars using the valuation estimates discussed below).

The adoption of a uniform format for annualizing agency estimates 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. Thus, this aggregation involves the assemblage of benefit and cost estimates that are not comparable.

Table 19. Estimate of Benefits and Costs of 20 Major Rules April 1, 1999 to September 30, 2001 (Annualized 2001 Dollars in Millions)				
1999-2000				
Regulation	**Agency**	**Benefits**	**Costs**	**Explanation**
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 emission 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.
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 2015. 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 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.
Handheld Engines	EPA	170-890	190-250	EPA reported only combined nitrogen oxide plus hydrocarbon emission reductions (Table 4 in 2001Report). We assumed that the reductions consist of 80% hydrocarbons and 20% nitrogen oxides. We valued hydrocarbons at $ 520-$2360 per ton and nitrogen oxides at $700-$4900 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		**8,600-23,180**	**5,540-7,100**	

2000-2001				
Regulation	**Agency**	**Benefits**	**Costs**	**Explanation**
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 Electronic 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 cost 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 agency figures.
Advanced Airbags	DOT	140-1,600	400-2,000	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 $70 billion using a discount rate of 3%, a rate explicitly specified EPA in this rule.
Arsenic and Clarifications	EPA	140-198	206	Both costs and benefits taken directly from Table 7.
National Emission Standards for Hazardous Air Pollutants for Chemical Recovery	EPA	293-393	32	Both costs and benefits taken directly from Table 7
Heavy-Duty Engine and Vehicle Standards	EPA	13,000	2,400	We estimated the present value of the stream of costs and benefits generated until 2030, deflated the present value to 2001$'s, and then annualized the streams.
2004 and Later Model Year Highway Heavy Duty Engines	EPA	1,840-12,650	482	We valued nitrogen oxide reductions at $700-$4,900 per ton and hydrocarbons at $520-$2,360 per ton.
Total		**26,435-43,789**	**10,445-12,045**	

Assumptions: 7 percent 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 from Viscusi.[53] All values converted to 2001 dollars. All costs and benefits stated on a yearly basis.

Valuation Estimates for Regulatory Consequences[54]

Agencies continue to take different approaches to 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 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 a figure of $116,500 per life-year saved in other contexts). OIRA valued those life-years at $116,500 each. For NHTSA's child restraint rule, OIRA used DOT's recommended estimate of $3 million per statistical life to value life saving benefits. [DOT, Fatality and Injury Risk Reduction: Departmental Guidance in the Conduct of Economic Evaluations] http://ostpxweb.dot.gov/VSL_1993_Guidance.pdf.

[53]W. Kip Viscusi, *Fatal Tradeoffs: Public & Private Responsibilities for Risk*. New York, NY, Oxford University Press, 1992, p. 65.

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

In cases where agencies have not adopted estimates of the value of reducing these risks, OIRA used estimates supported by the relevant academic literature.[55] OIRA did not attempt to quantify or monetize fatality risk reductions in cases where the agency did not at least quantify them.

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. 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 those rules where EPA provided quantified and monetized benefit and cost estimates.

Injury. For the child restraint rule, we adopted the Department of Transportation's approach of converting nonfatal injuries to "equivalent fatalities." 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.[56] 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.

I. *Change in Gasoline Fuel Consumption.* We valued reduced gasoline consumption at $.80 per gallon pre-tax. This equates to retail (at-the-pump) prices in the $1.10 - $1.30 per gallon range.

II. *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 published journal article [Brown and Savage, "The Economics of Double-Hulled Tankers," Maritime Policy and Management, Volume 23(2), 1996, pages 167-175.]

III. *Change in Emissions of Air Pollutants.* We used estimates of the benefits per ton for reductions in hydrocarbon and nitrogen oxide emissions derived from recent EPA regulatory analyses, as follows (1996$):

Hydrocarbon:	$520 and $2360 per ton
Nitrogen Oxide (stationary):	$350 and $2500 per ton
Nitrogen Oxide (mobile):	$700 and $4900 per ton

[55]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.

[56]National Highway Traffic Safety Administration, The Economic Cost of Motor Vehicle Crashes, 1994, Table A-1. http://www.nhtsa.dot.gov/people/economic/ecomvc1994.html

The estimates for reductions in hydrocarbon emissions were obtained from EPA's RIA for the 1997 rule revising the primary NAAQS for ozone and fine PM. OIRA has revised the estimates for reductions in NO_x emissions to reflect a range of estimates from recent EPA analyses for several rules and for proposed legislation. In particular, OIRA has adopted different benefit transfer estimates for NO_x reductions from stationary sources (e.g., electric utilities) and from mobile sources. EPA believes that there are a number of reasons to expect that reductions in NO_x emissions from utility sources achieve different air quality improvements relative to reductions from ground-level mobile sources. For example, mobile source tailpipe emissions are located in urban areas at ground level (with limited dispersal) while electric utilities emit NO_x from "tall stacks" located in rural (remote) locations with substantial geographic dispersal (Letter to Don Arbuckle, Deputy Administrator, OIRA from Tom Gibson, Associate Administrator, Office of Policy, Economics and Innovation, EPA, May 16, 2002.) There remain considerable uncertainties with the development of these estimates. The discussion below outlines the various EPA analyses serving as the basis for the NO_x benefit transfer values presented above and discusses the uncertainties that attend these estimates.

Analysis of recent EPA rules yield several estimates for the NO_x benefits per ton from electric utility sources. (See the Regulatory Impact Analyses for the "NO_x SIP Call" and the Section 126 rules, available on the web at http://www.epa.gov/ttn/ecas/econguid.html. In addition, see Memo to NSR Docket from Bryan Hubbell, Senior Economist, Innovative Strategies and Economics Group, EPA.) Based on these studies, the upper end of the range for the benefits of NO_x reductions from stationary sources (electric utilities) is $2500 per ton.

For mobile sources, EPA recently published the final Tier 2/Gasoline Sulfur rule RIA (EPA, 1999) and Heavy Duty Engine/Diesel Fuel RIA (EPA, 2000). For the Tier 2 rule, which affects light-duty vehicles, NO_x reductions account for around 90 percent of PM precursor emissions and 86 percent of ozone precursor emissions. Based on the final Tier 2/Gasoline Sulfur RIA, EPA estimates that NO_x reductions will yield benefits of $4,900/ton (1996$). EPA believes this analysis provides a more appropriate source for the NO_x benefit transfer value for mobile sources. (Letter from Tom Gibson, pp. B2 and B3, May 16, 2002.) Additional details on the Tier 2 benefits analysis are available in the Tier 2/Sulfur Final Rulemaking RIA, available on the web at http://www.epa.gov/oms/fuels.htm.

The Heavy Duty Engine/Diesel Fuel benefits analysis examined the impacts in 2030 of reducing SO_2 emissions by 141,000 tons and NO_x emissions by 2,750 thousand tons, as well as a 109,000 ton reduction in direct PM emissions. Based on this analysis, EPA estimates a value for NO_x reductions of $10,200/ton in 2030. (Letter from Tom Gibson, p.B3, May 16, 2002.) Complete details of the emissions, air quality, and benefits modeling conducted for the HD Engine/Diesel Fuel Rule can be found at http://www.epa.gov/otaq/diesel.htm and http://www.epa.gov/ttn/ecas/regdata/tsdhddv8.pdf. Because the Heavy Duty Engine/Diesel Fuel estimate includes an adjustment for income growth out to 2030 and involves reductions in several PM-related pollutants, OIRA has adopted a value of $4900 per ton from EPA's analysis of the Tier 2 rule as a benefits transfer value for reductions in NO_x emissions from mobile sources.

Reductions in the risk of premature mortality dominate the benefits estimates in all of these analyses. The size of the mortality risk estimates from the underlying epidemiological studies, the serious nature of the effect itself, and the high monetary value ascribed to prolonging life make mortality risk reduction the most important health endpoint quantified in these analyses.[57] Because of the importance of this endpoint and the considerable uncertainty among economists and policymakers as to the appropriate way to value reductions in mortality risks, EPA has developed alternative estimates for its "Clear Skies" legislation that show the potential importance of some of the underlying assumptions. (See "Human Health and Environmental Benefit Achieved by the Clear Skies Initiative" at http://www.epa.gov/clearskies.) OIRA has used this analysis to identify an alternative estimate of the benefits from NO_x reductions. In its Clear Skies analysis, EPA presented alternative benefits estimates of $14 billion and $96 billion per year in 2020, or a difference in the estimates of roughly a factor of seven.[58] Using this ratio, an alternative estimate of the benefits of NO_x reductions from stationary sources would be $350 per ton from stationary sources and $700 per ton from mobile sources.

OIRA recognizes 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. Examples of other factors include sources of emissions, meteorology, transport of emissions, initial pollutant concentrations, population density, and population demographics, such as the proportion of elderly and children and baseline incidence rates for health effects. Because of the uncertainties associated with benefits transfer, OIRA decided not to include three rules that are projected to achieve substantial reductions in SO_2 and PM emissions that OIRA included in previous years in the monetized estimates presented in Tables 5 and 6.[59]

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[57] There are several key assumptions underlying the benefit estimates for reductions in NO_x emissions, including:

1. Inhalation of fine particles is causally associated with premature death at concentrations near those experienced by most Americans on a daily basis. While no definitive studies have yet established any of several potential biological mechanisms for such effects, the weight of the available epidemiological evidence supports an assumption of causality.
2. All fine particles, regardless of their chemical composition, are equally potent in causing premature mortality. This is an important assumption, because fine particles from power plant emissions are chemically different from directly emitted fine particles from both mobile sources and other industrial facilities, but no clear scientific grounds exist for supporting differential effects estimates by particle type.
3. The concentration-response function for fine particles is approximately linear within the range of outdoor concentrations under policy consideration. Thus, the estimates include health benefits from reducing fine particles in both attainment and non-attainment regions.
4. The forecasts for future emissions and associated air quality modeling are valid.

[58] The difference between the estimates reflects several assumptions, including differences in the estimation and valuation of mortality risk and the valuation of a reduction in the incidence of chronic bronchitis.

[59] These are: Municipal Waste Combustors (1995), Emission Standards for New Locomotives (1997) and Emission Standards for Non-Road Diesel Engines (1998).

Adjustment for Differences in Time Frame Across These Analyses

Agency estimates of benefits and costs cover widely varying time periods. 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. For example, EPA only developed benefit estimates for a single year (2030) for the Tier 2 rule and the Heavy Duty Diesel Engine rules because of the difficulty of doing the air quality modeling necessary to support development of benefits estimates over multiple years. 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 20-year period.

In order to allow us to provide an aggregate estimate of benefits and costs, 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.[60]

Further Caveats

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, 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.

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[60] 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. For example, 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.

APPENDIX F. THE "REGULATORY RIGHT-TO-KNOW ACT"[61]

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) 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.).

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

PART 2: Seventh Annual Report to Congress on Agency Compliance with the Unfunded Mandates Reform Act of 1995

CHAPTER I: BACKGROUND

This report represents OMB's sixth annual submission to Congress on agency compliance with the Unfunded Mandates Reform Act of 1995. It details agency actions to involve State, local, and tribal governments in regulatory decisions that affect them, including expanded efforts to involve them in agency decision-making processes.

In last year's report to Congress on the benefits and costs of Federal regulations entitled, "Making Sense of Regulation," OMB also included the annual report on agency compliance with the Unfunded Mandates Reform Act (the Act). 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 accounts for the costs and benefits of rules and takes into consideration the interests of our intergovernmental partners. As OMB stated in last year's report, we intend to continue to publish these two reports together. This report on agency compliance with the Act covers the period between May and October of 2001 (rules published before May 2001 were described in last year's report.) Next year's report will encompass those rules and consultation activities undertaken from October of 2001 through September of 2002, which will correspond with the period covered by the cost-benefit report.

Although this year's report only covers a period of five months, the scope of consultation activities undertaken by Federal agencies such as Agriculture and Justice demonstrate this Administration's commitment to building strong relationships with our intergovernmental partners based upon the constitutional principles of federalism embodied in Title II of the Act. Even in the early stages of the new Administration, federal agencies were actively consulting with States, localities, and tribal governments in order to ensure that regulatory activities were conducted consistent with the requirements of the Act. Furthermore, next year's report will show an increased level of engagement, as several agencies have begun major consultation initiatives. Housing and Urban Development is working to increase State and local participation in a variety of community development projects, and Education has begun major consultation initiatives to implement the No Child Left Behind Act (NCLBA). For example, the NCLBA, which reauthorized the Elementary and Secondary Education Act and incorporated the major education reforms proposed by President Bush in his No Child Left Behind initiative, focused on accountability and school improvement. To implement NCLBA, Education established a negotiated rulemaking process that included the participation of individuals representing parents, students and educators. The result was the development of regulations implementing NCLBA's provisions on academic standards and accountability. Negotiated rulemaking efforts are expected to continue, as other portions of NCLBA are implemented.

Reflecting the Bush Administration's concern that many of our intergovernmental partners were not being consulted sufficiently on those issues that matter the most to them, OMB sought public comment in this year's draft report to Congress on the benefits and costs of Federal

regulation from State, local, and tribal governments as to what they perceived as failures in the consultation process. OMB received no public comments in response to this request. However, the Administration continues to seek the views of our intergovernmental partners, as their input will be invaluable as we continue to develop policies to further the rights of State, local, and tribal governments under the Act.

State and local governments have a vital constitutional responsibility to provide government services. They have the major role in providing domestic public services, such as public education, law enforcement, road building and maintenance, water supply, and sewage treatment. The Federal government contributes to that role by promoting a healthy economy and by providing grants, loans, and tax subsidies to State and local governments. However, over the past two decades, State, local, and tribal governments increasingly have expressed deep-felt concerns about the difficulty of complying with Federal mandates without additional Federal resources. In response, Congress passed the Unfunded Mandates Reform Act of 1995 (the Act).

Title I of the Act focuses on the Legislative Branch, addressing the processes Congress should follow before enactment of any statutory unfunded mandates. Title II addresses the Executive Branch**.** To a large extent, Title II codifies the provisions of Executive Order 12875 on the development of rules and regulations. It begins with a general directive for agencies to assess, unless otherwise prohibited by law, the effects of their rules on the other levels of government and on the private sector (Section 201). Title II also describes specific analyses and consultations that agencies must undertake for rules that may result in expenditures of over $100 million in any year by State, local, and tribal governments in the aggregate, or by the private sector. Specifically, Section 202 requires an agency to prepare a written statement for intergovernmental mandates that describes in detail the required analyses and consultations on the unfunded mandate. Section 205 requires that for all rules subject to Section 202, agencies must identify and consider a reasonable number of regulatory alternatives, and then generally select from among them the least costly, most cost-effective, or least burdensome option that achieves the objectives of the rule. Exceptions require the agency head to explain in the final rule why such a selection was not made or why such a selection would be inconsistent with law.

Title II requires agencies to "develop an effective process" for obtaining "meaningful and timely input" from State, local and tribal governments in developing rules that contain significant intergovernmental mandates (Section 204). Title II also singles out small governments for particular attention (Section 203). OMB's guidelines assist Federal agencies in complying with the Act and are based upon the following general principles:

- intergovernmental consultations should take place as early as possible, beginning before issuance of a proposed rule and continuing through the final rule stage, and be integrated explicitly into the rulemaking process;
- agencies should consult with a wide variety of State, local, and tribal officials;
- agencies should estimate direct costs and benefits to assist with these consultations;
- the scope of consultation should reflect the cost and significance of the mandate being considered;
- effective consultation requires trust and significant and sustained attention so that all who participate can enjoy frank discussion and focus on key priorities; and
- agencies should seek out State, local, and tribal views on costs, benefits, risks, and alternative methods of compliance, and whether the Federal rule will harmonize with and not duplicate similar laws in other levels of government.

Sections 206 and 208 of the Act direct OMB to send copies of required agency analyses to Congressional Budget Office (CBO), and to submit an annual report to Congress on agency compliance with Title II. Section 207 calls for the establishment of pilot programs for providing greater flexibility to small governments.

The remainder of the report discusses the results of agency actions in response to the Act between May and October of 2001. Since not all agencies take many significant actions that affect other levels of government, this report focuses on the agencies that have regular and substantive interactions on regulatory matters that involve States, localities, and tribes, as well as the private sector. Chapter 2 discusses agency consultation efforts. These include both those efforts required under the Act and the many actions conducted by agencies above and beyond these requirements, consistent with the spirit of the Act. Chapter 3 lists and briefly discusses the regulations meeting Title II's $100 million threshold and the specific requirements of Sections 202 and 205 of the Act. Four rules have met this threshold – none were intergovernmental mandates.

CHAPTER II: AGENCY CONSULTATION ACTIVITIES

Sections 203 and 204 of the Act require agencies to seek input from State, local and tribal governments on new Federal regulations imposing significant intergovernmental mandates. This chapter summarizes consultation activities by agencies whose actions significantly affect State, local and tribal governments.

Ten agencies (the Departments of Agriculture, Commerce, Health and Human Services, Housing and Urban Development, Interior, Justice, Labor, Transportation, the Environmental Protection Agency, and the Social Security Administration) have involved State, local and tribal governments not only in their regulatory processes, but also in their program planning and implementation phases. These agencies have worked to enhance the regulatory environment by improving the way in which the Federal government relates to its intergovernmental partners. In general, the Departments not listed here (e.g., State, Defense) do not often impose mandates upon States, localities or tribes and so have fewer occasions to consult with other levels of domestic government.

As the following descriptions indicate, Federal agencies are generally complying with both the letter and spirit of the Act by conducting a wide range of consultations. Agency consultations sometimes involve multiple levels of government, depending on the agency's understanding of the scope and impact of the rule. OMB continues to work with agencies to ensure that consultation occurs with the appropriate level of government.

DEPARTMENT OF AGRICULTURE

AGRICULTURAL MARKETING SERVICE (AMS)

Federal Pesticide Recordkeeping Program

Since the implementation of the Federal Pesticide Recordkeeping Program in early 1993, the emphasis of the Program has been to work cooperatively with State designated agencies dealing with pesticide regulatory programs to administer the Program. AMS recognizes 22 States as having authority to enforce State regulations that are comparable to the Federal regulations. AMS provides funding and technical support to many of these States to assure the State's Program and Federal Program mirror each other.

For those States under the Federal Program, AMS enforcement comes by way of cooperative agreements with the State designated agencies. The State agency and AMS personnel work closely together to assure that the administration of the Federal Program complements the State's Program.

On July 11-12, 2001, an annual meeting took place with State and Federal personnel to discuss issues and administration of the Federal and State programs. State representatives voiced their support for the Federal Program and with the way it is being administered. These

annual meetings provide a forum for open and frank discussion and are an opportunity to coordinate State and Federal work and educational programs for the upcoming year.

ANIMAL PLANT HEALTH INSPECTION SERVICE (APHIS)

APHIS has made vigorous efforts to consult State, local, and tribal governments on regulatory issues affecting these levels of government. Following are examples of APHIS consultation activities:

The Animal Health Safeguarding Review

In November 2000, APHIS established a cooperative agreement with the National Association of State Departments of Agriculture Research Foundation (NASDARF) to coordinate an assessment of the capabilities of U.S. and State governments, foreign governments, and the livestock industry to protect U.S. livestock and human health from animal diseases. A key part of the assessment was the performance of APHIS. The report's authors included State veterinarians, university and private animal health specialists, former APHIS associates, and experts from State departments of agriculture and the livestock industry. Over the course of 8 months, committee members traveled to U.S. program sites, met with participants in animal disease control programs, and drafted findings and recommendations that were later endorsed in a survey of stakeholders and personnel from State departments of agriculture. In October 2001, NASDARF issued "The Animal Health Safeguarding Review, Results and Recommendations." Groups to implement the recommendations are now being formed. These implementation groups will include, among others, APHIS and State representatives.

Federal Noxious Weeds Program

APHIS is considering significant changes in policy and actions pertaining to noxious weeds. On January 28, 2002, APHIS published a document in the Federal Register soliciting public comment on a new draft action plan for the Noxious Weeds Program. This document reflects current thinking on the changes necessary to improve the design and conduct of the program. It is based on comments received in response to a March 2000 advance notice of proposed rulemaking (ANPR), including comments from State departments of agriculture, and subsequent consultations with the National Plant Board (an organization of the plant regulatory agencies of each of the States and the Commonwealth of Puerto Rico). It incorporates many of the weed-related recommendations from the July 1999 Safeguarding Review of American Plant Resource, which was conducted by the National Plant Board. Those recommendations were based on suggestions from State and local governments and industry. APHIS issued its first noxious weed policy in 1993 and implemented weed program strategies to the extent possible under authority of the Federal Noxious Weed Act of 1974, which has now been superseded by the Plant Protection Act (PPA) of 2000. The PPA consolidates most of APHIS' statutory authorities, significantly broadens the definition of "noxious weed," and otherwise enhances the Agency's ability to address noxious weed problems.

Chronic Wasting Disease (CWD)

USDA is developing a program to eliminate CWD from farmed elk with State and industry support. On September 27, 2001, USDA announced the authorization of $2.6 million from the Commodity Credit Corporation to implement a farmed elk CWD surveillance and indemnity program. While considered rare, the disease has been diagnosed in farmed elk herds in 6 States and identified in free-ranging deer and elk in a limited area of northeastern Colorado, southeastern Wyoming, and the southwestern corner of Nebraska. CWD is classified as a transmissible spongiform encephalopathy (TSE), a group of progressive neurological diseases that includes scrapie and bovine spongiform encephalopathy. On February 8, 2002, APHIS published an interim rule to provide indemnity for infected and exposed herds destroyed because of CWD. APHIS plans to implement a herd certification program by 2003. In developing these programs, APHIS has consulted affected States and representatives from industry on the issues of compensation, surveillance, testing, and carcass disposal. APHIS expects to receive additional comments on the interim rule in 2002.

Bovine Tuberculosis Eradication Program

In the past year, APHIS has worked closely with States in which bovine tuberculosis exists. The goal is to increase the control of and accelerate eradication of the disease in the United States, while relieving unnecessary restrictions on the States. APHIS has consulted with the State of Michigan to develop guidelines that would be used to recognize two separate tuberculosis classification zones in the State. This would relieve unnecessary restrictions on that part of Michigan that does not present a high risk of tuberculosis. Additionally, APHIS worked closely with the State of Texas while developing an interim rule that will create a tuberculosis "buffer zone" through payment to owners of dairy cattle in the El Paso, TX, area for the destruction of their cattle and cessation of their dairy operations.

Foot-and-Mouth Disease

Following outbreaks of FMD in February 2001 in Great Britain and several countries in Europe, APHIS engaged in a number of activities to strengthen exclusion efforts and to ensure that adequate plans were in place to promptly eradicate the disease if it did occur here despite those efforts. These activities included extensive consultations with State, local, and tribal governments. For example, an FMD Awareness Workshop was held in Riverdale, MD, on March 29 and 30, 2001, for State agriculture commissioners, State veterinarians, and industry for California, at the request of Secretary Veneman. In April, approximately 45 Native American tribal leaders and representatives met in Riverdale, MD, for a briefing on FMD exclusion, outreach and public affairs efforts. During the height of the outbreaks in Great Britain, APHIS manned a toll-free telephone line from the agency's emergency operations center and held weekly conference calls connecting State agriculture commissioners, State veterinarians, and APHIS area veterinarians in charge and APHIS plant health directors. Throughout this process, APHIS received a number of informal comments which helped to shape

a proposed rule on compensation for animals destroyed in the event that FMD occurred in the United States.

Ongoing Consultations Regarding Plant Health

APHIS' Plant Protection and Quarantine (PPQ) program carries out numerous activities to detect and contain, and in some cases, to manage or eradicate plant pests damaging to agricultural and environmental resources of the United States. These programs are conducted cooperatively with State agencies, which share the costs with APHIS. Operational plans are prepared jointly and reflect the respective roles of State and Federal partners. APHIS consults regularly and frequently (sometimes on a daily basis during the active growing season) on program strategies, methods, operations, and progress. PPQ cultivates consultations with State agencies through National Plant Board meetings, task forces, and special committees to resolve issues of mutual concern. Specific examples of such consultations during January - October 2001 that have resulted in, or are expected to result in, regulatory changes include: consultations with State officials in California and Oregon, and with members of the National Plant Board related to the development of new regulations to prevent the spread of Phytopthera ramorum, a disease of oak and other plant species; and consultations with State officials in Texas and other southwestern States related to Karnal bunt compensation and interstate movement regulations. Based on those consultations, APHIS published an interim rule related to Phytopthera ramorum in the Federal Register on February 14, 2002.

Ongoing Consultations with Tribal Governments

APHIS is very active in consulting with Native American Tribes. Examples include regularly notifying tribes through tribal list servers of all APHIS documents published in the Federal Register; participating in national meetings, including the Intertribal Agriculture Council, Native American Fish and Wildlife Society, and the National Congress of American Indians (NCAI); and participating in monthly meetings with NCAI. Among those topics discussed with tribes this past year were the need for Tribal Codes and emergency response plans for animal and plant health emergencies; issues related to bison in Yellowstone National Park; and compliance with section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act.

FOOD AND NUTRITION SERVICE (FNS)

Summer Food Service Program (SFSP) Outreach Initiative

In September 2001, FNS convened a meeting of staff from the 14 State agencies authorized under the National School Lunch Act to operate a three-year pilot project which could lead to implementation of more streamlined accounting requirements for school and other public sponsors of SFSP that would bring SFSP requirements more in line with those of the School Lunch Program. Representatives from the Food Research and Action Center, America's Second Harvest, and the American School Food Service Association also attended. The result of the

meeting was collaboration on ways to promote the pilot project for eligible sponsors, to increase participation, and to identify needed technical assistance materials.

National Child and Adult Care Food Program State Director's Meeting

In March 2002, FNS staff participated in this biennial conference which focuses on current issues and new policies which affect State agencies and CACFP institutions. Staff presented sessions on the CACFP Management Improvement Initiative, afterschool snacks and suppers for nutritionally needy children, emergency homeless shelters, and adult day care.

National School Lunch Program Simplification of the Free and Reduced Price Application

Over the years, State and local school food service cooperators have recommended changes in the application for the National School Lunch Program's free and reduced price meals. FNS is working on the development of a new free and reduced price application which will be more user friendly while eliciting more accurate income information. FNS has been working very closely with State and local school food service personnel to obtain and implement their suggestions for improvement of the application. This consultation is expected to result in an improved application which will be released in 2002.

Special Supplemental Nutrition Program for Women, Infants & Children Directors Partnership

FNS updated WIC Policy Memorandum 98-9, Nutrition Risk Criteria, in March 2001. The update was developed through deliberation by and consultation with the Risk Identification Selection Collaborative, a Federal/State partnership established to achieve consistency in the nutrition risk criteria used to determine WIC Program eligibility.

The WIC Management Information Systems (MIS) Functional Requirements Document (FRED) is still under development and will be issued to all WIC State agencies in FY 2002. A Program Integrity and Technology conference, jointly sponsored by FNS and the National Association of WIC Directors (NAWD) was held in December 2001. FNS is coordinating with NAWD to co-sponsor a meeting in 2002 of the NAWD Electronic Benefit Transfer/Electronic Service Delivery Users Group, which is comprised of State representatives working on electronic benefit transfer/service delivery system plans and projects.

In conjunction with representatives of NAWD, FNS issued in December 2001 a document entitled ***WIC Nutrition Services Standards***, developed to improve the quality of nutrition services provided to WIC participants.

As part of the WIC WORKS Resource System, FNS conducts biannual mailings to State WIC agencies of materials that have been contributed to this online database which is dedicated to providing nutrition service tools for health and nutrition professionals.

WIC staff attend and participate as requested in the annual NAWD conferences; WIC also participated in the National Indian and Native American WIC Directors' Conference in the fall of 2001.

WIC and NAWD, in conjunction with the Centers for Disease Control and Prevention and six other partner organizations, worked on a WIC-Immunization Action Plan. The Plan was completed in July 2001. The purpose of the plan is to facilitate a national strategy to improve the immunization rates of children served by WIC while maintaining and protecting the WIC Program's core mission of providing effective nutrition services.

Commodity Supplemental Food Program Plain Language, Program Flexibility, and Accountability Rule

FNS solicited input from State and local CSFP operators in developing a proposed rule to amend CSFP regulations in "plain language," to reduce time and paperwork burdens for State and local agencies, increase flexibility in program operations, and strengthen program accountability. The rule will be published for public comment this year.

Food Distribution Program on Indian Reservations Food Package Review

In consultation with the National Association of Food Distribution Programs on Indian Reservations, FNS has instituted a process for the annual review of the FDPIR food package. A work group, comprised of tribally appointed FDPIR Program Directors, experts in the area of American Indian health and nutrition, USDA commodity procurement specialists, and FNS staff, has been convened to review proposed food package changes and make recommendations to FNS officials. The FY 2002 review team is expected to make its recommendations to FNS this summer.

Multi-Program Activities - Other Outreach

Outreach activities also include holding regular coordination meetings between program staff and the parties most concerned with implementing the provisions of food program related rules. Such meetings involve: Food Stamp Program Directors and State officials; regional Electronic Benefit Transfer coordinators and State contacts; FNS personnel and State WIC agency directors and their vendors; and FNS and State Child Nutrition Program directors.

A continuing liaison with State, local, and tribal program operators is maintained through their national organizations such as the American Public Welfare Association, National Governor's Association, the Child and Adult Care Food Program Sponsors Forum, the Child and Adult Care Sponsors Organization, the American Commodity Distribution Association, the National Association of Food Distribution Programs on Indian Reservations, and the National Commodity Supplemental Food Program Association.

FNS consulted with the National Association of Food Distribution Programs on Indian Reservations and its members on the development of an outreach poster for FDPIR. Program recipients participated in a photographic shoot for the poster, which was held at a FDPIR distributing agency in Miami, Oklahoma.

NATIONAL RURAL DEVELOPMENT PARTNERSHIP (NRDP)

The National Rural Development Partnership (NRDP) and State Rural Development Councils (SRDCs) were established in 1990 as part of the Presidential Initiative on Rural America to facilitate greater coordination of rural development policies and programs. As it enters its second decade, the NRDP continues to play a significant role in USDA outreach to State, local and tribal governments. There are currently 40 SRDCS. SRDCs are independent organizations that bring together Federal, State, local, and tribal governments with the private and non-profit sectors to identify rural communities' needs and build collaborative, coordinated responses and solutions.

The NRDP addresses a broad range of issues (e.g., transportation, health care, veterans' affairs, economic development, telecommunications and housing) that impact State, local and tribal governments. USDA and other Federal departments continue to use this capacity to improve the delivery of services to rural areas. The ultimate goal of the NRDP is to assist people in rural communities improve their quality of life. Examples are as follows:

In April 2001, the Wyoming Rural Development Council (WRDC) co-sponsored, with the Governor, the Eastern Shoshone Tribe, the Northern Arapaho Tribe, and the Wyoming Business Council, a three-day workshop entitled "Developing Effective Working Relationships with Indian Tribes and Organizations." The workshop provided 75 Federal, State, and local government officials and business leaders the knowledge necessary to develop and conduct effective working relationships with Indian Tribes and organizations. Governor Jim Geringer and the Tribal Chairs delivered keynote addresses. Various tribal members shared information with participants to give them a deeper understanding of Indian culture and practices. The Wyoming Business Council provided financial support and participated in the workshop. As a result of Wyoming's success, the Utah and Montana Councils are planning to hold similar workshops.

The Kansas Rural Development Council (KRDC) is effectively supporting the Rural Transportation Project undertaken to slow the rate of rail abandonment in Kansas and create a policy to help the State and its affected counties address problems arising from the loss of rail service to rural communities. KRDC organized public hearings and stakeholder meetings, worked with short-line railroad companies, kept State and Federal legislators informed of project progress, and developed rapport with the National Surface Transportation Board. The Council also designed and built the case for funding a rural transportation study and plan, pursued project funding, and developed a research proposal used to study rural transportation problems. KRDC's work produced tangible results: 920 of 1,000 miles of endangered track have been saved and the Kansas Department of Transportation has granted $150,000 for a rural transportation study to be completed in August 2002.

The North Dakota Rural Development Council (NDRDC), responding to a request from the Minneapolis Federal Reserve Bank, organized a workshop dedicated to a review of Indian Reservation lending from the standpoint of tribal sovereignty. The United Tribes Technical College, acting on behalf of their five Tribal Governments, hosted the first session on their Bismarck campus. There is an existing perception among lending organizations that tribal sovereignty is an inhibiting factor in the security of loans and the recuperation of debt. The goals of the workshop were to improve understanding of regulations governing tribal lending, open the doors of communication between the tribes and lending institutions, and ultimately improve mutual borrowing and lending access for tribal members and the financial community. As a result of the workshop, an Interagency Working Group on Reservation Lending was established in 2001. The Spirit Lake Sioux Nation of North Dakota agreed to pilot a focus project on their reservation, with emphasis on developing a uniform commercial code for the Tribe. The Money Smart program, a basic finance education program, will be offered to tribal housing authorities at all five North Dakota Reservations. The goal of the pilot project is to develop best practices that can apply in other States, Tribal governments, and lending institutions.

The National Rural Development Council (NRDC) is another component of the NRDP. The NRDC consists of senior program managers representing Federal departments, agencies, and national organizations. It provides exchanges of information and coordination across Federal agencies on issues affecting rural communities. It works on behalf of SRDCs at the national level. It raises awareness of the impact of Federal programs, and their rules and regulations, on rural areas. For instance, recently the NRDC hosted a presentation by OMB on the many definitions of rural used in Federal programs, and the resulting problems.

The NRDP has several task forces. One of these is the Health Care Task Force, which has worked closely with HHS on rural health care issues, including increasing the Medicare reimbursement rates for most ambulance services in rural areas. This Task Force also helped facilitate rural communities' responsiveness to the HHS Rural Initiative that Secretary Thompson announced at the July 2001 Joint NRDP - Community Development Society Conference.

The NRDP, through the NRDC, has established an impediments committee and process, which SRDCs can access to ameliorate Federal barriers that significantly hinder successful implementation of Federal programs in rural areas. The NRDC has reached out to tribal organizations to raise awareness of tribal issues and increase Tribal participation at both the National and State levels. For instance, in 2000-2001 the Chair of the NRDC was the representative from the National Congress of American Indians.

DEPARTMENT OF COMMERCE

It is the Department’s policy to consult with State, Local and Tribal governments concerning actions of the Department which might impact its intergovernmental partners. For instance, the National Marine Fisheries Service (NMFS) consults with representatives of State, Local and Tribal governments in the management of marine fisheries. NMFS consults

extensively with its State managing partners (from Maine through North Carolina) to ensure that conservation goals for Summer Flounder are met while minimizing confusion for fishermen. Summer flounder migrate up and down the East coast throughout the year, and whether they are found in State or Federal waters is largely influenced by the shape of the continental shelf and the season. In several States, summer flounder occur predominantly in State waters (i.e., within three miles from shore) during the spring of the year. During the later part of the year, they are more abundant farther offshore in Federal waters. Thus it is critically necessary for the Atlantic coastal States and the Federal government to coordinate management of summer flounder.

The summer flounder fishery is cooperatively managed by the Mid-Atlantic Fishery Management Council (Council),and the Atlantic States Marine Fisheries Commission (ASMFC), and NMFS. The Council has voting members from State fishery management agencies from New York, New Jersey, Delaware, Pennsylvania, Maryland, Virginia, and North Carolina; the ASMFC has voting members from State fishery management agencies from each of the coastal States from Maine through Florida.

In 2001, NMFS was under court order to achieve a certain level of Total Allowable Landings (TAL) that was lower than the TAL allowed by the ASMFC's interstate Fishery Management Plan (FMP). Initially, the Council recommended, and NMFS implemented, a Federal TAL of 17.91 million lbs, which was significantly lower than that set for State waters by the ASMFC (20.5 million lbs). This difference would have resulted in inconsistent commercial quotas, and inconsistent recreational harvest limits.

To resolve this inconsistency, NMFS planned a series of facilitated stakeholder meetings with interests representing State governments, commercial fishermen, recreational fishermen, and NGOs, including ASMFC. The goals of the first meeting were: to discuss the causes of the 2001 inconsistency; to try to reach agreement on consistent management measures for the 2001 fishery; and to discuss methods for preventing such inconsistencies in the future.

The initial facilitated meeting generated support for continuing discussions among interested parties. Such discussions included a special session in Baltimore in which the NMFS Assistant Administrator for Fisheries met with the State directors and the ASMFC. As a direct result of those consultations, NMFS and other interested parties were able to agree upon a TAL which best accommodated the needs of the States, the fishery and other interested stakeholders.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

HHS's Office of Intergovernmental Affairs (IGA) assists the Secretary in the development and implementation of the Department's longstanding intergovernmental consultation policies by ensuring that the Department diligently considers and incorporates the perspectives of State, local and tribal governments on emerging policy issues.

The chief tool used to accomplish this objective is the intergovernmental consultation process, in which the leadership of every agency and staff office of the Department plays a role.

IGA further uses the consultation process in its role as an intermediary between individual State, local and tribal governments and the Department. IGA is also responsible for ensuring that the rural perspective is included in Departmental policy, program and regulations and the Office oversees the HHS role in an interdepartmental effort on the coordination of community transportation resources and services.

Consultation with Tribes

The IGA houses the Departmental Tribal Consultation Unit and facilitates consultations for Tribes and Tribal organizations across the Department. In April 2001the Secretary hosted a meeting with tribal leaders of the major national tribal organizations to confirm tribal consultation and the HHS-wide tribal budget consultation sessions will continue. The third annual tribal budget consultation session for the FY 2003 budget was held in June 2001.

In August 2001, the Secretary traveled to tribal reservations of the Sault Saint Marie Tribe (MI), Lac Du Flambeau Tribe (WI), Red Cliff Band of Chippewa Indians (WI), and the Oglala Sioux Tribe (SD) to meet directly with elected tribal officials, discussing tribal priorities and needs, meeting with tribal community members, and touring tribal reservation facilities. Also in August, the Deputy Secretary visited the Chippewa Cree Tribe of Rocky Boy's Reservation and the Confederated Salish and Kootenai Tribes of the Flathead Nation in Montana.

Additional tribal consultations were organized on oral health needs and resources, the reauthorization of the Temporary Assistance for Needy Families program, the impact of gaming issues on health and human services, and the identification of funding sources. IGA also facilitated a policy briefing for the National Women Legislative Leaders Day held in Washington, DC. It was the first effort to include women tribal legislative leaders.

IGA participated on the Indian Health Service Title V Federal Core Team and Negotiated Rulemaking Committee and ASPE Title VI Tribal Self-Governance Feasibility Study. Both of these efforts entailed complex and sustained consultation and negotiation with tribal leaders.

Regional Consultations

The IGA also facilitates consultation through the work of the 10 HHS Regional Offices. Regional staff convened a series of conferences in cities throughout the region as part of an effort to reach adults who work with teens. Working in partnership with the U.S. Department of Education, HHS consulted with the State health department and local partners to tailor each conference to address health issues such as teenage pregnancy, substance abuse and violence and to look at ways to build strong partnerships in the community that would promote the health and well being of teens.

Regional staff planned an ongoing series of domestic violence conferences. These conferences were tailored to the expressed needs of the State, following consultation with State officials in the State's department of health and any other related departments.

Regional staff conducted four training/consulting on the Surgeon General's health initiatives resulting in timely approval of Healthy People 2010 plans. Additional assistance was provided to help develop access to health and dental care for Native Americans, with a focus on developing a culturally sensitive telemedicine program to provide traditional tribal medicine.

Since 9-11, the Regional staff has been promoting emergency preparedness through consultations with local jurisdictions and emergency management coordinators to develop emergency plans based on the New York City model.

CENTERS FOR MEDICARE AND MEDICAID SERVICES

CMS has worked closely with States to expedite the review process for Medicaid State plan amendments (SPAs) and has resolved the backlog of pending SPAs. Since January 2001, over 1,500 SPAs and waivers have been approved, including 346 SPAs that were part of the backlog. These SPAs and waivers have provided health care coverage to almost 1.8 million people and additional services to over 4.5 million people.

As another step to strengthen and improve the Medicaid and State Children's Health Insurance programs, CMS has instituted a Health Insurance Flexibility and Accountability Initiative (HIFA) to make it faster and easier for States to expand access to health care coverage for low-income individuals through the Medicaid program's section 1115 demonstration authority. This approach will permit States to expand insurance coverage through innovative approaches, including health insurance options available in the private sector. Two States have approved HIFA waivers, California and Arizona, and two other HIFA waivers are pending. CMS is also discussing HIFA programs with a number of other States and we expect to receive additional applications in the near future.

CMS is also working with States on model waiver programs related to prescription drugs, as is outlined in the President's budget. CMS recently approved a demonstration program in Illinois that will give an estimated 368,00 low-income seniors prescription drug coverage through the Medicaid program.

Thirty-six States have approved Breast and Cervical Cancer Prevention and Treatment SPAs. This is a new option for States, and it allows States to cover health care needs of a new categorically needy group of uninsured women who require treatment for breast or cervical cancer. Currently one State has a SPA pending, and 13 States still have the option to implement this new option.

In FY 2001, HHS was able to award $70 million in grants to 38 States and territories. These grants helped States design and implement effective and enduring improvements in community long term support systems to enable children and adults of any age who have disabilities or long term illnesses to live and participate in their communities; supported States' efforts to improve personal assistance services that are consumer-directed or offer maximum

individual control; and helped States transition eligible individuals from nursing facilities to the community. This year, Congress appropriated another $55 million for more System Change Grants. These grants will be used for another 54 grants in 40 States.

FOOD AND DRUG ADMINISTRATION

The Food and Drug Administration participates in 169 Partnership Agreements with a State or group of States within a particular region to address various regulatory issues. These partnerships strengthen Federal-State relationships, and provide valuable information exchanges between FDA and States in solving public health problems. The following are good examples of these agreements:

- Currently, FDA has partnership agreements with 26 States for the regulation of new x-ray assemblies or reassemblies. These partnerships include information sharing and cooperative inspection programs.

- Florida, Mississippi, and Hawaii are partners with FDA in the Food Safety Task Force. This task force was established to foster communications and cooperation within State and local food safety regulatory agencies and to promote the integration of statewide food safety systems.

- FDA and the New York State Department of Agriculture and Markets have an agreement to share reference material and surveillance information about food products that do not comply with FDA and New York State statutes and regulations. This agreement is intended to promote cooperation and eliminate redundancies in surveillance programs.

- FDA and the Massachusetts Department of Public Health have an agreement to conduct joint surveillance of MA harvested seafood and produce for pesticide residue analysis. This agreement is intended to eliminate redundancies in sampling and improve cooperation of FDA's and Massachusetts' regulatory programs.

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

In calendar year 2001, HUD did not promulgate any rules that contain a Federal mandate that will result in an expenditure of $100 million or more in any one year by State, local or tribal governments. In calendar year 2001, the first year of the new Administration, HUD did not issue a significant number of rules. However, in many instances, HUD consulted regularly, as its practice, with State, local and tribal governments on HUD programs and program processes, seeking input on ways in which HUD can better serve and better partner with its program constituents.

One of HUD's more significant consultations in calendar year 2001, with contemplation of rulemaking in late 2002 or early 2003, involved consultation with HUD's tribal partners. In late 2000, three laws were enacted that amended the Native American Housing Assistance and Self-Determination Act of 1996 (NAHASDA). NAHASDA reorganized the process of

providing housing assistance to Native Americans by replacing several separate assistance programs with a single block grant program. As required by NAHASDA, when enacted, HUD developed its regulations to implement this new program through negotiated rulemaking procedures. The three statutes that amended NAHASDA in late calendar year 2000 are the Fiscal Year 2001 HUD Appropriations Act (Pub.L.106-377, approved October 27, 2000); the Omnibus Indian Advancement Act (Pub.L. 106-568, approved December 27, 2000); and the American Homeownership and Economic Opportunity Act of 2000 (Pub.L 106-569, approved December 27, 2000).

In February, March, and April 2001, HUD sponsored a series of regional meetings with Indian tribes to determine tribal priorities for changes to the NAHASDA regulations. These consultation sessions, which were not limited to discussion of the statutory changes, highlighted key concerns and programmatic issues from tribes from across the country. In July 2001, HUD sponsored its eighth Native American National Homeownership Summit. The theme of the 2001 summit was "Working Together to Build Programs and Opportunities." During the Summit, ONAP and its tribal partners discussed the priority issues raised during the earlier regional consultation sessions, and the best methods for accomplishing the desired changes.

One result of these consultations was HUD's publication on April 18, 2001 (66 FR 37098) of a Federal Register notice announcing its intent to establish a negotiated rulemaking committee for purposes of revising the NAHASDA block grant formula. In addition, HUD considered the comments received from the Indian tribes during these consultations in determining the best methods for implementing the statutory changes to NAHASDA. In November 2001, HUD provided tribal government leaders with an opportunity to review and provide feedback on a draft HUD notice outlining these proposed implementation methods. HUD took these comments into consideration before issuing its notice to the Indian tribes on the methods to be used for implementation of the NAHASDA statutory revisions.

DEPARTMENT OF THE INTERIOR

U.S. FISH AND WILDLIFE SERVICE

Refuge Management Program

The refuge management policies collectively form a solid foundation to guide the most important aspects of modern refuge management. They represent the key steps to implement the National Wildlife Refuge System Improvement Act of 1997 and will help ensure that we administer national wildlife refuges consistently as a national network of lands, as called for in this Act.

The US Fish and Wildlife Service (the Service) is fulfilling the spirit of the Act by involving its stakeholders during policy development. After passage of the Act, an important first step was to provide colleagues in State fish and wildlife agencies a meaningful role in policy development. The Service asked the International Association of Fish and Wildlife Agencies to

facilitate State involvement. During the past two North American Wildlife and Natural Resources Conferences, the Service met with State directors to share drafts and allow for input. As the Service has developed each policy, it has encouraged its partners, especially the States and the public, to provide input. Particular concerns were addressed in final policies. This outreach effort is a new way of doing business for the Service that has given an influx of expertise and ideas and ultimately is helping to develop better policies and stronger partner relationships.

Migratory Bird Hunting Regulations

In 2001, after consultation with Indian tribes, the Service published special migratory bird hunting regulations for the 2001– 02 hunting season for Indian tribes. The Service publishes special Indian tribe regulations in response to tribes' requests for recognition of their reserved hunting rights and of some tribes' authority to regulate hunting by reservation members. The guidelines accommodate the reserved hunting rights and management authority of Indian tribes while ensuring that migratory birds receive necessary protection. Coordination with the tribes has been highly effective. This program continues to grow as the Service and participating tribes cooperatively work to conserve this important international resource.

Federal Aid

Programs operated by the Service provide grants to the States for such purposes as restoring sport fish and wildlife, providing boating access to the public, providing hunter and aquatic education opportunities, implementing conservation projects for species, and acquiring land associated with habitat conservation plans. After the Service awards funds to a State, the State must implement funded actions in accordance with applicable guidelines. The Service has published several new Manual chapters dealing with the award of Federal grants to, and audits of, the States. State partners and others interested in Federal grants were brought in to review the draft chapters, and all of the chapters are clearer and more effective as a result of these interactions.

National Wildlife Refuge System

In January 2001, the Service's National Wildlife Refuge System published four proposed policies: National Wildlife Refuge System Mission, Goals, and Purposes; Wilderness Stewardship; Appropriate Refuge Uses; and Wildlife-Dependent Recreational Uses. We extended the public comment period to approximately 160 days to facilitate meetings and discussions with the States on the content of the draft policies. The comments received from State partners during the course of five meetings helped shape and improve the final policies and regulations that will govern the administration of the Refuge System.

Endangered Species Program

In 2001 the Service published a rule to establish a migratory population of whooping cranes east of the Mississippi River between the States of Wisconsin and Florida. A team representing Federal and State governments and private organizations has been coordinating the project since 1998. A Cooperative Agreement exists between the Service and its partners—the International Crane Foundation, Operation Migration, the Wisconsin Department of Natural Resources, the U.S. Geological Survey–Patuxent Wildlife Research Center, and the Natural Resources Foundation of Wisconsin.

One of the world's rarest birds, the whooping crane is a federally endangered species in the United States. By 1941, only 21 whooping cranes existed in North America. Currently, wild whooping cranes exist in three flocks, only one of which is migratory. The species is vulnerable to extinction; all or most of these birds could be killed from a single event such as a hurricane, disease outbreak, toxic spill, or prolonged drought. To ensure that the whooping crane survives, the International Whooping Crane Recovery Team recommended that an additional migratory flock be established. If successful, the current project will result in the establishment of a second migratory population of whooping cranes.

Coordination with the many stakeholders of this project has been highly effective. We received approval and support for the project from the Atlantic and Mississippi Flyway Councils (formal organizations that generally include one representative from each State and Province in the flyway) and the States adjacent to the migration route. Twenty States have had varying levels of involvement: in addition to the direct flyway States of Wisconsin, Illinois, Indiana, Kentucky, Tennessee, Georgia, and Florida, 13 other States adjacent to the flyway route are also partners in the project.

MINERALS MANAGEMENT SERVICE

Offshore Minerals Management Program

The Offshore Program manages the mineral resources on the Outer Continental Shelf in an environmentally sound and safe manner. The Outer Continental Shelf Policy Committee, which includes State members, helps us with our mission. In October 2001, this committee established a subcommittee on education and outreach to develop recommendations for an education and outreach program with the public. This will encourage a national dialogue on Outer Continental Shelf oil and gas development.

The International Activities and Marine Minerals Division has been working with nine States along the east and gulf coasts to identify sand resources in Federal waters that could be used for beach renourishment and wetlands protection projects. In addition, MMS has conducted environmental studies to examine the biological and physical oceanographic implications of using sand from Outer Continental Shelf sites. During 2001, we conveyed over 4.7 million cubic yards of sand for shore protection projects.

Regional offices also contribute to our efforts to work with State, local and Tribal governments. For example, the Alaska Region is conducting an extensive outreach program associated with both pre-lease and post-lease activities of the Secretary's 5-year Oil and Gas Leasing Program, including:

- Government-to-government consultations with potentially affected federally recognized Indian Tribes;
- Meetings with commercial fishing groups, environmental organizations, and local governments to obtain views on leasing, exploration, or development proposals; and
- Public meetings held recently across the North Slope of Alaska and South Central Alaska to obtain input on Beaufort Sea and Cook Inlet sales.

Minerals Revenue Management Program

Our Minerals Revenue Management program (MRM) collects, verifies, and distributes mineral revenues from Federal and Indian lands. This program has been going through an extensive reengineering initiative for the past 3 years, encompassing its core business processes and automated support systems. MRM has consulted with its customers on every aspect of the reengineering effort.

State and Tribal Royalty Audit Committee

One means of consultation is the State and Tribal Royalty Audit Committee, comprised of State and Tribal audit managers who have cooperative audit agreements with MMS under the Federal Oil and Gas Royalty Management Act. The Committee meets at least quarterly, and subgroups of the committee may meet more often. This Committee has achieved results in a number of areas.

- State and Tribal auditors from Colorado, North Dakota, and Oklahoma helped design various tools used in the new compliance system and will help train system users.
- New Mexico is working with MMS on electronic data acquisition from company databases that should reduce information collection time and burden.
- Representatives from Colorado, Utah, Wyoming, and the Northern and Southern Ute Tribes helped design the compliance process for onshore oil and gas.
- Representatives from Colorado, Utah, New Mexico, Wyoming, and the Navajo and Crow tribes helped design the new compliance and asset management process for solid minerals. MMS also consulted with industry on improvements to the compliance activities.

Work with State and Tribal Auditors

MMS works on a continuing basis with State and tribal auditors to:

- Improve the language and content of orders sent to companies for royalty underpayment;
- Resolve valuation issues for royalty purposes involving Federal leases in their State or Indian leases on their Indian reservations;
- Develop case-specific valuation guidance for companies who request solid minerals valuation determinations; and
- Resolve complicated royalty disputes through negotiation.

Consultations with Tribal Auditors

MMS consulted with tribal auditors on a number of Indian royalty issues, including:

- MMS Form 4410—Certification for not Performing Dual Accounting.
- Strategy for completing audits of gas production from Indian leases in Montana and North Dakota.
- Enforcement actions involving major portion/index zone pricing and dual accounting aspects of the Indian Gas rule.
- Oil sales and marketing for production and sales on each reservation.

MMS is currently working to add new cooperative audit agreements with States and tribes. The Crow Tribe entered into a cooperative audit agreement with MMS in June 2001. We are currently in negotiations with Alaska for a Section 205 audit agreement for mineral royalties from Federal leases in Alaska.

Royalty Policy Committee

Another avenue of consultation is the Royalty Policy Committee (RPC). RPC provides policy advice representing the collective viewpoint of the States, Indians, mineral industry and other parties. This advice concerns performance of discretionary functions in the Department's management of Federal and Indian mineral leases and revenues. RPC reviews and comments on royalty management and other mineral-related policies and conveys the views of mineral lessees, operators, revenue payors, recipients, governmental agencies and the interested public. Some recent results from the RPC work include:

- State representatives worked together with MMS, Industry, and Interior Department Solicitor's Office to draft rules on accounting and auditing relief and prepayment of royalties for marginal properties.

- The RPC Coal subcommittee worked with MRM on issues about coal waste piles, advance royalties, and alternative valuation methods.

- Every six months MMS has meetings with tribal representatives in Montana to work out mineral royalty issues.

MMS clarified the policies and procedures related to its Intergovernmental Personnel Act (IPA) Fellowship Program. The program develops audit and compliance experience, knowledge and skills for Fellows from the Tribes and States. It provides a way for MMS and Tribes or States to learn about each other's functions and processes and helps improve understanding, communication, and cooperation between the parties. Four tribes have been involved in the IPA Fellowship Agreements: the Shoshone-Arapaho Tribes, the Crow Tribe, the Navajo Nation, and the Chippewa-Cree Tribe.

OFFICE OF SURFACE MINING

There are 24 coal mining states that regulate surface coal mining and reclamation operations under the Surface Mining Control and Reclamation Act of 1977 (SMCRA). During the specified time period, OSM met regularly with individuals from State and local governments on issues that affected them. OSM also met with organizations representing elected State officials on a regular basis.

State Regulatory Issues

On April 24, 2001, OSM's Acting Director attended and addressed the annual meeting of the Interstate Mining Compact Commission, which is a multi-State governmental organization that represents the natural resource interests of 17 States. State governors serve as commissioners. The Commission operates through several committees composed of representatives from State Departments of Natural Resources or Environmental Protection.

On May 15 & 16, 2001, OSM participated in an intergovernmental forum to discuss mine placement of coal combustion wastes. The forum was hosted by the Interstate Mining Compact Commission and the U.S. Environmental Protection Agency. The 43 forum participants discussed existing State and Federal provisions for regulating mine placement of coal combustion wastes, as well as other regulatory problems and issues.

On May 21-23, 2001, OSM, in cooperation with the Interstate Mining Compact Commission and the Western Interstate Energy Board, conducted a very successful meeting in St. Louis to review and discuss its new Ownership and Control Rule governing the issuance of surface coal mining permits. Representatives from 17 States attended the meeting.

Abandoned Mine Land Issues

OSM consults extensively with the National Association of Abandoned Mine Land Programs. The Association is an organization of 26 State agencies and 3 Indian tribes that implement federally funded programs to reclaim abandoned or inadequately restored land and water resources adversely affected by past coal mining. The Association, organized in 1982, provides a forum to address current issues, discuss common problems, and share new technologies regarding the reclamation of abandoned mine lands. It fosters positive and productive relationships between the States and Indian tribes and the Federal Government.

OSM participated in the Association's August national conference as well as other issue-specific meetings during the year.

Through the Appalachian Clean Streams Program, OSM works with States and watershed organizations to reclaim streams impacted by acid mine drainage from abandoned coal mines. This can involve directly helping them with grant applications as well as funding summer interns that work for watershed organizations, assisting in a wide variety of stream-related activities such as fund raising and complying with environmental regulations.

Coal Mining on Indian Lands

OSM is involved in an active partnership with representatives of tribal governments that have coal mining operations on tribal lands. Specifically, the Navajo Nation, the Hopi Tribe and the Crow Tribe are involved in the review of all permitting actions and representatives of these Tribes participate in the monthly inspections of mining operations and citizen complaint investigations.

OSM is helping revise the OSM-BIA-BLM Memorandum of Understanding (MOU) for the Management of Coal Mining on Indian Lands. The MOU is the result of unprecedented cooperation among 15 BIA, BLM and OSM offices as well as six Tribal governments (the Navajo Nation, the Crow, Hopi, Northern Cheyenne, Ute Mountain Ute and Southern Ute Tribes). Numerous meetings and discussions were held over the past few years to clarify inter-bureau roles, procedures and responsibilities. The bureaus were very successful in resolving long-standing field operational issues. The MOU is now being reviewed for signature by Interior officials. It will provide needed guidance to the field personnel of the three bureaus and will ensure consistent management of coal mining activities on Indian lands.

BUREAU OF LAND MANAGEMENT

BLM's planning process establishes goals and objectives for resource management and defines parameters for using BLM lands. During the planning process BLM considers socioeconomic impacts to State, local, and tribal governments and resource management programs.

Consultation with State, local, and tribal government is an agreement to maintain and exchange information. Consultation and coordination early in our planning process encourages identification of issues and concerns allowing managers to make appropriate adjustments to proposed actions.

Consultation with officials of federally recognized tribes provides them opportunities to comment on land use plans. It identifies cultural or historical resources on and off trust lands that could be affected by BLM activities. At a minimum, tribal governments must have the same level of involvement as State and county governments.

BLM can't delegate our authority to make decisions affecting the public lands we manage. However, BLM strives to cooperate and communicate with State, local, and tribal governments to implement sound decisions that support a community's economic and infrastructure development. BLM involves State and local governments by closely coordinating with State and local land use boards. In addition, all BLM land use plans or plan amendments and revisions must undergo a 60-day review Governor's consistency review before final approval.

DEPARTMENT OF JUSTICE

The Department has engaged aggressively in a wide variety of contacts and consultations with State, local, and tribal governments. In practice, the Department has demonstrated flexibility in responding to the complaints or concerns expressed by these levels of government. The outreach and consultation efforts of the Department are discussed in greater detail in this report.

September 11th Victim Compensation Fund of 2001

Shortly after the September 11 terrorist attacks, the President signed the September 11 Victim Compensation Fund of 2001 (the "Fund") into law as Title IV of Public Law 107-42 ("Air Transportation Safety and System Stabilization Act")(the "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.

As prescribed the Act, the Department of Justice (the "Department"), in consultation with a Special Master, was to promulgate regulations that effectuate the purpose of the Fund. The Fund is being administered by Special Master Kenneth R. Feinberg, who the Attorney General appointed on November 26, 2001. The Department of Justice, in consultation with Mr. Feinberg, recently promulgated its Final Rule, which sets forth the regulations that govern the program.

In promulgating its regulations, the Department depended mostly on outreach and consultation efforts. Indeed, the enormous feedback resulting from these efforts not only influenced but shaped most, if not all, the Department's decisions. These efforts were undertaken soon after the Act was enacted and continued for several months until the final days before the Final Rule was published. The Department met with various groups, including but not limited to, victims groups; elected officials from the Congress, New York State, and New York City; governmental agencies at the city, State, and Federal levels; Pentagon officials; private organizations specializing in victim compensation and ancillary issues; victims' employers; and, most importantly, victims' families.

The Department also solicited comments from the public both before and after issuing its "Interim Final Rule." People from all around the country and from foreign nations sent comments directly to the Department by way of land mail, email, and facsimile. All comments (more than 5000 total) were reviewed and considered in promulgating the Final Rule.

These outreach and consultation efforts played a crucial role in establishing and administering this unprecedented program.

OFFICE OF COMMUNITY ORIENTED POLICING SERVICES

COPS has a history of working closely with State and local government. Since its inception in 1994 through the Violent Crime Control Act, COPS has consulted regularly with professional law enforcement organizations, such as the International Association of Chiefs of Police, National Sheriffs Association, the Police Executive Research Forum, the Police Foundation, and NOBLE on current issues in law enforcement. COPS also maintains regular contact with intergovernmental organizations such as the U.S. Conference of Mayors, the National League of Cities, and the National Association of Counties, which provides the perspective of local government on law enforcement issues. Throughout the last seven years, COPS has conducted research and evaluations with local police departments to identify barriers and challenges to their implementation of community policing. COPS' consultation with State and local government is reflected in the training provided through the Regional Community Policing Institutes, best practices publications and other problem-specific guides, and targeted initiatives.

For example, in August 2001, COPS sponsored a CEO Symposium to discuss with law enforcement leaders what pressing issues they saw for the 21st century. This group identified recruitment, racial/ethnic profiling and technology challenges as their top priorities. In a follow-up symposium in direct response to the tragedies of September 11, law enforcement officials reiterated their original priorities and added the need for information sharing between Federal, State and local law enforcement. Responding to these priorities, the COPS Office, in partnership with the International Association of Chiefs of Police, will convene a national summit on law enforcement intelligence identification, collection, analysis, sharing and use in March 2002. The COPS Office will continue to respond to these emerging law enforcement needs through the development and delivery of training, information and working conferences, and best practices.

COPS provides training for specific grant programs. COPS has provided a variety of training for its technology grantees, including a series of workshops in 2001 and 2002 that assist them with planning, project management, purchasing and implementing of COPS-funded technology. In addition, the COPS Office will contact current MORE program applicants to determine if their technology needs have changed in light of the events of September 11. Since March 2000, the COPS Office has offered specific training to teams of COPS In Schools grantees for School Resource Officers and school administrators.

In 2001, COPS printed the Problem-Oriented Guide for Policing series for use by local law enforcement. These problem-specific guidebooks grew out of the COPS Office's knowledge of the kinds of issues police departments encounter and the difficulties they have in addressing them. The guidebooks provide law enforcement with problem-specific questions to assist in

identifying potential factors and underlying causes of specific problems (such as street prostitution, robberies at ATMs, and assaults in and around bars), identifies known responses to each problem, and provides potential measures to assess the effectiveness of problem-solving efforts.

COPS' targeted initiatives address specific issues in a particular jurisdiction or significant issues shared by law enforcement agencies across the country. For example, COPS provided funding to the Reno Police Department in 2001 to work in partnership with the Police Executive Research Forum to develop and field-test a new Police Training Officer manual. This initiative addressed the need to re-tool the dominant field training officer model to incorporate community policing and problem solving principles throughout the training experience. Racial profiling and its affect on police-community relations are a concern for many agencies across the country. COPS funded an initiative called Promoting Cooperative Strategies to Reduce Racial Profiling to address the need for racial profiling prevention strategies. This initiative will result in a comprehensive series of best practices that can be replicated by law enforcement agencies across the country.

By statute, COPS' grant programs address the needs of State, local and tribal government. Since 1994, COPS hiring and technology programs have provided funding for more 113,000 additional officers across the country. With the help of funds from COPS, thousands of police jurisdictions have hired additional officers and purchased timesaving technology that allows officers to spend more time policing.

FEDERAL BUREAU OF INVESTIGATION

National Instant Criminal Background Check System

By November 30, 2001, the third anniversary of the implementation of the National Instant Criminal Background Check System (NICS), the NICS had performed 26,421,632 background checks (up from 17,573, 038 the previous year) to determine whether the receipt of a firearm by prospective transferee would violate Federal or State law. Currently, the FBI conducts these checks for Federal Firearms Licensees (FFLs) in 37 States for long gun and/or handgun purchases, while 26 States conduct the checks in their role as Point of Contacts (POCs) for long gun and/or handgun purchases.

The FBI continues to work with its State and local partners regarding the operation of the NICS program by providing NICS implementation updates to the CJIS Advisory Policy Board (an advisory committee consisting of representatives of the law enforcement and criminal justice communities that provides advice to the Director of the FBI on the philosophy, concept, and operational principles of various criminal justice information systems managed by the FBI's Criminal Justice Information Services Division) and by working with State POCs to ensure the efficient and effective operation of the NICS.

In addition, over the past three years, the FBI has engaged in a concerted outreach effort to educate and assist tribal, State and local courts, court clerk's offices, and criminal justice agencies regarding the need to provide disposition information to the FBI in response to a NICS inquiry.

Sexual Offender Registration, Tracking, and Identification

The Jacob Wetterling Crimes Against Children and Sexually Violent Offender Registration Act provides a financial incentive for States to establish registration requirements for persons convicted of certain crimes against minors and sexually violent offenses. Megan's Law, Pub. L. No. 104-145, amended provisions of the Wetterling Act to require the release of registration information when necessary to protect the public. On July 21, 1997, at 62 FR 39009, the Attorney General published in the Federal Register final guidelines implementing the Wetterling Act and Megan's Law.

Subsequent to the publication of the current Wetterling Act guidelines, the Wetterling Act was amended by the Campus Sex Crimes Prevention Act (the "CSCPA"), section 1601 of Division B of Pub. L. No. 106-386, 114 Stat. 1464, 1537. The CSCPA provides special requirements relating to registration and community notification for sex offenders who are enrolled in or work at institutions of higher education. The deadline for States to achieve compliance with the CSCPA is October 27, 2002. Supplementary guidelines specifically addressing the CSCPA are forthcoming and will be published in the Federal Register.

Insights gained by the Department from working with States concerning the Wetterling Act-Megan's Law Guidelines have been instrumental in the drafting of the revised guidelines issued in 1999 and the guidelines for the CSCPA. These guidelines have been drafted to give States the maximum possible flexibility in developing conforming registration systems consistent with the statutory provisions.

Criminal Justice Information Services Advisory Policy Board

The Criminal Justice Information Services (CJIS) Advisory Policy Board (APB) is a Federal advisory committee representing Federal, State, and local criminal justice agencies. The APB makes recommendations to the FBI Director for policy and technical changes to the CJIS Systems. At their June 2001 meeting, the APB recommended the following significant policy changes that were subsequently approved by the Director.

A. The APB recommended that the policy for dissemination of National Crime Information Center (NCIC) hot file information clearly prohibit commercial sale. Before this change, secondary dissemination of NCIC Article, Boat, Foreign Fugitive, Gun, License Plate, Missing Person, active Protection Order, Securities, Unidentified Person, Vehicle, Vehicle/Boat Part and Wanted Person Files was discretionary with the State Control Terminal Agency.

B. The APB recommended expanding the authorized use of the Interstate Identification Index via Purpose Code "F" in instances in which (1) a firearm has been pawned or (2) a law enforcement agency in possession of a firearm is relinquishing possession to the rightful owner (including a family member in cases of suicide.) The use of Purpose Code "F" had been limited to weapons related background checks, such as firearms permits. This policy change was based on the requests of local and State law enforcement officials. Before a firearm is relinquished to the owner, the law enforcement officer can ensure that individual is not disqualified by Federal or State law from possessing the firearm. The National Instant Criminal Background Check System (NICS) is accessible by Federal Firearms Licensees for firearm purchases. However, there was no means for criminal justice agencies to determine whether a person is disqualified from possessing a firearm. The following scenario demonstrates the benefits of this policy change: As part of the conditions of a protection order, the respondent surrenders his firearms to the court. The respondent was not convicted of any criminal offense associated with this domestic dispute. Also, a criminal history record check is conducted during the protection order hearings and no record exists. When the order expires, the court, under the new access policy, performs a criminal history check prior to returning the firearms and determines that the respondent has recent felony conviction in a neighboring jurisdiction. This access would prevent a felon from obtaining a firearm.

OFFICE OF JUSTICE PROGRAMS

Executive Office for Weed and Seed

The Executive Office for Weed and Seed (EOWS) provides consultation concerning compliance with program requirements in a number of ways – via phone contacts, application workshops to assist communities in preparing applications which will meet DOJ requirements, and on-site technical assistance provided by EOWS staff and consultants.

Violence Against Women Office

The Violence Against Women Office (VAWO) works with State, local, and tribal governments on regulatory issues related to the Violence Against Women Act, including eleven grant programs administered by VAWO. In developing various regulations related to the grant programs, VAWO considered the comments of interested parties, including State, local, and tribal governments, and made certain suggested modifications. Similarly, VAWO will consider comments from these entities in revising the regulations to conform with the Violence Against Women Act of 2000.

VAWO has convened conferences for the State administrators of the STOP Formula Program and for other grantees, including State, local, and tribal governments, to provide information about program and regulatory requirements and to obtain input from grantees. For instance, VAWO sought input from State administrators in developing a required reporting form for the STOP Formula Program during a conference in spring, 2001. In addition, VAWO has taken several steps in 2001 and 2002 towards implementing recommendations made during a

tribal consultation held in September 2000 with leaders from Indian tribal governments to discuss the implementation of the STOP Violence Against Indian Women Discretionary Grant Program. VAWA has also organized several financial workshops for tribal grantees to clarify their administrative and financial requirements. These workshops occur on a regular basis and the next workshop will be held in May, 2002.

Corrections Program Office

In order to give the States additional time to use the Violent Offender Incarceration/Truth-in-Sentencing (VOI/TIS) grant funds, the Corrections Program Office (CPO) made all awards in years subsequent to 1996 supplements to the original award. This reduces the amount of paperwork and allows the States to meet their matching requirements easier. In addition, CPO offers continuing technical assistance to all grantees in order to aid the States in complying with the VOI/TIS Drug Testing Guidelines.

CPO continues to meet regularly with the Association of State Correctional Administrators (ASCA) in order to discuss and receive input and feedback on CPO public policy decisions. ASCA also remains actively involved, along with the Council for Juvenile Correctional Administrators, in assisting this Office in developing agendas for conferences and workshops in defining what are the technical assistance needs of States, localities, and tribal governments.

Drug Courts Program Office

At the Drug Courts Program Office, State Chief Justices and State Court Administrators are part of the official notification system for the awarding of drug courts grants. This allows these important players in the Drug Courts process full notification of on-going programs.

The Office continues its relationships with membership organizations that represent State and local organizations, including judges and administrators. These relationships have been effective in supplying information concerning the Office's accomplishments and programs to the entire country.

Over the course of 2001, the Office held a total of 60 training workshops for communities planning an adult, juvenile, family, or tribal drug court, as well as an implementation workshop for its tribal grantees.

BUREAU OF JUSTICE ASSISTANCE

The Bureau of Justice Assistance's (BJA) mission is to provide leadership and assistance in support of local criminal justice strategies to achieve safe communities. BJA's overall goals are to reduce and prevent crime, violence, and drug abuse, and to improve the functioning of the criminal justice system. To achieve these goals, BJA programs emphasize enhanced coordination and cooperation with States, territories, local jurisdictions, tribal governments,

public and private organizations, and faith-based organizations involved in criminal justice activities. BJA administers several grant programs, including the Local Law Enforcement Block Grant Program, the Edward Byrne Memorial State and Local Law Enforcement Assistance Formula Grant Program, and a number of more narrowly focused discretionary programs. Each program has its own directives, but all involve significant interaction with state, local and tribal governments. When issuing new guidance, BJA publishes them in the Federal Register and informs interested constituent groups through outreach meetings and special mailings.

Local Law Enforcement Block Grants (LLEBG) Program

The LLEBG Program provides units of government with funds to underwrite projects designed to reduce crime and improve public safety. Beginning in Fiscal Year (FY) 1999, BJA launched an Internet-based, end-to-end, paperless grants management system to administer the LLEBG Program. This user-friendly system enables States, chief executive officers, program contacts, applicants, and constituents to submit and receive information about the program and allows BJA to administer LLEBG funding and access data about funds usage in a more streamlined, efficient manner. Certain aspects and provisions within the LLEBG Program necessitate BJA's communication and coordination with constituent groups such as the National Association of Counties (NACO) and the National League of Cities.

BJA staff conducts on-site monitoring of grantees and hold hundreds of meetings, workshops, trainings, and technical assistance events each year, during which information is gathered by BJA that may be used to revise and update the administration of and policies governing the LLEBG Program. The LLEBG Program requirements include that local jurisdictions convene advisory boards and hold public hearings to review the proposed use(s) of LLEBG funds. These forums also provide the opportunity for constructive dialogue between members of the public and the grantees that, when transmitted to BJA, can lead to modifications in program requirements and improved guidance.

Through 'Ask BJA' (an on-line Q&A component), State agencies administering the LLEBG Program and local recipient jurisdictions' program managers may seek and receive guidance concerning the implementation of LLEBG-funded projects. An LLEBG Program Policy Review Board, internal within BJA, has the responsibility of analyzing and determining programmatic policy.

Edward Byrne Memorial State and Local Law Enforcement Assistance Formula Grant Program

BJA works in partnership with State governments to create safer communities and improve criminal justice systems. State agencies work in conjunction with State criminal justice boards to strategically plan and evaluate ways to improve the functioning of the criminal justice system, with an emphasis on drug trafficking, violent crime, and serious offenders. Information received from the State agencies during on-site monitoring visits, monthly conference calls, workshops, hands-on technical assistance, and meetings, assist BJA in simplifying and reducing the requirements imposed on States. During Fiscal Year (FY) 2001, BJA begin streamlining its

grants administration process by examining the amount of paperwork grantees must file to obtain their grants.

Beginning in FY 2002, the grant period was changed from three to four years to ease administrative requirements and support State trends in subgranting and expending funds. A change to a four-year Statewide Drug and Violent Crime Control Strategy with minimal annual updates also reduces the States' paperwork burden and allows more time to enhance strategic planning efforts. Additionally, BJA has begun to move towards an Internet-based, paperless grants management system that would further enhance communication and coordination.

Through the 'Ask BJA' on-line component, and other electronic and non-electronic means, State agencies administering the Byrne Program may seek and receive guidance concerning Byrne policies.

OFFICE OF JUVENILE JUSTICE AND DELINQUENCY PREVENTION

The Office of Juvenile Justice and Delinquency Prevention (OJJDP) is the Federal agency responsible for providing national leadership, coordination, and resources to develop and implement effective methods to prevent and reduce juvenile delinquency and improve the quality of juvenile justice in the United States.

The primary way that OJJDP consults with State, local, and tribal agencies and private entities regarding its programs is though the publication of an annual program plan. Pursuant to the provisions of Section 204 (b)(5)(A) of the Juvenile Justice and Delinquency Prevention (JJDP) Act of 1974, as amended, the Administrator of OJJDP must publish for public comment a proposed plan describing the program activities that OJJDP proposes to carry out during each fiscal year under Parts C and D of Title II of the JJDP Act. Taking into consideration comments received on this proposed plan, the Administrator then develops and publishes a final plan describing the particular program activities that OJJDP intends to fund during the fiscal year, using in whole or in part funds appropriated under Parts C and D of Title II of the JJDP Act.

OJJDP's State and Tribal Assistance Division (STAD) directly consults with State, local, and tribal governments regarding its program requirements in a number of ways. For example, STAD imparts technical assistance and seeks consultation from State and local governments concerning the regulatory requirements applicable to the Formula Grants Program, Juvenile Accountability Incentive Block Grants Program, Enforcing the Underage Drinking Laws Program, Community Prevention Program, and the Challenge Grants Program. In 2001, all of the States participated in a national workshop entitled "Back to Basics," where they were provided instruction about regulations and policies and were offered an opportunity to comment and advise OJJDP from the State perspective.

Each year, the Coalition for Juvenile Justice -- a national organization representing State Advisory Groups, that receives funding from OJJDP – prepares an annual report that provides recommendations to the President, the Congress, and the OJJDP Administrator on juvenile

justice issues, including the implementation of the Juvenile Justice and Delinquency Prevention Act (JJDP Act). This report is based, in part, on feedback from the juvenile justice field and thus serves to inform OJJDP about priority issues and concerns.

The State and Tribal Assistance Division conducts regular conference calls with State-level juvenile justice specialists who represent the four regions of the country (regions established by the Coalition for Juvenile Justice). These conference calls solicit input from the State specialists on STAD's administration of the six funding streams managed by the Division.

OFFICE FOR VICTIMS OF CRIME

The Office for Victims of Crime (OVC) administers and coordinates grants to State, local, and tribal governments for the purpose of crime victim compensation, crime victim assistance, child abuse prevention and treatment, victims' rights, and victims' services. OVC's regulatory mandate provides many opportunities for interaction between Federal, State, local, and tribal governments.

OVC's formula grants program distributes Crime Victims Fund monies to the States to support State crime victim compensation and assistance programs. OVC regularly consults with the States on the regulatory guidelines for these programs, and includes State personnel in the formulation, review, and evaluation of proposed program guidelines and regulations.

OVC also administers several discretionary grant programs in Indian Country. Two of these programs, the Children's Justice Act (CJA) Partnerships with Indian Communities, and the Victim Assistance in Indian Country (VAIC) grant program, provide grants directly to tribal government agencies to establish reservation-based services to crime victims. OVC uses a variety of means to collaborate with the tribes and States over issues connected with these programs, including an ongoing working group composed of State and tribal victim assistance personnel to advise OVC on regulatory matters. The CJA program regularly works with State and tribal governments to inform and improve the treatment of child abuse victims in Indian Country.

In Fall 2000, the 106th Congress passed the Victims of Trafficking and Violence Protection Act (P.L. 106-386) which provided aid for victims of terrorism and expanded OVC's authority to respond to incidents of terrorism in cases outside the United States. OVC is working to implement the International Terrorism Victims Compensation Program (ITVCP), a compensation program for U.S. nationals and non-citizen U.S. government employees who are victims of terrorism outside the United States. OVC has solicited the assistance and input of several State Victims of Crime Act (VOCA) administrators in developing the parameters of this new program.

OFFICE FOR CIVIL RIGHTS

Providing State Technical Assistance and Training Programs

Consistent with the Justice Department's current Strategic Plan, which highlights education and outreach as a key strategy in civil rights enforcement, OCR has in recent years focused on providing training and technical assistance to State planning agencies and their subgrantees. Beginning in fiscal year 1998, OCR designed a comprehensive technical assistance program for the administrative staffs of both funded State agencies and subgrantees. In most States, OCR has to repeat the daylong training sessions to accommodate the large number of subgrantees. In some States, to respond to the needs of remote jurisdictions, OCR has had to provide multiple daylong training programs at a variety of sites throughout the State.

OCR has made considerable progress in reaching its long-range goal of providing technical assistance to all fifty States and U.S. territories. As of January 1, 2002, OCR has conducted individually tailored civil rights training programs for California, Colorado, Florida, Michigan, Mississippi, North Carolina, Oregon, South Carolina, Tennessee, Texas, Utah, Washington, and West Virginia. In FY 2001, OCR also conducted a follow-up visit to Utah to determine the effectiveness of previous technical assistance efforts.

ENVIRONMENT AND NATURAL RESOURCES DIVISION

The Division works closely with State and local enforcement agencies in enforcing environmental law. The Division has emphasized cooperative enforcement through joint enforcement actions, through training and support of local prosecutors, and in the development of enforcement policy. Specifically, the Division frequently works with State attorneys general, local prosecutors and the National Association of Attorneys General. In addition, in its litigation on behalf of the Secretary of the Interior for the benefit of Indian tribes, the Division coordinates with the affected tribes.

ENRD joined with the States of Delaware and Louisiana, and a regional air pollution control agency in Washington State, in reaching a Clean Air Act agreement with companies operating nine petroleum refineries. ENRD joined with the States of Alabama, Arkansas, Nebraska, Utah, South Carolina and Texas in reaching agreements with a steel manufacturer under three environmental statutes - the Clean Air Act, Clean Water Act and the Resource Conservation and Recovery Act ("RCRA"). The consent decree requires operation of pollution control equipment for nitrogen oxide emissions, remediation of areas of contamination and improvements in waste management. ENRD joined with the State of California in reaching a settlement with a DDT manufacturer and others for injuries to natural resources and cleanup costs resulting from releases of DDT in the Pacific Ocean in the vicinity of Los Angeles, California. ENRD joined with the States of Minnesota, Ohio and Louisiana and with Wayne County, Michigan in reaching settlement with a petroleum refinery under four environmental statutes - the Clean Air Act, RCRA, the Comprehensive Environmental Response, Compensation and Liability Act and the Emergency Planning and Community Right to Know Act. The consent

decree requires operation of pollution control technologies and reduction of emissions of nitrogen oxides, sulfur dioxide, particulate matter, and carbon monoxide by approximately 24,000 tons per year.

Federal, State and Local Task Forces for Criminal Environmental Enforcement.

Almost all Federal environmental statutes provide for delegation of programs to the States and recognize State enforcement authorities. Therefore, from the beginning of the Federal environmental criminal program, it has been essential to work closely with State and local agencies. Today, in nearly every case, information and other assistance is sought and obtained from State and local law enforcement and regulatory agencies. More importantly, however, such efforts are now going far beyond the solicitation of information and review of files, to the formation of task forces and other means of cooperation and coordination.

These task forces have been formed in many districts to address environmental crimes and related enforcement concerns. The Division's attorneys act as members of the task forces as they work jointly with Assistant United States Attorneys on cases in the district, but also provide information, general assistance, and support to all such task forces as called upon. One good example of a closely coordinated criminal environmental prosecution in the past year was brought against a petroleum refinery operator in Texas for covering up violations under the Clean Air Act and for submitting false statements.

Counsel for State & Local Affairs.

Since 1994, the Division has included a counsel whose function is to serve as a liaison with State and local governments.

Indian Resources

The Indian Resources Section represents the United States in its capacity as trustee for American Indian tribes. To this end, the Section litigates cases in order to establish and protect the following: treaty hunting and fishing rights; tribal water rights; tribal lands and natural resources; and tribal jurisdiction and authority. The Section also defends actions by the Secretary of the Interior and Congress intended to further tribal sovereignty and Indian rights. This litigation is of vital importance to Indian tribes and Indian people.

Although the Indian Resources Section represents the interests of the United States and particularly the interests of the Interior Department, these interests are often aligned with the interests of Indian tribes. DOJ, therefore, works both informally and formally with tribes in pursuing litigation and negotiating settlements. In the past several years DOJ has had remarkable success in working with tribes, States, and private parties to settle disputes. Examples of recent water rights settlements include working with the Shivwits Band of the Paiute Indian Tribe of Utah, the State of Utah, and area irrigation districts to secure enactment of the Shivwits Band of the Paiute Indian Tribe of Utah Water Rights Settlement Act and working

with the Chippewa Cree Tribe of the Rocky Boy's Reservation and the State of Montana to settle the Chippewa Cree Tribe of the Rocky Boy's Reservation's water rights. With regard to treaty fishing rights, DOJ worked closely with five Michigan tribes and the State of Michigan to negotiate a consent decree in *United States v. Michigan,* regarding treaty fishing rights in Lake Michigan.

DEPARTMENT OF LABOR

OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION

OSHA-Approved State Plans

State and local governments and their employees are specifically excluded from Federal coverage under the Occupational Safety and Health Act; thus, there is no OSHA intergovernmental mandate with regard to State and local governments. However, States that elect to accept responsibility (and up to 50 percent Federal funding of the cost of their program) for occupational safety and health enforcement in their State must first obtain OSHA approval of their "State plan," and as a condition of that approval, extend their protection to State and local workers. (States may also obtain approval of Public Employee Only State Plans.) Thus, in 24 States and two Territories, OSHA standards apply to State and local governments, as part of a voluntary program, not as a Federal mandate. (In January 2001, OSHA initially approved the New Jersey Public Sector Only State Plan, covering the workplace safety and health of State and local government employees in New Jersey.) Nonetheless, OSHA does seek and consider State and local government views through its own and the State plans' standards promulgation processes.

OSHA actively seeks input on proposed standards and regulations from States participating in the program through its regular coordination with its State plan partners. OSHA meets regularly with the State plans States by attending meetings of their organization, the Occupational Safety and Health State Plan Association (OSHSPA). At these meetings, specifics of new and proposed standards and regulations are discussed.

OSHA's relationship with the approved State plans is based on the principle of partnership. The basic policies and procedures for monitoring State plans were developed as a Federal-State initiative over several years. The primary focus of program evaluation is the States' progress toward achieving their own OSHA-approved, results-oriented goals, in a manner consistent with the approach taken by OSHA under the Government Performance and Results Act (GPRA). This allows the States real flexibility to tailor their programs to State-specific circumstances, including the safety and health of State and local government workers. OSHA also monitors whether the States meet statutory mandates. The States' efforts are reported annually in both State and Federal evaluation reports. OSHA also continues to assist the States with various technology and data issues as part of this initiative.

OSHA's proposed rule revising 29 CFR Part 1953 (66 FR 56043), which streamlines the process for submission, review and approval of plan supplements, including changes to State occupational safety and health legislation and standards, was developed in conjunction with a Federal/State Task Force and has been discussed extensively at meetings of the Occupational Safety and Health State Plan Association. The proposed regulatory change, published on October 6, 2001, includes an explicit statement of OSHA's longstanding statutory interpretation that States may implement their adopted regulations, standards, and procedures without needing to obtain prior Federal approval. Final action on the proposed regulatory revision will likely result in a reduction in the burden estimate.

PENSION AND WELFARE BENEFITS ADMINISTRATION

Definition of Collective Bargaining Agreement (ERISA section 3(40))

This regulation will establish criteria for determining whether an employee benefit plan is established or maintained under or pursuant to one or more collective bargaining agreements for purposes of its exclusion from the Multiple Employer Arrangement (MEWA) definition in section 3(40) of the Employee Retirement Income Security Act of 1974 (ERISA), and thus exempted from State regulation. The Department has developed a revised proposal utilizing a Negotiated Rulemaking Advisory Committee (the Committee) appointed by the Secretary in 1998. The Committee is composed of representatives from labor unions, multi-employer plans, employer/management associations, Railway Labor Act plans, third party administrators, independent agents and brokers of health care products, insurance carriers, and the Federal government. State insurance regulators were represented through the participation of the National Association of Insurance Commissioners (NAIC). State insurance regulators also participate in a meeting of the Committee, for the purpose of reviewing public comments to the proposed rule.

Final Rule for Reporting by Multiple Employer Welfare Arrangements and Certain Other Entities that Offer or Provide Coverage for Medical Care to the Employees of Two or More Employers

The Department is currently finalizing this rule based on a previously published interim final rule governing certain reporting requirements under Title I of ERISA for multiple employer welfare arrangements (MEWAs) and certain other entities that offer or provide coverage for medical care to the employees of two or more employers. The interim final rule requires the administrator of a MEWA, or other entity, to file a form (Form M-1) with the Secretary of Labor for the purpose of determining whether the requirements of Part 7 of ERISA are being met. Since publishing the interim final regulation, the Department has received numerous comments that are being incorporated into the final regulation. The Department receives and shares information with State insurance commissioners through periodic consultations with NAIC representatives on the Form M-1, the instructions for Form M-1, and the interim final regulation. In June 2001, the Department delivered a presentation on MEWAs and the Form

M-1 to the NAIC. Discussions have resulted in a request by the Commissioners that the Form M-1 database become available for their use.

MINE SAFETY AND HEALTH ADMINISTRATION

MSHA continues to work closely with representatives from State, local, and tribal governments, and academia. A designated individual in each State government serves as a point of contact between MSHA and that State. A number of States have agencies that regulate mining in that State. MSHA works particularly closely with these agencies. MSHA co-sponsors institutional meetings with the Virginia Polytechnic Institute and State University (Virginia Tech) and the University of Utah, where scientific papers concerning mine safety and health are presented. Representatives from the State's regulatory agencies sit on the advisory boards for these meetings, and in that capacity suggest the agenda and topics.

Many local governments operate mines, typically rock quarries or sand and gravel pits to produce material for road construction and maintenance. These mines are under MSHA's jurisdiction, and MSHA actively seeks input to proposed standards and regulations from these interests, and involves them in other outreach efforts. MSHA manages a number of grants to States for mine safety and health activities.

A yearly grant to the Navajo Nation finances miner training and special emphasis training for citizens. Mining in this area is unique in a number of ways. For instance, coal slurry is usually moved to power plants by railroad cars, trucks or conveyor belts. Coal slurry from the mine on Navajo Nation territory moves through a pipeline, using a combination of pumping stations and gravity flow, to a power plant several hundred miles away. Another unique aspect of this mine is that many citizens live on the mine property. Regular vehicular traffic, such as automobiles and school buses, share common roads with heavy mining equipment. Some of the funds from these grants are used for public awareness to teach the dangers inherent to these situations. MSHA also works with a number of school boards to promote outreach programs aimed at teaching children the dangers of playing in and around abandoned mine shafts and swimming in quarries.

Efforts to facilitate an open exchange of ideals and information between the mining public and operators are on-going. MSHA held a number of stakeholders meetings throughout the country seeking input to the Agency's strategic plan. Representatives from various States provided comments and suggestions that, along with those from other groups such as industry and labor, were incorporated into the draft plan. To assist operators in implementing new rules, MSHA has developed compliance-related material, such as compliance guides, sample plans, informational material, and forms.

ENVIRONMENTAL PROTECTION AGENCY

Since passage of the Unfunded Mandates Reform Act in 1995, and Executive Order 13132 on Federalism in 1999, EPA has taken steps to include government officials from States, localities, and Tribes in the development of regulations, policies, and guidance that affects them. Among other steps, the Agency has:

- finalized Agency guidance for EO 13132; Federalism; which includes procedures for the EO's implementation, technical guidance on how to analyze impacts on States and communities, and guidance on selecting appropriate techniques for sharing information and gathering advice from State and local officials during the formative stages of the policy process;

- expanded training of Agency staff regarding intergovernmental consultations to include Regional offices; and

- continued to offer technical assistance to agency program staff from the Office of Congressional and Intergovernmental Relations.

EPA is also seeking to strengthen its partnership with tribal governments through implementation of EO 13175: Consultation with Tribal Governments. Since the Executive Order became effective, EPA has been closely examining rules under development for any potential effect on Tribes and seeking consultation with them under appropriate circumstances. The Agency has formed a workgroup, with the participation of tribal representatives, to develop a consultation guidance for Agency personnel. EPA held several meetings with Tribal leaders to get input from them about developing means of effective consultation with the Tribes.

Consultation Mechanisms, General Outreach Activities and Communication Aids

EPA has several mechanisms to help State, local, and tribal officials learn about EPA's regulatory plans and to let them know how they can participate in the rule-development process. For example, EPA distributes reprints of the semi-annual *Regulatory Agenda* to more than 300 State, local, and tribal government organizations and leaders. EPA also participates in a Federal government- wide State/Local Governments Web site. In addition, the Agency supports hotlines in both EPA Headquarters and the Regions where callers can get information on a range of topics, including regulatory and compliance information (these communication aids are further highlighted below).

In addition, EPA has chartered a cross-media FACA advisory body, the Local Governments Advisory Committee. Its Small Communities Advisory Subcommittee routinely advises the Agency on issues and concerns, and makes recommendations on regulations,

policies, and guidance affecting the development and delivery of environmental services. The Tribal Operations Committee similarly addresses tribal interests. EPA program offices regularly work with groups of State, local, and tribal officials to address specific environmental and programmatic issues. Examples include media-specific FACA committees, regulatory negotiation advisory committees and policy dialogue groups.

The Agency continues to work with States under the National Environmental Performance Partnership System (NEPPS), principally through the Environmental Council of the States (ECOS). The objective is to ensure that the States are informed and involved in Agency activities, particularly those affecting State-implemented programs. Most of this work is accomplished through committees that have both State and EPA members, but also through forums that are open to other stakeholders. EPA and the ECOS have an active joint work group to address continuing implementation issues and work to identify and remove remaining barriers to effective implementation of NEPPS. ECOS has also initiated a number of other projects with EPA consultation including work on children's health issues, a partnership to build locally and nationally accessible environmental systems, and development of core performance measures.

The Office of Pollution Prevention and Toxics (OPPT) has a number of ongoing outreach mechanisms related to its mission activities that allow OPPT to routinely secure State and tribal insights and advice. These processes have been institutionalized in many ways and are therefore to some extent independent of specific rulemaking.

Some of the most important are identified below: Established in early 1990's the Forum on State Tribal Toxics Action (FOSTTA) was created as a vehicle through which the Office of Pollution Prevention and Toxics (OPPT) gets State and tribal involvement in OPPT decision making.

OPPT also utilizes the State Federal FIFRA Issues Research and Evaluation Group (SFIREG) which was established in 1974 by cooperative agreement between EPA and the American Association of Pesticide Control Officials, the association that represents State level pesticide regulatory officials. SFIREG identifies, analyzes and provides State comment on, pesticide regulatory issues, and provides a mechanism for ongoing exchange of information about EPA and State pesticide programs. With a full committee and two subcommittees, there is a total of eight regularly scheduled meetings each year offering State officials the opportunity to meet with EPA. Regulations in progress are routinely brought to these meetings for discussion.

Some specific examples of results of consulting with SFIREG include the formation of joint EPA-State workgroups to deal with a number of issues/projects, such as: (1) developing guidance documents for use by EPA Regions and State agencies to define Quality Management and Quality Assurance procedures for State pesticide programs (completed in 2000); (2) improving or clarifying a number of pesticide labeling issues, including products used in public health mosquito control programs, restricted reentry intervals for agricultural workers, label precautions to protect bees and other pollinators, and new requirements for the safe handling and use of phosphine gas fumigants (these are on-going now). EPA has also used SFIREG to

provide State input on labeling policy in general through comments on revisions to the Label Review Manual used by EPA staff.

EPA has also developed a variety of materials intended to help small governments more easily understand agency regulations.

Profile of Local Government Operations: The Profile details all of the environmental requirements with which a local government must comply. Information in the Profile is organized on the basis of operations, i.e., motor vehicle servicing, property management, etc. This makes it easier for the representative of a local government responsible for an operation to find out about all of the environmental requirements that might impact his or her operation and where to get more detailed compliance information.

Local Government Environmental Assistance Network (LGEAN): EPA helps support this Internet-based information service (that has parallel toll-free voice and fax-back options). LGEAN provides a first stop for local government officials with questions about environmental compliance. The site contains a wealth of information from EPA and eight participating non-governmental organizations. Users can ask questions of experts, consult with their peers, review and comment on developing regulations, and find the full text or summaries of State and Federal environmental statutes. LGEAN alerts users to hot topics and new developments in environmental compliance, tells them where to find technical and financial assistance, and provides them with a grant writing tutorial.

Small Government Agency Plan: The Agency's interim Small Government Agency Plan supplements the intergovernmental consultations described above. The Plan outlines the analysis rule writers complete to determine whether the regulatory requirements of a rule might uniquely affect small governments. Under the plan, EPA encourages attention to such factors as whether small governments will experience higher per-capita costs due to economies of scale, whether they would need to hire professional staff or consultants for implementation, or if they would be required to purchase and operate expensive or sophisticated equipment. The findings under the Small Government Agency Plan are published in the *Federal Register* with proposed and final rules. When there are unique or significant impacts on small governments, a range of actions are taken to inform and assist them.

Newsletter/Internet Site for Small Governments: Under a cooperative agreement funded by EPA, the International City/County Management Association (ICMA) publishes a newsletter designed for small governments covering regulatory and other environmental program activities of interest to them. ICMA's *Environmental SCAN* is also published electronically on the Internet. Access is free to anyone interested in local government issues; the ICMA site is linked electronically to EPA's Federal Register site so that readers interested in a regulation covered in the newsletter can immediately gain access to the actual text. As part of the project, ICMA has also conducted several workshops for small government officials on regulatory and other environmental management topics.

Guide to Federal Environmental Requirements for Small Governments: EPA also publishes and distributes the small communities guide --a reference handbook to help local officials become familiar with Federal environmental requirements that may apply to their jurisdictions. In the guide, Federal regulations are explained in a simple, straightforward manner. Mandated programs described in the guide include those for which small communities have major responsibilities, such as landfills, public power plants, sewerage and water systems.

Regional Guides to Federal Environmental Requirements for Small Governments: EPA Region VIII publishes and distributes a small community reference handbook to help local officials in Colorado, Montana, North and South Dakota, Utah and Wyoming become familiar with Federal environmental requirements that may apply to their jurisdictions. In the guide, Federal regulations are explained in a simple, straightforward manner. In addition, up-to-date contact lists for State environmental programs are included.

National Online Dialogue on Public Involvement: In July 2001, EPA convened an innovative, online "e-gov" dialogue to obtain input from the public about how to improve public involvement in EPA's decisionmaking process. A portion of this 10-day discussion dialogue was devoted to public involvement issues related to State, local, and Tribal governments. An expert panel consisting of representatives from State, local, and Tribal governments led the discussion, which focused on the three key issues: public involvement "best practices" of States, tribes and local governments; public involvement in delegated programs; and ways EPA can support local government participation in EPA decisionmaking. Participants posted over 75 messages on these topics, and additional messages also related to State, local and Tribal government issues. EPA organized and made the dialogue record available online to the public, and plans to continue to use much of this material in public involvement training for EPA staff as well as to inform policy implementation. The success of this e-gov dialogue is paving the way for future e-gov approaches and opportunities.

State and Local Government Input on EPA's Public Involvement Policy: In December 2000, EPA released a draft Public Involvement Policy that recognizes and reflects, among other things, the changing and growing relationship between EPA and State and local governments. EPA's previous 1981 Public Involvement Policy contained public involvement requirements for delegated programs, since most State and local governments then had limited capacity to carry out environmental programs and associated public involvement activities. In contrast, the final 2002 Policy will emphasize EPA assistance to and partnerships with delegated programs' public involvement activities. EPA received comments from 26 State agencies, 12 local governments, and four tribal governments on the draft Policy, and is revising the draft Policy based on received comments and additional meetings with States. States expressed strong interest in partnering more with EPA on public involvement activities, and in utilizing the tools (training, evaluation and sharing information) that EPA is creating to enhance public involvement in the Agency's decisions. At the same time that EPA was receiving public comments on the draft Policy, EPA prepared a draft implementation plan for the Policy and invited States and Tribes to assist informally in developing the implementation plan. The final implementation plan is expected to be released with the final Public Involvement Policy in spring 2002.

Office of Solid Waste and Emergency Response

Revoking the Case-by-Case (CBC) Extension of the Effective Date of Land Disposal Restrictions for Hazardous Wastes Generated at the FMC Pocatello, Idaho facility

FMC had operated their Pocatello, Idaho facility for over 50 years to manufacture elemental phosphorus that was shipped to other facilities to produce phosphates and other phosphorus-based products. The facility is located on the Shoshone-Bannock Tribe's lands, referred to as the Fort Hall Indian Reservation. This facility generated five large-quantity hazardous waste streams that were reactive and ignitable and posed unique handling, treatment, and disposal problems because of the presence of elemental phosphorous and cyanide. Each of these waste streams also contained varying levels of Naturally Occurring Radioactive Material, which most off-site commercial TSDs are not permitted to manage. Because there was no available commercial treatment capacity, we granted a national capacity variance and two case-by-case (CBC) extensions of the LDR effective date for these wastes to allow FMC the time to construct an on-site treatment plant and begin operating it by May 2002. These extensions of the LDR effective date allowed FMC to continue disposing these five hazardous wastes in two n-site surface impoundments (referred to as Pond 17 and Pond 18). In mid-October 2001, FMC decided that elemental phosphorus production at the facility was no longer cost effective, and would close it by the end of the year (2001). FMC likewise halted construction of the onsite treatment plant on which they had already spent over $100 million for the design and construction.

FMC's decision to stop work on the treatment plant could be seen as a basis for revocation, since FMC agreed to complete the treatment plant as a condition for receiving the CBC extension. This is the first time EPA had considered revoking a CBC extension. FMC initially asked that the CBC be terminated on December 31, 2001 to conduct an orderly shutdown and secure the facility in a way that ensures worker safety and minimizes waste, and leaves the plant and equipment in a secure and environmentally safe condition. However, FMC then attempted to revise their plans and schedule for decommissioning the facility. FMC submitted a revised plan that would allow the original CBC extension date of May 26, 2002 be left intact to permit them to place phossy water, generated during decommissioning, into the onsite ponds. The Tribes opposed the continued disposal of these untreated wastes in the onsite surface impoundments. They expressed again a long-held concern about the emissions of phosphine and hydrogen cyanide from these ponds into the air, the potential mismanagement (e.g., overtopping) of the surface impoundments, and potential groundwater contamination. After having discussions with Tribal staff, EPA Region 10 staff and the State of Idaho, EPA concluded the best environmental solution was to allow FMC to implement their original shutdown plan and operate the Pocatello facility until December 31, 2001. EPA decided to revoke their CBC extension on January 1, 2002. In late November, EPA provided the Tribes with a draft letter to FMC, for their review and comment, that provided its tentative decision to revoke the CBC extension, in its entirety, as of January 1, 2002. EPA and the Tribes reached a

consensus that the FMC CBC extension should be revoked effective January 1, 2002. On December 21, the letter was sent to FMC, notifying them of this decision by EPA.

Small Government Pilot Projects and Capacity Building

Policy on Flexible State Enforcement Responses to Small Community Violations

EPA's Office of Enforcement and Compliance Assurance (OECA) issued the Policy on Flexible State Enforcement Responses to Small Community Violations in 1995. The policy establishes parameters within which a State can expect EPA to defer to the State's decision to address a small community's environmental violations with comprehensive, capacity-building compliance assistance instead of with the traditional enforcement action and penalty. The policy gives States the flexibility to help small communities address environmental problems on a "worst things first" basis. The policy also creates a new incentive for small communities to ask the State for help when they think they may have an environmental problem.

Developed as a result of the Agency's ongoing dialog with small communities, this policy is intended to address the concern that small communities that lack the technical resources needed to comply with all environmental regulations may not seek help for fear of becoming entangled in the enforcement process. Small localities making substantial progress towards compliance in accordance with a schedule developed with State assistance will generally not be subject to State or Federal enforcement actions.

Based on EPA's experience so far in Oregon, the policy works as follows. Environmental Partnerships with Oregon Communities (EPOC) offers compliance assistance to a small community that requires assistance to meet its environmental obligations. A team of experts from the State performs a comprehensive review of the communities operations to identify all current environmental violations and areas of concern for future violations. If a community cannot correct all its violations quickly, the State negotiates an enforceable compliance schedule which establishes a specified time period for correcting the violations on a priority basis. The community then addresses those violations according to the schedule, beginning with those that have the greater potential impact on health and/or the environment. The State refrains from taking enforcement actions and waives or reduces penalties that normally would be assessed for violations, so long as the small community is making "good faith" efforts towards implementing the schedule.

Of course, small communities that do not meet the negotiated compliance schedule may be faced with State or Federal enforcement actions. The policy does not apply to criminal violations and EPA retains its independent authority to take immediate action in the event of any violation that represents an "imminent and substantial endangerment" to the public or the environment. More than a dozen Oregon communities have signed such agreements and others are "in the pipeline." Nebraska conducts a similar program. Under the Nebraska Environmental Partners Program (NEPP), more than 200 communities have conducted comprehensive environmental self-assessments with the assistance of State government agencies of the state of

their environmental compliance. Although no violations have been identified, NEPP has developed compliance assistance and funding strategies to address the compliance issues that have been identified through the self-assessment process.

In 2001, EPA published a Federal Register notice taking public comment on possible revisions to the Policy. Following extensive information gathering from stakeholders, EPA published a Federal Register Notice on January 23, 2002 (67FR3185) that discussed the history and intent of the Policy on Flexible State Enforcement Responses to Small Community Violations, the limited extent to which States have chosen to implement the Policy, and the major reasons for limited implementation, as identified by stakeholders. The Notice discusses various options for addressing those impediments, and solicits public comment on possible revisions to the Policy. Public comments are due to EPA by April 23, 2002.

SOCIAL SECURITY ADMINISTRATION

The Old-Age, Survivors and Disability Insurance programs under title II of the Social Security Act are exempt from the Unfunded Mandates Act of 1995. The Social Security Administration's (SSA) rules generally do not raise Unfunded Mandates Reform Act issues. EPA does consider the effects of each of its regulatory initiatives on State/local/tribal governments, and have developed a consultation process with the "Big 7" organizations.

Although SSA had no final rules formally covered by the Unfunded Mandates Reform Act during this period, SSA did follow the spirit of the Act in planning for implementation of the Ticket to Work and Work Incentives Improvement Act of 1999. The final rules were published on December 28, 2001. Throughout 2001, SSA sponsored and participated in numerous educational forums throughout the country in order to stimulate discussion about the Ticket to Work program. SSA employed its long-standing relationship with the State vocational rehabilitation agencies through a variety of meetings, forums and other conversations to gain insight as to how to develop these rules. Furthermore, SSA consulted on a regular basis with those States selected for the first round of the Ticket to Work rollout and the Department of Education's Rehabilitation Services Administration in preparing the rules. The final rules reflect its efforts to respond to the issues raised by the States during these consultations.

In most cases, SSA's existing rules that affect State/local/tribal governments do so because the governments have voluntarily entered into an agreement with SSA. For example:

- In the Supplemental Security Income (SSI) program, SSA makes the Medicaid determination for a State, and includes the State supplementation payment in the SSI check, only for those States that have chosen to have SSA do so.
- State Disability Determination Services that make the disability determination for SSA do so as part of an agreement with us, and fund their activities as appropriate.

SSA continues to examine all its rulemaking activities and assess the need to consult with or address concerns raised by State, local and tribal governments.

DEPARTMENT OF TRANSPORTATION

In developing the Administration's hazardous materials transportation reauthorization legislative proposal, RSPA and the DOT Hazmat Reauthorization Team gave special consideration to the needs of our State, local government and Indian tribe enforcement partners. Through the Cooperative Hazardous Materials Education Development (COHMED) Program and through State and local government comments to a hazmat reauthorization legislative docket, we became aware of a threat to States' ability to enforce the Federal hazardous materials transportation law, 49 U.S.C. 5101 et seq. The State and local governments described a lawsuit that asserted that their enforcement procedures and standards had to match the Federal standards or otherwise should be preempted. They stated that preemption of their no-fault approach to hazmat transportation violations would eviscerate their compliance programs and undermine their ability to partner with the Federal Government in this area. In response to the State and local government concerns, DOT inserted in the Administration's hazmat reauthorization bill a provision exempting from Federal preemption State, local or tribal procedures, penalties, or other standards used to enforce hazmat transportation requirements. That pro-State provision is part of the Administration's bill that was sent to Congress, was introduced by request in both houses (S.1669, HR 3276), and is under consideration in Congress.

CHAPTER III: A REVIEW OF SIGNIFICANT REGULATORY MANDATES

Federal agencies issued four rules that were subject to Sections 202 and 205 of the Unfunded Mandates Reform Act because they require expenditures in any year by State, local or tribal governments, in the aggregate, or by the private sector, of at least $100 million. The Department of Energy issued one proposed rule; the Department of Transportation issued two proposed rules, and the Environmental Protection Agency issued one proposed rule. There were no rules for which agency analyses demonstrated expected expenditures in any year by State, local or tribal governments, in the aggregate, totaling more than $100 million. All of the rules issued, which were covered by the Act because of expenditures exclusively by the private sector.

OMB worked with the agencies to ensure that the selection of the regulatory option for final rules fully complied with the requirements of Title II of the Act. For proposed rules, OMB often worked with the agency to ensure that they also solicited comment on alternatives. These were generally alternatives that could, in light of further public comment and additional analysis, be shown to be the least costly, most cost-effective, or least burdensome option at the final rule stage. Agency statements regarding compliance with the Act are included with the descriptions of the rules below.

DEPARTMENT OF ENERGY
Energy Efficiency Standards for Central Air Conditioners and Heat Pumps (NPRM)

This rule proposes to revise the energy conservation standards for central air conditioners and central air conditioning heat pumps to a level of 20 percent, which is the amount DOE determined was the maximum amount that was economically feasible. Consistent with this proposed determination, DOE proposes a Seasonal Energy Efficiency Rating of 12, with a corresponding Heating System Performance Factor of 7.4. These standards would apply to manufacturers in 2006.

DOE estimates that the proposed standards, if adopted, would not result in the expenditure by the private sector of $100 million or more in a year, with the exception of one year in which industry expenditures could total approximately $110 million. DOE believes that this proposed rule would establish energy conservation standards for central air conditioners and heat pumps that are designed to achieve the maximum improvement in energy efficiency that DOE determined to be both technologically feasible and economically justified.

DEPARTMENT OF TRANSPORTATION
Tank Level or Pressure Monitoring Devices (NPRM)

This rule proposes various regulatory options for the use of tank level or pressure-monitoring devices as mandated by the Oil Pollution Act of 1990. The rule would set minimum standards for the performance and use of these devices on single-hull tank ships and single-hull tank barges carrying oil as cargo.

DOT estimates that the present value of the total cost of the options in this proposed rule range from $82 million to $211 million. All the costs will be incurred during the three-year to five-year phase in period. The Department proposed eight options and sought public comment.

Tire Pressure Monitoring Systems (NPRM)

This rule proposes to establish a new Federal Motor Vehicle Safety Standard that would require tire pressure monitoring systems to be installed in new passenger cars and in new light trucks and multipurpose passenger vehicles. The proposal includes alternative approaches.

DOT estimates that this proposed rule would not result in the expenditure by State, local, or tribal governments, in the aggregate, of more than $100 million annually, but it would result in the expenditure of that magnitude by vehicle manufacturers and/or their suppliers. The Department proposed two alternative standards and sought public comment.

ENVIRONMENTAL PROTECTION AGENCY
Control of Emissions From Nonroad Large Spark Ignition Engines and Recreational Engines (Marine and Land-Based) (NPRM)

This rule proposes emission standards for several groups of nonroad engines including large spark-ignition engines such as those used in forklifts and airport tugs; recreational vehicles using spark-ignition engines such as off-highway motorcycles, all-terrain vehicles, and snowmobiles; and recreational marine diesel engines.

EPA estimates that this proposal will not result in Federal mandates for State, local or tribal governments, but determined that the rule does contain Federal mandates that may result in expenditures of more than $100 million to the private sector in any single year. EPA believes that the proposal represents the least costly, most cost-effective approach to achieve the air quality goals of the rule.