United States General Accounting Office

GAO

Report to Congressional Requesters

September 2003

RULEMAKING

OMB's Role in Reviews of Agencies' Draft Rules and the Transparency of Those Reviews

GAO-03-929

September 2003

RULEMAKING

OMB's Role in Reviews of Agencies' Draft Rules and the Transparency of Those Reviews

GAO Highlights

Highlights of GAO-03-929, a report to congressional requesters

Why GAO Did This Study

Under Executive Order 12866, the Office of Management and Budget's Office of Information and Regulatory Affairs (OIRA) reviews hundreds of agency rules each year before they are published in the *Federal Register*. Those reviews can have a significant effect on a broad array of public policies. GAO was asked to (1) describe OIRA's review process and any changes in its policies or processes in recent years, (2) provide detailed information about rules submitted by nine health, safety, or environmental agencies that were returned, withdrawn, or changed at OIRA's suggestion, and (3) describe how OIRA decided that certain existing rules merited high priority review.

What GAO Recommends

GAO recommends that the OMB Director build on recent improvements that have been made in the transparency of the OIRA review process. In particular, GAO recommends that agencies be instructed to document substantive changes made at OIRA's suggestion to draft rules submitted for review whenever they occur, not just changes that OIRA recommended during formal reviews.

OMB said the factual foundations of our report were well grounded but disagreed with most of our recommendations, saying that the report had not demonstrated the need or desirability of changing the agency's existing level of transparency.

www.gao.gov/cgi-bin/getrpt?GAO-03-929.

To view the full product, including the scope and methodology, click on the link above. For more information, contact Victor Rezendes at (202) 512-6806, or rezendesv@gao.gov.

What GAO Found

The formal process by which OIRA reviews agencies' proposed and final rules is essentially unchanged since Executive Order 12866 was issued in 1993. However, there have been several changes in OIRA's policies in recent years, including increased use of public letters explaining why rules were returned to the agencies and prompting the development of new rules, increased emphasis on economic analysis, stricter adherence to the 90-day time limit for OIRA review, and improvements in the transparency of the OIRA review process (although some elements of that process are still unclear). Underlying many of these changes is a shift in how recent OIRA administrators view the office's role in the rulemaking process—from "counselor" to "gatekeeper." OIRA sometimes reviews drafts of rules before they are formally submitted, and OIRA has said it can have its greatest influence on agencies' rules during this informal review period. However, OIRA contends that agencies need only document the changes made to rules during what are sometimes very brief formal review periods.

Because about 400 rules were changed, returned, or withdrawn during the 1-year period that GAO examined, the review focused on 85 rules from the nine health, safety, or environmental agencies with five or more such rules. OIRA significantly affected 25 of those 85 rules. The Environmental Protection Agency's rules were most often significantly changed, and almost all of the returned rules were from the Department of Transportation. OIRA's suggestions appeared to have at least some effect on almost all of the 25 rules' potential costs and benefits or the agencies' estimates of those costs and benefits. Outside parties contacted OIRA before or during its formal review regarding 11 of the 25 rules that OIRA significantly affected. In 7 of these 11 cases, at least some of OIRA's recommendations were similar to those of the outside parties, but we could not determine whether those contacts influenced OIRA's actions. The agencies' docket files did not always provide clear and complete documentation of the changes made during OIRA's review or at OIRA's suggestion, as required by the executive order. However, some agencies clearly documented these changes, sometimes including changes suggested during OIRA's informal reviews.

OIRA did not publicly disclose how it determined that 23 of the 71 rules nominated by the public for change or elimination in 2001 merited high priority review. As explained to GAO, OIRA desk officers made the initial determinations regarding issues with which they were familiar, subject to the approval by OIRA management. The Mercatus Center at George Mason University made most of the nominations overall and in the high priority group. Regulatory agencies or OIRA have at least begun to address the issues raised in many of the 23 suggestions. OIRA's 2002 nomination and review process was different from the 2001 process in several respects (e.g., broader request for reforms, more responses from more commentors, prioritization of the suggestions being made by the agencies, and clearer discussion of process and criteria).

Contents

Appendixes

Tables

Figures

Abbreviations

APA	Administrative Procedure Act
APHIS	Animal and Plant Health Inspection Service
ARSA	Aeronautical Repair Station Association
BLM	Bureau of Land Management
CEA	Council of Economic Advisors
CEED	Center for Energy and Economic Development
CFR	Code of Federal Regulations
CWD	chronic wasting disease
DOE	Department of Energy
DOI	Department of the Interior
DOL	Department of Labor
DOT	Department of Transportation
EEAC	Equal Employment Advisory Council
EEOC	Equal Employment Opportunity Commission
EPA	Environmental Protection Agency
EPF	Employment Policy Foundation
FAA	Federal Aviation Administration
FDA	Food and Drug Administration
FMCSA	Federal Motor Carriers Safety Administration
FTE	full-time equivalent
HHS	Department of Health and Human Services
ICR	information collection request
MACT	maximum achievable control technology
MGD	million gallons per day
MOU	memorandum of understanding
NCP	nonconformance penalty
NHTSA	National Highway Traffic Safety Administration
NMMA	National Marine Manufacturers Association
OFCCP	Office of Federal Contract Compliance Programs
OIRA	Office of Information and Regulatory Affairs
OMB	Office of Management and Budget
OSHA	Occupational Safety and Health Administration
PRA	Paperwork Reduction Act
RCRA	Resource Conservation and Recovery Act
RFG	reformulated gasoline
RIN	regulation information number
SBA	Small Business Administration
SDWA	Safe Drinking Water Act
TPMS	tire pressure monitoring system
TSS	total suspended solids

USDA	Department of Agriculture
VSL	value of a statistical life
VSLY	value of a statistical life year
WRAP	Western Regional Air Partnership

GAO
Accountability * Integrity * Reliability

United States General Accounting Office
Washington, D.C. 20548

September 22, 2003

The Honorable Richard J. Durbin
Ranking Minority Member
Subcommittee on Oversight of Government Management,
Restructuring, and the District of Columbia
Committee on Governmental Affairs
United States Senate

The Honorable Joseph I. Lieberman
Ranking Minority Member
Committee on Governmental Affairs
United States Senate

In response to your request, this report on the regulatory review process of the Office of Management and Budget's (OMB) Office of Information and Regulatory Affairs (OIRA) (1) describes OIRA's review process and any changes in its policies or processes in recent years, (2) provides detailed information about rules submitted by nine health, safety, or environmental agencies that were returned, withdrawn, or changed at OIRA's suggestion, and (3) describes how OIRA decided that certain rules merited "high priority" review. We include recommendations to the Director of OMB to improve the transparency of the OIRA review process.

As we agreed with your office, unless you publicly announce the contents of this report earlier, we will not distribute it until 30 days from the date of this letter. We will then send copies to the Director of OMB and will provide copies to others on request. It will also be available at no charge on GAO's Web site at http://www.gao.gov.

If you have any questions concerning this report, please call me or Curtis Copeland at (202) 512-6806. Key contributors to this report were Ben Atwater, Tim Bober, and Joseph Santiago.

Victor S. Rezendes
Managing Director, Strategic Issues

Executive Summary

Purpose

The Office of Information and Regulatory Affairs (OIRA) within the Office of Management and Budget (OMB) is a relatively small office (currently, 55 full-time equivalents), but it can have a significant—if not determinative—effect on a broad array of federal regulations that agencies issue to enact statutes and establish specific requirements. Under Executive Order 12866, OIRA reviews hundreds of significant proposed and final rules from all federal agencies (other than independent regulatory agencies) before they are published in the *Federal Register*. As a result of OIRA's review, many draft rules are changed before publication, withdrawn before a review is completed, or returned to the agencies because, in OIRA's opinion, certain aspects of the rule need to be reconsidered.

Despite its importance, OIRA's regulatory review function generally is not well documented or well understood. Therefore, the Ranking Minority Members of the Senate Committee on Governmental Affairs and its Subcommittee on Oversight of Government Management, the Federal Workforce, and the District of Columbia requested that we examine and report on certain aspects of OIRA's operations. Specifically, we were asked to (1) describe OIRA's current regulatory review policies and processes and determine whether, and if so how, those policies have changed in recent years, (2) provide detailed information about the effects of OIRA's reviews of rules submitted by nine health, safety, and environmental agencies that were returned to the agencies for reconsideration, withdrawn at OIRA's request, or significantly changed in response to OIRA's reviews during a 1-year period, and (3) describe how OIRA determined that certain existing rules listed in its reports to Congress on the costs and benefits of federal regulations merited high priority review for potential modification or rescission. We also examined the transparency of the OIRA's review process. To address these objectives, we interviewed OIRA representatives, former OIRA officials, agency officials, and others knowledgeable about the OIRA review process. We also examined documentation at both OIRA and regulatory agencies to determine the effect of OIRA's reviews. Specific elements of our methodology are discussed in the sections below.

Background

The Paperwork Reduction Act of 1980 established OIRA to provide central agency leadership and oversight of governmentwide efforts to reduce unnecessary paperwork burden and manage information resources. In 1981, OIRA's responsibilities expanded when Executive Order 12291 authorized it to review all proposed and final regulations from nonindependent regulatory agencies—between 2,000 and 3,000 rules each

year. OIRA's regulatory review function under this executive order was highly controversial, with concerns raised about its effects on separation of powers, public participation, transparency, and the timeliness of agencies' rulemaking efforts. In September 1993, Executive Order 12866 replaced Executive Order 12291 and made several changes to OIRA's regulatory review function. For example, Executive Order 12866 limits OIRA's regulatory reviews to nonindependent agencies' "significant regulatory actions" (e.g., rules expected to have an annual effect of $100 million or more on the economy or raising other coordination, budgetary, or policy issues). As a result, the number of OIRA reviews declined to about 500 to 700 each year. The executive order also generally requires OIRA to complete its review within 90 days after an agency formally submits a draft regulation, and contains several "transparency" provisions that require both OIRA and the agencies to disclose certain information about the review process. For example, section 6 of the order requires agencies to publicly identify the substantive changes made to rules during OIRA's review and at OIRA's suggestion or recommendation. It also requires OIRA to disclose all of the documents exchanged between the agencies and OIRA during the review process. The executive order and related OIRA guidance also identify some regulatory principles and analytical practices (e.g., considering the costs and benefits of a proposed regulation and assessing alternative approaches) that help to guide OIRA's reviews of agencies' draft regulatory actions.

In January 1998, we reported on the implementation of the transparency requirements in Executive Order 12866 that are applicable to rulemaking agencies.[1] We concluded that complete documentation of all substantive changes made in the rules, and of all the changes that OIRA had suggested, was available to the public for only about one-quarter of the 122 rules that we reviewed. The agencies' rulemaking dockets had only some or no documentation for the remaining rules, and we could not always determine whether OIRA had made available all relevant documents exchanged between the agencies and OIRA. We recommended that the Director of OMB provide the agencies with guidance on how to implement these transparency requirements. OMB disagreed with our recommendations in this area and did not implement them.

[1]U.S. General Accounting Office, *Regulatory Reform: Changes Made to Agencies' Rules Are Not Always Clearly Documented*, GAO/GGD-98-31 (Washington, D.C.: Jan. 8, 1998).

Results in Brief

OIRA's formal review process is essentially unchanged since Executive Order 12866 was issued in 1993. However, there have been several changes in OIRA policies and practices in recent years, particularly since the current OIRA Administrator took office in July 2001. Those changes, some of which the Administrator said would "have a long-lasting impact on the regulatory state," include increased use of public letters explaining why OIRA returned rules to the agencies for their reconsideration (return letters) and suggesting regulatory action (prompt letters), increased emphasis on benefit-cost analysis and peer review, stricter adherence to the 90-day time limit for OIRA review, improvements in the transparency of the OIRA review process, and an increase in the size and skills of OIRA's staff. However, some of these changes are not as significant a departure from previous practice as they initially appear. Underlying many of the changes in OIRA's policies is a shift in how the Administrator (and, ultimately, the President) views OIRA's role in the regulatory process—less of a "counselor" to the agencies and more of a "gatekeeper." Prior to the formal executive order review process, OIRA sometimes informally reviews agencies' draft rules, and OIRA has said it can have a significant influence on the rules during this informal review period.

OIRA's database indicated that about 400 draft rules were changed, returned, or withdrawn from OIRA during the 1-year period from July 2001 through June 2002. Therefore, we focused our examination of the effects of OIRA's review on 85 changed, returned, or withdrawn rules that had been submitted by the nine health, safety, or environmental agencies with 5 or more such rules.[2] We concluded that OIRA had significantly affected 25 of the 85 rules by suggesting changes that revised the scope, impact, or costs and benefits of the rules, returning the rules for reconsideration by the agency, or, in one case, requesting that the agency withdraw the rule from review. The Environmental Protection Agency's (EPA) rules were most often significantly changed, and almost all of the returned rules were from the Department of Transportation (DOT), as was the rule withdrawn at OIRA's request. Many of OIRA's actions in these cases appeared to have been prompted by concerns about the cost and cost effectiveness of the regulatory options that agencies selected, in keeping with general

[2]Our unit of analysis was technically the submission of a rule to OIRA for Executive Order 12866 review, rather than the rule itself, because some of the rules were reviewed by OIRA more than once (e.g., submitted, reviewed, and withdrawn, then resubmitted, reviewed again, and published). However, for simplicity we refer to these executive order submissions as rules in this report.

principles established by Executive Order 12866 and related OIRA guidance. In almost all of the 25 rules that were significantly affected, OIRA's actions appeared to have at least some effect on the potential costs and benefits associated with the rule or prompted revisions to the agency's estimates of those costs and benefits. As permitted by the executive order, outside parties contacted OIRA before or during the formal review period regarding 11 of these 25 rules.[3] Although OIRA's positions regarding 7 of the 11 rules were similar in some respects to those expressed by the outside parties, it is impossible to determine the extent to which those contacts might have influenced OIRA's actions, if at all. OIRA might have reached the same conclusions in the absence of those contacts. The transparency of the agencies' and OIRA's actions during these 85 reviews varied, with the docket files for between 45 percent and 62 percent of the rules providing clear and complete documentation of all elements expected under the two relevant portions of the executive order. However, a few agencies exhibited exemplary transparency practices.

In May 2001, OIRA asked the public to nominate rules that it believed should be modified or rescinded. OIRA decided that 23 of the 71 nominations that it received merited high priority review, but did not publicly disclose how those determinations were made. Representatives of OIRA told us that the agency's desk officers initially determined which nominations should be placed in the high priority category, subject to the approval by OIRA management, with the final decisions made by the Administrator. Forty-four of the 71 nominations were from the Mercatus Center at George Mason University, as were 14 of the 23 high priority nominations.[4] As of May 2003, regulatory agencies or OIRA had addressed or begun to address the issues raised in many of these 23 suggestions. In March 2002 OIRA again solicited public comments on regulations in need of reform. However, this effort was different from the 2001 process in several respects (e.g., broader request for reforms, more responses from more commentors, no ranking of the suggestions being made by the agencies, nominations to strengthen rules, and clearer discussion of process and criteria).

[3]OIRA defines outside parties as "persons not employed by the executive branch."

[4]The Mercatus Center is an education, research, and outreach organization affiliated with George Mason University. The Center's Regulatory Studies Program includes a public interest comment project, which analyzes agencies' regulatory proposals during the public comment process, before the rules become final. The Regulatory Studies Program is headed by Dr. Wendy Lee Gramm, Administrator of OIRA from 1985 to 1988.

Although both OIRA and some of the rulemaking agencies have improved the transparency of the regulatory review process, our review indicated that some elements of the process remain unclear. For example, neither OIRA nor the agencies are required to disclose why rules are withdrawn from review, and the descriptions that OIRA discloses about its contacts with outside parties is often not very helpful. In particular, OIRA representatives said neither they nor the rulemaking agencies are required to disclose the changes made to rules while they are under informal review—the period in which OIRA said it can have its greatest effect. This interpretation of this aspect of the executive order's transparency requirements restricts those requirements to the formal review period, which can be as short as 1 day.

Principal Findings

OIRA's Regulatory Review Process and Changes in Policies/Practices

OIRA's formal regulatory review process begins when the rulemaking agency sends a draft proposed or final rule and other parts of the review package to OIRA. OIRA desk officers do not use a standard "checklist" in their reviews, but most OIRA regulatory reviews are similar in that all rules must be consistent with applicable law, the President's priorities, and the principles in Executive Order 12866, and must not conflict with the policies or practices of other agencies. OIRA regulatory reviews differ somewhat depending on the content of the draft rules. For example, if the rule contains a collection of information under the Paperwork Reduction Act, the desk officer would also review the rule for compliance with that act. If the draft rule is "economically significant," the desk officer would review the agency's economic analysis. There is usually some form of communication between OIRA and the agency during the review, most commonly by e-mail or telephone. OIRA desk officers always consult with and obtain the consent of the appropriate resource management officer on the budget side of OMB before approving a rule. OIRA may also consult with others within the Executive Office of the President or other agencies, managing an interagency review process.

In some cases, OIRA also reviews drafts of agencies' rules before formal submission (e.g., large rules with statutory or judicial deadlines and/or that require discussions with other agencies). OIRA indicated that these informal reviews are increasing, and that reviews before formal submission can have a substantial effect on the agencies' regulatory analysis and the

substance of the rules—before the agencies' positions become too entrenched. OIRA also informally consulted with agencies and reviewed agencies' draft rules before formal submission during previous administrations.

OIRA representatives told us that the formal process the office uses to review draft rules has been essentially the same since Executive Order 12866 was established in 1993. However, several notable changes in OIRA's policies and practices have occurred since the current Administrator took office in July 2001, including (1) an overall resurgence in the "gatekeeper" role that OIRA played shortly after it was established, (2) increased use of return letters, (3) greater emphasis on economic analysis and the issuance of new draft guidelines on economic analysis, (4), fewer reviews extending beyond the 90-day limit, (5) the use of "prompt" letters that suggest regulatory priorities to the agencies, (6) improvements in the transparency of OIRA's regulatory review process (e.g., electronic access to information about rules under review and fuller disclosure of OIRA's contacts with outside parties), and (7) expansion of the size and expertise of OIRA staff. In some cases, though, the changes are less different from previous practices than they initially appear. For example, in the first 8 months after the Administrator took office, OIRA returned 21 of the nearly 400 rules it reviewed to the agencies—more returns than in the previous 7 years combined. However, in the subsequent 15 months OIRA returned only 2 of the more than 850 rules that it reviewed. Also, OIRA prompted agencies to initiate rulemaking in particular areas during previous administrations—albeit not through public letters.

OIRA's Effect on Changed, Withdrawn, and Returned Rules

Because of the large number of draft rules that had been changed, withdrawn, or returned to the agencies from July 1, 2001, through June 30, 2002, we focused our analysis on the rules that were submitted by health, safety, or environmental agencies or offices with five or more rules that were changed, withdrawn, or returned during this 1-year period.[5] This resulted in the selection of 85 rules from 9 agencies: the Animal and Plant Health Inspection Service (APHIS) within the Department of Agriculture;

[5]Most of other agencies that submitted five or more such rules submitted rules that involved transfer payments (e.g., reimbursement rates to doctors' medical services in rules submitted by the Centers for Medicare and Medicaid Services within the Department of Health and Human Services).

the Food and Drug Administration (FDA) within the Department of Health and Human Services; the Occupational Safety and Health Administration (OSHA) within the Department of Labor; the Federal Aviation Administration (FAA), Federal Motor Carrier Safety Administration (FMCSA), and National Highway Traffic Safety Administration (NHTSA) within DOT; and the Offices of Air and Radiation, Solid Waste and Emergency Response, and Water within EPA.

We concluded that OIRA's review had a significant effect on 25 of the 85 draft rules. In 17 of the 25 rules, OIRA recommended the revision, elimination, or delay of certain provisions in the draft regulatory text, the addition or revision of regulatory alternatives that provided more flexible and/or less costly compliance options, or the revision of agencies' cost and/or benefit estimates for the rules. EPA submitted 14 of the 17 rules that were significantly changed at OIRA's suggestion. For example, at OIRA's suggestion, EPA took the following actions:

- Eliminated manganese from a list of hazardous constituents in a final rule on the identification and listing of hazardous wastes (see app. II, ID 56).

- Delayed the compliance date for states to report two types of emissions in a final rule on consolidated emissions reporting (ID 50).

- Made compliance requirements more flexible in a proposed rule on pollutant discharge elimination systems for large cooling water intake structures at existing power generating facilities by allowing options for a site-specific approach to minimizing environmental harm (ID 68).

- Revised the benefit-cost and cost-effectiveness estimates in a proposed rule on emissions from spark ignition marine vessels and highway motorcycles (ID 54).

OIRA returned 7 of the 25 rules to the agencies for reconsideration (6 of which had been submitted by DOT). For example, OIRA returned a NHTSA final rule on tire pressure monitoring systems because, in the office's opinion, the agency's analysis did not adequately demonstrate that NHTSA

had selected the best available regulatory alternative (ID 78).[6] OIRA returned a proposed FAA rule on certification of pilots, aircraft, and repairmen for the operation of light sport aircraft because it believed that the agency's regulatory analysis did not sufficiently justify the rule (ID 73). OIRA also requested that an FAA rule be withdrawn by the agency. Overall, we determined that rules submitted by three of the agencies (FAA, EPA's Office of Air and Radiation, and EPA's Office of Water) were much more often significantly affected by OIRA's review than rules submitted by the other six agencies in our study.

In 22 of the 25 rules that OIRA significantly affected, the changes appeared to have an effect on either the costs and/or benefits of the rules or the agencies' estimates of those costs and/or benefits. For example, in the above-mentioned EPA rule on cooling water intake structures, the approach that OIRA recommended was expected to have somewhat lower benefits than the approach EPA proposed but was estimated to cost significantly less, thereby yielding much larger net benefits. In the tire pressure monitoring system rule, NHTSA inserted (at OIRA's suggestion) additional estimates of some costs and benefits of regulatory alternatives and added information about benefits that might be realized with different regulatory alternatives.

In 34 of the 60 rules that OIRA did not significantly affect, the changes that OIRA suggested primarily involved revisions to the language in the preambles of the draft rules (e.g., expanding or clarifying agencies explanations of certain issues) or suggestions that the agencies request public comments on particular issues. Although we did not consider these types of changes to be "significant," they were substantive in that they made the rules easier to understand and/or could affect the final versions of the rules. OIRA suggested only minor editorial changes or no changes to 20 rules and returned 2 others for procedural rather than substantive reasons. Four rules were withdrawn from OIRA's review solely at the agencies' initiative or because of a "mutual decision" made by the agencies and OIRA.

[6]NHTSA revised the final rule to address OIRA's concerns. However, the U.S. Court of Appeals recently held that the rule was contrary to the intent of the tire safety legislation and arbitrary and capricious under the Administrative Procedure Act. *Public Citizen, Inc. v. Mineta*, No. 02-4237 (2d Cir. Aug. 6, 2003).

Materials in the OIRA docket or the rulemaking agencies' dockets indicated that outside parties (most commonly representatives of regulated entities) had contacted OIRA regarding 11 of the 25 rules that OIRA significantly affected (including 8 of the 15 rules submitted by EPA that were significantly affected). In 7 of the 11 rules, at least some of the actions that OIRA recommended were similar to those suggested to OIRA by outside parties. For example:

- In the above-mentioned rule on cooling water intake structures, OIRA's suggested revisions of the regulatory language regarding the use of a site-specific approach to minimizing environmental harm were similar to those previously recommended by representatives of the electric industry during their contacts with OIRA (ID 68).

- In letters and meetings with OIRA, representatives from steel manufacturers and a chemical company opposed the listing of manganese as a hazardous waste constituent in an EPA final rule (ID 56). Subsequently, the main focus of OIRA's suggested changes to this rule was the deferral of final action on all parts of the rule identifying manganese as a hazardous constituent.

However, it is impossible to determine whether OIRA's contacts with those outside parties affected its conclusions; OIRA may have reached the same conclusions without those contacts. In the four other cases, OIRA's recommended actions did not appear to be similar to those suggested by outside parties. OIRA generally disclosed its contacts with outside parties; we identified only four such contacts regarding the rules in our review that OIRA had not disclosed. However, because our knowledge of such contacts is generally limited to what OIRA or the agencies disclose, we cannot be sure that there were not other contacts that did not come to our attention.

Rules and Regulatory Programs Selected for High Priority Review

Congress has required OMB to submit "recommendations for reform" with its recent reports on the costs and benefits of federal regulations. In May 2001, OIRA asked the public to suggest "specific regulations that could be rescinded or changed that would increase net benefits to the public." Of the 71 nominations that OIRA received, 44 were from the Mercatus Center at George Mason University. OIRA reviewed the suggestions and selected 23 of them for high priority review—including 14 of the 44 Mercatus nominations. In its December 2001 final report, OIRA said the high priority designation indicated that it was inclined to agree with the

recommendation. However, OIRA did not indicate in the report how it made that determination. OIRA representatives described the process to us as a "bottom up" exercise, with desk officers making the initial determinations and the final decisions being made by the OIRA Administrator. Five of the 23 rules designated for high priority review had been issued at the end of the Clinton Administration, and 13 had been issued by EPA or were environmental in nature.

As of May 2003, most of these 23 high-priority review items were at least in the process of being addressed by either the rulemaking agencies or OIRA. For example:

- One of the nominations focused on a Department of Energy (DOE) rule issued in January 2001 that would have raised the energy efficiency of new central air conditioners by 30 percent. In May 2002, DOE withdrew the rule and issued a new rule raising the efficiency level by 20 percent.

- An EPA July 2000 final rule regarding allowable amounts of pollution in water ("total maximum daily load") was also the subject of a suggested change. In March 2003, EPA published a final rule withdrawing the July 2000 rule. By May 2003, a draft of a new proposed rule was undergoing informal interagency review.

However, in a few cases the agencies and/or OIRA decided not to take any action or had not made a decision regarding the rules in question.

In March 2002, OIRA again asked the public to nominate rules for reform, and received suggestions involving 267 regulations and 49 guidance documents from approximately 1,700 individuals, trade associations, nonprofit organizations, and others. In contrast to the first round, OIRA asked the public to nominate not only regulations that could be rescinded or changed, but also rules that could be expanded. Also, OIRA did not designate certain nominated rules for high priority review. Instead, OIRA forwarded the nominations to the appropriate agencies for their review and prioritization, and suggested that the agencies rely on three criteria: efficiency, fairness, and practicality. Although most of the nominations sought modifications that would increase regulatory flexibility or rescind rules, more than a quarter of them suggested making rules more stringent or developing new rules.

Improvements Notwithstanding, OIRA's Review Process Is Still Not Well Documented or Clear

OIRA and some of the agencies whose rules we examined have taken several steps to improve the transparency of the regulatory review process and its outcomes since our last review. For example, OIRA's disclosure of its contacts with outside parties is now triggered by the start of informal review, not just formal reviews, and OIRA is now providing electronic access to review information. Also, some agencies' dockets now more clearly indicated the changes made to their rules than was the case during our previous review 5 years ago, and some agencies' practices in this area were exemplary (FDA, FMCSA, and EPA's Office of Water).

However, the agencies still varied in the extent to which the transparency requirements in Executive Order 12866 were satisfied. Where the requirements were applicable, the agencies clearly identified the substantive changes made between the draft submitted for review and the action subsequently announced in only about 45 percent of the rules. The agencies clearly identified the changes made at OIRA's suggestion or recommendation in about 62 percent of these rules. FAA had no such documentation available, and OSHA said it did not keep the information in its docket to ensure that it is not part of the official rulemaking record if a lawsuit is filed. Other agencies had copies of e-mails between them and OIRA discussing changes that had been made to the rules, but we could not tell whether these e-mails represented all or just some of the changes that had been made.

Also, several aspects of the OIRA review process remain unclear, and could be improved to better allow the public to understand the effects of OIRA's reviews. For example:

- There is no requirement that either OIRA or the agencies explain why rules are withdrawn before OIRA completes its review.

- Although the executive order requires OIRA to disclose its contacts with outside parties regarding rules under review, the information that OIRA provides in its publicly available meeting log often does not allow the public to know what rule is being discussed or what parties were represented.

- The executive order requires OIRA to disclose "all documents exchanged" between the office and the rulemaking agency during the review, but OIRA said it would not do so regarding exchanges between the agencies and OIRA staff at the level where most such exchanges occur.

- The "consistent with change" category in OIRA's public database does not indicate whether the changes made to agencies' rules during the formal review process had been suggested by OIRA or the agencies, or whether the changes were substantive or editorial in nature.

- The agencies differed considerably regarding what types of changes made to their rules were "substantive" and therefore needed to be documented. For example, documentation for some rules included changes made to both the regulatory text and the agencies' explanations of their rules, while other documentation only included changes to the regulatory text.

- OIRA said informal submission of a draft rule for review triggers the office's disclosure requirements regarding its contacts with outside parties, but OIRA representatives said it does not trigger the requirements that the office and the rulemaking agency disclose the changes made during the review—even though OIRA has said it can have a significant influence on agencies' draft rules during this informal review period. OIRA indicated that the transparency requirements only apply to the formal review period—which can be as short as 1 day—even though OIRA may have been reviewing substantive drafts of agencies' rule weeks or even months in advance of the formal review period.

In some cases, the agencies or OIRA included materials in their files (e.g., substantive changes made during OIRA's informal review) that, while not required by the executive order as interpreted by OIRA, provided valuable insights regarding OIRA's effect on the development of those rules. Although OIRA indicated that disclosure of substantive changes made to agencies rules during informal review could have a "chilling effect" on OIRA-agency interactions, we saw no evidence of that effect in those instances where the substantive changes were already being disclosed. However, we recognize that OIRA and the agencies should be able to discuss regulatory matters in general without having to document and disclose those communications.

Recommendations for Executive Action

We recommend that the Director of the Office of Management and Budget:

- Define the transparency requirements applicable to the agencies and OIRA in section 6 of Executive Order 12866 in such a way that they include not only the formal review period, but also the informal review

period when OIRA says it can have its most important impact on agencies' rules. Doing so would make the trigger for the transparency requirements applicable to OIRA's and the agencies' interaction consistent with the trigger for the transparency requirements applicable to OIRA regarding its communications with outside parties.

- Change OIRA's database to clearly differentiate within the "consistent with change" outcome category which rules were substantively changed at OIRA's suggestion or recommendation and which were changed in other ways and for other reasons.

- Improve the implementation of the transparency requirements in the executive order that are applicable to OIRA. Specifically, the Administrator should take the following actions:

  - More clearly indicate in the meeting log which regulatory action was being discussed and the affiliations of the participants in those meetings.

  - Because most of the documents that are exchanged while rules are under review at OIRA are exchanged between agency staff and OIRA desk officers, OIRA should reexamine its current policy that only documents exchanged by OIRA branch chiefs and above need to be disclosed.

  - Establish procedures whereby either OIRA or the agencies disclose the reasons why rules are withdrawn from OIRA review.

- Improve the implementation of the transparency requirements in the executive order that are applicable to rulemaking agencies. Specifically, the Administrator should take the following actions:

  - Define the types of "substantive" changes during the OIRA review process that agencies should disclose as including not only changes made to the regulatory text but also other, noneditorial changes that could ultimately affect the rules' application (e.g., explanations supporting the choice of one alternative over another and solicitations of comments on the estimated benefits and costs of regulatory options).

  - Instruct agencies to put information about changes made in a rule after submission for OIRA's review and those made at OIRA's

suggestion or recommendation in the agencies' public rulemaking dockets, and to do so within a reasonable period after the rules have been published.

- Encourage agencies to use "best practice" methods of documentation that clearly describe those changes (e.g., like those used by FDA, EPA's Office of Water, or FMCSA).

Agency Comments and Our Evaluation

On August 8, 2003, we provided a draft of this report to the Director of the Office of Management and Budget for his review and comment. On September 2, 2003, the Administrator of OIRA provided written comments on the draft report. (See app. V for a copy of these comments.) The Administrator said OIRA believed the "factual foundations of the report are well grounded," and was pleased that the report noted improvements in the timeliness of OIRA's reviews and the transparency of the review process. He indicated that OIRA agreed with our recommendation to improve the clarity of the office's meeting log, but said OIRA did not agree with all of the recommendations in the draft report. He said the report had not demonstrated the need or desirability of changing the agency's existing "unprecedented" level of transparency, and cited several specific examples. However, we continue to believe that improvements can and should be made to improve the transparency of the OIRA review process. The difficulties that we experienced during this review clearly demonstrated that OIRA's reviews are not always transparent to the public. (See chapter 5 for a fuller description of OMB's comments and our evaluation.)

Introduction

Federal regulation, like taxing and spending, is one of the basic tools of government used to implement public policy. Regulations generally start with an act of Congress and are the means by which statutes are enacted in specific requirements are established. Federal agencies issue more than 4,000 regulatory actions each year on topics ranging from the timing of bridge openings to the permissible levels of contaminants in drinking water. The costs and benefits associated with all federal regulations has been a subject of great controversy, with the costs estimated in the hundreds of billions of dollars and the benefits estimates even higher. During the past 50 to 60 years, Congress and various presidents have developed an elaborate set of procedures and requirements to guide the federal rulemaking process. One of the most important yet least understood of these requirements is the provision that federal agencies (other than independent regulatory agencies) submit their draft rules to the Office of Information and Regulatory Affairs (OIRA) within the Office of Management and Budget (OMB) for review before being published in the *Federal Register*. Although a relatively small office (about 55 full-time equivalent or "FTE" positions), OIRA reviews can have a significant—if not determinative—effect on federal rulemaking and, therefore, public policy.

Because OIRA's regulatory review function is not well understood, the Ranking Minority Members of the Senate Committee on Governmental Affairs and its Subcommittee on Oversight of Government Management, the Federal Workforce, and the District of Columbia requested that we examine and report on certain aspects of its operation. Specifically, they requested that we (1) describe OIRA's current regulatory review policies and processes and determine whether, and if so how, those policies have changed in recent years, (2) provide information about health, safety, and environmental rules from nine selected agencies that were returned to the agencies for reconsideration, withdrawn at OIRA's request, or significantly changed in response to OIRA's reviews during a 1-year period, and (3) describe how OIRA determined that certain existing rules listed in its reports to Congress on the costs and benefits of federal regulations merited high priority review for potential modification or rescission.

Background

OMB is part of the Executive Office of the President, along with such agencies as the Council of Economic Advisors (CEA), the Council on Environmental Quality, and the Office of Science and Technology Policy. These agencies help develop and implement the policies and programs of the President. As figure 1 shows, OIRA is one of the statutory offices within OMB—which are sometimes collectively referred to as the

"management" side of OMB. Other OMB offices include the resource management offices, which review agencies' budget submissions and are sometimes collectively referred to as OMB's "budget" side.[1]

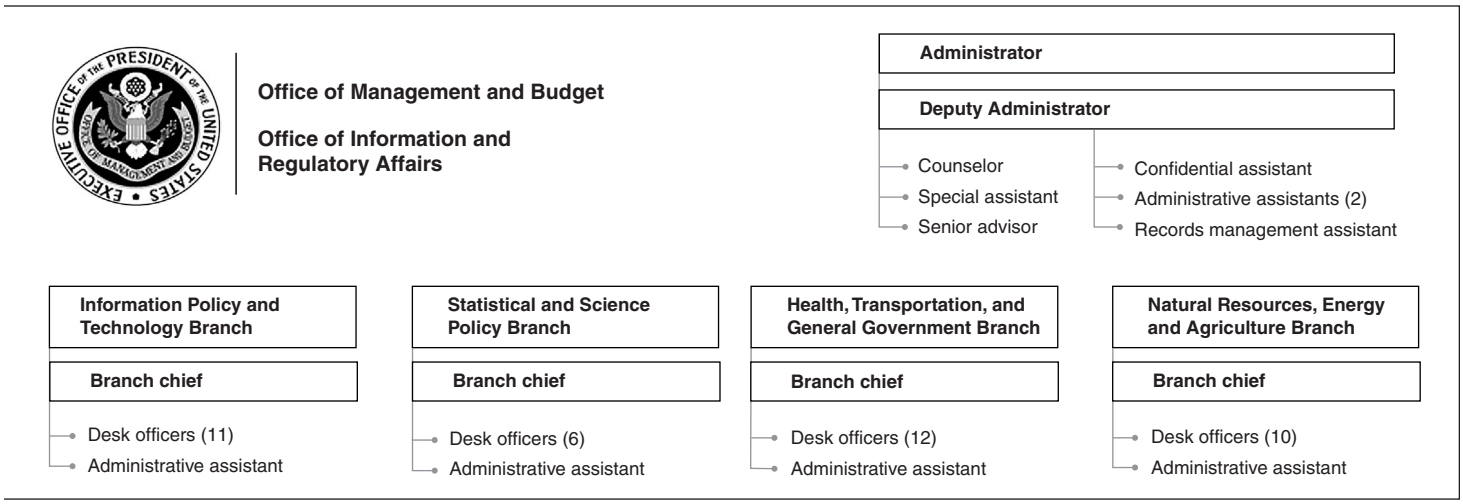
Figure 1: OIRA Is One of the Statutory Offices within OMB

Source: GAO.

The Administrator of OIRA is appointed by the President, subject to the advice and consent of the Senate. As figure 2 illustrates, OIRA currently has four branches: (1) Information Policy and Technology, (2) Statistical and Science Policy, (3) Health, Transportation, and General Government, and (4) Natural Resources, Energy, and Agriculture. Of these, the last two branches are primarily responsible for reviewing agencies' draft proposed and final regulations under Executive Order 12866. However, as discussed later in this report, the other branches as well as other parts of OMB and the Executive Office of the President may be consulted during their reviews.

[1]For a discussion of these offices, see U.S. General Accounting Office, *Office of Management and Budget: Changes Resulting From the OMB 2000 Reorganization*, GAO/GGD/AIMD-96-50 (Washington, D.C.: Dec. 29, 1995).

Figure 2: Organization of OIRA



Source: GAO.

The Rulemaking Process and Presidential Review

The basic process by which federal agencies develop and issue regulations is spelled out in the Administrative Procedure Act of 1946, as amended (APA), codified at 5 U.S.C. section 553. Among other things, the APA generally requires agencies to (1) publish a notice of proposed rulemaking in the *Federal Register*, (2) allow interested persons an opportunity to participate in the rulemaking process by providing "written data, views, or arguments," and (3) publish the final rule 30 days before it becomes effective. However, the APA allows agencies to issue final rules without a previous notice of proposed rulemaking in certain cases.[2]

The Paperwork Reduction Act (PRA) of 1980 established OIRA to provide central agency leadership and oversight of governmentwide efforts to reduce unnecessary paperwork burden and improve the management of information resources. Specifically, the act required OIRA to review and approve agencies' proposed collections of information before the agencies could collect information from the public. In recent years, OIRA has

[2]We previously reported that about half of all final rules published during 1997 were published without a notice of proposed rulemaking. See U.S. General Accounting Office, *Federal Rulemaking: Agencies Often Published Final Actions Without Proposed Rules*, GAO/GGD-98-126 (Washington, D.C.: Aug. 31, 1998).

reviewed between 3,000 and 5,000 proposed collections of information each year under the PRA. Although many federal regulations have an information collection component, the PRA did not specifically authorize OIRA to review or comment on the substance of those regulations.

Nevertheless, centralized review of agencies' regulations within the Executive Office of the President has been part of the rulemaking process for more than 30 years. For example:

- In 1971, President Nixon established a "Quality of Life Review" program in which agencies submitted all significant draft proposed and final rules to OMB, which then circulated them to other agencies for comment. In their submissions, agencies provided a summary of their proposals, a description of the alternatives that they considered, and the cost of those alternatives.

- In 1974, President Ford issued Executive Order 11821, which required agencies to prepare an "inflation impact statement" for each "major" proposed rule before publication in the *Federal Register*, and to send a summary of those statements to the Council on Wage and Price Stability when the rule was published. The council would then review the statement and either provide comments to the agency or participate in the comment process.

- In 1978, President Carter issued Executive Order 12044, which (among other things) required agencies to publish semiannual agendas of any significant rules under development and to prepare a regulatory analysis that examined the cost-effectiveness (i.e., the least cost of achieving the objective) of alternative regulatory approaches for major rules. President Carter also established (1) a "regulatory analysis review group" to review the analyses prepared for certain major rules and to submit comments during the comment period, and (2) a "regulatory council" to coordinate agencies' actions to avoid conflicting requirements and duplication of effort.

Perhaps the most significant development in this evolution of presidential review of rulemaking occurred in 1981 when President Reagan issued

Executive Order 12291.[3] The executive order replaced Executive Order 12044 and established a set of general requirements for rulemaking—e.g., that (to the extent permitted by law) (1) the potential benefits of a regulatory action must outweigh the potential costs to society, (2) regulatory objectives should maximize net benefits to society, and (3) agencies should select the regulatory alternative involving the least net cost to society. The order also required federal agencies (other than independent regulatory agencies) to send a copy of each draft proposed and final rule to OMB before publication in the *Federal Register*. In addition, it required covered agencies to prepare a regulatory impact analysis for each "major" rule, and authorized OMB to review "any preliminary or final Regulatory Impact Analysis, notice of proposed rulemaking, or final rule based on the requirements of this Order."[4] As a result of this order, OIRA's responsibilities were greatly expanded from paperwork reviews to examinations of the substance of covered agencies' proposed and final rules—between 2,000 and 3,000 reviews per year.[5] In 1985, President Reagan extended OIRA's influence even further by issuing Executive Order 12498, which required nonindependent agencies to submit a regulatory plan to OMB for review each year that covered all of their significant regulatory actions underway or planned.

The expansion of OIRA's role in the rulemaking process as a result of these executive orders was not without controversy. Concerns were raised by members of Congress, public interest groups, and others regarding a variety of issues, including whether OIRA's role violated constitutional separation of powers, and the effect that OIRA's review had on public participation under the APA and the timeliness of agencies' rulemaking. (Neither the order nor OIRA guidance placed any time limits on OIRA's reviews.) Concerns were also raised regarding the transparency of OIRA's reviews, specifically whether OIRA had become a clandestine conduit for

[3]See, for example, Erik D. Olson, "The Quiet Shift of Power: Office of Management & Budget Supervision of Environmental Protection Agency Rulemaking Under Executive Order 12291," *Virginia Journal of Natural Resources Law, 4 (Fall 1984), 1-80.*

[4]The order defined a "major rule" as any regulation likely to result in (1) an annual effect on the economy of $100 million or more, (2) a major increase in costs or prices for consumers or others, or (3) significant adverse effects on competition, employment, investment, productivity, innovation, or international competitiveness.

[5]For a discussion of OIRA's review process under this order, see U.S. General Accounting Office, *Regulatory Review: Information on OMB's Review Process*, GAO/GGD-89-101FS (Washington, D.C.: July 14, 1989).

outside influence in the rulemaking process. In response to those criticisms, in June 1986, the OIRA Administrator issued a memorandum for the heads of departments and agencies subject to the executive orders describing OIRA procedures to improve the transparency of the process. For example, the memorandum said that only the Administrator or the Deputy Administrator could communicate with outside parties regarding rules submitted for review, and that OIRA would make available to the public all written materials received from outside parties. OIRA also said that it would, upon written request, make available all written correspondence between OIRA and the agency head regarding a draft submitted for review.

In 1987 the National Academy of Public Administration published a report on presidential management of agency rulemaking that summarized the criticisms of the OIRA regulatory review effort as well as the positions of its proponents.[6] The report also described a number of issues in regulatory review and offered recommendations for improvement. For example, the report recommended that "regulatory management be accepted as an essential element of presidential management." It also recommended that regulatory agencies "log, summarize, and include in the rulemaking record all communications from outside parties, OMB, or other executive or legislative branch officials concerning the merits of proposed regulations."

In 1988 the Administrative Conference of the United States also examined the issue of presidential review of agency rulemaking and concluded that the reviews could improve coordination and resolve conflicts among agencies. However, the conference also said presidential review "does not displace responsibilities placed in the agency by law nor authorize the use of factors not otherwise permitted by law." The Conference recommended public disclosure of proposed and final agency rules submitted to OIRA under the executive order, communications from OMB relating to the substance of rules, and communications with outside parties, and also recommended that the reviews be completed in a "timely fashion."[7]

[6]National Academy of Public Administration, *Presidential Management of Rulemaking in Regulatory Agencies* (January 1987).

[7]The National Academy of Public Administration and the American Bar Association have also recognized the potential value of presidential regulatory review. However, they too recommended reforms such as improved transparency and better communication between OIRA and agency staff.

Executive Order 12866

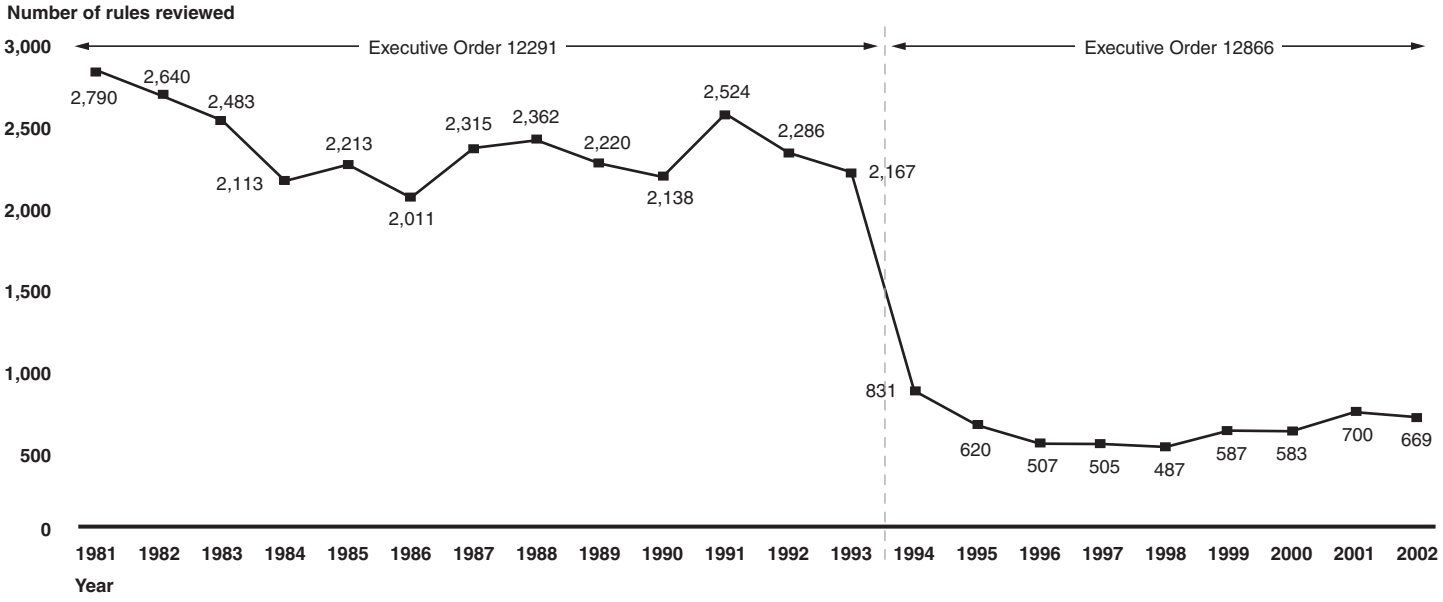
On September 30, 1993, President Clinton issued Executive Order 12866 on "Regulatory Planning and Review," which revoked Executive Orders 12291 and 12498 and established a new regulatory philosophy and set of principles, as well as a new process for OIRA review. In its statement of regulatory philosophy, the executive order states, among other things, that agencies should assess all costs and benefits of available regulatory alternatives, including both quantitative and qualitative measures. It also provides that agencies should select regulatory approaches that maximize net benefits (unless a statute requires another approach). Where permissible and applicable, the order states agencies should adhere to a set of principles, including (1) consideration of the degree and nature of risk posed when setting regulatory priorities, (2) adoption of regulations only upon a "reasoned determination that the benefits of the intended regulation justify its costs," and (3) tailoring regulations to impose the least burden on society needed to achieve the regulatory objectives. Some of the stated objectives of the order are "to reaffirm the primacy of Federal agencies in the regulatory decision-making process; to restore the integrity and legitimacy of regulatory review and oversight; and to make the process more accessible and open to the public." Section 2(b) of the order assigns responsibility for review of agency rulemaking to OMB, and specifically names OIRA as "the repository of expertise concerning regulatory issues." The order also named the Vice President as principle advisor to the President on regulatory policy, planning, and review.

Section 6 of Executive Order 12866 established agency and OIRA responsibilities in the centralized review of regulations. Like its predecessor, the new executive order limits OIRA reviews to rules published by agencies other than independent regulatory agencies. However, in contrast to the broad scope of review under Executive Order 11291, the new order limits OIRA reviews to actions identified by the rulemaking agency or OIRA as "significant" regulatory actions, which are defined in section 3(f) of the order as the following:

> "Any regulatory action that is likely to result in a rule that may (1) have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive order."

As figure 3 shows, by focusing OIRA's reviews on significant rules, the number of draft proposed and final rules that OIRA examined fell from between 2,000 and 3,000 per year under the Executive Order 12291 to between 500 and 700 rules per year under Executive Order 12866.

Figure 3: Number of Rules That OIRA Reviewed Dropped Under Executive Order 12866



Source: OIRA.

Executive Order 12866 also differs from its predecessor in other respects. For example, the order required that OIRA generally complete its review of proposed and final rules within 90 calendar days. It also requires both the agencies and OIRA to disclose certain information about how the regulatory reviews were conducted. For example, agencies are required to identify for the public (1) the substantive changes made to rules between the draft submitted to OIRA for review and the action subsequently announced and (2) changes made at the suggestion or recommendation of OIRA. OIRA is required to provide agencies with a copy of all written communications between OIRA personnel and parties outside of the executive branch, and a list of the dates and names of individuals involved in substantive oral communications. OIRA is also instructed to maintain a

public log of all regulatory actions under review and of all of the above-mentioned documents provided to the agencies.[8]

In October 1993, the OIRA Administrator issued guidance to the heads of executive department and agencies regarding the implementation of Executive Order 12866. The section of that guidance on "Openness and Public Accountability" that discussed the order's transparency requirements indicated that the requirement that agencies identify for the public the changes made at the suggestion or recommendation of OIRA only applies to changes made after draft rules are formally submitted to OIRA for review. In January 1996, OIRA published a document that described "best practices" for preparing the economic analysis of significant regulatory actions called for by the executive order. This document was revised and issued as guidance in 2000, and is described in greater detail in chapter 2 of this report.

Prior Report on Transparency Requirements

In January 1998, we reported on the implementation of some of the transparency requirements in Executive Order 12866 within selected agencies.[9] We concluded that the agencies had complete documentation of changes made during OIRA's review for only about 26 percent of the 122 regulatory actions that we reviewed. The agencies had complete documentation of the changes that OIRA suggested or recommended for only about 24 percent of the rules. In other cases the agencies had some documentation that changes had been made, but it was not clear whether all such changes had been documented. In addition, the documentation that we were able to locate was sometimes not available to the public or hard to find. In our report, we recommended that OIRA provide agencies with guidance on how to implement the transparency requirements in the executive order. Specifically, we said the guidance should require the agencies to include a single document in the public rulemaking docket for each regulatory action that (1) identified all substantive changes made during OIRA's review and at the suggestion or recommendation of OIRA or

[8]For a discussion of the differences between the transparency requirements under Executive Order 12291 and Executive Order 12866, see William D. Araiza, "Judicial and Legislative Checks on Ex Parte OMB Influence Over Rulemaking," *Administrative Law Review*, 54 (Spring 2002), 611-630, and Peter M. Shane, "Political Accountability in a System of Checks and Balances: The Case of Presidential Review of Rulemaking," *Arkansas Law Review*, 48 (1995), 161-214.

[9]GAO/GGD-98-31.

(2) states that no changes were made.[10] We also said that the guidance should point to best practices in some agencies to suggest how other agencies could organize their dockets to best facilitate public access and disclosure. OIRA disagreed with our recommendations and did not implement them.

Objectives, Scope, and Methodology

The overall objective of this assignment was to determine how OIRA conducts its regulatory reviews. The requesters indicated that little was known about those reviews, the effects that outside parties have on OIRA decision making, or the impact of OIRA decisions on the American public. Our specific objectives were the following:

- Describe OIRA's current regulatory review policies and processes and determine whether, and if so how, those policies and processes have changed in recent years.

- Identify the rules issued by selected agencies that were reviewed by OIRA between July 1, 2001, through June 30, 2002, and that were either significantly changed at OIRA's direction, returned by OIRA for further consideration by the agencies, or withdrawn by the agencies at OIRA's suggestion. For each such rule, (a) describe the changes made by OIRA, the reasons why the rule was returned or withdrawn, and any subsequent activity regarding the rule, (b) describe, to the extent possible, the effects of the changes, returns, and withdrawals on the rule's original benefits and costs, and (c) determine whether there are any indications that the actions OIRA took were traceable to suggestions offered by regulated entities or outside parties and, if so, whether OIRA publicly disclosed their involvement. We also examined OIRA's and the agencies' application of the transparency requirements in the executive order and related guidance.

- Describe how OIRA determined that certain existing rules listed in its reports to Congress on the costs and benefits of federal regulations merited high priority review. Specifically, determine (a) which organizations or persons suggested that these rules be reviewed, (b) what process OIRA used to select and prioritize the rules, (c) the extent

[10]As used in this report, a rulemaking "docket" is the official repository for documents or information related to an agency's rulemaking activities and may include any public comments received and other information used by agency decisionmakers.

to which OIRA publicly disclosed its selection and priority-setting process, and (d) the current status of those rules.

A detailed discussion of our methodology and scope limitations is provided in appendix I. In brief, we defined OIRA's "current" regulatory review policies and processes as those in place as of June 2002 or later. To describe those policies and processes and any changes in recent years, we reviewed relevant documents (e.g., executive orders, legislation, and OMB guidance) and interviewed current OIRA and agency staff, two former OIRA Administrators, and knowledgeable officials and staff from external groups that are actively involved in observing and commenting on the federal regulatory process.

We focused our efforts in the second objective on those rules submitted for OIRA review that met the following criteria: (a) the rule was submitted to OIRA as a proposed, interim final, or final rule, (b) OMB completed its review of the rule between July 1, 2001, and June 30, 2002, (c) the rule was returned to the rulemaking agency by OIRA, withdrawn from OIRA's review by the agency, or changed after submission for OIRA's review, and (d) it was included among the set of health, safety, or environmental rules from those agencies or subagencies that OIRA's Executive Order Review database indicated had five or more rules returned, withdrawn, or changed during the period in scope for this objective. A total of 85 rules from nine agencies—the Animal Plant and Health Inspection Service (APHIS); Food and Drug Administration (FDA); Occupational Safety and Health Administration (OSHA); Department of Transportation's (DOT) Federal Aviation Administration (FAA); Federal Motor Carrier Safety Administration (FMCSA); and National Highway Traffic Safety Administration (NHTSA); and the Environmental Protection Agency's (EPA) Office of Air and Radiation, Office of Solid Waste and Emergency Response, and Office of Water—met these criteria.[11] We also reviewed documents in both agencies' and OIRA's rulemaking dockets, and interviewed OIRA and agency officials to obtain information about the regulatory review process for the individual rules included in our scope.

[11]These nine agencies submitted a total of 102 proposed, final, or interim final rules to OIRA during this 1-year period. Another EPA rule that met these criteria was dropped from our review because, although OIRA had cleared the submitted rule with changes, it has not yet been publicly announced due to homeland security issues.

Our work to address the third objective focused on the particular rules identified for high priority review in the 2001 and 2002 versions of OMB's annual report to Congress on the costs and benefits of federal regulations. We reviewed any available documentation describing the process that OIRA used to select certain rules for high priority review. We also interviewed OIRA representatives and representatives of other relevant agencies and organizations to determine how the classifications were made and why the particular selected rules were designated as high priority.

The specific limitations to our engagement are identified with each of our findings. In general, our findings were sometimes limited to the documentation that was available. Some types of OIRA's influence on rules may not be reflected in the documentation we relied on in this review. For example, in a previous review DOT officials told us that they will not even propose certain regulatory provisions because they know that OIRA will not find them acceptable.[12] Also, we cannot be sure that we have identified all changes to the selected rules that were made at the direction or suggestion of OIRA (e.g., changes made during informal OIRA reviews that were not documented), nor can we be sure that we identified all the effects of such changes on the rules or all instances in which an outside party may have influenced OIRA's actions. We conducted our review from July 2002 through May 2003 at the headquarters offices of the above-mentioned agencies in accordance with generally accepted government auditing standards. We verified data elements that we used from OIRA's database and found only minor differences between that database and information in OIRA's and agencies' files. Therefore, we concluded that the data were sufficiently reliable for purposes of our report. We provided a draft of this report to OMB for comment. The comments that we received, and our evaluation of those comments, are reflected in the "Agency Comments and Our Evaluation" section of chapter 5 of this report.

[12]U.S. General Accounting Office, *Regulatory Reform: Implementation of the Regulatory Review Executive Order*, GAO/T-GGD-96-185 (Washington, D.C.: Sept. 25, 1996).

Some of OIRA's Regulatory Review Policies Have Changed

Our first objective was to describe OIRA's current regulatory review policies and processes and determine whether, and if so how, those policies and processes have changed in recent years. We determined that OIRA's formal regulatory review process under Executive Order 12866 sometimes also includes informal reviews before the official submission of draft rules by the agencies. Both types of reviews focus on the draft rules' adherence to applicable laws, executive orders, guidance documents, and the President's policies. The OIRA review process is essentially unchanged since the office began reviewing rules in 1981. The most significant changes occurred in 1993 with the issuance of Executive Order 12866. However, there have been several other changes in policies and emphasis in recent years, particularly since the current OIRA Administrator took office in July 2001. Those changes include increased use of return letters and the advent of "prompt" letters, increased emphasis on benefit-cost analysis and peer review, stricter adherence to the 90-day period for OIRA review, improvements in the transparency of the OIRA review process, and an increase in the size and skills of OIRA staff. However, some of these changes are not as significant a departure from previous practice as they initially appear. Underlying many of these changes is a shift in how the Administrator views OIRA's role in the regulatory process.

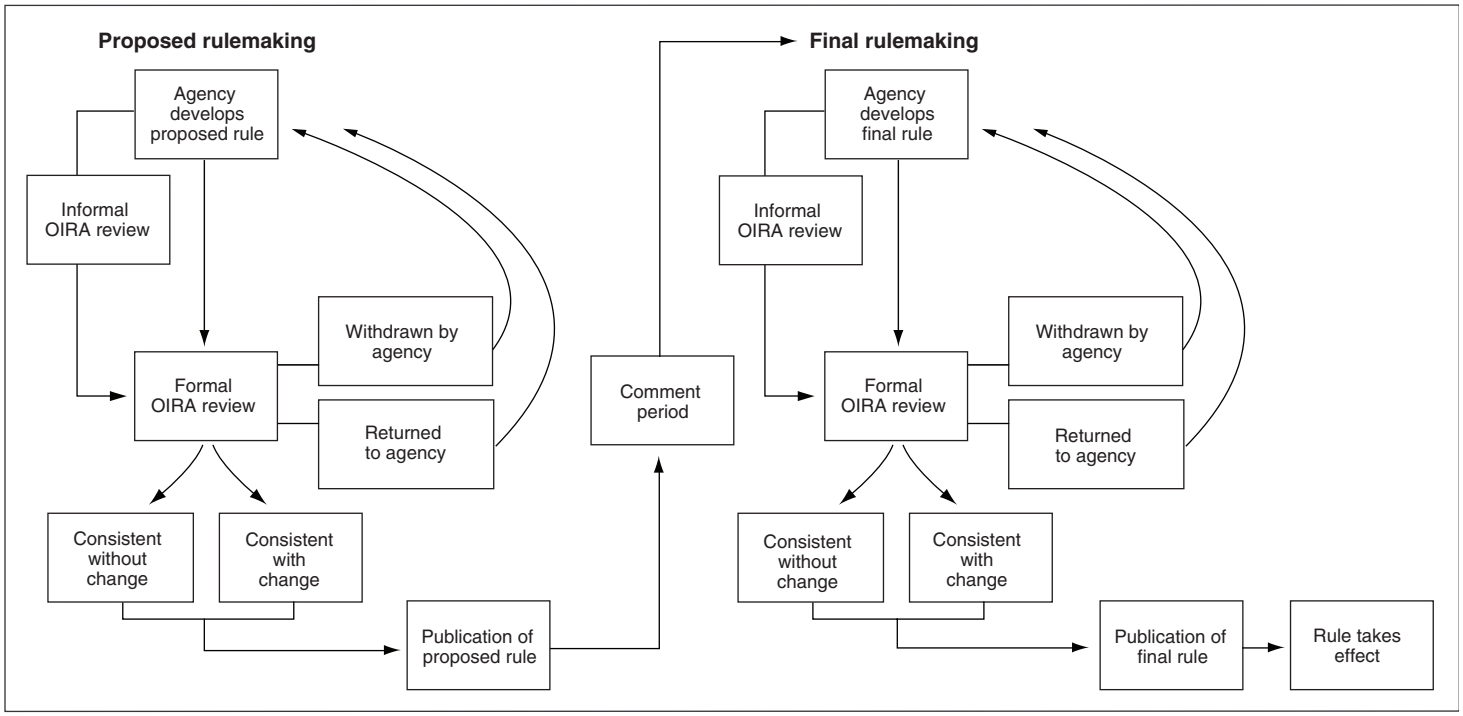
OIRA Regulatory Review Process

As noted in chapter 1 of this report, Executive Order 12866 limits OIRA's regulatory reviews to significant rules that are initiated by agencies other than independent regulatory agencies.[1] The executive order also establishes certain requirements regarding how those reviews are conducted (e.g., generally requiring the reviews to be completed within 90 calendar days after the rule is submitted to OIRA). Although the overall process that OIRA uses to review covered agencies' draft rules is described in the executive order or other OIRA publications, the specific details about how the office conducts its reviews are not well understood. One rulemaking agency official described the review process to us as a "black box" into which agencies submit rules that later come out intact, changed, withdrawn, or returned.

[1]Representatives of OIRA told us that the agency occasionally reviews other material, such as agencies' guidance documents or notices, reports and budget information shared with OIRA by resource management officers on the budget side of OMB, and draft legislation. However, these materials are not covered by the executive order's review requirements.

As figure 4 shows, OIRA reviews agencies' draft rules at both the proposed and final stages of rulemaking.[2] In each phase, the rulemaking agency formally submits a regulatory review package to OIRA (consisting of the rule, any supporting materials, and a transmittal form) and OIRA initiates a review. During the review process, OIRA analyzes the draft rule in light of the principles of Executive Order 12866, and discusses the package with staff and officials at the rulemaking agency, and, if the occasion warrants, with other agencies with whom interagency coordination will be necessary. In the course of that process, the draft rule that is submitted by the agency often changes. In some cases, agencies withdraw the draft rule from OIRA during the review period and the rule may or may not be subsequently resubmitted to OIRA.

Figure 4: The OIRA Regulatory Review Process



Source: GAO.

[2]OIRA also reviews some rules at the Advance Notice of Proposed Rulemaking stage.

At the end of the review period, OIRA either concludes that the draft rule is consistent with the principles of the executive order (which occurs in the vast majority of cases) or returns the rule to the agency "for further consideration."[3] If a draft rule that was determined to be consistent with the executive order had been modified in the course of the review, the rule is coded in the OIRA database as "consistent with change" (regardless of the source or extent of the change). If no changes have been made to the draft rule during the review, the rule is coded as "consistent without change." OIRA only codes rules as "consistent with no change" if they are exactly the same at the end of the review period as the original submission. Even editorial changes made at the rulemaking agency's initiative can cause a rule to be coded "consistent with change."

If the draft is a proposed rule, upon completion of OIRA's review the agency may then publish a notice of proposed rulemaking and, in accordance with the APA, obtain comments during the specified period (usually at least 30 days), review the comments received, and make any changes to the rule that it believes are necessary to respond to those comments. If the draft is a final rule, the agency may publish the final rule after OIRA concludes its review and the rule will take effect either at that point or at some later date specified by the agency. OIRA representatives emphasized that the office does not "approve" or "disapprove" draft rules. They noted that the rulemaking agency has been vested with authority by Congress to issue regulations, and said OIRA's review of draft rules under Executive Order 12866 does not displace that authority. They said any changes that are made to draft rules as a result of that review are made by the rulemaking agency, not OIRA.

Figure 4 also illustrates that for some rules there are two distinct phases of OIRA's review: (1) a formal review period after the rule is officially submitted to OIRA and (2) an informal review period before submission of the rule.

Formal Review

According to OIRA representatives, the formal regulatory review process begins when the rulemaking agency sends the draft rule to the OIRA docket librarian (either electronically or hand carried), who logs the receipt of the

[3]As discussed in detail later in this report, more than 70 percent of draft rules submitted to OIRA in recent years have been coded as either "consistent with change" or "consistent with no change." At most, only about 3 percent of the rules were coded as "returned."

rule and forwards it to the appropriate desk officer. The representatives said that OIRA desk officers do not use a standard "checklist" to review agencies' rules, but indicated that most reviews are similar in certain respects. Section 6 of Executive Order 12866 states that the OIRA Administrator is to provide meaningful guidance and oversight "so that each agency's regulatory actions are consistent with applicable law, the President's priorities, and the principles set forth in this Executive order, and do not conflict with the policies or actions of another agency." The laws applicable to specific regulations vary, but always include the specific statutory authority under which each regulation is being developed (e.g., the Clean Air Act or the Occupational Safety and Health Act) as well as a variety of crosscutting regulatory statutes (e.g., the APA and the Regulatory Flexibility Act).

The principles in Executive Order 12866 that are intended to guide covered agencies' rulemaking practices (and therefore guide OIRA's review practices as well) include the following:

- Identify and assess available alternatives to direct regulation;
- design regulations in the most cost-effective manner to achieve the regulatory objective;
- assess both the costs and benefits of the intended regulation, and propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs;
- base decisions on the best reasonably obtainable scientific, technical, economic, and other information;
- identify and assess alternative forms of regulation; and
- tailor regulations to impose the least burden on society.

In addition, the executive order's "regulatory philosophy" provides that "in deciding whether and how to regulate, agencies should assess all costs and benefits of available regulatory alternatives, including the alternative of not regulating." It goes on to state that, unless a statute requires another regulatory approach, "in choosing among alternative regulatory approaches, agencies should select those approaches that maximize net benefits."

The type of review that OIRA conducts sometimes depends on the type of draft rule submitted. For example, if the draft rule contains a collection of information covered by the Paperwork Reduction Act, OIRA representatives said that the desk officer would also review it for compliance with the act. (They indicated that conducting both reviews simultaneously can be more difficult if different offices within the rulemaking agencies are responsible for the rule and the information collection.) If the draft rule is "economically significant" (e.g., has an annual impact on the economy of at least $100 million), the executive order requires agencies to prepare an economic analysis describing, among other things, the alternatives that the agency considered and the costs and benefits of those alternatives. For those economically significant rules, the desk officers review the economic analyses using the "best practices" document developed in January 1996 and the related guidance document issued in 2000. (These documents are described in more detail later in this report.)

In addition to Executive Order 12866, there are several memoranda and guidance documents from OMB and/or the OIRA Administrator that provide additional details regarding the content of OIRA's regulatory reviews. For example, on September 20, 2001, the OIRA Administrator sent a memorandum to the President's Management Council on "Presidential Review of Agency Rulemaking by OIRA." An attachment to the memorandum described "the general principles and procedures that will be applied by OMB in the implementation of E.O. 12866 and related statutory and executive authority." For example, the attachment indicated that the office would, where appropriate, (1) include an evaluation of whether the agency has, in assessing exposure to a risk or environmental hazard, conducted an adequate risk assessment, (2) give "a measure of deference" to regulatory impact analyses and other supporting technical documents that have been peer reviewed in accordance with specified procedures,[4] (3) ensure that regulatory clearance packages satisfy the requirements in other executive orders (e.g., include the certifications required by Executive Order 13132 on "Federalism" and Executive Order 13175 on "Consultation and Coordination with Indian Tribal Governments"), (4) consult with the Small Business Administration (SBA) and the SBA Chief Counsel for

[4]For example, the memorandum indicated that peer reviewers should (1) be selected primarily on the basis of necessary technical expertise, (2) disclose to agencies any prior positions on the issues at hand, and (3) disclose to agencies their sources of personal and institutional funding.

Advocacy, and (5) evaluate the possible impact of the draft rule on the programs of other federal agencies. (Several of these elements are discussed more fully later in this chapter, including OMB's guidance on economic analysis.)

OIRA representatives said that there is usually some type of communication (often via e-mail or telephone) between the desk officer and the rulemaking agency regarding specific issues in the draft rule. The representatives said briefings and meetings are sometimes held between OIRA and the agency during the review process, with branch chiefs, the Deputy Administrator, and/or the Administrator involved in some of these meetings.[5] They also said that the desk officers always consult with the resource management officers on the budget side of OMB as part of their reviews, and reviews of draft rules are not completed until those resource management officers sign off. (In fact, they said that the resource management offices might take the lead in the review for rules involving the "transfer" of federal funds within society.) If the draft rule is economically significant, they said the desk officer would also consult with an economist to help review the required economic analysis. For other rules the OIRA representatives said the desk officer might consult with other OIRA staff on issues involving statistics and surveys, information technology and systems, or privacy issues. In certain cases, OIRA may circulate a draft rule to other parts of the Executive Office of the President (e.g., the Office of Science and Technology Policy or the Council on Environmental Quality) or other agencies (e.g. SBA for rules having an impact on small businesses, or DOE, DOT, the Department of Agriculture, and the Department of the Interior for certain EPA rules). In those cases, OIRA may not only review the rule itself, but also manage an interagency review process.

Executive Order 12866 generally requires OIRA to complete its regulatory reviews within certain time frames—(1) within 10 working days of submission for any preliminary actions prior to a notice of proposed rulemaking (e.g., a notice of inquiry or an advance notice of proposed rulemaking) or (2) within 90 calendar days of submission for all other regulatory actions (or 45 days if OIRA had previously reviewed the material and there had been no material changes in the facts or circumstances upon

[5]OIRA representatives said the Administrator's personal involvement in a review depends on a variety of factors, such as whether the rule involves an issue of interest to him or whether it is likely to be controversial.

which the regulatory action was based). At the conclusion of its review, they said OIRA notifies the issuing agency by telephone. At that point, the agency may publish the rule in the *Federal Register*.

As noted previously, a draft rule that has been reviewed and judged consistent with the executive order may be coded in the office's database as "consistent with no change" (meaning that OIRA considered the draft rule as submitted to be consistent with all applicable requirements) or "consistent with change" (which means that the draft rule was changed at either the issuing agency's initiation or at the suggestion of OIRA, and that OIRA then considered the changed rule to be consistent with all applicable requirements). If the rule is returned to the issuing agency for reconsideration, the executive order requires OIRA to provide a written explanation for the return. Section 7 of Executive Order 12866 originally required the President or the Vice President to resolve any disagreements or conflicts between or among agency heads or between OMB and any agency that cannot be resolved by the OIRA Administrator. However, in February 2002, Executive Order 13258 reassigned the Vice President's responsibilities in this area to the President's chief of staff.

Executive Order 12866 also requires OIRA to take certain actions to ensure greater openness, accessibility, and accountability in the regulatory review process. For example, the order says that a representative from the agency issuing the regulation must be invited to any meeting between OIRA personnel and persons not employed by the executive branch of the federal government regarding a rule under executive order review.[6] It also requires OIRA to forward to the issuing agency within 10 working days any written communications between such outside contacts and OIRA personnel, as well as the dates and names of such outside contacts involved in substantive oral communications with OIRA staff. Other requirements include public disclosure of such written and oral communications, and the maintenance of a publicly available log containing, among other things, the status of all regulatory actions. After the regulatory action has been published in the *Federal Register* or otherwise issued (or after the agency announces it will not publish or issue the action), the executive order requires OIRA to make available to the public "all documents exchanged

[6]The agency officials that we talked with during our review generally indicated that they attended these meetings but sometimes did not participate. However, DOT considers these meetings "ex parte communications," and generally does not attend. (In fact, DOT has a written policy of not attending these meetings.)

between OIRA and the agency during the review." The executive order established other transparency requirements for rulemaking agencies (e.g., requiring them to identify substantive changes made to draft rules during OIRA's review and at the suggestion or recommendation of OIRA).

Informal Review

In its December 2001 report on the costs and benefits of federal regulations, OIRA stated that the office's original review process "was designed as an end-of-the-pipeline check against poorly conceived regulations."[7] However, OIRA also stated that by the time an agency formally submits a rule to OIRA for review there may be "strong institutional momentum" behind the proposal and, as a result, the agency may be reluctant to address certain issues that OIRA analysts might raise. Therefore, OIRA indicated "there is value in promoting a role for OIRA's analytic perspective earlier in the process, before the agency becomes too entrenched." OIRA went on to state the following:

> "A common yet informal practice is for agencies to share preliminary drafts of rules and/or analyses with OIRA desk officers prior to final decision making at the agency. This practice is useful for agencies since they have the opportunity to educate OIRA desk officers in a more patient way, before the formal 90-day review clock at OMB begins to tick. The practice is also useful for OIRA analysts because they have the opportunity to flag serious problems early enough to facilitate correction before the agency's position is irreversible."

However, because of its size, OIRA cannot informally review each of the hundreds of significant proposed and final rules that are submitted to the office each year. OIRA representatives told us that a variety of factors could trigger informal discussions about a forthcoming rule. For example, they said informal reviews are sometimes used when there is a statutory or legal deadline for a rule or when the rule has a large impact on society and requires discussion with not only OMB but also other federal agencies. Therefore, they said informal review is more likely regarding rules issued by certain agencies (e.g., EPA, DOT, the Department of Agriculture, and the Department of Health and Human Services) that issue those types of rules. OIRA representatives also said there is an important distinction between informal *consultations* between OIRA and agency staff that may occur at any time and informal *reviews* that occur when OIRA is provided a substantive draft of a rule.

[7]Office of Management and Budget, "Making Sense of Regulation: 2001 Report to Congress on the Cost and Benefits of Regulations and Unfunded Mandates on State, Local and Tribal Entities," (December 2001).

There have been some indications that OIRA has increased its use of informal reviews in recent years. For example, in its March 2002 draft report to Congress on the costs and benefits of federal regulation, OIRA said "agencies are beginning to invite OIRA staff into earlier phases of regulatory development in order to prevent returns late in the rulemaking process. It is at these early stages where OIRA's analytic approach can most improve on the quality of regulatory analyses and the substance of rules." Similarly, the Administrator said "we are trying to transform OIRA from an end-of-the-pipeline organization to one that also engages in early promotion of good policies and prevention of bad ones." He also said "an increasing number of agencies are becoming more receptive to early discussions with OMB, at least on highly significant rulemakings." As OIRA noted, that receptivity may be enhanced by the threat of a returned rule. In early 2002, the Administrator said OIRA was trying "to create an incentive for agencies to come to us when they know they have something that in the final analysis is going to be something we're going to be looking at carefully. And I think that agencies that wait until the last minute and then come to us—well, in a sense, they're rolling the dice."[8] Perhaps the clearest manifestation of OIRA's early involvement in rulemaking occurred in 2002, when OIRA and EPA began what EPA described as an "unusual collaboration," working closely together to develop a rule curbing pollution from diesel-powered nonroad vehicles. EPA also indicated that it would collaborate with OIRA on the design of an "innovative regulatory analysis" for the rule.

However, OIRA informally consulted with agencies and reviewed agencies' draft rules before formal submission during previous administrations as well. For example, in September 1996, the then-OIRA Administrator testified that her office is sometimes "involved earlier and more deeply in an agency rulemaking—before the agency has completed all of its own evaluation and its internal and/or interagency coordination, and has become invested in its decision." An OIRA representative told us that informal reviews probably had been conducted since OIRA began reviewing rules, but became more common when Executive Order 12866 was adopted in 1993 and OIRA's reviews were focused on "significant" rules. He said because these more complex rules can take years to develop, it makes sense for agencies to involve OMB earlier in the process

[8]Rebecca Adams, "Regulating the Rule-Makers: John Graham at OIRA," *CQ Weekly*, 60 (Feb. 23, 2002), 520-526.

so that policy disagreements can be discussed before substantial amounts of staff work is conducted.

Changes in Regulatory Review Policies

According to OIRA representatives, the process that OIRA uses to review draft rules has been essentially the same since that process was established in 1981. OIRA representatives indicated that the review process had changed less in recent years than the changes that occurred with the advent of Executive Order 12866 in 1993 (e.g., the focus on "significant" rules, the 90-day clock, and the transparency requirements). In presentations before various groups, the OIRA Administrator has said that the office is "pursuing the agenda of quality regulation under the terms of the Clinton-Gore executive order, which we believe…is based on sound principles and procedures."

However, there have been several subtle yet notable changes in OIRA policies and practices in recent years—particularly since the current OIRA Administrator took office in July 2001. In October 2002, the Administrator said "the changes we are making at OMB in pursuit of smarter regulation are not headline grabbers: No far-reaching legislative initiatives, no rhetoric-laden executive orders, and no campaigns of regulatory relief. Yet we are making some changes that we believe will have a long-lasting impact on the regulatory state."

Some of OIRA's review policies and practices that the Administrator and others have identified as significant changes are clear departures from the policies evident in previous administrations. However, other recent OIRA policies and practices are only incrementally different from those evident in previous administrations or have caveats that must be recognized in their implementation.

OIRA as Regulatory "Gatekeeper"

Overall, there has been a notable change in how recent Administrators (and perhaps more generally, how recent administrations) have viewed OIRA's role in the rulemaking process and its relationships with rulemaking agencies—in essence, whether OIRA should play a more collaborative, consultative role in relation to the agencies, or whether OIRA should take on more of a "gatekeeper" role. This change in philosophy has implications for virtually all of OIRA's responsibilities, and may be a precipitating factor for many of the other changes identified in this section of our report.

Perhaps the clearest indications of this change in philosophy are in the public statements of recent Administrators. For example, in a May 1994 report to the President on the first 6 months of Executive Order 12866, the Administrator of OIRA at the time said the relationship between OIRA and the agencies had "vastly improved" and that "rule writers and rule reviewers were learning to work together as partners rather than as adversaries." Officials we spoke with in 1996 at both EPA and DOT confirmed this perception. In testimony before the Senate Committee on Governmental Affairs in September 1996, the Administrator said, "we have consciously changed the way we relate to the agencies" and described that change as a "paradigm shift" from the relationship during previous administrations. She described OIRA's relationship with rulemaking agencies as "collegial" and "constructive," and said OIRA was "not in the business of playing 'gotcha' with them."[9] She cited an article that she said accurately described OIRA's approach as a "consensual process," and that said OIRA functioned "more as a counselor during the review process than as an enforcer of the executive order."[10] She also emphasized that this collaborative approach yielded better results than a more confrontational OIRA-agency relationship.

Another former OIRA Administrator voiced similar sentiments during our review. He said that during his and his predecessor's tenure in the mid-to-late 1990s OIRA acted in a spirit of partnership with agencies submitting regulations for review. He also said that although agencies were not allowed to do whatever they wanted, OIRA did not dictate how regulations should be written and worked with the agencies to ensure transparency and fairness in the rulemaking process.

The current Administrator has characterized OIRA's role and relationship with the agencies in quite different terms. For example, in its December 2002 report on the costs and benefits of federal regulations, OIRA described itself as the "gatekeeper for new rulemakings."[11] In a speech, the current Administrator described OIRA's regulatory review process as "a

[9]Testimony before the Senate Committee on Governmental Affairs, September 25, 1996.

[10]William Niskanen, "Clinton's Regulatory Record: Policies, Process, and Outcomes," *Regulation* (1996), 27-28.

[11]Office of Management and Budget, "Stimulating Smarter Regulation: 2002 Report to Congress on the Costs and Benefits of Federal Regulations and Unfunded Mandates on State, Local, and Tribal Entities," (December 2002).

form of consumer protection to protect people from poorly designed rules." He went on to say that OMB's process of centralized oversight "is a device to strengthen the hands of scientists, engineers and economists within the agencies—they now know that regulatory proposals cannot survive OMB review without careful supporting analysis." He also said OMB review is a device "to combat the tunnel vision that plagues the thinking of single-mission regulators." The Administrator has also compared OIRA's role in reviewing agencies' proposed regulations to OMB's role in reviewing agencies' budget requests:

"Now, no one would suggest that agencies should be permitted to negotiate their 'on-budget' resources from Congress, without any OMB review. Likewise, Presidents realize that regulatory expenditures, while off budget, require fiscal restraint for the same reasons that the size of public budgets need to be restrained. If the President restrains the federal budget without restraining regulation, regulatory advocates may simply respond by urging Congress to shift regulatory costs from the federal budget to states and the private sector. In other words, the President cannot manage the Nation's fiscal health without managing the regulatory state."

Comments from both the current and former OIRA Administrators suggest that the change in the philosophy underlying OIRA's regulatory review function may be, at least in part, a function of the change in the presidency that the office serves. A previous Administrator emphasized that OIRA is part of the Executive Office of the President, and the President is the office's chief client. Therefore, she said, a change in the presidency has a profound effect on how OIRA operates. She also said each new Administrator of OIRA—and ultimately each new administration—represents a reaction to the previous Administrator and administration. Just as the Clinton administration's OIRA was a reaction to the administrations that preceded it, she said the current Bush administration's OIRA is a reaction to the Clinton period. Similarly, in March 2002, the current OIRA Administrator said "Presidents use the powers of OMB regarding agency action to advance Administration priorities and policy objectives… We should remember that OMB is an office within the

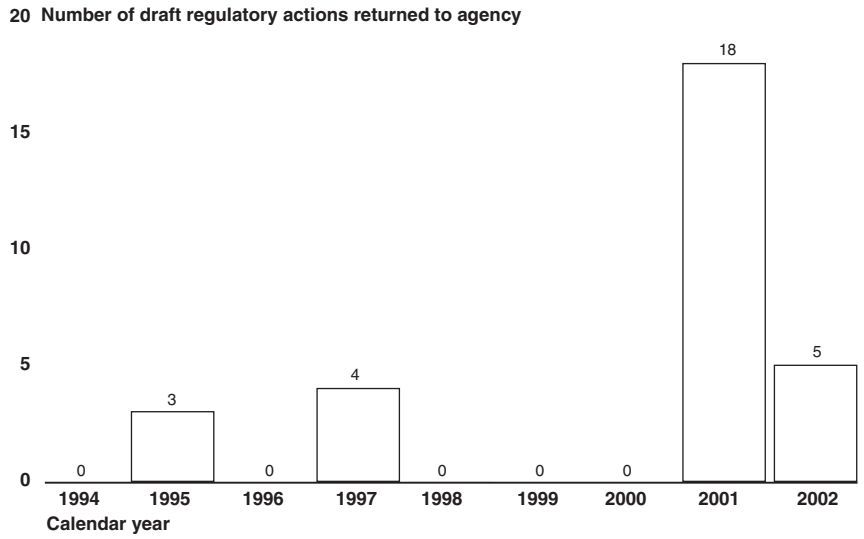
Executive Office of the President and its actions necessarily reflect Presidential priorities."[12]

Increased Use of Return Letters

One clear indication of the emergence of OIRA's "gatekeeper" role is the office's increased use of return letters since 2001. During the first 7 full calendar years that Executive Order 12866 was in place (1994 through 2000), OIRA generally reviewed between 500 and 700 rules each year but returned very few of them to the agencies—three rules in 1995 and four in 1997. (See fig. 5.) However, although the total number of rules reviewed each year remained about the same, the number of rules returned to the agencies increased dramatically in 2001. In fact, OIRA returned almost three times as many rules that year (18 rules) than in the 7 previous years combined. All of the returns during calendar year 2001 occurred after the current Administrator took office in July 2001. In calendar years 2001 and 2002 combined, OIRA returned a total of 23 rules to the agencies.

[12]Others have also noted the salience of presidential priorities in OIRA's operations. See, for example, Susan E. Dudley and Angela Antonelli, "Congress and the Clinton OMB: Unwilling Partners in Regulatory Oversight?," *Regulation* (Fall 1997), 17-23. The authors noted "OIRA is supposed to simultaneously provide independent and objective analysis, and report to the president on the progress of executive policies and programs. When those functions conflict, the presidential agenda will most certainly prevail over independent and objective analysis."

Figure 5: OIRA Returned More Rules to Agencies in Calendar Year 2001 Than in the 7 Previous Years Combined



Source: OMB.

DOT had the most rules returned during 2001 and 2002 (eight), followed by the Social Security Administration (five), the Department of Veterans Affairs (four), and the Department of Housing and Urban Development (two). The Department of Agriculture, the Office of Personnel Management, EPA, and SBA each received one return letter. In the letters, OIRA commonly said that it returned the rules because of concerns about the agencies' analytic approach—such as whether the agency had considered all reasonable regulatory alternatives, or had selected the alternative that would produce the greatest net benefits. In its December 2002 report on the costs and benefits of regulations, OIRA reported that 10 of the 22 rules returned by October 2002 had been resubmitted and approved for publication.

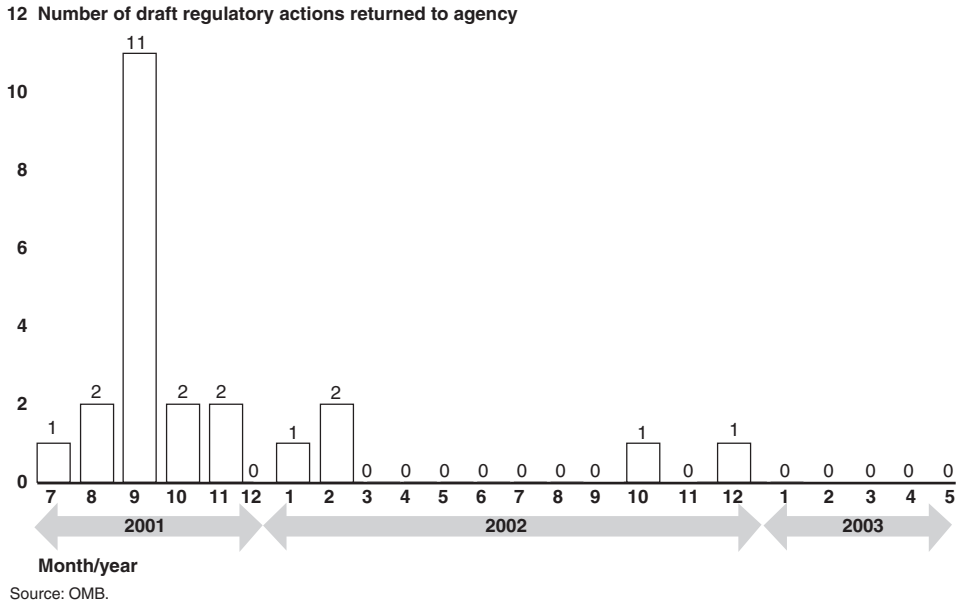
Recent OIRA Administrators have taken very different positions regarding the use of return letters, reflecting the philosophical differences between the administrations in OIRA's relationship with the agencies and explaining the dramatic change in the use of returns. For example, two former OIRA Administrators during the previous administration told us that the objective of the review process was to achieve an end result that was mutually agreeable, and that they viewed return letters as evidence of a failure of the collaborative review process. One of the former

Administrators noted that the agencies and OIRA are parts of the same administration "team," so any public failure to agree on how a rule should be written could only be seen as a breakdown of that process.

In contrast, the current OIRA Administrator said in one of his speeches that the office is using a "carrot and stick" strategy in its efforts to encourage better regulatory analysis, and that the "stick" has been the revival of the return letter. In its March 2002 draft report on the costs and benefits of federal regulations, OIRA noted that no rules had been returned to the agencies for reconsideration during the previous administration's final 3 years, and said "the degree of OIRA's actual effectiveness can be questioned when it declines to use its authority to return rules." OIRA noted that under the current administration the office had revived the return letter, "making clear that OMB is serious about the quality of new rulemakings."

However, OIRA's increased use of return letters appears to have been short lived. As figure 6 shows, the sharp increase in the use of return letters was primarily in the current Administrator's first 8 months in office (July 2001 through February 2002). During that period, OIRA returned 21 of the 415 rules that it reviewed to the agencies. More than half (11) of the 21 rules that OIRA returned during this period were sent to the agencies in a single month—September 2001. However, during the following 15-month period (from March 2002 through May 2003), OIRA returned to the agencies only 2 of the 863 rules that it reviewed—about the same pace as during the previous administration.

Figure 6: OIRA Returned Only Two Rules Between February 2002 and May 2003



Source: OMB.

In its December 2002 report on the costs and benefits of federal regulations, OIRA indicated that the decline in the number of returns since February 2002 was a reflection of the improved quality of regulatory packages. OIRA also said that an even more important factor was the "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."

Greater Emphasis on Economic Analysis

Some of the officials from rulemaking agencies who regularly interact with OIRA also told us that there is a greater expectation now than several years ago that the agencies' economic analyses (both benefit-cost and cost-effectiveness) will be thorough. Officials from one agency described it as a "more relentless emphasis" on benefit-cost analysis, and said OIRA is expecting the agencies to devote more money and effort to refining their analyses to develop rules that are more cost effective. Officials in another agency said there had been a perceptible "stepping up the bar" regarding what is expected in agencies' analyses. They also said that OIRA is looking for greater quantification of benefits and more justification and breakdown

of marginal benefits of every line item in the agency's rules, and that OIRA now expects agencies to do a benefit-cost analysis for all regulatory options, not just for the option that the agency selected.

OIRA representatives pointed out that their office has always pushed for agencies to do a better job with their analyses. However, they confirmed that the current Administrator is somewhat more interested in having the agencies do better analyses than previous Administrators. In fact, they said the current Administrator said early in his tenure that he would return a rule if the analysis needed work, even if the rule itself was acceptable.

Emphasis on 90-day Period for Review

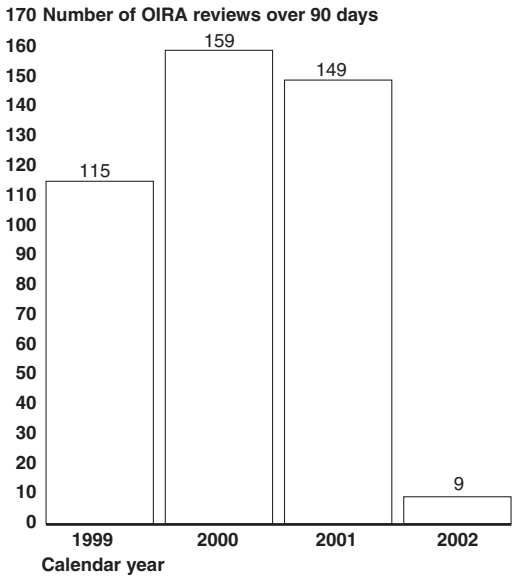
Another clear change in OIRA regulatory review policy since the current OIRA Administrator took office has been a stricter adherence to the time frames for OIRA review. As mentioned earlier in this report, Executive Order 12866 generally requires OIRA to complete its regulatory reviews within 90 calendar days of submission for all draft proposed and final rules. The executive order allows the review period to be extended once upon the written permission of the OMB Director and at the request of the rulemaking agency.[13] According to a former OIRA Administrator, the 90-day time limit in the executive order was put in place because of "strident complaints" about the length of reviews during the previous administrations' implementation of Executive Order 12291 in the 1980's and early 1990's. However, she said the time limit created an unintended "perverse incentive" for the agencies to respond to OMB suggestions late in the 90-day period, and then suggest that the rule be approved because of the time limit. As a result, she said, review periods were often extended beyond the 90-day limit.

As figure 7 indicates, during each of the calendar years 1999, 2000, and 2001, more than 100 OIRA reviews exceeded the 90-day limit (115, 159, and 149, respectively). However, during calendar year 2002 (the current Administrator's first full year in office) only 9 reviews lasted longer than 90 days. According to an OIRA representative, virtually all of the extensions of the review periods in each of these 4 years were done at the request of the agency issuing the rule. (However, officials from one agency and a

[13]The executive order actually says review periods can be extended only if the agency requests an extension *and* the OMB Director provides written permission. However, an OIRA representative said that extensions have been provided if either condition is met.

previous OIRA Administrator told us that OIRA sometimes asked the agency to request an extension.)

Figure 7: The Number of OIRA Reviews Lasting More Than 90 Days Dropped Sharply in 2002



Source: OMB.

The dramatic decline in the number of reviews lasting more than 90 days is traceable to clear differences in philosophy between Administrators regarding the importance of this requirement. For example, in September 1997 the OIRA Administrator at the time testified that "when two or more agencies are at loggerheads over a regulatory issue, it may well take more than 90, or even 120, days to obtain needed data and analyses, to conduct the appropriate evaluation, and to arrange for the policy officials in the interested agencies to come to agreement." For that and other reasons she opposed draft legislation that would have imposed a statutory time limit on OIRA reviews. Another OIRA Administrator during the previous administration told us during our review that he considered it more important to "get the rule right" rather than rigidly adhere to a 90-day time limitation. Several of the agency officials that we contacted during this review confirmed that view, saying that during the previous administration OIRA often worked with the agencies after the 90-day deadline had passed in order to resolve comments or questions. In contrast, in May 2002 the

current OIRA Administrator said "agencies have sometimes been forced to wait 6 months, a year, or even longer to get an answer from OMB. We have changed that practice. I have instructed my staff that no rule will stay longer than 90 days at OMB without my personal authorization." According to OIRA's December 2002 report on the costs and benefits of regulations, the office now regards the 90-day review limit as "a performance indicator for a strong regulatory gatekeeper." OIRA representatives confirmed that close adherence to the 90-day clock is new, and said that OIRA management tracks all rules that have been under formal review for more than 60 days. They also said that a benefit of stricter adherence to the 90-day review limit is that it forces officials to make decisions sooner, thereby moving the review along more quickly.

Officials from several rulemaking agencies also told us that OIRA staff currently seem much more focused on the 90-day clock than during the previous administration. In fact, concerns about adherence to this fixed review period might have precipitated some of the return letters that have been more common during the current administration. For example, in the September 14, 2001, return letter to DOT, the OIRA Administrator said "(s)ince the resolution of the concerns will take some additional time, I am returning the draft final rule on flight data recorders to the Department for your reconsideration." The return letters for this rule and for one other rule were sent to the agencies shortly after the rules' 90-day review periods had ended. An OIRA representative told us that the 90-day clock may play a role in some returns, but not always.

Officials in other agencies also said that rules are sometimes returned or withdrawn at OIRA's request when time is running out on the 90-day clock and it is recognized that more time is needed to resolve issues "off the clock" or during a separate 90-day period. Representatives of OIRA told us they do not request that agencies withdraw rules, and emphasized that it is the agencies—not OIRA—that ultimately make withdrawal decisions. They also said agencies sometimes withdraw rules as a negotiating strategy.

Although an increased emphasis on the 90-day time limit is clearly an area of change in recent years, the formal review period itself may be somewhat of an artificial construct if OIRA and the agency had been substantively discussing the rule and/or exchanging drafts of the rule before formal submission. For example, on December 10, 2001, EPA formally submitted a draft rule to OIRA on proposed nonconformance penalties for heavy-duty diesel engines. OIRA's database indicates that it completed its review 10

days later on December 20, 2001. However, public documents indicate that EPA and OIRA met with outside parties in early October 2001 and mid-November 2001 to discuss the rule, and that EPA informally submitted a version of the draft rule and its economic analysis to OIRA in late October 2001—weeks before the 10-day formal review period began. (See GAO ID 53 in app. II of this report.) OIRA records indicate that the formal review period for an EPA Clean Water Act rule in which OIRA made significant changes was even shorter—1 day. (See GAO ID 69 in app. II of this report.)

Use of Prompt Letters

Another change in OIRA policies and practices has been the development of a new form of communication with the agencies—the "prompt letter." In its December 2002 report on the costs and benefits of federal regulations, OIRA stated that the office had historically been a reactive force in the regulatory process, responding to proposed and final rules that were generated by federal agencies. However, the report went on to say that OIRA had recently begun "taking a more proactive role in suggesting regulatory priorities for agency consideration," and the prompt letter is the format by which those suggestions are brought to the agencies' attention.

By the end of May 2003, OIRA had sent nine prompt letters to regulatory agencies.[14] Several of the initial prompt letters recommended that the agencies consider taking regulatory actions regarding particular issues. Notably, the letters did not always suggest that the agency publish a rule on the issue, sometimes recognized that the agency had already begun taking action, and generally left the final decision to the agency regarding what action to take. For example:

- In September 2001, OIRA sent a letter to the Department of Health and Human Services suggesting that FDA publish a final rule requiring that the amount of trans fatty acid present in food be included in a product's label. However, OIRA said the agency should review the comments received on its proposed rule and proceed to final rulemaking "if appropriate."

[14]OIRA listed two items on the "prompt letters" page of its Web site that did not appear to be prompt letters—a June 2002 EPA press release regarding an EPA-OIRA collaboration and a January 2003 memorandum to the heads of selected independent agencies asking them to consider recommendations for reform that OIRA had received from the public.

- Also in September 2001, OIRA sent a letter to OSHA requesting that the agency "consider whether promotion of (automatic external heart defibrillators) should be elevated to a priority." However, OIRA said it understood that OSHA had limited resources and other constraints, and was simply asking the agency to consider the matter.

- In December 2001, OIRA sent a letter to DOT encouraging NHTSA to give greater priority to modifying its frontal occupant protection standard by establishing a high-speed, frontal offset crash test. OIRA recognized that the agency had already signaled its intent to move forward with this standard, and also recognized NHTSA's resource constraints and other legislative mandates.

- In May 2002, OIRA sent a letter to the Office of Federal Housing Enterprise Oversight recommending that the office consider developing a rule strengthening the corporate governance of Fannie Mae and Freddie Mac, and to require them to make certain public disclosures.

- In May 2003, OIRA sent a letter to the Departments of Agriculture and Health and Human Services requesting them to "further incorporate the large body of recent public health evidence linking food consumption patterns to health and disease" as the departments revise their dietary guidelines and update the "Food Guide Pyramid." Specifically, OIRA recommended that the revisions "emphasize the benefits of reducing foods high in trans fatty acids and increasing consumption of foods rich in omega-3 fatty acid."

Other OIRA prompt letters were even less focused on rulemaking or guidance, instead recommending that the agencies better focus certain research or programs. For example, in December 2001 OIRA sent a letter to EPA highlighting "some critical research needs that can help target environmental-protection investments to the most important sources of (fine particulate matter) and thereby better inform cost-benefit studies of future air pollution control policies." OIRA recognized that EPA already devoted a substantial share of its research budget on particulate matter, but suggested that the research focus on three particular issues. Similarly, in February 2003, OIRA sent a letter to the Department of Energy raising several issues regarding a particular energy modeling system, and suggested changes in that system that would, in OIRA's view, better enable the agency to assess the potential of hybrid-electric and diesel powered vehicles.

In March 2002 the OIRA Administrator said that the prompt letters issued as of that date "have emerged primarily from discussions with my professional staff," but encouraged the public to submit ideas for prompts. In another speech he said the use of prompt letters "enables OMB to publicly identify areas where agencies might improve regulatory policies." He also said that prompt letters differ from the more definitive presidential directive in that the letters represent a "public request that is intended to stimulate agency and public deliberation," and emphasized that "final decisions about priorities remain with the agencies."

Although OIRA's use of public prompt letters is new, the concept of OIRA (or, more generally, the President) making regulatory suggestions to the agencies is not.[15] One former OIRA Administrator told us that every administration has had certain areas of regulatory emphasis and has communicated those ideas to rulemaking agencies in a variety of ways. She said that if OIRA wanted the agencies to initiate rulemaking in a particular area, "we could get the agencies' attention without using a letter." Similarly, another former OIRA Administrator said that during his tenure if OIRA thought an agency should regulate in a particular area, he would call an agency official and talk about the issue rather than sending a public prompt letter than could embarrass the agency. Officials in one agency also indicated that these types of communications had existed previously—albeit not publicly. As indicated in the following quote from its December 2002 report on the costs and benefits of federal regulation, OIRA identified the *public* nature of the prompt letter as a distinguishing feature:

"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."

An OIRA branch chief told us that the office still does, on occasion, call an agency on the telephone and suggest areas for regulation. He said the strategy used (telephone versus prompt letter) depends on a variety of

[15]See Elena Kagan, "Presidential Administration," *Harvard Law Review*, 114 (2001): 2,245-2,385, who asserted that recent presidents have increasingly made agencies' regulatory activity into an extension of their own policy and political agendas. She said President Clinton did so primarily by "exercising directive authority over these agencies," using formal directives to the heads of executive agencies to "set the terms of administrative action and prevent deviation from his proposed course."

circumstances, but noted that prompt letters are more "transparent" and may have more impact than a telephone call.

Several of the agencies have taken some type of action in response to the OIRA prompt letters, and other actions were planned. For example, in December 2001 OSHA issued a technical information bulletin regarding the use of defibrillators in the workplace. In July 2003, FDA published a final rule on trans-fatty acids. NHTSA said that it planned to issue a notice of proposed rulemaking on offset crash testing in 2003.

Post-Review Letters

In 2001 and 2002, OIRA sent a total of five "post-review letters" to rulemaking agencies and posted those letters on its Web site. As of May 2003, no post-review letters had been sent since August 2002. OIRA representatives said that although individual branch chiefs or desk officers had previously provided staff-level comments to rulemaking agencies at the conclusion of reviews, the use of a public letter signed by the Administrator to convey those comments represented a change in OIRA policy.

In some of the post-review letters, OIRA expressed concerns about the rulemaking agencies' analyses and the cost-effectiveness of the rules that were similar in many respects to the concerns that the office had expressed in the previously mentioned return letters. For example, after OIRA completed its review of EPA's draft proposed rule on "Control of Emissions from Nonroad Large Spark-Ignition Engines and Recreational Engines (Marine and Land-Based)" in September 2001, the OIRA Administrator sent a letter to EPA noting that he was "concerned that the regulatory analysis is not sufficient to support a reasoned determination on the appropriate regulation of these sources." Specifically, he said that the analysis did not "provide a benefit/cost analysis integral to the decision-making process" and did not evaluate any alternatives as required by the Unfunded Mandates Reform Act of 1995 and Executive Order 12866. The Administrator said he expected improvements to the analysis to be submitted before the final rule was submitted, and said EPA and OIRA should schedule "quarterly meetings to review the progress in developing a refined analysis."

However, in other post-review letters, OIRA expressed other types of comments. For example:

- In an October 2001 letter regarding an FAA draft proposed rule on "Traffic Alert and Collision Avoidance Systems," the OIRA Administrator

recognized that despite the rule's high cost compared to its benefits, the agency had "limited alternatives available under the statute." In that regard, he indicated that the department and the agency should share with Congress "any information made available by the public that bears on the reasonableness of implementing the statute." He also encouraged FAA to carefully assess the impact of the rule on small entities and the financial health of the industry "in light of recent events."

- In a June 2002 letter regarding a NHTSA final rule on tire pressure monitoring systems, the OIRA Administrator expressed his appreciation for the "significant improvements NHTSA made in the regulatory analysis," and encouraged the agency to conduct a study examining the relative frequency of different causes of crashes.

- In an August 2002 letter regarding a Department of Housing and Urban Development rule on improving the process for obtaining mortgages, the OIRA Administrator encouraged the department to continue its work to improve and simplify the proposed forms, and suggested that the department "further strengthen the economic and regulatory flexibility analyses."

A former OIRA Administrator told us that the office's current use of public post-review letters represents a change in policy from the previous administration. She said that during the previous administration OIRA might have spoken with an agency about what it should be doing before a proposed rule was resubmitted, but OIRA would not have put those comments in writing. She described the previous process as "non-public post review comments," and said written material was too confrontational.

Transparency Improvements

On numerous occasions, the current OIRA Administrator has identified improvements in the transparency of the office's regulatory review process as a key area of change, and has described the establishment of a climate of openness at OIRA as his "first priority." The Administrator said the information that OIRA discloses about its reviews is intended to "diminish the culture of secrecy and mystery that has surrounded my Office since it was launched early in the Reagan Administration," and said that "more openness at OMB about regulatory review will enhance public appreciation of the value and legitimacy of a centralized analytical approach to regulatory policy." He also described the transparency of OIRA's regulatory review process as "critical to our ability to improve the nation's regulatory

system," and said "only if it is clear how the OMB review process works and what it does will Congress and the public understand our role and the reasons behind our decisions." He also said "we see openness not simply as a canon of good government but as a strategy to transform the public debate about regulation to one of substance…rather than process." Similarly, in May 2002 the OMB Director said that one way to establish public confidence in the "consumer protection" mission of OMB is "maximum openness."

Disclosure of Contacts with Outside Parties

In October 2001, the OIRA Administrator sent a memorandum to OIRA staff (and published it on the office's Web site) that, among other things, delineated OIRA's disclosure procedures regarding substantive communications with outside parties (i.e., persons not employed by the executive branch) while rules were under review. Many of the procedures listed were the same as or clarifications of the disclosure requirements in Executive Order 12866. For example, like the executive order, the memorandum said that (1) only the Administrator or a particular designee can receive substantive telephone calls from outside parties, (2) a representative from the issuing agency must be invited to any meeting between OIRA personnel and outside parties, and (3) OIRA must send to the regulatory agency all written communications between OIRA personnel and outside parties within 10 days.

However, the Administrator's October 2001 memorandum also extended the executive order's disclosure requirements in certain areas. For example, the memorandum said that OIRA would disclose substantive telephone calls with outside parties about a rule under review if the calls are *initiated* by the Administrator, not just the calls that the Administrator *receives* from outside parties. Also, the memorandum said that OIRA considers a rule to be under review for purposes of OIRA's disclosure requirements regarding outside parties not just during the formal review process, but *before* formal submission of the review package (i.e., during the previously mentioned informal review period) if OIRA has started a "substantive discussion with the agency concerning the provisions of a draft rule or OIRA has received the rule in draft." As a result of this change in policy, for the first time OIRA began disclosing letters, telephone conversations, and meetings that occurred during the informal review period. In its 2001 report on the costs and benefits of federal regulations, OIRA described why the office believed that these outside contacts before a rule is formally submitted should be disclosed.

"Interested outside parties have gradually learned about this informal process of agency-OIRA discussion and thus attempts are made to provide information to agency and OIRA analysts. In order to protect the integrity of OIRA and the administrative record, an informal practice has developed that communications between OIRA and outside parties are treated as 'covered by E.O. 12866' as soon as a rulemaking has proceeded to a point where OIRA desk officers have received from agencies copies of preliminary draft regulatory text or analysis."

However, OIRA representatives that we contacted during this review emphasized that a rule is not considered under review with regard to these disclosure requirements if OIRA and an agency are in general consultation about an issue, but the consultation has not become "substantive" and/or the agency has not submitted a substantive draft of a rule for informal review. Therefore, at that "preinformal review" stage of the process, OIRA can communicate with outside parties about the issue and not have to disclose those communications.

The October 2001 memorandum also announced that much of the information generated through the disclosure requirements would be available to the public on the agency's Web site, including summary information on meetings, phone calls, and other oral communications with outside parties and a list of the written correspondence that OIRA had received from outside parties. The memorandum said that other information previously available in hard copy and/or in the OIRA docket library would also be posted to the Web site (e.g., monthly regulatory review lists and statistics and the text of written outside communications).[16] Improving access to information about OIRA's review process by putting the information on the office's Web site has been widely hailed as a significant improvement in the transparency of the regulatory review process.[17]

However, we concluded that some of the information that OIRA provides on its Web site regarding its communications with outside parties is not very informative. As a result, it is sometimes difficult to understand what

[16]The October 2001 transparency memorandum indicates that covered telephone calls and correspondence must be logged and/or sent to the rulemaking agency within 10 working days. An OIRA representative told us that meetings are typically logged within 3 or 4 days. He also said that materials provided to OIRA at meetings are only available in hard copy in the OIRA docket, not electronically.

[17]An OIRA representative told us that the office had not made this information available electronically during previous administrations because of resource constraints.

rule a meeting was about or the affiliations of the meeting participants. For example, during our review the OIRA Web site provided the following descriptions:

- On February 3, 2003, an OIRA desk officer had a meeting with a person whose affiliation was listed as "Albemarle" regarding an EPA issue identified as "N-Propyl Bromid (nPB)."

- On October 24, 2002, OIRA leadership and staff met with four individuals regarding a Centers for Medicare and Medicaid Services issue identified as "Outpatient."

- On June 27, 2002, the Administrator and other OIRA staff met with several individuals whose affiliations were listed as "TPLG," "American Association," "Powell Golstein," and "Hunton & Williams" regarding a Centers for Medicare and Medicaid Services issue identified as "Inherent Reasonableness."

- On April 26, 2002, OIRA and OMB leadership and staff met with several individuals regarding a General Services Administration issue identified as "DOT Gov Rule: 3090-AH41." Two of the non-OMB participants' affiliations were listed as "NASCIO" and "PTI."

The OIRA Web site included a column for each meeting in which the client being represented by an outside party could be identified. However, we found that this column was usually blank. An OIRA representative told us that he recognized that OIRA could sometimes do a better job describing the rule being discussed at meetings as well as the affiliations of the meeting participants, and said that he had already notified OIRA staff that the information posted on executive order meetings should be clearer regarding these issues (e.g., no abbreviations when identifying the affiliations of outside parties).

OIRA's practice of providing minimal information to the public about its meetings with outside parties stands in contrast to the more formal, APA-driven practices of certain agencies that we reviewed. For example, on October 26, 2001, the OIRA Administrator and three OIRA staff members met with representatives of the automobile industry regarding a NHTSA tire pressure monitoring proposed rule. Two representatives from NHTSA were also present. The OIRA web page listed the names and affiliations of those present. However, the DOT electronic docket contained a memorandum providing that information and also described the positions

taken by the various parties at the meeting. The memorandum indicated it was prepared pursuant to DOT Order 2100.2, which requires that DOT agencies prepare a report on meetings with outside parties for the rulemaking docket. The DOT order also says "a mere recitation that on X day a meeting was held with listed persons to discuss a named general subject is inadequate."

Disclosure of OIRA-Agency Interactions

The Administrator's October 2001 memorandum also briefly discussed the requirements in Executive Order 12866 regarding disclosure of OIRA's interactions with the rulemaking agencies. For example, it stated that OIRA would, upon request, provide certain materials to the public after a reviewed rule had been published, including the draft as originally submitted, any material submitted by the agency during the review, pages where changes occurred in the course of review, and correspondence between OIRA and the agency that had been exchanged during the review.

However, OIRA representatives told us that the term "during the review" in this context has a different meaning from the term "under review" with regard to OIRA's contacts with outside parties. As mentioned previously, OIRA considers a rule under review whenever *informal* review begins, and said it would disclose all contacts with outside parties after that date. In contrast, OIRA considers the period "during the review" in relation to its contacts with the rulemaking agencies to include only a rule's *formal* review period. Therefore, whereas OIRA discloses its contacts with outside parties during informal reviews, it does not disclose its contacts with rulemaking agencies during this period.

Similarly, OIRA representatives also said that the transparency requirements in the executive order that are applicable to the agencies are not triggered by informal reviews. As noted previously, the executive order requires agencies to identify for the public (1) "the substantive changes between the draft submitted to OIRA for review and the action subsequently announced," and (2) "those changes in the regulatory action that were made at the suggestion or recommendation of OIRA." The OIRA representatives said they considered the second of these requirements to be a subset of the first, and that the term "the draft submitted to OIRA for review" refers to the draft rule submitted for formal review, not any drafts submitted for informal review.

Therefore, under this interpretation of the executive order, an agency could submit a draft rule to OIRA for informal review, make changes in response to multiple OIRA suggestions and recommendations, and neither the

agency nor OIRA would have to disclose those changes to the public. If the rule was not subsequently changed during the formal review period, OIRA would code the rule in its database as "consistent with no change" and the public would never know that OIRA had influenced its development.

OIRA representatives told us that drafts of a rule that are informally submitted to OIRA do not represent the agency's official position, and therefore should not be disclosed to the public even after the rule is published. They also said that postpublication disclosure of communications between OIRA and the agency that occur prior to formal rule submission could have a "chilling effect" on those communications in the future. Similarly, in its 2002 report on the costs and benefits of regulations, OIRA said it 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." However, in the same report, OIRA said "it is at these early stages where OIRA's analytic approach can most improve the quality of regulatory analyses and the substance of rules."

During our review we found evidence that some of these OIRA-agency communications are being disclosed. OIRA's and the agencies' dockets for several of the rules that we examined in chapter 3 of this report contained e-mails and faxes between OIRA and the agency about rules under informal review. Those documents proved very helpful to us in determining what changes had been made to agencies' rules at the suggestion of OIRA.

Other Caveats

There are also other caveats to the OIRA-agency transparency requirements in the executive order and the Administrator's October 2001 memorandum. For example, OIRA representatives told us that the requirement in the executive order that OIRA make available to the public "all documents exchanged between OIRA and the agency" issuing the regulation applies only to exchanges made by OIRA staff at the branch chief-level and above. Therefore, any e-mails, faxes, or other documents exchanged between OIRA desk officers and staff in regulatory agencies about rules under review do not have to be disclosed.[18] OIRA said that this

[18]However, in practice we found evidence that such communications are, at least in some cases, disclosed. OIRA's docket for several of the rules that we examined in chapter 3 of this report contained e-mails and faxes between the OIRA desk officer and agency staff about rules under review.

"branch chiefs and above" distinction had been the office's policy during the previous administration as well.

Other OIRA-agency interactions are not covered by any transparency requirements. For example, if OIRA returns a rule to an agency for reconsideration, the executive order requires the Administrator to provide the agency with a written explanation for the return. The return letter is then made available to the public. After OIRA concludes its review and a rule is published, the executive order requires the agency to disclose to the public the substantive changes made during OIRA's review and those made at OIRA's suggestion or recommendation. However, if an agency withdraws a rule from OIRA during its review—either at its own initiative or at the recommendation of OIRA—neither the agency nor OIRA is required to disclose the reason.[19]

OIRA's "Open Door" Policy on Meetings with Outside Parties

In its December 2002 report on the costs and benefits of federal regulations, OIRA said that it had adopted an "open door approach to meeting with outside parties." In explanation, OIRA representative told us that if a party outside of the federal government wanted to meet with OIRA about a rule under review or a matter of general regulatory policy, OIRA would always try and accommodate that request. OIRA representatives emphasized that these meetings are initiated by the outside parties, not OIRA. However, a former OIRA Administrator told us that she did not believe that this "open door" policy was new, and said OIRA had meetings with outside interest groups "all of the time" during her tenure in the mid-1990s.

Information on the OIRA Web site indicated that from October 2001 through March 2003, OIRA had more than 100 meetings with outside parties. Of these, at least 85 were with representatives of regulated entities (primarily private companies); environmental and other public interest

[19]Agency officials told us that if a rule is withdrawn after having been formally proposed, an agency may publish a "withdrawal" notice in the *Federal Register*. If the rule is withdrawn before being proposed, they said the only documentation may be a notation in the "completed action" section of the Unified Agenda of Federal Regulatory and Deregulatory Actions. However, OIRA's involvement may not be revealed in either form of documentation.

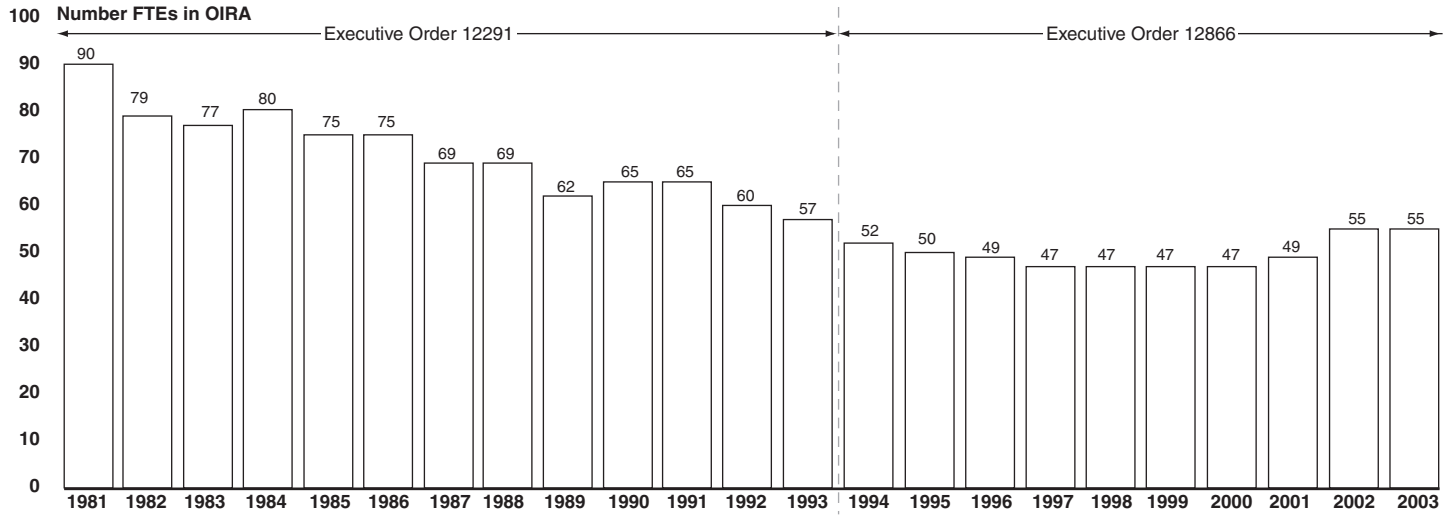
groups were involved in 8 meetings.[20] OIRA representatives said that one possible explanation for the apparent imbalance in those with whom OIRA meets is that there are more regulated entities that are directly affected by agencies' regulations than public interest groups who have a more general interest in the issues. However, another possible explanation is that, while OIRA has said that it will meet with any organization that wants to meet with it about a rule under review, representatives of several public interest groups told us some such groups have made a policy decision to not request meetings with OIRA. They said they take this position because their groups do not believe that OIRA is the proper locus of authority or decision making with regard to rulemaking issues.

Hiring of Additional Staff Specialists

OIRA has also changed the office's human capital strategy in recent years, increasing both the number of staff and adding new types of expertise. As figure 8 shows, when OIRA was created in fiscal year 1981 the office had an FTE ceiling of 90 staff members. By 1997, the number of FTEs allocated to OIRA declined to 47—a nearly 50 percent reduction since 1981. OIRA noted in its December 2002 report on the costs and benefits of regulations that the decline in OIRA staffing during this period was more pronounced than the decline in OMB as a whole, and occurred at a time when OIRA was given new statutory responsibilities (e.g., concerning unfunded mandates, small business, regulatory accounting, and information policy) and when regulatory agencies' staffing and budgetary levels were increasing. Also during this period, though, with the advent of Executive Order 12866 in late 1993, the number of rules that OIRA reviewed went from between 2,000 and 3,000 per year to between 500 and 700 per year.

[20]The other meetings were with representatives of state, local, or tribal governments (11 meetings), Members of Congress (2 meetings), or individuals/organizations that could not be readily identified (8 meetings).

Figure 8: OIRA Recently Reversed a 20-year Decline in Staffing



Source: OMB.

As the figure shows, OIRA's staffing authorization began to increase in 2001, and by 2002 the office had 55 authorized FTEs.[21] Between 2001 and 2003, OIRA had hired five new "specialist" or "expert" staff members who were intended to provide new science and engineering expertise to OIRA:

- A risk assessor who received her Ph.D. in environmental health/molecular toxicology from the University of Washington and who most recently had been a science and technology fellow at EPA's National Center for Environmental Assessment.

- An epidemiologist who received her Ph.D. in geography (resources management) from Clark University and who had worked on exposure assessment issues at EPA and was an environmental professor and researcher at the schools of health at Johns Hopkins University and Harvard University.

[21]OIRA's FTE total includes a number of positions that are not regularly involved in the review of rules under Executive Order 12866, including staff within the Information Policy and Technology branch and the Statistical and Science Policy branch, and administrative staff within the office. As of July 2003, 22 full-time OIRA analysts were primarily responsible for the regulatory and paperwork reviews of all federal agencies.

- An engineer who received his Ph.D. in health policy from Harvard University and a Masters of Science from the Massachusetts Institute of Technology in civil and environmental engineering and technology and policy. He previously worked at Resources for the Future and the consulting firm Industrial Economics Incorporated.

- A health economist who received her Ph.D. in health policy from Harvard University and a Master of Science degree in earth systems from Stanford University. She formerly worked at the American Enterprise Institute.

- An economist who received his Ph.D. in economics from the University of North Carolina at Chapel Hill and who formerly worked at FDA's Center for Food Safety and Applied Nutrition.

In its December 2002 report on regulatory costs and benefits, OIRA said these hires would facilitate collaboration with staff in the Office of Science and Technology Policy and would "enable us to develop a more diversified pool of expertise to ask penetrating technical questions about agency proposals." In an October 2002 speech, the Administrator said that these new hires also reflected "the increasing importance of science-based regulation in the federal agencies." He also indicated that his vision for how OIRA should be staffed is similar to that outlined in a 1993 book by Stephen Breyer (later appointed to the Supreme Court), who suggested the creation of a small, technically-trained group within OMB that offered its members a special civil service career path—similar to that of the French Conseil d' Etat.[22] Breyer also indicated that this group might assume OIRA's mandate to review agencies' proposed rules, "augmented by its missions to rationalize risk regulation and seek tradeoffs." The OIRA Administrator said "although I am not sure that the British or French civil service are exactly the right analogies, I do have in mind a talented and analytically keen staff who know how markets work, how government works, and respect the role of expertise and values in solving national problems."

Both former OIRA Administrators with whom we spoke supported increasing the number of OIRA staff. However, both also indicated that they never felt that OIRA was lacking in technical expertise and that they could always tap into the resources available in other parts of the

[22]Stephen Breyer, *Breaking the Vicious Circle: Toward Effective Risk Regulation* (Cambridge, Mass.: Harvard University Press, 1993).

Executive Office of the President (e.g., the Office of Science and Technology Policy or the Council of Economic Advisors) or other agencies if the need arose. An OIRA branch chief said the office still utilizes staff from other agencies from time to time, in addition to using its new "in house" expertise.

Relationship With SBA Office of Advocacy

In March 2002, the OIRA Administrator and the SBA chief counsel for advocacy signed a memorandum of understanding (MOU) committing OIRA and the Office of Advocacy to work together to ensure that federal agencies comply with the Regulatory Flexibility Act.[23] As part of OIRA's regulatory reviews, the MOU requires OIRA to consider whether agencies should have prepared regulatory flexibility analyses under the act. If the Office of Advocacy has concerns about an agency's analysis, the MOU requires OIRA to provide a copy of the draft rule to that office. Also, the MOU says that OIRA would help the Office of Advocacy develop guidance for agencies to follow in complying with the act. In May 2003 testimony before the House Committee on Small Business, the OIRA Administrator said that this agreement would enhance OIRA's and SBA's ability to ensure that agencies are meeting their Regulatory Flexibility Act responsibilities.

However, in that same testimony the Administrator said that the memorandum of understanding would "formalize OIRA's long-standing practice of involving the Office of Advocacy in our review of agency regulations." In response to recommendations in our March 1994 report on the administration of the Regulatory Flexibility Act, the SBA chief counsel for advocacy said that she would send OMB a copy of any written notifications of noncompliance with the act that she sends to the agencies during the rulemaking process.[24] She and the Deputy Administrator of OIRA said they would work together to develop criteria and procedures for determining agency compliance with the act. The Deputy Administrator also said that if the chief counsel notified OMB about an agency's compliance with the Regulatory Flexibility Act, OMB would discuss the issue with the agency before concluding its review of any final regulations.

[23]In August 2002, the President signed Executive Order 13272, which also urged agencies to give proper consideration to small entities in their rulemaking.

[24]U.S. General Accounting Office, *Regulatory Flexibility Act: Status of Agencies' Compliance*, GAO/GGD-94-105 (Washington, D.C.: Apr. 27, 1994).

Proposed New Guidelines on Economic Analysis

One of the more controversial elements of OIRA's regulatory review function involves its examination of agencies' regulatory impact analyses that are required in support of the 70 to 110 rules that the office has reviewed in recent years that are "economically significant" (e.g., have a $100 million impact on the economy). As of May 2003, OIRA's approach to these reviews had not officially changed. However, OIRA had initiated a process that may ultimately result in alterations to its current procedures.

In January 1996, OIRA published a document entitled "Economic Analysis of Federal Regulations Under Executive Order 12866." Developed by a group established by the OIRA Administrator and cochaired by a member of the Council of Economic Advisers (CEA), the document described "best practices" for preparing the economic analysis of significant regulatory actions called for by the executive order.[25] In general, the guidance states that the agencies' analyses should contain three elements: (1) a statement of the need for the proposed action, (2) an examination of alternative approaches, and (3) an analysis of benefits and costs. Within each of these areas, the guidance provides additional information. For example, in the discussion of benefits and costs, the guidance addresses such issues as discounting (when benefits and costs occur at different times), the treatment of risk and uncertainty, and general methods for valuing health and safety benefits (e.g., the monetary valuation of reductions in the risk of illness, injury, and premature death). Each of these issues can have a major effect on agencies' estimates of benefits and costs. For example, in a February 2003 speech the OIRA Administrator noted that the present value of 1,000 lives saved 50 years from now is 608 when evaluated at 1 percent discount rate, 228 when evaluated at 3 percent, and 34 when evaluated at 7 percent.[26]

In its December 2002 final report on the costs and benefits of federal regulations, OIRA noted that it had initiated "a process of refinement" to the guidance. In its February 2003 draft report, OIRA said the review was again cochaired by the Administrator and a member of the CEA, and published proposed revised guidelines for comment. OIRA said the key changes in the proposed guidelines included the following:

[25]The 1996 best practices document was modified and issued as guidance in 2000.

[26]"Valuing Health: An OMB Perspective," speech given before the Conference on Valuing Health Outcomes: An Assessment of Approaches (Feb. 13, 2003).

- The proposal encourages agencies to perform both cost-effectiveness and benefit-cost analyses in support of major rules, where feasible, because the two techniques offer regulators somewhat different but useful perspectives. In the previously mentioned February 2003 speech, the Administrator described cost-effectiveness analysis as a "bang for the buck" exercise in which the payoff is measured in health units rather than dollars. However, since cost-effectiveness analysis only provides relative comparisons, he said benefit-cost analysis is still needed to determine whether the benefits of any particular alternative justify the costs. Also, the Administrator said that OMB believes that multiple effectiveness measures based on different value assumptions and research designs should be encouraged (which he said can lead to inconsistency). To promote more consistency, he said OMB would sponsor interagency discussions about the most promising and practical effectiveness measures. Also, he said OMB would request that agencies provide it with their original data on mortality and morbidity to allow OMB to compare across agencies using similar assumptions and methods (as an aid to performance-based budgeting).

- When the benefits and costs of rules are expected to occur in different periods, the proposal recommends that agencies report the results of their analyses using multiple discount rates. Historically, OMB has recommended a uniform 7 percent rate of discount for these rules. Now, the proposal recommends that the results be computed at both 3 percent and 7 percent for rules with impacts primarily within this generation. However, for rules with intergenerational impacts, the proposal permits additional sensitivity analysis with rates as low as 1 percent.

- For rules that are expected to have a more than $1 billion impact on the economy, the proposal calls for agencies to employ formal probability analysis of benefits and costs (rather than a single number) unless the benefits and costs are known with a high degree of certainty. The Administrator said that information on probabilities is crucial when agencies must decide whether to act now, based on imperfect science, or whether to collect additional information prior to rulemaking—particularly in relation to "low-probability, high-consequence events such as the events of September 11th."

The February 2003 draft guidelines also noted that two widely used techniques were being used to assign a monetary value to projected reductions in premature mortality—(1) the value of a statistical life (VSL)

and (2) the value of a statistical life year (VSLY). The guidelines pointed out a number of technical issues associated with the appropriate use of these measures, and said "in all instances…agencies should consider providing estimates of both VSL and VSLY, while recognizing the developing states of knowledge in this area." Subsequently, AARP and other organizations expressed concern that use of the VSLY approach could lead to an undervaluing of the lives of older adults. On May 30, 2003, the OIRA Administrator sent a memorandum to the President's Management Council that again recommended that agency benefit-cost analysts present both VSL and VSLY methods. However, the Administrator cautioned that a "simple VSLY method" (i.e., assuming that saving 10 life years is 10 times more valuable than saving 1 life year) "could underestimate benefits significantly when applied to rules that primarily or significantly benefit senior citizens." He went on to say that, "when benefit estimates based on the VSLY method are presented, as OMB has encouraged since 1996, I recommend that agencies present analyses with larger VSLY estimates for senior citizens."[27]

In February 2003, OIRA released the draft guidelines for public comment. After the comment period, OIRA said that it planned to conduct an interagency review of the draft guidelines. Until this process is complete, OIRA said that it would continue to use the 1996 best practices guidance document. However, as noted earlier in this chapter, some agency officials told us that OIRA already expects agencies' cost-benefit analyses to be more thorough than they were required to be several years ago.

New Guidelines on Risk Assessment

Some (but by no means all) of OIRA's regulatory reviews evaluate whether an agency's assessment of the exposure to a risk or environmental hazard was properly conducted. Risk assessment is a complex but valuable set of tools for federal regulatory agencies, helping them to identify issues of potential concern, select regulatory options, and estimate the range of a forthcoming regulation's benefits. As we noted in our August 2001 report, the statutory and legal context in which risk assessments are conducted determine the general focus and goals of an agency's risk assessment activities, and also may shape how those assessments are supposed to be

[27]The Administrator noted that EPA's most recent VSLY estimates were $434,000 per life-year saved for persons over age 65 and $172,000 per life year saved for those under age 65.

conducted.[28] Therefore, different agencies (and different offices within those agencies) may have distinctive concerns regarding chemical risks. OIRA's January 1996 "best practices" guidance contains a section on risk assessment, stating in general terms the qualities of a good assessment. For example, it says that assessments "should present results representing a range of plausible scenarios, together with any information that can help in providing a qualitative judgment of which scenarios are more scientifically plausible." It also says that risk assessments "must provide some estimates of the probability distribution of risks with and without the regulation" and, where possible, "some estimates of central tendency (e.g., mean and median) must be provided in addition to ranges, variances, specified low-end and high-end percentile estimates, and other characteristics of the distribution."

In 1996, Congress adopted a basic standard of quality for the use of science in health decisions under the Safe Drinking Water Act (SDWA). Specifically, Congress provided that if an agency's decision under the statute was based on science, it should use "(i) the best available, peer-reviewed science and supporting studies conducted in accordance with sound and objective scientific practices, and (ii) data collected by accepted methods or best available methods (if the reliability of the method and the nature of the decision justifies the use of data)." Congress also adopted a standard for the dissemination of public information involving risks under SDWA, providing that agencies should "ensure that the presentation of information on (risk) effects is comprehensive, informative, and understandable." In addition, Congress required that agencies should, to the extent practicable, specify and make available to the public in a supporting document information on (1) each population addressed by any estimate of applicable risk effects, (2) the expected risk or central estimate of risk for the affected populations, (3) each appropriate upper-bound or lower-bound estimate of risk, (4) each significant uncertainty identified in the process of the risk assessment (and any studies that would help resolve the uncertainty), and (5) relevant peer-reviewed studies regarding the estimated risk effects.

In his September 2001 memorandum on presidential review of agency rulemaking, the OIRA Administrator proposed expanding the applicability of these requirements to statutes other than SDWA. Specifically, he

[28]U.S. General Accounting Office, *Chemical Risk Assessment: Selected Federal Agencies' Procedures, Assumptions, and Policies*, GAO-01-810 (Washington, D.C.: Aug. 6, 2001).

recommended that each agency consider adopting or adapting these standards for judging the quality of scientific information that it uses about risk. These recommendations were subsequently contained in information quality guidelines intended to ensure and maximize the quality, objectivity, utility, and integrity of a wide range of information disseminated by federal agencies.[29] The Administrator said that under these guidelines "the public will be provided an opportunity to challenge any health risk information disseminated by a federal agency that does not adhere to the OMB and agency guidelines. Agencies will be expected to provide a prompt and objective response to these challenges." An OIRA representative said the office considered the SDWA risk assessment standards "reasonable" and a "model" approach the could be used in regulations under other statutes (unless, of course, those other statutes prohibited that approach).

Deference to Peer Reviewed Regulatory Analyses

In his September 2001 memorandum on "Presidential Review of Agency Rulemaking by OIRA," the OIRA Administrator said OMB recommended that agencies subject regulatory impact analyses and other supporting documents to independent, external peer review. He also delineated certain peer review practices that OMB recommended, including (1) selection of reviewers primarily on the basis of necessary technical expertise, (2) disclosure of reviewers' prior positions on the issues at hand as well as sources of personal and institutional funding, and (3) implementation of the review in an open and rigorous manner. In the previously mentioned information quality guidelines, OMB noted that if peer review is used to help satisfy the "objectivity" standard, the review process should meet these criteria. The OIRA Administrator has described EPA's 2001 decision on arsenic as an example of a quality, peer-reviewed study.

Although OIRA did not require greater use of peer review by rulemaking agencies in this September 2001 memorandum, the Administrator said that OIRA would "be giving a measure of deference" to agencies' analyses that were developed in conjunction with certain peer review principles.[30] In one of his speeches he said that this deference to peer reviewed studies was

[29]For a copy of these guidelines, see 67 *Fed. Reg.* 8452 (Feb. 22, 2002).

[30]Shortly before the publication of this report, on August 29, 2003, OIRA proposed a standard analytical process by which all "significant regulatory information" that federal agencies intend to disseminate would be peer reviewed.

intended to serve as an incentive to improved regulatory analysis—the "carrot" portion of the "carrot and stick" approach mentioned previously.

However, two former OIRA Administrator indicated that similar deference was given during the previous administration to peer reviewed regulatory analyses, and that the current administration's initiative in this area reflected a change in the degree to which deference is given rather than a substantial change of direction. On the other hand, they also said the current policy is more explicit than the previous administration's approach.

OIRA's Effects on Rules Submitted for Executive Order Review Varied

OIRA had a significant effect on 25 of the 85 draft proposed and final rules from nine selected agencies that it reviewed between July 1, 2001, and June 30, 2002; 17 of the rules were significantly changed by OIRA, 7 were returned to the agencies for reconsideration, and 1 was withdrawn by the agency at OIRA's request.[1] Almost all of the rules that were significantly changed at OIRA's suggestion were from EPA. Almost all of the returned rules were from DOT, as was the rule withdrawn at OIRA's request. Many of OIRA's actions in these cases were prompted by concerns about the quality of the agencies' regulatory analyses and/or whether the agencies had selected the most cost-effective regulatory option. For 22 of the 25 rules, OIRA's actions appeared to have at least some effect on the costs and benefits associated with the rule or to have prompted revisions in the agency's estimates of those costs and benefits. There was evidence that outside parties had contacted OIRA before or during OIRA's formal review period regarding about half of the significantly changed rules, two of the returned rules, and the rule withdrawn at OIRA's request. Although OIRA's positions regarding these rules were sometimes similar to those expressed by outside parties, it is impossible to determine the extent to which those contacts might have influenced OIRA's actions, if at all. ORIA might have reached the same conclusions in the absence of those contacts. Some of the agencies did not clearly identify all of the changes made to their rules during OIRA's review or at OIRA's suggestion—as required by Executive Order 12866. However, other agencies clearly identified those changes.

OIRA Significantly Affected About One-Third of the Rules That the Selected Agencies Submitted for Review

Our second objective was to provide detailed information on rules that were significantly changed by OIRA, withdrawn at OIRA's initiative, or returned to the agencies for reconsideration. According to the OIRA database, from July 1, 2001, through June 30, 2002, OIRA completed 642 reviews of agencies' draft regulatory actions submitted under Executive Order 12866. The dispositions of these reviews were as follows:

- About 33 percent (214) were coded in the database as "consistent with no change," indicating that OIRA considered the rules consistent with the executive order as submitted.

[1]Our unit of analysis was technically the submission of a rule to OIRA for Executive Order 12866 review, rather than the rule itself, because some of the rules were reviewed by OIRA more than once. However, for simplicity we refer to these executive order submissions as rules in this report.

- About 50 percent (322) were coded as "consistent with change," indicating that the rules had changed after being submitted to OIRA, and that OIRA subsequently concluded that the rule was consistent with the executive order's requirements.

- About 8 percent (50) were coded as "withdrawn" by the agency.

- About 3 percent (21) were coded as "returned" to the agency by OIRA.

- About 5 percent (35) had some other disposition (e.g., "sent improperly," "emergency," or "statutory or judicial deadline").

Because the number of changed, returned, or withdrawn rules governmentwide during this time frame was so large (393), we focused this part of our review on 85 proposed and final rules with those dispositions that were submitted to OIRA by nine selected agencies or offices: [2]

- The Animal and Plant Health Inspection Service within the Department of Agriculture.

- The Food and Drug Administration within the Department of Health and Human Services.

- The Occupational Safety and Health Administration within the Department of Labor.

- The Federal Aviation Administration, the Federal Motor Carrier Safety Administration, and the National Highway Traffic Safety Administration within the Department of Transportation.

- The Offices of Air and Radiation, Solid Waste and Emergency Response, and Water within EPA.

We selected these agencies and offices because the OIRA database indicated they had the most rules that were changed, withdrawn, or returned during the relevant 1-year period.

[2]See appendix I for a more detailed description of our objectives, scope, and methodology, and appendix II for information about each of the 85 submissions.

Table 1 shows the number of rules with each type of OIRA disposition within each of the selected agencies or offices. We generally did not question the rule dispositions used in the OIRA database. However, we included one rule from EPA's Office of Air and Radiation in the "consistent with change" category that had been coded as a "deadline case" in the database because publicly available information indicated that the rule had been changed in response to OIRA's review (ID 41).[3] It is unclear whether other rules with "deadline case" outcome codes in the database were also changed by OIRA, or why other rules that we reviewed with legal deadlines were not coded as deadline cases.[4] Also, we dropped one rule from EPA's Office of Solid Waste and Emergency Response that was coded "consistent with change" because it had not been published in the *Federal Register* at the time of our review.

Table 1: Selected Agencies' Regulatory Submissions by Outcome

Agency	Number of rules reviewed between July 1, 2001, and June 30, 2002, that were coded in the OIRA database as			Total
	Consistent with change	Returned to agency	Withdrawn by the agency	
APHIS	12	0	1	13
FDA	7	0	2	9
OSHA	5	0	0	5
DOT-FAA	5	6	1	12
DOT-FMCSA	6	0	0	6
DOT-NHTSA	5	1	1	7
EPA Office of Air and Radiation	14	1	0	15
EPA Office of Solid Waste and Emergency Response	9	0	0	9
EPA Office of Water	8	1	0	9
Total	71	9	5	85

Source:OIRA's database.

[3]See, for example, Arthur Allen, "Where the Snowmobiles Roam," *Washington Post Magazine* (Aug. 18, 2002).

[4]OIRA's database has a separate field, separate from the field on reviews' outcomes, that identifies submissions with legal deadlines. Twenty-two of the 85 rules that we reviewed were coded in OIRA's database as having a statutory or judicial deadline.

Note: Data in each category reflect the number of proposed, final, and interim final rules that OIRA reviewed between July 1, 2001, and June 30, 2002, but do not include other types of regulatory actions submitted to OIRA during this period (e.g., notices, prerules, or emergency rules). As discussed later in this report, the nine returned rules included two improper submissions—one from FAA and one from the EPA Office of Air and Radiation.

Although the OIRA database was useful in focusing our review on certain agencies and rules, the categories used in that database are broader than the specific types of rules targeted in this section of our report—those that were *significantly* affected by *OIRA*.

- The "consistent with change" category includes *all* rules that were changed between their formal submission to OIRA for review and their issuance by the agency, regardless of the source or the significance of the changes made—not just those that were *significantly* changed at OIRA's request. For example, even if the only change made to a rule during OIRA's review was the correction of a legal citation made by the submitting agency, the rule would be coded in the database as "consistent with change."

- The "returned" category includes *all* returns, not just those that were substantively "returned for reconsideration." Therefore, if OIRA returned a rule solely because it was not subject to OIRA review (e.g., was improperly submitted), it would be coded in the database as a "returned" rule.

- The "withdrawn" category includes *all* rules withdrawn by the agencies during OIRA's review, not just those that were withdrawn at the initiation of OIRA. Therefore, if an agency erroneously submitted a rule to OIRA and withdrew it solely at the agency's initiative, the rule would be coded in the OIRA database as "withdrawn."

Because of the breadth of these categories, we had to gather additional information on each of the 85 changed, returned or withdrawn rules to determine which ones had been significantly affected by OIRA and, therefore, met our more specific criteria.

Ultimately, we determined that 25 of the 85 rules from these agencies were significantly affected by OIRA's review. Specifically, we concluded that 17 of the 71 rules that were coded as "changed" in the database were significantly affected by OIRA. Seven of the nine rules coded as "returned" were returned by OIRA for substantive reasons. One of the five "withdrawn" rules was returned at the initiation of OIRA.

OIRA Did Not Significantly Affect Many of the "Changed" Rules

We used a variety of information sources (e.g., agency and OIRA docket materials and interviews with agency officials) to place each of the 71 rules coded as "consistent with change" into one of three categories:

1. *Significant changes*—i.e., rules in which the most significant changes attributed to OIRA's or OMB's suggestions affected the scope, impact, or estimated costs and benefits of the rules as originally submitted to OIRA.[5] Usually, these significant changes were made to the regulatory language that would ultimately appear in the *Code of Federal Regulations*.

2. *Other material changes*—i.e., rules in which the most significant changes attributed to OIRA's or OMB's suggestions resulted in the addition or deletion of material in the explanatory preamble section of the rule. For example, OIRA may have recommended that agencies provide better explanations for certain rulemaking actions and/or suggested that agencies ask the public to comment on particular aspects of the rules.

3. *Minor or no OIRA/OMB changes*—i.e., rules in which the most significant changes attributed to OIRA's or OMB's suggestions resulted in editorial or other minor revisions, or rules in which changes occurred prior to publication but not at the suggestion of OIRA or OMB. Where no changes were made at OIRA's or OMB's suggestion, the changes that caused the rule to be coded "consistent with change" could have been initiated by the regulatory agency itself or by another federal agency (e.g., the Office of the Federal Register).[6]

We placed each of the rules that we examined into the appropriate category based on the most significant changes attributed to either OIRA or OMB—even if the regulatory agencies initiated more significant changes to their rules during the period of OIRA's review than did OIRA.[7]

[5]The agencies sometimes attributed suggested changes to OMB and sometimes specifically to OIRA. In a few instances, OMB staff outside of OIRA suggested the changes.

[6]Because the executive order does not require agencies to document nonsubstantive changes, three of the rules we included in this category were ones in which it was clear all the changes were minor, but the source of the changes (i.e., whether they were made at the suggestion of OMB/OIRA) could not be identified.

Table 2 presents the results of our analysis by agency. We concluded that 17 of the 71 rules coded as "consistent with change" in the OIRA database (about 24 percent) were significantly changed as a result of OIRA's suggestion or recommendation, 34 of the rules had other material changes attributable to requests by OIRA, and 20 rules had only minor changes or no changes at OIRA's suggestion or recommendation. Fourteen of the 17 significantly changed rules were from EPA—all but one of which were from the agency's Offices of Air and Radiation or Water. Three other rules had significant changes attributed to suggestions from OIRA or OMB—two APHIS rules regarding indemnity payments for the destruction of diseased animals and one NHTSA rule on tire pressure monitoring systems. (See app. II for the coding and detailed descriptions of the changes made to each of the 71 rules.)

[7]For example, after submitting its rule on emission standards for surface coating of metal furniture to OIRA, EPA reanalyzed data from the covered industry and revised the emission limits to be less stringent than those originally proposed—what we would have considered a "significant" change if suggested by OIRA (ID 47). However, because the most significant OIRA-suggested change was the addition of text to the preamble clarifying the agency's analysis and requesting comments on a particular provision, we coded this rule as having had "other material changes."

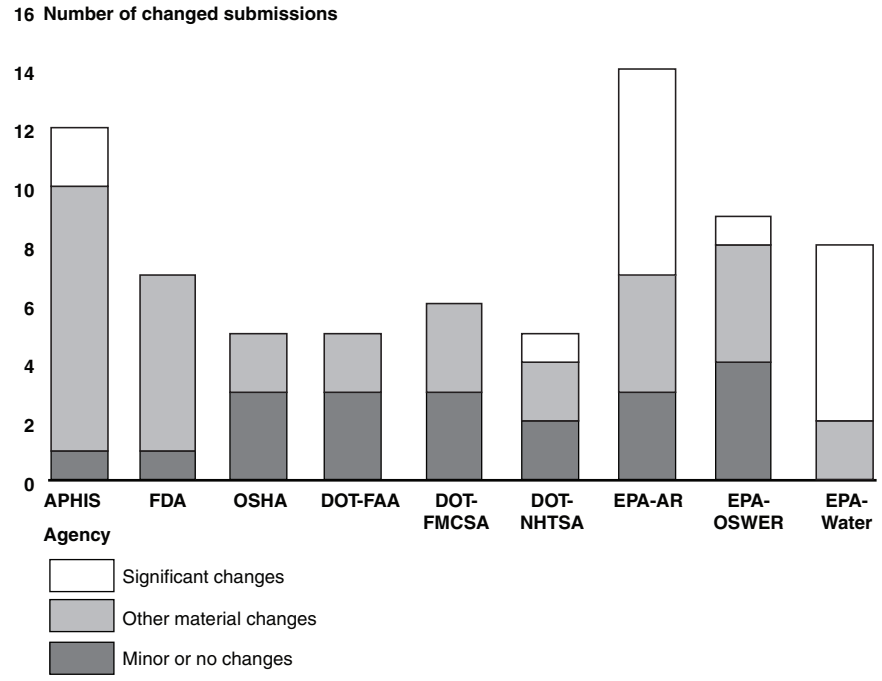
Table 2: Nature of Changes Made at the Suggestion or Recommendation of OIRA

Agency	Number of rules by most significant level of change suggested by OIRA			Total rules changed after submission to OIRA
	Significant changes	Other material changes	Minor or no changes	
APHIS	2	9	1	12
FDA	0	6	1	7
OSHA	0	2	3	5
DOT-FAA	0	2	3	5
DOT-FMCSA	0	3	3	6
DOT-NHTSA	1	2	2	5
EPA Office of Air and Radiation	7	4	3	14
EPA Office of Solid Waste and Emergency Response	1	4	4	9
EPA Office of Water	6	2	0	8
Total	17	34	20	71

Source: GAO analysis.

As figure 9 illustrates, rules from EPA's Office of Air and Radiation and Office of Water were more often significantly changed at the suggestion of OIRA than rules from the other agencies and offices that we examined.

Figure 9: EPA Air and Water Rules Were More Often Significantly Changed at the Suggestion of OIRA



Source: GAO.

Types of Significant Changes Made at OIRA's Suggestion/Recommendation

In 6 of the 14 EPA rules that were significantly changed, the primary effect of OIRA's suggestions or recommendations was to delay or eliminate certain regulatory provisions that were included in the draft rules as submitted to OIRA. For example:

- In response to OIRA concerns about the information collection request associated with an EPA Office of Air and Radiation final rule on consolidated emissions reporting, EPA delayed the compliance date for states to report on two types of emissions (ID 50).

- OIRA's suggestions also prompted the deletion of provisions covering marine and highway motorcycle engines from an EPA Office of Air and

Radiation proposed rule on emissions from nonroad large spark-ignition engines and recreational engines (ID 41).[8]

- EPA eliminated manganese from a list of hazardous constituents in an Office of Solid Waste and Emergency Response final rule on the identification and list of hazardous wastes in response to comments from OIRA (ID 56).

In four other significantly changed EPA rules, OIRA suggestions encouraged the agency to change, add, or select regulatory alternatives that generally provided more flexible and/or less costly compliance options to regulated entities. For example:

- OIRA suggestions led to changes in an EPA Office of Water proposed rule on pollutant discharge elimination systems for large cooling water intake structures at existing power generating facilities that (1) lowered the performance standard in the rule, (2) made compliance requirements more flexible by allowing options for a site-specific approach to minimizing environmental harm, and (3) broadened a restoration option whereby firms may repair environmental harm rather than comply with the designated performance standard (ID 68). OIRA believed that these options were not only less burdensome, but also would yield greater net benefits.

- In a related EPA Office of Water final rule on minimizing environmental impact from cooling water intake structures at new facilities, OIRA-suggested changes included (1) the addition of criteria that would allow more facilities to qualify for lower performance standards, (2) a changed requirement so that facilities only needed to use screens to minimize impingement mortality of fish and shellfish if certain criteria were met, and (3) the addition of an exception to intake flow requirements regarding cooling water intake structures located in a lake or reservoir (ID 65).

In three other EPA rules and the NHTSA tire pressure monitoring systems rule, OIRA suggested significant changes to the agencies' regulatory impact analysis. For example:

[8]The marine and motorcycle engines provisions later resurfaced as a separate rule (ID 54).

- OIRA suggestions prompted EPA to make changes regarding the discount rates and fuel prices that the agency used to estimate the potential costs of a proposed rule on nonconformance penalties and emission standards for heavy-duty diesel engines and vehicles (ID 53).

- Similarly, OIRA comments led EPA to revise the cost-benefit and cost-effectiveness estimates in a proposed rule on emissions from spark ignition marine vessels and highway motorcycles (ID 54).

In both of the APHIS rules with significant changes attributed to requests from OMB, the changes reduced the potential total cost to the federal government of paying indemnities to owners of animals destroyed or for other measures taken to avoid the spread of certain communicable diseases among animals (IDs 9 and 12).

Rules With "Other Material Changes" Attributable to OIRA

We concluded that in 34 (about 48 percent) of the 71 "consistent with change" rules, regulatory agencies made "other material changes" in response to OIRA's suggestions or recommendations. Typically, these changes augmented an agency's explanation of certain provisions in the rule, clarified the agency's basis for decisions made about regulatory options or assumptions, better explained the potential impact of different options, or requested public comments and data on regulatory options or costs. For example, in response to OIRA's suggestions or recommendations:

- APHIS revised the preamble to a rule that updated plant pest regulations to (1) clarify that the proposed regulations would not cover genetically modified organisms, (2) acknowledge there is a continuum of risk related to regulated organisms, (3) solicit comments about the adequacy of criteria APHIS used to identify organisms for inclusion, and (4) solicit comments on the data elements that would have to be addressed in a proposed notification system (ID 6).

- FDA added or revised information to the preamble of a final rule on notification and recordkeeping requirements for exports to clarify its responses to public comments on the proposed rule (ID 13).

- OSHA revised the preamble to a rule on procedures for handling discrimination complaints (1) to add information and request public comment regarding the whistle-blower model that OSHA chose and (2) to clarify that certain procedures would be triggered at the "request of the named person" (the person alleged to have violated the act) (ID 21).

- EPA's Office of Air and Radiation revised the preamble of its proposed rule on national emission standards for hazardous air pollutants from surface coating of metal furniture to request public comments on (1) its conclusion that the creation of subcategories in the rule was not warranted and (2) whether there were alternative means of monitoring performance for add-on controls at source facilities that would be as effective and less expensive than the proposed requirements (ID 47).

Rules in Which OIRA Suggested Minor Changes or No Changes

OIRA suggested only editorial or other minor changes, or no changes at all, in 20 (about 28 percent) of the 71 rules coded in the OIRA database as "consistent with change." These minor changes included rearranging existing text for clarity, correcting spelling errors, making word choice changes, and adding or correcting procedural language, such as where to submit public comments on the rules being published. For example:

- The only two changes that OIRA suggested in a FMCSA rule on certification of safety auditors, investigators, and inspectors were to delete a redundant sentence and to correct the number cited for a relevant executive order (ID 33).

- In an EPA proposed rule on a national ambient air quality standard for ozone, OIRA suggested rewording three similar statements in the preamble regarding EPA's views about "using plausible but highly uncertain assumptions" (ID 42).

- The only change made at OIRA's suggestion in an EPA hazardous waste management rule concerning cathode ray tubes and mercury-containing equipment was to revise a request for comments on extending the "speculative accumulation time of used, broken CRTs" to "two or more years" instead of just "two years" (ID 62).

As noted previously, although we concluded that OIRA suggested only minor changes or no changes to these rules, some of them appeared to have been significantly changed during the period of OIRA's review at the initiative of the agencies.

Most of the Rules That OIRA Returned Were for Reconsideration

Two of the nine rules from the selected agencies that were coded as "returned" in the OIRA database were returned because they were improperly submitted for review. The other seven rules were returned to the issuing agencies for reconsideration—five rules from FAA, one from NHTSA, and one from EPA.

In each of these seven cases, OIRA sent the rulemaking agency a "return letter" describing its rationale for returning the rule. The letters indicated that the returns for reconsideration were most often triggered by OIRA concerns about the quality of agencies' regulatory analyses or the cost-effectiveness of the proposed regulatory options. For example:

- OIRA said it returned a proposed FAA rule on certification of pilots, aircraft, and repairmen for the operation of light sport aircraft because it believed that the regulatory analysis did not sufficiently justify the rule (ID 73).

- OIRA returned another FAA draft final rule after raising questions and concerns about the relative cost-effectiveness of requiring additional flight data recorder parameters (ID 77).

- OIRA returned a NHTSA final rule on tire pressure monitoring systems because, in OIRA's opinion, NHTSA's analysis did not adequately demonstrate that the agency had selected the best available alternative (ID 78).

- OIRA returned an EPA rule on water quality standards for Indian country because, among other issues, EPA did not provide a quantitative analysis of the costs and benefits that could result from this regulatory action (ID 80).

In other cases, OIRA cited coordination issues as its rationale for the returns. For example, in one rule OIRA suggested to FAA that a concurrent review of the aging aircraft and corrosion control plan rules could assist in determining the most cost-effective way to detect and correct problems affecting aging aircraft safety (IDs 76 and 74). In another FAA rule on Part 145 repair stations, OIRA cited concerns from the Department of State regarding the effect of the rule on international treaties (ID 72). (However, FAA officials told us during our review that FAA and the Department of State had resolved these concerns prior to the rule's submission to OIRA, so the rule might have been returned because of a misunderstanding.)[9] Another factor that seems to have influenced at least some of the returns was the 90-day limit for OIRA's reviews. In return letters for three rules, OIRA specifically mentioned the need for additional time to resolve some

[9]FAA resubmitted the rule, with no revisions, on the same day that it was returned. Ten days later, OIRA completed its review of the resubmitted version "consistent with no change."

of its issues and comments as part of the explanation for returning draft rules for reconsideration.

As of May 2003, five of the seven rules that OIRA returned for reconsideration by the rulemaking agencies had been resubmitted by the agencies, completed another review by OIRA, and were published in the *Federal Register*. Publication of one other rule—FAA's proposed revision of digital flight data recorder regulations—was still pending, according to FAA officials, but EPA had not resubmitted its proposed rule on federal water quality standards for Indian country to OIRA.

Agencies, Not OIRA, Initiated Most Withdrawals

Neither OIRA nor the regulatory agencies are required to document why rules are withdrawn from OIRA's review. Therefore, we relied primarily on testimonial evidence from agency officials to determine whether the five rules within the scope of our review had been withdrawn at the suggestion of OIRA or OMB. We determined that only one of the five rules appeared to have been withdrawn at OIRA's initiative—FAA's Part 145 Review rule on repair stations (ID 84). FAA's docket included a chronology of developments regarding this rule with an entry stating that OIRA instructed the agency to withdraw the rule. FAA officials explained that OIRA suggested this withdrawal due to "concerns from industry and the State Department."[10] (As noted previously, OIRA representatives told us they do not request that agencies withdraw rules, and emphasized that it is the agencies—not OIRA—that ultimately make withdrawal decisions. However, they also said that agencies sometimes withdraw rules as a negotiating strategy.)

Agency officials characterized two of the withdrawals as "mutual decisions" made by their agencies and OIRA. In one of these cases, an APHIS rule on importation of clementines from Spain, an agency official said that the rule was withdrawn pending the close of a comment period on a related document published by the agency, because keeping the rule at OIRA until then would have taken OIRA's review period beyond 90 days (ID 81). (It was resubmitted about a month later and subsequently coded "consistent with change.") In the other case, an FDA rule on records and reports concerning new animal drugs, the agency officials characterized the mutual decision as a compromise to address the fact that the old

[10]This was the same rule that was subsequently resubmitted, returned to FAA by OIRA, resubmitted yet again, and ultimately completed OIRA review with no changes.

proposed rule was "stale" (ID 82). (The rule was later published as an "interim final" rule to permit additional public comment without having to restart the rulemaking at the proposed rule stage.) The remaining two rules—an FDA proposed rule concerning dietary ingredients and supplements and a NHTSA rule on light truck fuel economy standards—were withdrawn solely at the initiative of the agency or its executive department (IDs 83 and 85). All five of the withdrawn rules that we examined were subsequently resubmitted to OIRA by the agencies and were later characterized by the office as consistent with the executive order.

Rules from FAA and EPA's Office of Air and Radiation and Office of Water Were More Often Significantly Affected by OIRA

As table 3 shows, when the results for all the changed, returned, or withdrawn rules are combined, it is clear that the rules submitted by FAA and EPA's Office of Air and Radiation and Office of Water were most often significantly affected by OIRA's review. During the period covered by our review, about 56 percent of the rules from these agencies (20 of 36) were significantly affected. In contrast, only about 10 percent of the rules from the remaining six agencies (5 of 49) were significantly affected by OIRA's review.

Table 3: Rules from FAA and EPA's Office of Air and Radiation and Office of Water Were Most Often Significantly Affected by OIRA Review

	Rules submitted to OIRA for executive order review		
		Significantly affected by OIRA	
Agency	Total	Number	Percent
APHIS	13	2	15
FDA	9	0	0
OSHA	5	0	0
DOT-FAA	12	6	50
DOT-FMCSA	6	0	0
DOT-NHTSA	7	2	29
EPA-Office of Air and Radiation	15	7	47
EPA-Office of Solid Waste and Emergency Response	9	1	11
EPA-Office of Water	9	7	78
Total	85	25	29

Source: GAO analysis.

OIRA representatives suggested that the differences in the extent to which OIRA significantly affected agencies' rules might actually be a function of differences in the importance or impact of the rules submitted—not whether they are from one agency or another. The representatives said that OIRA typically spends more time and effort reviewing economically significant rules that are likely to have the biggest impact on society. Therefore, they indicated that agencies like EPA that produce a number of economically significant rules were more likely to have their rules significantly affected by OIRA's review than agencies like FDA that did not submit as many economically significant rules.

As table 4 shows, 14 of the 85 rules that we examined were economically significant. We concluded that 5 of those 14 rules (36 percent) had been significantly affected by OIRA's review. In comparison, we concluded that 20 of the 71 rules that were not economically significant (28 percent) had been significantly affected by OIRA's review. Therefore, although OIRA was slightly more likely to have had a major effect on economically significant rules than other rules, the difference was not statistically significant.[11]

Table 4: OIRA Was Only Slightly More Likely to Significantly Affect Economically Significant Rules

Type of rule	Rules submitted to OIRA for executive order review		
		Significantly affected by OIRA	
	Total	Number	Percent
Economically significant	14	5	36
Not economically significant	71	20	28
Total	85	25	29

Source: GAO analysis.

[11]We performed a statistical analysis using Fisher's exact test to determine if there was a statistically significant association between whether the rules reviewed by OIRA were economically significant and whether the rules were significantly affected by OIRA. The test results ($p = 0.43$) did not support a hypothesis that a statistically significant association exists.

Notably, all six of the FAA rules that OIRA significantly affected were not economically significant. Of the 14 EPA Office of Air and Radiation and Office of Water rules that OIRA significantly affected, only 3 were economically significant.

OIRA Affected the Costs and Benefits or Estimates in Some Rules

In 22 of the 25 rules that we concluded had been significantly affected by OIRA's suggestions or recommendations, OIRA appeared to have influenced either (1) the expected costs and/or benefits of the rules and/or (2) the agencies' estimates of those costs and/or benefits. The focus of OIRA's changes in most of these cases appeared to be on reducing the costs and regulatory burdens, improving the cost-effectiveness of the rules, and/or yielding greater net benefits. This focus is consistent with the emphasis in Executive Order 12866 and the related "best practices" document and guidance on improving regulatory net benefits and cost-effectiveness and minimizing the cost burden of regulation.

OIRA-Suggested Changes That Appeared to Have Affected Costs and Benefits

In at least 12 rules, OIRA or OMB suggested changes to the regulatory text that could reasonably be expected to affect the potential costs and/or benefits of the regulations. Sometimes there was direct evidence in the docket materials of those effects. For example:

- In an EPA Office of Water proposed rule on pollutant discharge elimination systems for large cooling water intake structures at existing power generating facilities, OIRA recommended that the agency select a regulatory alternative that it believed would yield substantially greater net benefits (ID 68). The approach that EPA originally proposed would have cost an estimated $610 million per year, with estimated benefits of $890 million per year, yielding net benefits of $280 million. However, OIRA recommended that EPA select another approach that, while having estimated benefits of $735 million, was expected to cost only $280 million, yielding net benefits of $455 million.

- In another example, an APHIS rule regarding foot-and-mouth disease, OMB suggested changes in the indemnity payments that were, in turn, reflected in the agency's revised estimates of the rule's costs and benefits (ID 12).

However, in most of the cases in which OIRA suggested changes to regulatory text, the documentary evidence of how those changes affected

the rules' costs and/or benefits was more limited and less clear. In some cases the rules at issue were not "economically significant," so the regulatory agencies were not required to prepare formal quantitative assessments of the rules' expected costs or benefits. In another case, the agency prepared those assessments but did not include complete copies of the original and revised versions of the cost and benefit estimates in the regulatory dockets. Therefore, we were unable to compare the agencies' estimates to determine the effect of the OIRA-suggested changes in the regulatory text.

Nevertheless, even in the absence of such documentation, we believe that it is reasonable to assume in at least some cases that the OIRA-suggested elimination or delay of certain regulatory provisions in the text of draft rules as submitted to OIRA would also eliminate or delay the expected costs and/or benefits associated with those provisions. The following are examples of OIRA suggested changes in regulatory text that appeared to affect the rules' expected costs and/or benefits:

- APHIS revised the regulatory text in a proposed rule on payment of indemnity for animals affected by foot-and-mouth disease to eliminate compensation coverage for certain voluntary actions taken by owners of animals, thereby reducing potential costs to the federal government (ID 12). However, according to an APHIS official (and as explained in the preamble of the proposed rule), not providing compensation for the care and feeding of "official vaccinates" that could be used as a "fire wall" around infected animals to help prevent the spread of the disease, and eliminating compensation for cleaning and disinfecting non-susceptible animals that could spread the disease even if they cannot themselves become infected, could impede eradication efforts, thus reducing overall benefits to society.[12]

- EPA changed the regulatory text in a final rule regarding cooling water intake structures at new facilities to provide regulated entities the flexibility to use more alternatives or exceptions to compliance with the rule's requirements and standards (ID 65). These changes could reasonably be expected to reduce at least some of the regulated entities' costs of compliance with those requirements and standards, without any documented change in benefits.

[12]Official vaccinates are livestock vaccinated as part of a foot-and-mouth eradication program.

- EPA deferred final action on adding manganese to the list of hazardous waste constituents, thereby also deferring the potential costs and benefits of designating manganese as a hazardous waste constituent, with an unknown effect on net benefits (ID 56).

- EPA delayed compliance dates in two provisions of a proposed rule setting national emission standards for hazardous air pollutants from surface coating of wood building products, thereby producing corresponding delays in the costs and benefits expected for the rule (ID 51).

OIRA-Suggested Changes that Affected Agencies' Estimates of Costs and Benefits

In 14 rules (including some of the ones described above with regulatory text changes), OIRA specifically commented on and requested changes in the agencies' analyses of the economic impacts of the draft regulations. Six of the seven rules that OIRA returned to agencies for reconsideration fell into this category. Although OIRA sometimes suggested revisions in existing estimates and calculations, OIRA more often suggested changes that added or clarified information and analysis presented on a draft rule's economic impacts. For example:

- EPA responded to OIRA comments and suggestions by revising cost-benefit and cost-effectiveness estimates for a proposed rule regarding emissions from spark-ignition marine vessels and highway motorcycles (ID 54). As a result of the changes, the estimated annual costs to manufacturers were reduced by $4 million and the estimated annual fuel savings to the public were increased by $4.3 million.

- OIRA returned an FAA proposed rule on certification of pilots, aircraft, and repairmen for the operation of light sport aircraft with a request that the agency prepare additional revised analyses of the potential impacts (ID 73). OIRA's comments focused on the analytical baseline FAA had used and the regulatory alternatives presented. Among other things, OIRA suggested that, as part of an improved analysis of alternatives, FAA could consider means of improved compliance and enforcement of regulations currently in place.

- At OIRA's suggestion, NHTSA inserted additional estimates of some costs and benefits of regulatory alternatives (e.g., adding estimates of the total estimated costs of the proposed alternatives, where the original draft only provided estimates of average cost per vehicle), added additional information about the potential range of injuries and deaths

prevented and other benefits that might be realized with different regulatory alternatives, and identified unquantified benefits and costs that might be associated with its proposed rule on tire pressure monitoring systems (ID 36).

A Focus on Costs, Cost-Effectiveness, and Net Benefits

In general, the focus of OIRA's changes in most of these cases appeared to be on reducing costs and regulatory burdens, improving the cost-effectiveness of the rules, or maximizing the rules' net benefits. For example, OIRA returned six rules for reconsideration because of concerns that the agencies' analyses had not adequately captured all economic effects of the rules or presented regulatory options that OIRA did not believe were cost-effective. In the changed rules, reducing costs or improving cost-effectiveness was sometimes accomplished by suggesting additional, more flexible regulatory options, but it was not always clear whether reductions in costs would necessarily be accompanied by increases in net benefits to society. For example, in response to an OIRA suggestion, EPA eliminated a regulatory provision requiring a minimum net reduction if steel facilities used a voluntary pollutant trading mechanism called a "water bubble (ID 71)." EPA's original draft rule noted that the mechanism had been structured in a way to produce an additional benefit because the amount of the pollutant discharges pursuant to the bubble had to be 10-percent to 15-percent less than the discharges otherwise authorized by the rule without the bubble. However, eliminating this minimum net reduction requirement might encourage more regulated entities to use this voluntary mechanism to comply with the standards of the rule at lower cost. The potential change in net benefits to society is therefore not clear.

Although attention to the cost side of economic effects was most prevalent in OIRA's comments and suggestions, in at least four cases OIRA also suggested specific changes in agencies' estimated benefits of their rules. OIRA suggested several changes regarding the benefits estimates of NHTSA's proposed tire pressure monitoring system rule, in particular inserting additional information about benefit estimates, such as the range of injuries and deaths prevented, stopping distance effects, and average tire life increases (ID 36). OIRA also suggested adding a discussion on the effect of human factors on the benefits of tire pressure monitoring systems. When OIRA returned NHTSA's draft final rule on tire pressure monitoring systems, the office stated that the technical foundation for NHTSA's estimates of safety benefits needed to be better explained and subjected to sensitivity analysis (ID 78). OIRA also questioned some of EPA's estimates

of the environmental impacts associated with a proposed rule on emissions from nonroad large spark-ignition engines and recreational engines (ID 41). In an indemnity program to address chronic wasting disease (CWD) in cervids (antler-bearing animals, such as elk and deer), OIRA asked APHIS to avoid citing as a benefit the avoidance of disease in humans caused by CWD because this possibility was considered remote by a Harvard risk analysis (ID 9).

There were also cases in which OIRA did not directly affect the expected costs or benefits of a rule but nevertheless suggested changes to an agency's discussion of the rule's costs and benefits. In 19 such rules that were changed after submission, OIRA suggested clarification or revision of the information presented in the rule about estimated costs and benefits or how they were calculated, solicited comments on a regulatory agency's cost-benefit estimates, or requested comments on ways to make a regulation more cost-effective or less costly and burdensome. (At least 2 of the 22 rules that we identified as having costs and/or benefits directly affected by OIRA's actions also had such clarifications or requests for comments inserted at OIRA's suggestion.)

Again, many of OIRA's comments and suggested changes were focused on the costs of the proposed regulatory actions, although in these cases OIRA's suggestions most often helped to clarify the potential costs of regulatory alternatives or how an agency had estimated those costs. In at least seven rules, OIRA specifically suggested that agencies solicit public comments and data on the potential costs and burdens of proposed regulations or suggestions for alternative regulatory options that would be more cost-effective or less burdensome. By focusing attention and soliciting comments on cost and burden issues, particularly at the proposed rule stage, these revisions to preamble language might prompt changes in the costs and benefits of the rules in future iterations of the rules.

Appendix II includes more detailed information on the extent to which OIRA's regulatory reviews had an effect on the potential costs and benefits of individual rules within the scope of our report.

Outside Parties Contacted OIRA Regarding about Half of the Rules OIRA Significantly Affected

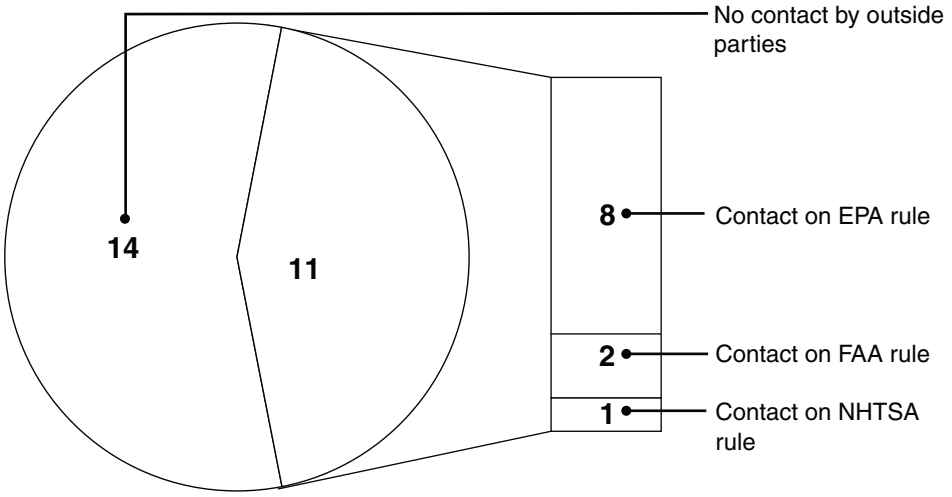
Another part of this objective was to determine whether there was any evidence that the actions that OIRA took (e.g., to suggest significant changes to rules or to return them to the agencies for reconsideration) were traceable to suggestions offered by regulated entities or other parties outside of the federal government. It is not possible to independently determine what motivated OIRA's actions with regard to any of the rules that it reviewed. However, we did identify a number of instances in which outside parties directly contacted OIRA regarding rules that OIRA later significantly affected. Those direct contacts took the form of either a meeting with OIRA representatives or a letter sent to OIRA before or during the period of OIRA's review.[13] We also identified similarities between the actions that OIRA suggested or recommended to the agencies and those advocated to OIRA by outside parties through those direct contacts.

Outside parties directly contacted OIRA regarding 11 of the 25 rules that OIRA significantly affected—8 of the rules that were significantly changed as a result of OIRA's suggestions or recommendations, 2 of the rules that OIRA returned to the agencies for reconsideration, and the 1 withdrawal that was made at OIRA's request. As figure 10 shows, 8 of these 11 rules were from EPA, FAA submitted 2 of the rules, and 1 was a NHTSA submission.[14] In all 11 cases, representatives of regulated entities were involved in those contacts with OIRA. In 3 of the 11 cases, environmental and other public interest groups also contacted OIRA about the rules.

[13]In some OIRA files, we found evidence that OIRA had reviewed copies of substantive comments on previous versions of the draft rule currently under review. Because these were public docket materials previously submitted to the regulatory agencies, not OIRA, we did not consider them as evidence of direct contact with OIRA by external parties. Also, there was evidence that external parties contacted OIRA after the formal review period regarding two other substantively changed submissions, but such postreview contacts could not have affected the outcome of OIRA's reviews in those cases.

[14]The two FAA submissions were actually the same Part 145 repair station regulation. One of the submissions resulted in a withdrawal and one resulted in a return (IDs 84 and 72, respectively).

Figure 10: Outside Parties Most Often Contacted OIRA Regarding EPA Rules



Source: GAO.

In 7 of the 11 cases where there was direct contact with OIRA by outside parties, at least some of the actions that OIRA recommended or took appeared to be similar to those suggested to OIRA by regulated parties. (OIRA did not recommend changes that were similar to *all* of the changes suggested by the regulated entities.) Environmental or other public interest groups had also directly contacted OIRA in 3 of these 7 cases, but OIRA's actions did not appear to be similar to the suggestions offered by those groups. Examples of the 7 cases include the following:

- As a result of its review of an EPA Office of Water rule on cooling water intake structures at existing power-generating facilities, OIRA suggested changes that lowered the draft performance standard and added compliance flexibility to the rule by allowing, among other things, options for a site-specific approach to minimizing environmental harm (ID 68). Some of OIRA's suggested revisions of the regulatory language were similar to those proposed by representatives of the electric industry—in particular, the site-specific approach—during their contacts with OIRA regarding this rule. (The representatives of the electric industry also proposed other changes to this rule that OIRA did not recommend to EPA.) Representatives of an environmental interest group also contacted OIRA regarding this rule, advocating that EPA's regulations be based on nationally uniform standards and not on case-by-case, site-specific determinations.

- During its review of an EPA final rule on identification and listing of hazardous waste, industry representatives from steel manufacturers and a chemical company sent letters and met with OIRA opposing the listing of manganese as a hazardous waste constituent due to concerns about the costs that the rule would impose on certain facilities (ID 56). Industry representatives had raised similar points in the public comments they submitted during the proposed rule stage of this rulemaking, but EPA was not persuaded to revise its draft of the final rule after considering those comments. The main focus of OIRA's extensive changes in this rule was the deferral of final action on all parts of the draft rule that would have identified manganese as a hazardous contaminant, as in the original proposed rule and EPA's draft final rule.

- In a draft final rule on tire pressure monitoring systems, NHTSA included provisions that would eventually have mandated use of direct sensing technologies, rather than indirect technologies, for such systems (ID 78).[15] Representatives of automobile manufacturers contacted OIRA to raise concerns that "the structure of the final rule will have the effect of eliminating indirect tire pressure monitoring systems as a compliance option." They also argued that there was no evidence that safety benefits would be noticeably different between systems using indirect and direct sensing technologies. OIRA returned this rule to NHTSA for reconsideration, citing as its reason that the agency's analysis did not adequately demonstrate that NHTSA had selected the best available option and raising concerns regarding NHTSA's analysis of the safety impacts of regulatory alternatives. OIRA subsequently completed a review (consistent with no change) of NHTSA's resubmitted version of the rule (with a revised analysis of safety issues, costs, and benefits of direct and indirect system alternatives) that allowed either type of sensing technology through a phase-in period and deferred until 2005 a decision on which performance standards would be effective after 2006.

However, it is impossible to determine the extent to which the suggestions made by the regulated parties might have influenced OIRA's actions, if at all. OIRA might have independently reached the same conclusions or had

[15]Direct tire pressure monitoring systems have a tire pressure sensor in each tire that transmits pressure information to a receiver. Indirect systems do not have tire pressure sensors. Current indirect systems rely on the wheel speed sensors in an anti-lock braking system to detect and compare differences in the rotational speed of a vehicle's wheels, which can correlate to differences in tire pressure.

the same concerns even if the regulated entities had not contacted OIRA. An OMB representative told us that in many of these meetings outside parties have raised issues that had already been expressed in public comments, meetings between the outside parties and the regulatory agencies, trade papers, news articles, and other venues—all of which might have been reviewed by OIRA.

On the other hand, in 4 of the 11 cases in which regulated parties directly contacted OIRA, OIRA's actions or suggestions to the agencies did not appear to be similar to the actions or suggestions that the regulated parties advocated. Examples of these cases include the following:

- Representatives of the steel industry contacted OIRA regarding an EPA final rule on effluent limitations guidelines, pretreatment standards, and new source performance standards for the iron and steel manufacturing point source category (ID 71). In the letter requesting a meeting with the OIRA Administrator, the steel industry representatives asserted that EPA's revised effluent limitation guidelines were not technically, economically, or legally justified, and also raised concerns about specific aspects of EPA's benefit-cost analysis. The only substantive change that OIRA suggested in this rule, however, was to eliminate a preexisting "minimum net reduction" provision in regulations that applied if facilities used a "water bubble" alternative mechanism for trading pollutants.

- Similarly, representatives from a number of regulated parties requested that OIRA return FAA's draft final rule on part 145 repair stations to the agency with instructions to prepare a supplemental notice of proposed rulemaking and essentially restart most of the rulemaking process (IDs 84 and 72). However, OIRA's actions to have the agency withdraw the rule and, later, to return the rule to the agency for reconsideration cited issues unrelated to those voiced by the regulated entities. When FAA resubmitted the same draft rule a third time, OIRA completed its review of the rule with an outcome of "consistent with no change." An industry representative that we interviewed said that the industry groups ultimately did not get the changes in the rule that they wanted from OIRA.

Appendix III contains case studies that provide more detailed information about each of the rules for which we found evidence that outside parties had contacted OIRA.

OIRA Generally Disclosed Outside Contacts

As noted in chapter 2 of this report, Executive Order 12866 requires OIRA to maintain a publicly available log containing the dates and names of those involved in substantive oral communications (e.g., telephone calls or meetings) between OIRA personnel and outside parties and the subject matter discussed. We used the OIRA list of substantive outside communications to help us identify the information presented above and examined other material to identify those contacts, including agencies' rulemaking dockets.

Overall, we identified only two meetings that OIRA had with outside parties and two letters to OIRA from outside parties regarding the rules in our review that OIRA had not disclosed at the time of our review:

- The OIRA docket contained a letter indicating that OIRA had met in October 2001 with representatives from the iron and steel industry in relation to an EPA draft rule that would have added manganese to a list of hazardous waste constituents (ID 56). However, when we examined OIRA's meeting log in early 2003 there was no record of this meeting. (OIRA subsequently added this meeting to its on-line meeting log.)

- A July 2001 letter sent to OIRA in relation to the FAA part 145 rule was included as part of a regulated entity's testimony before a congressional committee (IDs 84 and 72). However, OIRA's docket did not contain a copy of this correspondence at the time of our review. (OIRA subsequently added this letter to its docket.)

- EPA's docket included a February 2002 letter from the Center for Energy and Economic Development to the OIRA Administrator regarding revisions to a regional haze rule (ID 48).[16] However, we did not find a copy of this letter in OIRA's docket. EPA's docket for this rule also included a copy of an e-mail message from OIRA to EPA noting that a meeting at OMB had been scheduled at the Center's request for February 5, 2002. However, we did not find documentation for this meeting during our review of OIRA's dockets and logs. (OIRA's docket did contain a copy of a letter from another outside party regarding this rule.)

[16]The Center for Energy and Economic Development is a nonprofit organization formed by coal-producing companies, railroads, a number of electric utilities, and related organizations.

However, we have no way of knowing whether there were other meetings with outside parties or other letters from those parties about rules in our review that did not come to our attention. Our knowledge of such meetings or correspondence is generally limited to what OIRA or the agencies disclose in their files. OIRA representatives told us that some of the letters mailed to OIRA after the events of September 11, 2001, and the anthrax letters in October 2001 may not have been delivered, and said they were committed to disclosing all outside contacts regarding rules under review.

Documentation of OIRA's Reviews Varied, but Some Agencies' Practices Improved Transparency

Agencies varied in the extent to which they satisfied the documentation requirements in Executive Order 12866, but most of the agencies satisfied those requirements for most of their rules. However, having materials in the agencies' rulemaking dockets does not necessarily mean that OIRA's effects on the rules were fully transparent. The executive order also requires OIRA to disclose certain information about its review process, and we concluded that OIRA generally satisfied those requirements regarding the rules that we reviewed.

Agencies Varied in Extent to Which Documentation Requirements Were Satisfied

One of the stated purposes of Executive Order 12866 is to make the federal rulemaking process more accessible and open to the public. Toward that end, the executive order places certain public disclosure and documentation requirements on regulatory agencies or OIRA. However, some types of actions are not covered by these requirements and, therefore, do not have to be disclosed or documented by either party. Also, in some cases the executive order does not clearly indicate what must be disclosed or documented.

In general, the applicability and nature of the disclosure and documentation requirements in the executive order depends on the outcome of OIRA's review. If an agency withdraws a rule from OIRA's review, neither the agency nor OIRA are required to disclose the reason. However, if OIRA returns a rule to an agency for reconsideration, section 6(b)(3) of the executive order requires the OIRA Administrator to provide the issuing agency with a written explanation delineating the pertinent section of the order on which OIRA is relying. For rules that OIRA reviews and are subsequently published in the *Federal Register*, the executive order requires agencies to make the rule and any cost or benefit information prepared available to the public. Two other sections of the order establish

specific documentation requirements regarding changes made to rules submitted to OIRA for review:

- Section 6(a)(3)(E)(ii) of the order states that agencies must "identify for the public, in a complete, clear, and simple manner, the substantive changes between the draft submitted to OIRA for review and the action subsequently announced." However, neither the executive order nor OIRA's October 1993 guidance on its implementation defines what the term "substantive changes" means.

- Section 6(a)(3)(E)(iii) of the order requires agencies to "identify for the public those changes in the regulatory action that were made at the suggestion or recommendation of OIRA."

OIRA's October 1993 guidance on the implementation of the order considers the second requirement to be a subset of the first. Therefore, under this interpretation, the agencies are only required to identify the changes made at OIRA's suggestion or recommendation after formal submission of the rule to OIRA—not during any informal review period that precedes formal submission. OIRA also took this position in response to recommendations in our 1998 report on the implementation of these transparency requirements and during this review. This distinction is important because, in some of the 25 rules that we concluded had been significantly changed at OIRA's suggestion or recommendation, OIRA suggested significant changes prior to formal submission of the rule to OIRA. Also, some of the rules that were reviewed informally for weeks or months had very short formal review periods—in some cases as little as a few days.

To determine agencies' compliance with these documentation requirements, we considered the required information to have been "identified for the public" if it was available in the agencies' public docket for the relevant rule. We coded the level of documentation in the agencies' dockets for each changed rule into one of four categories, reflecting whether (1) all changes were clearly documented, (2) changes were identified but it was not clear that all changes had been documented or at whose initiative, (3) no changes were documented in the agencies' public rulemaking docket, or (4) the Executive Order 12866 documentation requirements were not applicable.[17] The first requirement is not applicable when there were no changes made to the rule during OIRA's review that the agencies considered "substantive." Even if there were substantive changes made during OIRA's review, the second requirement is not applicable if

those changes were not made at the suggestion or recommendation of *OIRA*. We made our determinations regarding agencies' compliance with these requirements solely on the basis of the information that would be available to a member of the public if he/she had reviewed the docket for a given rule.[18] Furthermore, because the executive order places responsibility to document changes on the agencies rather than OIRA, our determinations only reflect material available in the regulatory agencies' dockets, not materials in OIRA's public files.[19] Table 5 presents the results of our analysis of agencies' compliance with both documentation requirements in the executive order.

[17]We conducted a similar exercise in our previous GAO report on this subject. See GAO/GGD-98-31.

[18]In many cases, the agencies prepared supplementary memoranda or summaries for us that provided additional information and explanations regarding the changes made in various rules. In those cases, we used the supplementary information to address other elements of our review—such as the nature of changes attributed to OIRA—but did not consider the materials specifically prepared for our review to be public documents within the dockets.

[19]It is notable that these dockets sometimes contained information that the agencies were not required to disclose under OIRA's interpretation of the executive order—and that information frequently provided valuable insights to our determinations regarding the nature of OIRA's changes. For example, the agencies sometimes disclosed changes that were not "substantive," and sometimes disclosed changes that OIRA made to rules before they were formally submitted to OIRA.

Table 5: Agencies' Compliance with Executive Order 12866 Documentation Requirements Was Mixed

Agency	Changes made during OIRA review period				Changes made at OIRA's suggestion or recommendation				Total number of changed rules
	All changes clearly identified	Not clear that all changes had been identified	No changes identified in docket	Not applicable	All changes clearly identified	Not clear that all changes had been identified	No changes identified in docket	Not applicable	
APHIS	1	8	0	3	4	5	0	3	12
FDA	7	0	0	0	6	0	0	1	7
OSHA	0	0	4	1	0	0	2	3	5
DOT/FAA	0	0	2	3	0	0	2	3	5
DOT/FMSCA	4	0	0	2	2	0	0	4	6
DOT/NHTSA	0	1	0	4	1	0	0	4	5
EPA Office of Air and Radiation	1	9	1	3	2	7	1	4	14
EPA Office of Solid Waste and Emergency Response	2	3	0	4	5	0	0	4	9
EPA Office of Water	8	0	0	0	8	0	0	0	8
Total	23	21	7	20	28	12	5	26	71

Source: GAO analysis.

For the rules where the requirements were applicable, the results were mixed. As discussed in more detail later in this report, some agencies (FDA, FMCSA, and EPA's Office of Water) provided clear documentation in their rulemaking dockets of all of the changes made to their rules during OIRA's review and at OIRA's suggestion or recommendation. In contrast, other agencies (FAA and OSHA) did not have any documentation of the changes made in their dockets. FAA officials told us that their agency had not been documenting changes made during OIRA's review, but would do so in the future and put the documentation in the agency's rulemaking docket.[20] OSHA officials said the documentation was available from the Office of the Solicitor, and said that if a member of the public wanted information on changes made during OIRA's review it would be provided upon specific request. (OSHA officials said that they keep the information

in the Office of the Solicitor in order to ensure that the OIRA-directed change documentation is not part of the official rulemaking record if a lawsuit is filed.) However, because there is nothing in the OSHA rulemaking docket to identify that documentation of OIRA changes exists or is available, a member of the public interested in finding this information would have to know to specifically request the relevant documentation from the Office of the Solicitor.

For the remaining agencies (APHIS, NHTSA, and EPA's Offices of Air and Radiation and Solid Waste and Emergency Response), it was unclear that the documentation available in the dockets covered all of the relevant changes to their rules. For example, these agencies sometimes included in their dockets copies of e-mails between OIRA and the agencies discussing changes that had been made to the draft rule. However, we could not tell whether these e-mails represented all or only some of the changes that had been made. In other cases, agencies documented changes made, but it was not clear if any of the changes had been at the suggestion or recommendation of OIRA. Agency officials later told us that, in these cases, the documentation that we found represented all of the changes that had been made to the rules during OIRA's review or at OIRA's initiative. Therefore, it may be that the lack of clarity regarding these agencies' adherence to the documentation requirements in the executive order reflected unclear or inadequate labeling and attribution of the sources of changes, rather than the absence of documentation.

Agencies Varied in How Changes to Draft Rules Were Documented

Executive Order 12866 does not specify how agencies should document the changes made to draft rules after their submission to OIRA, nor is there any governmentwide guidance that directs agencies how to do so. OIRA representatives told us that it is up to each agency to decide how its rulemaking dockets are kept and how they satisfy the executive order's requirements. Not surprisingly, therefore, the regulatory agencies in our review had different methods of documenting changes to the rules that OIRA reviewed under Executive Order 12866. In the cases of DOT and EPA, which each had three agencies or program offices in our review, the documentation practices also varied across their agencies and offices.

[20]As table 5 shows, the executive order's documentation requirements were not applicable in three of the five FAA changed rules we reviewed because only minor (nonsubstantive) changes had been made to those rules.

How Changes Were Identified

For example, there were clear differences among the agencies in how they "identified for the public" the changes made to draft rules after their submission to OIRA and at the suggestion or recommendation of OIRA.

- The most common method was the inclusion in the public rulemaking docket of a marked-up copy of the rule (or selected pages thereof) as submitted to OIRA or after the review was completed showing the changes made during the review process. In some cases these marked-up copies were done by hand, but in other cases a "redline/strikeout" version was prepared electronically, printed, and placed in the public docket. Agencies with this type of documentation included FMCSA, NHTSA, and EPA's Office of Solid Waste and Emergency Response. In addition to a marked-up version of its rules, FDA also included a standard cover form that identified the information placed in the dockets to address each part of the executive order's documentation requirements.

- Some agencies' documentation included the above marked-up versions of the rules and/or copies of e-mail messages of faxes between OIRA and the regulatory agencies reflecting the changes that were being made to the rules. Agencies with this type of documentation included EPA's Office of Air and Radiation and APHIS.

- For all but one of the dockets prepared by EPA's Office of Water, the office included a detailed memorandum addressing each of the executive order's documentation requirements, summarizing the development and review of the rule and identifying all substantive changes made and those made at the suggestion of OIRA.[21]

How Sources of Changes Were Identified

The regulatory agencies also differed in how they identified the *source* of the changes (e.g., whether the changes had been made at the suggestion of OIRA or at the agency's initiative). Most commonly, the agencies noted the source of the changes in the margins of their marked-up versions of at least some of the rules (e.g., APHIS, FDA, and FMCSA). In those cases where e-mails or faxes were used for documentation, the sources of the changes were usually apparent from those documents (e.g., EPA's Office of Air and

[21] The other Office of Water docket included an annotated "redline/strikeout" version of the revised rule. The Corps of Engineers prepared the docket for one rule jointly issued by the Corps and EPA's Office of Water and similarly included an annotated "redline/strikeout" version of the revised rule.

Radiation). If the agency prepared a summary memorandum (e.g., EPA's Office of Water), the sources were usually identified in that memorandum. However, in some cases the agencies did not clearly indicate which of the changes that they identified were from OIRA and which were from the agencies.

Other Differences in Documentation

Other areas in which the agencies' documentation practices differed included the following:

- Officials in some of the agencies (e.g., APHIS, FDA, and NHTSA) indicated that the only changes to their rules that they considered "substantive" were those that affected the impact or text of the rule as it appeared in the Code of Federal Regulations (although the executive order does not specify that only changes to regulatory text are substantive). However, in practice most of these agencies documented both regulatory text changes and other changes to the preambles of their rules (particularly those that we previously identified as "other material changes" in which OIRA suggested that the agency clarify or solicit comments on a particular issue). Other agencies documented all changes to their rules, even those that were editorial or otherwise minor in nature.

- Some agencies documented changes made to their rules by OIRA prior to formal submission (e.g., EPA Office of Air and Radiation), while others did not.

- Some of the agencies documented when there had been no substantive changes made to their rules (e.g., EPA Office of Air and Radiation), while others did not (e.g., FAA and NHTSA).

Some Agencies Demonstrated "Best Practices"

Overall, we often found it difficult to identify the changes that had been made to agencies' rules during OIRA's review and/or at the suggestion or recommendation of OIRA by reviewing material in the agencies' rulemaking dockets. As noted previously, one agency (FAA) had done nothing at the time of our review to document these changes, and another agency (OSHA) placed its documentation in the Office of the Solicitor, not the agency's rulemaking docket. (Therefore, a member of the public would have to know to ask for the materials from that office.) Other agencies did not document any changes if the changes were not, in their opinion, "substantive." In another case the agency simply provided a copy of the rule as submitted to OIRA and a copy of the rule as published in the *Federal*

Register, with no indication of what had changed in the text. In still other cases, the changes were indicated in a "redline/strikeout" version of the rule, but the photocopied redline version was so indistinct that it was difficult to identify or attribute all of the changes. The agencies appeared to do a better job of documenting the changes that had been initiated by OIRA than in clearly identifying whether other substantive changes had been made to the rules *by the agencies or other parties* after submission to OIRA. For several of the rules, the agencies added material to the public dockets shortly before we arrived or after we told the agencies we could not find documentation for certain rules that had been changed. For example, FMCSA added documentation of changes made to a rule that OIRA had finished reviewing in May 2002 after we asked about the rule during a meeting with FMCSA officials in February 2003. Executive Order 12866 does not specify when agencies must "identify for the public" the changes made during OIRA's review.

In marked contrast, the documentation practices used by some of the agencies and offices in our review—FDA, FMCSA and EPA's Office of Water—represented what we consider to be "best practices" that not only met the minimal requirements of the Executive Order 12866 but also made clear how the rules had changed during OIRA's review and which changes were made at OIRA's suggestion.

- EPA's Office of Water usually did this through detailed memoranda prepared for the docket specifically to address the executive order's requirements. For example, in the Office of Water's rule on proposed changes to meat and poultry effluent limitations guidelines and standards, EPA included a detailed cover memorandum specifically addressing the executive order's requirements (ID 67). The memorandum not only identified all of the substantive changes made at OIRA's suggestion, it also identified the substantive EPA changes made independent of other reviewers. Also, the memorandum identified nonsubstantive changes that had been suggested by OMB and others (e.g., SBA and the Department of Agriculture). Copies of relevant documents were attached to the memorandum as well as copies of suggested changes that were sent to the agency by the OIRA desk officer.

- FMCSA often provided a "redline/strikeout" version of the revised rule after OIRA's review, clearly annotating the changes that had been made to the rule between submission of the manuscript to OIRA and its publication, as well as the source of each change. For example, in

several places in the agency's interim final rule regarding a safety monitoring system and compliance initiative for Mexico-domiciled motor carriers operating in the United States, FMCSA identified changes that had been made at the request of OIRA, at the request of the Office of the *Federal Register*, or at FMCSA's initiative after the submission of a previous version of the rule to OIRA (ID 32).

- FDA used a standard one-page cover form with attached copies of the rule in which the agency had marked the changes made to the rule and annotated the sources of those changes. The FDA form, as well as some similar forms we found in EPA's dockets, had the additional benefit of allowing agency officials to affirmatively indicate whether there were substantive changes made to a rule during OIRA's review and, separately, whether there were changes made at the suggestion or recommendation of OIRA. For example, in the agency's draft final rule on food additives, FDA included the cover memorandum and a copy of the rule as submitted to OIRA with hand-written annotations of FDA and OIRA changes (ID 17). In addition, FDA included a copy of its responses to detailed OMB questions about the final rule.

Many Rules Nominated for Reform Are Being Changed

Our third objective was to describe how OIRA determined that certain existing rules merited high priority review. With regard to OIRA's 2001 review effort, our specific objectives were to determine (a) which organizations or persons suggested that the rules be reviewed, (b) what process OIRA used to select and prioritize the nominations, (c) the extent to which OIRA publicly disclosed its selection and priority-setting process, and (d) the current status of those rules. We also compared that review effort to a second review that OIRA initiated in 2002.

In summary, OIRA received 71 nominations from the public in response to its May 2001 request for suggestions of rules that should be modified or rescinded. Of these, 44 nominations were from the Mercatus Center at George Mason University. OIRA selected 23 of the 71 nominations for high priority review—14 of which were originally nominated by the Mercatus Center. The only other organizations that nominated more than one of the suggestions that OIRA so designated were the Equal Employment Advisory Council and the Employment Policy Foundation (two suggestions each). Representatives of OIRA told us that the office's desk officers initially determined which issues merited high priority review, subject to the approval by OIRA management. Although OIRA fully disclosed the source of each of the nominations that it received and defined the priority categories that it used, the office did not publicly describe how it decided which nominations merited high priority review. As of May 2003, regulatory agencies or OIRA have at least begun to address the issues raised in many of the suggestions. In March 2002 OIRA again solicited public comments on regulations in need of reform, and in response received more than 300 suggestions. However, this time OIRA forwarded the suggestions to the relevant federal agencies for review and prioritization. In general, OIRA explained the process used for this second round of nominations more clearly and completely than was done for the first round.

Mercatus Center Nominated Most Rules Selected for High Priority Review in 2001 Report

Section 628(a)(3) of the fiscal year 2000 Treasury and General Government Appropriations Act required OMB to submit "recommendations for reform" with its report on the costs and benefits of federal regulations. In the portion of its May 2001 draft report responding to this requirement, OIRA said it did not have enough information to make recommendations for the reform of specific regulations or regulatory programs, and asked for recommendations and comments on rules and regulatory programs that could be "of concern to the public." Specifically, OIRA said the following:

"We would like to receive suggestions on specific regulations that could be rescinded or changed that would increase net benefits to the public by either reducing costs and/or increasing benefits. We would appreciate if commenters identified regulations that are obsolete or outmoded, and could be rescinded or updated."

OIRA asked that commenters provide their suggestions in a particular format (e.g., name of regulation, agency regulating, citation, and description of problem) and invited commenters to suggest "any other reforms to the regulatory development and oversight processes that would improve regulatory outcomes."

In its December 2001 final report, OIRA said it received 71 suggestions in response to its request from 33 commentators involving 17 agencies. In an appendix to the report listing the suggestions, OIRA indicated that 44 of them came from the Mercatus Center at George Mason University. The report also indicated that OIRA had completed an initial review of the suggestions and placed them into one of three categories: (1) "high priority," meaning that OIRA was inclined to agree with and look into the suggestion, (2) "medium priority," meaning that OIRA needed more information about the suggestion, or (3) "low priority," meaning that OIRA was not convinced that the suggestion had merit. OIRA listed 23 of the suggestions in the first category, and said a "prompt letter" might be sent to the responsible agency for its "deliberation and response." Eight of the 23 high priority suggestions involved regulations from EPA, 5 suggestions involved regulations from the Department of Labor (DOL), and 2 each from the Departments of Health and Human Services (HHS), Agriculture (USDA), and the Interior (DOI). Five of the 23 suggestions involved rules that had been issued at the end of the Clinton administration and delayed by a January 20, 2001, memorandum from Assistant to the President and Chief of Staff Andrew H. Card, Jr. (Card memorandum) directing federal agencies to, among other things, postpone the effective dates of certain regulations for 60 days.[1] As table 6 shows, 13 of the 23 recommendations came from the Mercatus Center, and one was a joint recommendation from Mercatus and the Association of Metropolitan Water Agencies.

[1]For a discussion of this memorandum and the rules delayed, see U.S. General Accounting Office, *Regulatory Review: Delay of Effective Dates of Final Rules Subject to the Administration's January 20, 2001, Memorandum*, GAO/02-370R (Washington, D.C.: Feb. 15, 2002).

Table 6: The Mercatus Center Suggested Most of the 23 "High-Priority Review" Rules

Commenter	Regulation at issue	Agency issuing regulation
Mercatus Center	Central air conditioner and heat pump energy conservation standards	Department of Energy
Mercatus Center	Standards for privacy of individually identifiable health information	HHS
Mercatus Center	Food labeling: trans fatty acids in nutrition labeling	HHS/Food and Drug Administration
Mercatus Center	Hardrock mining	DOI/Bureau of Land Management
Mercatus Center	Snowmobile use in Rocky Mountain National Park	DOI/National Park Service
Mercatus Center	Davis-Bacon Act "helpers" regulation	DOL/ Employment Standards Administration
Mercatus Center	Hours of service of drivers	DOT/Federal Motor Carrier Safety Administration
Mercatus Center	Total maximum daily loads	EPA
Mercatus Center	Economic incentive program guidance	EPA
Mercatus Center	New source review 90-day review background paper	EPA
Mercatus Center	Concentrated animal feeding operations effluent guidelines	EPA
Mercatus Center/ Association of Metropolitan Water Agencies	Arsenic in drinking water	EPA
Mercatus Center	Roadless area conservation (draft environmental impact statement)	USDA/ Forest Service
Mercatus Center	Forest Service planning rules	USDA/Forest Service
Notre Dame University	Title IV regulations under the Higher Education Act	Department of Education
Equal Employment Advisory Council	Office of Federal Contract Compliance Programs' (OFCCP) equal opportunity survey	DOL/OFCCP
Equal Employment Advisory Council	Uniform Guidelines on Employee Selection Procedures	Equal Employment Opportunity Commission
Employment Policy Foundation (EPF)	Procedures for certification of employment based immigration and guest worker applications	DOL/Employment and Training Administration
LPA, Inc.	Overtime compensation under the Fair Labor Standards Act	DOL/Wage and Hour Division

(Continued From Previous Page)

Commenter	Regulation at issue	Agency issuing regulation
EPF/National Partnership for Women and Families	Record keeping and notification regulations under the Family and Medical Leave Act	DOL/Wage and Hour Division
American Chemistry Council	Mixture and derived from rule under the Resource Conservation and Recovery Act	EPA
City of Austin	Drinking water regulations under the Safe Drinking Water Act	EPA
American Petroleum Institute	Notification of substantial risk under the Toxic Substances Control Act	EPA

Source: OMB.

In its December 2002 report, OIRA noted that several commenters questioned the 2001 comment process because the Mercatus Center provided a majority of the recommendations for reform. OIRA said it believed that, if there was a problem with that process, "it was not that the Mercatus Center was too active but that other potential commenters were silent." An OIRA representative told us during this review that the Mercatus Center had systematically tried to analyze and comment on a wide range of rules, and it simply submitted the analyses that it had done. A Mercatus Center official told us that the center had submitted nominations regarding all of the rules on which it had commented since 1997.[2]

How High Priority Review Selections Were Made

Although OIRA identified the source and ranking of each of the suggestions that it received, the office did not fully explain in its report to Congress how it decided that 23 of the suggestions merited high priority review. During our review, OIRA representatives told us that those determinations were made through a very informal, "bottom-up" process, with OIRA staff initially looking at the nominations with which they were most familiar and making some preliminary decisions that were then reviewed by the branch chiefs and others. They said the OIRA Administrator made the final decision regarding which rules should be in the high priority category.

[2]She said that the Mercatus Center actually submitted a total of 58 suggestions for reform. However, several of the suggestions were about the same rule, so OIRA's report only listed the 44 comments that were about different rules.

In its December 2002 final report, OIRA noted that 8 of the 23 high-priority nominations listed in the December 2001 report addressed EPA rules, and another 5 addressed rules that could be considered environmental in nature. However, OIRA said "an examination of OIRA's decision-making 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." OIRA noted that only 13 of 33 environmental rules that were nominated were rated as a high priority for review and said some of these 13 rules had already been established as an administration priority for review.

Status of Rules Selected for High Priority Review

As of May 2003, the status of the rules that were the subject of the 23 high-priority suggestions varied. OIRA said in its December 2002 final report that, in some cases, the agencies had "convinced us that reform is unnecessary or not appropriate at this time." For example, OIRA noted that EPA had decided not to modify its rule on arsenic in drinking water, and DOL had decided that changes in the Davis-Bacon regulations were not appropriate at that time. However, as the following examples illustrate, in many cases the responsible agencies took action on the suggestions or were in the process of taking action:

- One of the nominations focused on a Department of Energy rule issued in January 2001 that would have required that the energy efficiency of new central air conditioners be increased by 30 percent. The commenter said that the department did not adequately consider differences among consumers and may have overstated projected energy savings. In May 2002, DOE withdrew the rule and issued a new rule requiring a 20 percent increase in energy efficiency. The new rule's effective date was August 2002.

- EPA's July 2000 final rule regarding allowable amounts of pollution in water ("total maximum daily load") was also the subject of a suggested change. Specifically, the commenter said the revisions to the program in that rule were overly prescriptive and could prove costly to the states. In October 2001, EPA published a notice delaying the effective date of the rule until April 2003. In March 2003, EPA published a final rule withdrawing the July 2000 rule. By May 2003, a draft of a new proposed rule was undergoing informal interagency review.

- Another commenter questioned the assumptions underlying a May 2000 proposed rule that would alter the hours of service for motor carrier

drivers (e.g., trucks and buses). In April 2003, FMCSA published the final rule that changed the scope and the requirements from the proposal. For example, the final rule exempts buses from its coverage. Most of the final rule's provisions were scheduled to take effect in June 2003.

- One commenter expressed concerns about Department of Education regulations under Title IV of the Higher Education Act, indicating that the rules were redundant and placed "inappropriate administrative burdens on institutions of higher learning." In November 2002, the department published a final rule amending regulations under the Higher Education Act, and said the amendments were designed to "reduce administrative burden for program participants, and to provide them with greater flexibility to serve students and borrowers." The rules were generally scheduled to take effect in July 2003.

In these and many other cases, it is impossible to know whether the changes that the agencies made and were making to rules were initiated or affected by their designation as an item for high priority review. However, OIRA representatives noted that some of the changes that agencies were making to their rules began as a consequence of the administration's Card memorandum review in January 2001—not their later designation as an item for high priority review. Appendix IV provides information on the status of each of the 23 high priority rules as of May 2003.

Second Round of Nominations Was Different

Section 624 of the Treasury and General Government Appropriations Act of 2001, also known as the "Regulatory Right-to-Know Act," required OIRA to include "recommendations for reform" in its cost-benefit report each year. Therefore, in its March 2002 draft report, OIRA repeated its solicitation of public comments on regulations or regulatory programs in need of reform. However, OIRA's second effort to identify rules for further review differed from its 2001 effort in the following respects.

- In the 2001 effort, OIRA asked the public to identify "regulations that could be rescinded or changed that would increase net benefits to the public by either reducing costs and/or increasing benefits." However, in the 2002 effort OIRA asked the public to nominate reforms to specific rules that would increase net benefits to the public, including not just the elimination or modification of existing rules but also "extending or expanding existing regulatory programs." OIRA also specifically

requested comments on regulations affecting small businesses, and invited comments on agencies' practices regarding guidance documents.

- Whereas OIRA received only 71 nominations in 2001, primarily from one commentor, in the December 2002 report OIRA said it received comments on 267 regulations and 49 guidance documents from approximately 1,700 individuals, firms, trade organizations, and others. Many of the 23 items that OIRA designated for high priority review during the 2001 process were again nominated. Although most of the nominations sought modifications that would increase regulatory flexibility or rescind rules, more than a quarter of them suggested making rules more stringent or developing new rules.

- In the first effort, OIRA reviewed the nominations and decided which ones merited high priority review. In the second effort, OIRA indicated that the agencies would be responsible for initially reviewing and prioritizing the suggested items. OIRA said it did so because of the large volume of nominations, and because the agencies could bring to bear "their extensive knowledge and resources, which will provide a basis for selecting reform priorities in consultation with OIRA."

- As noted previously, OIRA did not fully explain in its report to Congress regarding the 2001 review how it decided which rules merited high priority review. However, in the December 2002 report OIRA discussed in some detail how it processed the nominations and suggested three criteria that the agencies should use to conduct their evaluations: (1) efficiency (reforms that can maximize net benefits, including improvements to the economy, environment, and public health and safety), (2) fairness (nominations with the potential for desirable distributive impacts and process considerations), and (3) practicality (nominations that are more important than others and that can be implemented under existing statutory authority).

OIRA asked the Small Business Administration's Office of Advocacy to review all of the nominations and identify those that it believes could reduce unjustified regulatory burdens on small businesses. OIRA asked that agencies complete their initial review of the nominations and discuss them with OIRA by the end of February 2003. An OIRA representative told us that the office met with the agencies that had the most nominated rules (i.e, EPA, HHS, DOT, and DOL) in January and February 2003 and emphasized that the final decisions on which suggestions to pursue would be up to the agencies.

Conclusions and Recommendations

Conclusions

OIRA has been reviewing agencies' draft rules for more than 20 years, and those reviews have become an established and important part of the federal rulemaking process. While OIRA reviews clearly have an analytical component (e.g., ensuring compliance with legal and procedural requirements and conformance with principles of economic analysis), they are also a way to ensure that the agencies' regulatory programs are consistent with administration priorities (within applicable legislative constraints). OIRA is part of the Executive Office of the President, and the President is OIRA's chief client. Because it represents the President and because it reviews hundreds of significant rules each year from dozens of federal agencies, OIRA can have a major influence on the direction of a wide range of public policies.

Our review documented OIRA's direct influence with regard to more than two dozen rules in which it suggested significant changes that were ultimately adopted by the rulemaking agencies. OIRA's presence in the rulemaking process may also have a subtler, more indirect effect on agencies' decision making—discouraging them from submitting rules that OIRA is unlikely to find acceptable and encouraging them to make the case for the regulations that they do submit more carefully. However, the OIRA regulatory review process is not well understood or documented, and the effect that OIRA's reviews have on individual rules is not always easy to determine.

Agency and OIRA Documentation Not Always Clear

Concerns about the effect that OIRA was having on agencies' rules led to the adoption of transparency requirements in section 6 of Executive Order 12866. For nearly 10 years the executive order has required agencies to identify for the public the substantive changes in regulatory actions that were made between the drafts submitted to OIRA and the actions subsequently announced, and to identify the changes made to the drafts at the suggestion or recommendation of OIRA. Some of the agencies that we focused on in our review (EPA's Office of Water, FDA, and FMCSA) had what we considered to be "best practices" of documenting these changes, although their methods of documentation varied considerably. However, in other agencies the documentation of the changes made to their rules was either unavailable or unclear, making it difficult for us to determine what effect OIRA's review had on their rules. For example:

- Some agencies did not comply with the executive order's transparency requirements at all (FAA) or did not put the required information in the

agencies' public dockets (OSHA). In a few cases, the agencies did not put the information in the dockets until months after the rules had been published (i.e., not until we asked for the files as part of this review). The agencies correctly noted that neither the executive order nor OIRA guidance establishes a time limit by which the documentation had to be provided.

- In many cases, it was unclear whether the documentation that the agencies provided was complete (e.g., the agencies provided multiple drafts, "change pages," and/or memoranda identifying alterations that had been made to their rules, but there was no indication that the changes identified represented *all* of the substantive changes made to the rules).

- In some cases, it was unclear which changes that the agencies identified were suggested by OIRA and which were suggested by others (e.g., the rulemaking agencies themselves).

- In other cases, it appeared that the agencies focused their efforts on documenting changes that had been suggested by OIRA but did not clearly document whether others had initiated substantive changes in the rules during the OIRA review period.

- The agencies also differed in what they considered a "substantive" change that required documentation. Some of the agencies identified all changes made to their rules during OIRA's review, regardless how small. However, other agencies said they only considered changes to the text of the rule as it appears in the *Code of Federal Regulations* to be "substantive." Our review indicated that some changes made to the preambles of the agencies' rules (e.g., suggestions that agencies solicit comments on particular issues) could affect their application, and therefore appeared to us to be "substantive."

The executive order also places certain transparency requirements on OIRA. For example, the order requires OIRA to disclose any substantive communications it has with outside parties regarding rules under review, and the status of all regulatory actions under review. After a regulatory action that it reviewed has been issued, OIRA is required to disclose all documents exchanged between OIRA and the agency during the review. However, in some cases the documentation that OIRA provided regarding the rules it reviewed did not clearly illustrate what occurred. For example,

- OIRA's descriptions of its contacts with outside parties sometimes did not clearly indicate what rule was being discussed or what organizations those parties represented.

- OIRA's coding of some of the outcomes of its reviews made our review more difficult. In particular, the "consistent with change" code included any type of change made to a rule, regardless of its significance or source. As a result, an agency's action to correct a legal citation or a misspelling is coded the same as a significant change to the text of a rule that was suggested by OIRA. Also, OIRA's use of an outcome code of "deadline case" for some rules provided no information on whether the reviews of such rules were completed with or without changes. The usefulness of that outcome code is also questionable, given that OIRA's database already has a separate field to identify rules with legal deadlines.

- As interpreted by OIRA, the requirement that OIRA disclose documents exchanged with the agencies only applies to documents exchanged by staff at the branch chief level and above. Therefore, under this interpretation, OIRA is not required to disclose any documents that are e-mailed or faxed between OIRA desk officers and regulatory agency personnel—the level at which such exchanges are most likely to occur. Nevertheless, during our review we sometimes discovered staff-level e-mails and other documentation in the agencies' or OIRA's dockets, and that information was very useful in explaining what had happened to rules undergoing OIRA review. We have no way of knowing how often other documents were exchanged at the staff level and not disclosed.

There also appears to be a gap in the transparency requirements applicable to OIRA regulatory reviews. If OIRA returns a rule to the rulemaking agency for reconsideration, the executive order requires OIRA to explain in writing why the rule was returned. If a rule is substantively changed while under review at OIRA, the executive order requires the agency to identify those changes for the public. However, neither the rulemaking agencies nor OIRA are required to disclose why rules are withdrawn from review. Our review indicated that withdrawals can be initiated by the agencies, can be requested by OIRA, or can be a joint decision. If a rule is withdrawn and not subsequently published, the agencies may not create a docket into which any explanation for the withdrawal could be disclosed. Therefore, in those instances, OIRA may be the most logical site for any withdrawal disclosure—just as it is for returns. If the withdrawn rule is subsequently

published, the agencies could document the reasons for the withdrawals in the rulemaking docket.

Opportunity to Build on Improvements in Transparency

The current OIRA Administrator has made several notable improvements in the transparency of the office's regulatory reviews. For example, by placing information about the rules under review and OIRA's contacts with outside parties on the office's Web site, the Administrator has made that information much more accessible to the public than it had been previously. Also, recognizing that outside parties were increasingly contacting OIRA during the informal review periods that sometimes precede formal submission, the Administrator changed the trigger for the disclosure requirements applicable to OIRA's interactions with outside parties from the start of the formal review period to the start of any informal review period. As a result, OIRA now discloses substantive communications (e.g., phone calls, meetings, and correspondence) with outside parties involving specific rules that occur any time after OIRA receives a draft rule from the agency or begins substantive discussions with an agency about the provisions of a draft rule. Disclosing the office's interactions with outside parties at this stage of the rulemaking process can go a long way toward eliminating what the Administrator referred to as "the culture of secrecy and mystery" that has surrounded OIRA for more than 20 years.

However, another result of this change in policy is that the trigger for the transparency requirements applicable to OIRA regarding its interaction with outside parties (the start of informal review) is now inconsistent with the trigger for the transparency requirements applicable to OIRA and the agencies regarding their interactions with each other (the start of formal review). We agree with the Administrator that it is useful and important that the public know about OIRA contacts with outside parties while rules are undergoing informal review. However, we also believe that it is at least as important for the public to know whether substantive changes were made to agencies' draft rules during this period, and in particular, whether those changes were suggested by OIRA.

The transparency requirements in Executive Order 12866 were intended to allow the public to understand what changes had been made to agencies' rules during OIRA's review and at OIRA's suggestion. During our review we discovered that formal OIRA review periods can be as short as 1 day, but informal review periods can go on for weeks or even months in advance of formal reviews. Therefore, restricting the transparency requirements in

Executive Order 12866 only to a brief period of formal review seems antithetical to the intent of those requirements. We also discovered that agencies sometimes provided the public with documentation of changes occurring during informal OIRA reviews—even though they were not required to do so. In several cases that documentation helped us to identify significant changes that had been suggested by OIRA and to better understand how the published rule was developed. Based on that documentation and other evidence that was available, we concluded that OIRA's reviews appeared to have had a significant effect on 25 of the 85 rules that we examined. However, because neither OIRA nor the rulemaking agencies are required to document the changes during informal review, we do not know whether there were other "consistent with change" rules (or even rules coded as "consistent with no change") that were significantly altered at the suggestion of OIRA.

In several speeches during the past 2 years the OIRA Administrator has emphasized the importance of transparency, describing the establishment of a climate of openness at OIRA as his "first priority" and stating that "more openness at OMB about regulatory review will enhance public appreciation of the value and legitimacy of a centralized analytical approach to regulatory policy." Also, on more than one occasion, OIRA has said that it can have its most significant effect on agencies' draft rules before they are formally submitted to OIRA for review. Therefore, it is not clear why OIRA believes that the executive order's transparency requirements should not cover the part of the review period when the most important changes can occur. Real transparency about the effects of OIRA's reviews would require either OIRA or the rulemaking agencies to disclose the changes made to agencies' draft rules during informal review. Under OIRA's current interpretation of the executive order's requirements, the public might never know about some of the most significant changes that are made to agencies' rules.

We recognize that there are limits to what should be disclosed regarding OIRA's interactions with the rulemaking agencies. OIRA and the agencies should be able to discuss regulatory matters in general without having to document and disclose those communications. However, if the published version of a rule reflects substantive changes that OIRA recommended to the draft rule, even if those changes were recommended during informal review, we believe that the agencies should document the changes so that the public can understand how the rule was developed. We also recognize that it may not always be clear when informal reviews begin (e.g., when "substantive" discussions with agencies have begun regarding draft rules).

However, OIRA must make that determination now regarding the disclosure of its contacts with outside parties. Also, although OIRA representatives indicated that postpublication disclosure of communications between OIRA and the agency that occur prior to formal rule submission could have a "chilling effect" on those communications in the future, that effect does not appear to have taken place in those agencies that already disclose those communications. Further, our interactions with the agencies and OIRA during this review indicated that a requirement that substantive changes be disclosed during any part of OIRA's review would not pose practical difficulties for either party. Both OIRA and the agencies know what substantive changes are made to agencies' rules during the review period (whether formal or informal) and the source of those changes.

Although the current Administrator has substantively improved the ability of the public to understand the OIRA regulatory review process, we believe that there are several additional initiatives that OIRA can undertake to further improve the transparency of the review process without sacrificing the confidentiality of OIRA-agency consultations.

Recommendations

We recommend that the Director of the Office of Management and Budget:

- Define the transparency requirements applicable to the agencies and OIRA in section 6 of Executive Order 12866 in such a way that they include not only the formal review period but also the informal review period when OIRA says it can have its most important impact on agencies' rules. Doing so would make the trigger for the transparency requirements applicable to OIRA's and the agencies' interaction consistent with the trigger for the transparency requirements applicable to OIRA regarding its communications with outside parties.

- Change OIRA's database to clearly differentiate within the "consistent with change" outcome category which rules were substantively changed at OIRA's suggestion or recommendation and which rules were changed in other ways and for other reasons.

- Improve the implementation of the transparency requirements in the executive order that are applicable to OIRA. Specifically, the Administrator should take the following actions:

- More clearly indicate in the OIRA meeting log which regulatory action was discussed and the affiliations of the participants in those meetings.

- Because most of the documents that are exchanged while rules are under review at OIRA are exchanged between agency staff and OIRA desk officers, OIRA should reexamine its current policy that only documents exchanged by OIRA branch chiefs and above need to be disclosed.

- Establish procedures whereby either OIRA or the agencies disclose the reasons why rules are withdrawn from review.

- Improve the implementation of the transparency requirements in the executive order that are applicable to agencies. Specifically, the Administrator should:

  - Define the types of "substantive" changes during the OIRA review process that agencies should disclose as including not only changes made to the regulatory text but also other, noneditorial changes that could ultimately affect the rules' application (e.g., explanations supporting the choice of one alternative over another and suggestions that agencies solicit comments on the estimated benefits and costs of regulatory options).

  - Instruct agencies to put information about changes made to rules after submission for OIRA's review and at OIRA's suggestion or recommendation in the agencies' public rulemaking dockets, and to do so within a reasonable period after the rules have been published.

  - Encourage all agencies to use "best practice" methods of documentation that clearly describe the changes made to agencies' rules (e.g., like those practices used by FDA, EPA's Office of Water, or FMCSA).

Agency Comments and Our Evaluation

On August 8, 2003, we provided a draft of this report to the Director of OMB for his review and comment. We also provided a draft to APHIS, FDA, DOL, DOT, and EPA for technical review. We received several technical suggestions from these agencies, which we incorporated as appropriate. For example, at the request of certain agencies, some of the entries in appendix II now provide both the title of the rule as submitted to OIRA and

the title as published in the *Federal Register*. We also made minor changes to the body of the report clarifying why certain rules were changed or withdrawn.

On September 2, 2003, the Administrator of OIRA provided written comments on the draft report. (See app. V for a copy of these comments.) The Administrator said OIRA believed the "factual foundations of the report are well grounded," and was particularly pleased that the report noted improvements in the timeliness of OIRA's reviews and the transparency of the review process. He also said that OIRA plans to review its implementation of the transparency requirements and, in particular, would work to improve the clarity of its meeting log. However, the Administrator said OIRA did not agree with all of the recommendations in the draft report, and did not believe that the report had demonstrated the need or desirability of changing the agency's existing "unprecedented" level of transparency. He then discussed several specific issues, describing why he disagreed with the recommendations. The bullets below summarize his concerns and present our response.

- The Administrator said that OIRA did not believe that disclosure of "deliberations" that occur during informal review of rules would improve the rulemaking process. He also said that Congress and the courts have recognized the importance of confidentiality during the deliberative process and said it would not be appropriate for OIRA to waive the "deliberative privilege" for rulemaking agencies. However, we did not recommend that OIRA's deliberations with the agencies be disclosed. Our recommendation was that, after a rule has been published in the *Federal Register*, agencies disclose any substantive changes made to draft rules—whether those changes were made during the formal review process or an informal review. As we said in the draft report, real transparency regarding the substantive changes made to agencies' draft rules during OIRA's review requires disclosure of those changes *whenever* they occurred. Excluding the portion of the review process when OIRA has said it can have its most significant effect seems to seriously call into question the transparency of that process. The desirability of such disclosure was clearly demonstrated during our review when agencies disclosed substantive changes made to their rules during informal review at the suggestion or recommendation of OIRA. Those disclosures greatly facilitated our understanding of the extent to which OIRA affected the rules at issue.

- The Administrator said that the draft report does not explain why changes are needed to the "longstanding practice" of limiting the disclosure of documents exchanged during the review process to only documents that were exchanged at the OIRA branch chief level and above. In our draft report, we recommended that OIRA reexamine that policy because our review of OIRA's and the rulemaking agencies' files indicated that most of the documents exchanged occurred below the branch chief level. Therefore, only requiring disclosure of documents exchanged at a level at which they rarely are exchanged seems inconsistent with the spirit of transparency.

- The Administrator indicated that the draft report does not explain why agencies or OIRA should disclose why rules are withdrawn from review, again noting that nondisclosure has been a "longstanding practice." He also indicated that rules are withdrawn at the request of the rulemaking agency and that OIRA does not believe it is appropriate for it to "waive the deliberative privilege" by disclosing why rules are withdrawn. However, as we noted in our report, the executive order already requires disclosure regarding rules that are changed or returned to the agencies. Withdrawals are the only substantive action that can be taken without explanation or documentation. Further, our review indicated that OIRA sometimes initiates these withdrawals (even though they were technically "requested" by the agencies).

- The Administrator noted that the draft report recommended that OIRA differentiate within the "consistent with change" category in its database those rules that were substantively changed at OIRA's suggestion or recommendation and those rules that were changed in other ways and for other reasons. He then referred to the former Administrator's response to our 1998 report, indicating that OIRA continues to believe that it is better to provide the public with copies of the draft regulations reviewed by OIRA than to clearly delineate which changes were substantive. First of all, we did not address the issue of the "consistent with change" category in our 1998 report. Further, we concluded during this review that it is extremely difficult to determine what changes had been made in different versions of draft rules that sometimes were hundreds of pages in length—much less to determine which of those changes were substantive. The executive order requires rulemaking *agencies* to identify *for the public* the substantive changes made to draft rules "in a complete, clear, and simple manner." It does not place the responsibility on the public to identify changes made to agency rules. Also, simply providing copies of the rules as they entered

and exited OIRA does not necessarily identify changes made at OIRA's suggestion or recommendation.

- Finally, the Administrator indicated that he disagreed with our recommendation that OIRA encourage agencies to use "best practices" in disclosing changes made to their rules and said that OIRA would defer to the agencies on this issue (as it did during the previous administration). He also said OIRA expected that many of the differences in agencies' documentation practices that we identified should be eliminated by the administration's e-rulemaking initiative (which would consolidate each agency's public docket into a single governmentwide docket).[1] Our examination of agencies' rulemaking dockets during this review indicated that the documentation of changes made during OIRA's review was often confusing and, at times, totally absent. Also, section 2(b) of the executive order states "to the extent permitted by law, OMB shall provide guidance to agencies" and that OIRA "is the repository of expertise concerning regulatory issues, including methodologies and procedures that affect more than one agency." Therefore, we believe that OIRA has a responsibility under the executive order to instruct agencies regarding the order's transparency requirements (just as it has done with regard to other issues). Further, the consolidation of the agencies' dockets in the administration's e-rulemaking initiative will not address the deficiencies that we observed regarding the contents of some of those dockets. The confusing documentation (or the absence of documentation) will just be more accessible to the public.

Overall, we continue to believe that improvements can and should be made to improve the transparency of the OIRA review process. We recognize and applaud the improvements that the current Administrator has made in this area. However, the difficulties that we experienced during this review clearly demonstrated that OIRA's reviews are not always transparent to the public. Weaknesses were apparent regarding both the coverage and the implementation of the requirements placed on both OIRA and the rulemaking agencies. Our review also indicated that, when OIRA and the rulemaking agencies disclosed changes and communications beyond what

[1]For an examination of the first module of this initiative, see U.S. General Accounting Office, *Electronic Rulemaking: Efforts to Facilitate Public Participation Can Be Improved*, GAO-03-901 (Washington, D.C.: Sept. 17, 2003).

is currently required, those practices greatly enhanced our (and the public's) ability to understand how rules are made.

Objectives, Scope, and Methodology

This appendix presents more detailed information about our reporting objectives, the scope and methods used to address each of the objectives and subobjectives, and the most significant limitations of our findings and analyses.

Objectives

The general purpose of this engagement was to examine and report on how the Office of Management and Budget's Office of Information and Regulatory Affairs (OIRA) conducts its regulatory review function and the outcomes of those reviews. Specifically, we were asked to:

1. Describe OIRA's current regulatory review policies and processes and determine whether, and if so how, those policies and processes have changed in recent years.

2. Identify the rules issued by selected agencies that were reviewed by OIRA between July 1, 2001, and June 30, 2002, and that were either significantly changed at OIRA's direction, returned by OIRA for further consideration by the agencies, or withdrawn by the agencies at OIRA's suggestion. For each such rule, (a) describe the changes made by OIRA, the reasons why the rule was returned or withdrawn, and any subsequent activity regarding the rule, (b) describe, to the extent possible, the effects of the changes, returns, and withdrawals on the rule's original benefits and costs, and (c) determine whether there are any indications that the actions OIRA took were traceable to suggestions offered by regulated entities or outside parties and, if so, whether OIRA publicly disclosed their involvement.[1] We also examined OIRA's and the agencies' application of the transparency requirements in Executive Order 12866 and related guidance.

3. Describe how OIRA determined that certain existing rules listed in its reports to Congress on the costs and benefits of federal regulations merited high priority review. With regard to OIRA's 2001 report, our specific objectives were to determine (a) which organizations or persons suggested that the rules be reviewed, (b) what process OIRA used to select and prioritize the nominations, (c) the extent to which OIRA publicly disclosed its selection and priority-setting process, and (d) the current status of those rules. Another specific objective was to

[1]OIRA defines outside parties as "persons not employed by the executive branch."

compare that 2001 effort to the process OIRA used regarding a second round of nominations for OIRA's 2002 report.

Scope and Methodology

Objective 1

Under the first objective, our primary focus was on describing OIRA's regulatory review policies and processes in place as of June 2002 or later. To determine whether and to what extent those policies and processes have changed in recent years, we focused mainly on identifying changes that may have occurred since the previous administration. However, to provide additional context on the evolution of the OIRA review processes, we also identified the major changes that have occurred since OIRA began carrying out a regulatory review function in 1981.

To describe the policies and processes used by OIRA to conduct regulatory reviews, we reviewed relevant primary documents, such as executive orders, legislation, OMB guidance, and memoranda, speeches, and documents from the OIRA administrator describing aspects of the review process. We also reviewed other historical and secondary documents that provided background and context on the framework for OIRA's regulatory reviews. We interviewed current and former OIRA officials to provide additional information on the changes, if any, in the agency's regulatory review policies and processes. We supplemented the documentary and testimonial evidence obtained from OIRA with interviews and document reviews at selected regulatory agencies that are subject to OIRA's regulatory reviews.

For this objective, and the other two objectives, we also interviewed officials and staff from outside (nonfederal) groups representing public interest groups and regulated entities that are actively involved in observing and commenting on the federal regulatory process. Participants in these meetings included representatives of the American Bakers Association, American Road and Transportation Builders Association, Center for Regulatory Effectiveness, Exxon/Mobil, Mercatus Center, National Association of Home Builders, National Association of Manufacturers, National Federation of Independent Business Research Foundation, Natural Resources Defense Council, National Roofing

Contractors Association, OMB Watch, Public Citizen, and United States Chamber of Commerce.

Objective 2

With regard to the second objective, we used OIRA's Executive Order Review database to identify the draft regulatory actions that agencies had submitted for OIRA's review during the 1-year time period (July 1, 2001, through June 30, 2002) specified in the congressional request. Because a given draft regulatory action could have been submitted for OIRA's review more than once before final publication or disposition, our unit of analysis was each separate submission to OIRA, which is what OIRA's database reflects, rather than each rule. However, to simplify reporting, we refer to these submissions as rules in this report.

Out of the total of 642 draft items submitted for OIRA's review during the 1-year time period, we identified 393 draft rules from 81 agencies and offices for which OIRA's database had coded the outcome of the review as "returned," "withdrawn," or "consistent with change." Because we could not devote the time and resources that would have been necessary to search dockets for all of these rules at all of the agencies, we limited our efforts to selected rules and agencies, focusing on the agencies with the largest numbers of affected rules, as discussed and agreed to in consultation with the requesters. Specifically, we agreed to focus our efforts on the rules submitted for OIRA regulatory reviews that met the following criteria:

- The submission to OIRA was a draft health, safety, or environmental rule.
- The rule was submitted to OIRA as a proposed, interim final, or final rule (i.e., we did not include other items, such as prerules and white papers, that agencies also sometimes submitted for OIRA's review).
- OIRA completed its review of the rule between July 1, 2001, and June 30, 2002.
- The rule was returned to the rulemaking agency by OIRA, withdrawn from OIRA's review by the agency, or changed after its submission to OIRA.

- The rule was from an agency or subagency that OIRA's Executive Order Review database indicated had five or more rules returned, withdrawn, or changed during the time period in scope for this objective.

We identified 85 draft regulatory actions that met these criteria. The 85 rules were submitted for OIRA's review from nine agencies—the Animal Plant and Health Inspection Service (APHIS), the Food and Drug Administration (FDA), the Occupational Safety and Health Administration (OSHA), the Department of Transportation's (DOT) Federal Aviation Administration (FAA), Federal Motor Carrier Safety Administration (FMCSA), and National Highway Traffic Safety Administration (NHTSA), and the Environmental Protection Agency's (EPA) Office of Air and Radiation, Office of Solid Waste and Emergency Response, and Office of Water. We generally did not question the rule dispositions used in the OIRA database. However, we included one rule from EPA's Office of Air and Radiation in the "consistent with change" category that had been coded as a "deadline case" in the database because publicly available information indicated that the rule had been changed in response to OIRA's review.[2] It is unclear whether other rules with "deadline case" outcome codes in the database were also changed by OIRA, or why other rules that we reviewed with statutory or legal deadlines were not coded as deadline cases.[3] We also dropped one rule from EPA's Office of Solid Waste and Emergency Response that had a "consistent with change" outcome code in OIRA's database because it had not been published in the *Federal Register* at the time of our review. (See app. II for information on each of the selected submissions.)

We were asked to address three specific topics regarding the selected rules: (1) the nature of the changes attributed to OIRA or the reasons that rules were withdrawn or returned at OIRA's initiation, (2) the effect of OIRA's actions on the costs and/or benefits of the rules, and (3) contact with OIRA by external parties regarding these rules. Because Executive Order 12866 also imposes certain documentation requirements on agencies and OIRA regarding OIRA's regulatory review process, we also addressed compliance with those requirements as a fourth part of our analysis of the 85 rules.

[2]See, for example, Arthur Allen, "Where the Snowmobiles Roam," *Washington Post Magazine* (Aug. 18, 2002).

[3]OIRA's database has a separate field, separate from the field on reviews' outcomes, that identifies submissions with legal deadlines. Twenty-two of the 85 rules that we reviewed were coded in OIRA's database as having a statutory or judicial deadline.

In general, to address these four areas we reviewed the available documents in both agency and OIRA rule dockets. We also interviewed officials at the agencies and OIRA to obtain information about the regulatory review process for the individual rules included in our scope. We then used an iterative process to develop summary findings and determinations on each rule. Multiple reviewers from our team independently examined and coded the information and materials that had been collected. We then held a series of meetings to discuss and reach consensus on the coding and description of results for each rule. We vetted these preliminary results with OIRA and the agencies to address outstanding questions and obtain their feedback on the accuracy of our findings and determinations. We incorporated their comments as appropriate before developing our official draft report for formal agency comments. The analysis and coding process for each of the four areas also had some unique aspects, as described below.

Nature and significance of OIRA's effects on rules

The review outcome categories used in the OIRA database are broader than the specific types of rules targeted by our second objective—those that were *significantly* affected by OIRA. Therefore, we had to gather additional information on each of the 71 changed, 9 returned, and 5 withdrawn rules to determine which ones had been significantly affected by OIRA and, therefore, met our more specific criteria.

First, we used a variety of information sources (e.g., agency and OIRA docket materials and interviews with agency officials) to place each of the 71 rules that had been changed after submission to OIRA into one of three categories, based on the most significant changes attributed to either OIRA or OMB.[4] Our three coding categories were:

1. *Significant changes*—This category included rules in which the most significant changes attributed to OIRA or OMB affected the scope, impact, or estimated costs and benefits of the rules as originally submitted to OIRA. Usually, these significant changes were made to the regulatory language that would ultimately appear in the *Code of Federal Regulations*.

[4]The agencies sometimes attributed changes to OMB and sometimes specifically to OIRA. In a few instances, OMB staff outside of OIRA suggested the changes. There were also rules in which the regulatory agencies initiated more significant changes during the period of OIRA's review than did OIRA.

2. *Other material changes*—This category covered rules in which the most significant changes attributed to OIRA or OMB resulted in the addition or deletion of material in the explanatory preamble section of the rule. For example, OIRA may have recommended that agencies provide better explanations for certain rulemaking actions and/or suggested that agencies ask the public to comment on particular aspects of the rules.

3. *Minor or no OIRA/OMB changes*—We used this category to identify rules in which the most significant changes attributed to OIRA's or OMB's suggestions resulted in editorial or other minor revisions, or rules in which changes occurred prior to publication but not at the suggestion of OIRA or OMB. Where no OIRA/OMB changes were made, the changes that caused the rule to be coded "consistent with change" in OIRA's database could have been initiated by the regulatory agency itself or by another federal agency (e.g., the Office of the Federal Register). Because the executive order does not require agencies to document nonsubstantive changes, three of the rules we included in this category were ones in which it was clear that all the changes were minor, but the source of the changes (i.e., whether they were made at the suggestion of OIRA/OMB) could not be identified.

Identifying returned rules significantly affected by OIRA and OIRA's rationale for the returns was more straightforward. When OIRA returns a rule to an agency for reconsideration, section 6(b)(3) of Executive Order 12866 requires the OIRA Administrator to provide the issuing agency with a written explanation delineating the pertinent section of the order on which OIRA is relying. OIRA has posted copies of its return letters, including those relevant to rules within the scope of our engagement, on the OMB Web site. OIRA identified other rules that were returned for nonsubstantive reasons as "improper submissions" in its database.

There are no documentation requirements on agencies or OIRA covering withdrawn rules, so we relied primarily on testimonial evidence from agency officials to determine whether OIRA, rather than the submitting agency, had initiated the withdrawal. In one case, however, a withdrawn rule from FAA that was subsequently resubmitted to OIRA and published, the agency docket included a written chronology for the rulemaking process that attributed the withdrawal to OIRA's action.

Effect of OIRA's reviews on costs and benefits

We considered two types of actions attributed to OIRA or OMB as potential evidence that OIRA directly affected the costs and/or benefits of the rule

compared to those expected under the draft version of the rule submitted for OIRA's review. These were when (1) OIRA or OMB suggested changes to a draft rule's regulatory text that could reasonably be expected to affect the potential costs and/or benefits of the regulations (e.g., changing the proposed federal share of an indemnity payment) and (2) OIRA specifically commented on and requested changes in the agencies' analyses of the economic impacts of the draft regulations. With regard to the first type of action, we believed that it was reasonable to assume that OIRA-suggested elimination or delay of certain regulatory provisions in the text of draft rules as submitted to OIRA would also eliminate or delay the expected costs and/or benefits associated with those provisions. We also identified and reported on other changes suggested by OIRA that, while not directly affecting regulatory provisions or cost-benefit estimates, otherwise revised, clarified, or requested comments on issues relevant to the agencies' discussion of potential costs and/or benefits of a rule. We consulted with our Chief Economist in making our determinations and describing the potential effects of OIRA's actions.

Evidence of outside contacts regarding rules under OIRA review

Another part of this objective was to determine whether there was any evidence that the actions that OIRA took (e.g., to suggest significant changes to rules or to return them to the agencies for reconsideration) were traceable to suggestions offered by regulated entities or other parties outside of the federal government. It is not possible to independently determine what motivated OIRA's actions with regard to any of the rules that it reviewed. However, as part of our review, we checked whether OIRA had direct contact with such outside parties regarding rules that OIRA significantly affected. We defined "direct contact" as taking the form of either oral communications with OIRA (meetings or phone calls) or written communications (correspondence) sent directly to OIRA officials before or during the period of OIRA's review. In some OIRA files, we found evidence that OIRA had reviewed copies of substantive comments on previous versions of the draft rule currently under review. Because these were public docket materials previously submitted to the regulatory agencies, not OIRA, we did not consider them as evidence of direct contact with OIRA by outside parties. If there was evidence that outside parties had contacted OIRA, we also examined whether there were similarities between the actions that OIRA suggested or recommended to the agencies and those advocated to OIRA by external parties through those direct contacts.

Transparency of agencies' and OIRA's documentation of reviews

Our primary focus with regard to agencies' compliance with documentation requirements of Executive Order 12866 was on determining

whether the agencies had publicly documented changes made in rules between submission for OIRA's review and publication in the *Federal Register*. Section 6(a)(3)(E)(ii) of the order states that agencies must "identify for the public, in a complete, clear, and simple manner, the substantive changes between the draft submitted to OIRA for review and the action subsequently announced." However, neither the executive order nor OIRA's October 1993 guidance on its implementation defines what the term "substantive changes" means. Section 6(a)(3)(E)(iii) of the order requires agencies to "identify for the public those changes in the regulatory action that were made at the suggestion or recommendation of OIRA." OIRA's October 1993 guidance on the implementation of the order considers the second requirement to be a subset of the first. Therefore, under this interpretation, the agencies are only required to disclose the changes made at OIRA's suggestion or recommendation after formal submission of the rule to OIRA—not during any informal review period that precedes formal submission.

To determine agencies' compliance with these documentation requirements, we considered the required information to have been "identified for the public" if it was available in the agencies' public docket for the relevant rule. We coded the level of documentation in the agencies' dockets for each changed rule into one of four categories, reflecting whether (1) all changes were clearly documented, (2) changes were identified but it was not clear that all changes had been documented or at whose initiative, (3) no changes were documented in the public docket, or (4) the Executive Order 12866 documentation requirements were not applicable.[5] The first requirement is not applicable when there were no changes made to the rule during OIRA's review that the agencies considered "substantive." Even if there were substantive changes made during OIRA's review, the second requirement is not applicable if those changes were not made at the suggestion or recommendation of *OIRA*. We made our determinations regarding agencies' compliance with these requirements solely on the basis of the information that would be available to a member of the public if he/she had reviewed the docket for a given rule.[6] Further, because the executive order places responsibility to document changes on the agencies rather than OIRA, our determinations only reflect material available in the regulatory agencies' dockets, not

[5] We conducted a similar exercise in our previous GAO report on this subject. See GAO/GGD-98-31.

materials in OIRA's public files.[7] However, we did use information from the OIRA files to identify rule changes that agencies should have documented.

Our primary focus with regard to OIRA's compliance with documentation requirements was to see if (1) when returning rules to agencies for reconsideration, the OIRA Administrator provided the issuing agency with a written explanation delineating the pertinent section of the order on which OIRA relied in returning the rule, as required by section 6(b)(3) of the executive order, and (2) OIRA had documented written and oral communications with outside parties regarding rules under review by OIRA, as required by section 6(b)(4) of the order. To address the first item, we confirmed that OIRA had prepared a return letter for each of the rules it returned to agencies for reconsideration of substantive issues. To address the second item, we reviewed OIRA's docket files, meeting logs (both the paper-based and on-line versions), and phone logs. We also checked other potential sources of information on contacts with outside parties regarding the 85 rules, especially the agencies' regulatory docket files on these rules.

Objective 3

Our work to address the third objective focused on the particular rules, and OIRA's processes for selecting and ranking those rules, identified for high priority review in the 2001 and 2002 versions of OMB's annual report to Congress on the costs and benefits of federal regulations. In order to address the third objective, we reviewed any available documentation describing the process that OIRA used to select certain rules for high priority review. We also interviewed OIRA officials and officials in other relevant agencies and organizations to determine how the classifications were made, and reasons why the particular selected rules were designated as high priority.

[6] In many cases, the agencies prepared supplementary memos or summaries for us that provided additional information and explanations regarding the changes made in various rules. In those cases, we used the supplementary information to address other elements of our review—such as the nature of changes attributed to OIRA—but did not consider the materials specifically prepared for our review to be public documents within the dockets.

[7]It is notable that these dockets sometimes contained information that the agencies were not technically required to disclose—and that information frequently provided valuable insights to our determinations regarding the gravity of OIRA's changes. For example, the agencies sometimes disclosed changes that were not "substantive," and sometimes disclosed changes that OIRA made to rules before they were formally submitted to OIRA.

Limitations

The most important limitations to our engagement were related to the second objective. In particular:

- Our analysis of individual rules submitted for OIRA's review was limited to the 85 rules and 9 agencies or offices that met specific selection criteria. We did not review all 393 rules from all 81 agencies or offices that OIRA's database indicated had rules changed, returned, or withdrawn during the 1-year period from July 1, 2001, through June 30, 2002.

- Some types of OIRA's influence on rules may not be reflected in the documentation we relied on in this review. For example, DOT officials told us in 1996 that they will not even propose certain regulatory provisions because they know that OIRA will not find them acceptable. Also, the documentation that we reviewed generally did not reflect the OIRA-suggested changes that were not adopted by the agencies.

- We cannot be sure that we have identified all changes to the selected rules that were made at the suggestion or recommendation of OIRA (e.g., changes made as a result of informal OIRA reviews that were not documented). Neither can we be sure to have identified all the effects of such changes on the rules or all instances in which an external party may have influenced OIRA's actions.

- Given the available documentation, we were not able to clearly attribute all changes or actions taken regarding the selected rules to OIRA or to the actions or influence of outside parties. We cannot attribute any cause-effect relationships in those instances where both OIRA's comments or changes regarding a particular rule and the suggestions of an external party on that same rule were similar. Likewise, any identified changes in the benefits and costs of selected rules after OIRA's reviews may not be attributable in whole or in part to changes made at OIRA's suggestion.

- Characterizing the nature of changes made to the rules, particularly the extent to which they are "significant," is inherently subjective. We attempted to mitigate this limitation by (1) establishing criteria to generally categorize the nature of changes, (2) using multiple reviewers for each rule, and (3) obtaining views of agency and OIRA officials on whether we had accurately identified and characterized the nature of OIRA's effect on each rule.

- Our knowledge of OIRA contacts by outside parties, such meetings or correspondence, was generally limited to what OIRA or the agencies disclosed in their files. Although in one case we found documented evidence of such contact through materials posted by a trade group—evidence that did not appear in either the OIRA or agency files—we do not know whether there were other meetings with outside parties or other letters from those parties about rules in our review that did not come to our attention.

Summary Information on Selected Rules Submitted to OIRA for Executive Order Review between July 2001 and June 2002

This appendix contains three tables that summarize GAO's findings and determinations regarding 85 health, safety, or environmental rules submitted for OIRA's review by nine selected agencies (APHIS, FDA, OSHA, DOT-FAA, DOT-FMCSA, DOT-NHTSA, EPA-Office of Air and Radiation, EPA-Office of Solid Waste and Emergency Response, and EPA-Office of Water) that we examined to address our second reporting objective. The three tables present information on, respectively, rules that were changed after being submitted for OIRA's review (table 7), rules that OIRA returned to the agencies (table 8), and rules that were withdrawn after having been submitted for OIRA's review (table 9).

Explanation of Table Contents

The following paragraphs identify the analytical contents of each table and provide definitions of the codes we used. In general, for each analytical category, we used a process of separate coding by each GAO team member, followed by a discussion to reconcile any differences and reach consensus on the most appropriate code. We then shared our preliminary findings and determinations with OIRA and the regulatory agencies to obtain a "fact check" on the descriptive information and also solicited their comments or clarifications regarding our coding determinations.

Table 7: Summary of Findings and Determinations for Changed Rules

- *GAO ID* – This column provides a unique GAO case identification number for each executive order submission to OIRA that we reviewed to address our second reporting objective. Note that our unit of analysis was the submission of a draft regulation for OIRA's review, not the rule itself. Therefore, a given draft regulation could have been submitted to OIRA more than once with more than one outcome. In such cases, each separate submission that fell within the scope of our review would appear under a different GAO ID.

- *Executive order review submission* – This column provides general information about the draft regulation submitted for OIRA's review. As noted above, our unit of analysis was the submission to OIRA, so the titles presented here are those that appear in OIRA's data base on the submissions it has received, not the titles of the rules as published in the *Federal Register*. We also identify the draft rule's Regulation Identifier Number (RIN),[1] its type (proposed, final, or interim final rule), the time

period for OIRA's formal review of the rule, and when and where the cleared version of the rule was published in the *Federal Register*.[2]

- *Nature of OMB/OIRA changes* – This column represents GAO's interpretation of the nature of the changes suggested by OMB or OIRA, in particular whether the changes made to the rule in response to OMB or OIRA significantly affected the draft rule. We used any available information to categorize and describe the changes attributed to OMB or OIRA (e.g., agency docket materials, OIRA files, interviews with agency officials, and any memos or e-mails on the changes that agency officials specifically prepared to address this GAO engagement). We characterized the nature of the changes for each of the changed rules using three categories, with a code assigned to each rule *for the most significant level of change observed*. The three categories were:

1. Significant changes – We used this category for rules in which changes attributed to OMB or OIRA resulted in a revision to the scope, impact, or estimated costs and benefits of the rule compared to the draft version originally submitted to OIRA. Most often, these were rules in which changes were made to the regulatory language of the draft regulation (i.e., amendments to the *Code of Federal Regulations*).

2. Other material changes – We used this category for changes that did not have as significant an effect as "significant changes," but did result in adding or deleting material to the original text. Most often, these changes were in the preambles of the rules, rather than the regulatory text, and involved clarifying an agency's explanation of certain provisions in the rule, clarifying the agency's basis for decisions made about regulatory options or assumptions, better explaining the potential impact of different options, and requesting public comments and/or data on regulatory options or costs.

[1] The RIN is assigned by the Regulatory Information Service Center to identify each rulemaking cycle listed in *The Regulatory Plan* and the Unified Agenda of federal agencies, as directed by Executive Order 12866. Also, OMB has asked agencies to include RINs in the headings of their Rule and Proposed Rule documents when publishing them in the *Federal Register* to make it easier for the public and agency officials to track the publication history of regulatory actions throughout their development.

[2] In addition to the date of publication, we provide the location of the published rule using the *Federal Register's* standard format (e.g., 66 FR 55530 indicates that the rule was published starting on page 55530 of volume 66).

3. Minor editorial changes or no OMB or OIRA changes – This category was used both for rules with changes that, at best, represented editorial corrections and revisions (e.g., rearranging existing text, correcting spelling, word choice changes, and adding or correcting boilerplate language, such as where to submit comments) and rules in which no changes were made at the suggestion or recommendation of OMB or OIRA.

- *Evidence that OMB/OIRA changes affected the potential costs or benefits of the submitted rule* – We usually only assigned a "yes" code under this topic if documentation of OMB or OIRA changes to a rule specifically showed that cost-benefit, cost-effectiveness, Paperwork Reduction Act burden estimates, or similar information on regulatory impacts had been edited or changed at the suggestion of OMB or OIRA. However, in the case of rules with substantive changes (additions or deletions) in the regulatory language, we assumed that adding or deleting entire provisions would have at least some effect on the potential costs or benefits of the rule, compared to the draft version submitted to OIRA.

- *Evidence that outside parties contacted or met with OMB/OIRA regarding the submitted rule* – A "yes" code under this topic indicates that we found documentation that an outside (nonfederal government) party or parties had directly contacted OMB or OIRA regarding a particular rule before or during OIRA's formal review period for that rule. Direct contacts were either through a meeting or correspondence.[3] Most often, this evidence came from OIRA's files and logs, but sometimes the documentation came from a regulatory agency's docket on that rule.

Table 8: Summary of Findings and Determinations for Returned Rules

- *GAO ID and Executive Order Review Submission* – (Columns as described under table 7, except that information about the publication of the rule, if applicable, appears under a separate column on subsequent activity.)

[3]We also checked OIRA's phone logs regarding calls related to Executive Order 12866 reviews, but found no evidence of such calls before or during OIRA's formal review periods of the rules within our scope.

- *Reason for OIRA's return of the rule* – For each rule, we summarized the information presented in OIRA's return letter or, for the "improper" submissions with no return letters, cited the classification from OIRA's regulatory review database. In some cases, we supplemented these descriptions with additional information provided by regulatory agency officials.

- *Evidence that outside parties contacted or met with OIRA regarding this submission* – (As described under table 7.)

- *Evidence of subsequent activity regarding this submission* – Our focus under this topic was identifying information regarding resubmission and publication of the rule after OIRA had returned it. If an agency provided information that the rule has not yet been resubmitted and/or published, we also report that.

Table 9: Summary of Findings and Determinations for Withdrawn Rules

- *GAO ID and Executive Order Review Submission* – (As described under table 7, except that information about the publication of the rule, if applicable, appears under a separate column on subsequent activity.)

- *Reasons for withdrawal of the submitted rule* – For each rule, we report the explanation provided by the regulatory agency and/or OIRA regarding the withdrawal of the rule. Our primary focus under this item, per our congressional request, was on identifying whether the rule had been withdrawn at the suggestion of OIRA.

- *Evidence that outside parties contacted or met with OIRA regarding this submission* – (As described under table 7.)

- *Evidence of subsequent activity regarding this submission* – (As described under table 8.)

Table 7: Findings and Determinations for Rules Changed after Submission to OIRA

GAO ID	Executive order review submission	Nature of most significant OMB/OIRA changes	Evidence that OMB/OIRA changes affected costs or benefits	Evidence that outside parties contacted OMB/OIRA
APHIS				
1	Mexican Hass Avocado Import Program Proposed rule RIN 0579-AB27 OIRA review period: 06/13/2001 to 07/05/2001 Published 07/13/2001 (66 FR 36892)	Other material changes Information was added to the preamble regarding several topics—e.g., a previous amendment to Hass avocado regulations, an APHIS review of the Hass avocado import program, a study on fruit flies, responses to commenter concerns, and a new section summarizing the regulatory impact analysis. Also, there were minor rewording changes throughout. An APHIS official characterized most OIRA changes to the rule as minor editorial comments but said that other changes strengthened the agency's explanation for the rule. There were no substantive changes to the regulatory language.	No	No
2	Karnal Bunt; Compensation for the 1999-2000 and Subsequent Crop Seasons Final rule RIN 0579-AA83 OIRA review period: 07/26/2001 to 07/31/2001 Published 08/06/2001 (66 FR 40839)	Minor editoral changes or no changes Changes were limited to minor clarifications and a sentence change in the Paperwork Reduction Act section in the preamble. There were no changes in the regulatory language.	No	No

(Continued From Previous Page)

GAO ID	Executive order review submission	Nature of most significant OMB/OIRA changes	Evidence that OMB/OIRA changes affected costs or benefits	Evidence that outside parties contacted OMB/OIRA
3	Importation Prohibitions Because of Bovine Spongiform Encephalopathy (BSE) Interim final rule RIN 0579-AB26 OIRA review period: 04/18/2001 to 07/27/2001 Published 08/14/2001 (66 FR 42595)	Other material changes A section was added to the preamble noting that APHIS would obtain BSE risk factor data from trading partners and, if significant risk was indicated, APHIS would take action to restrict animal product imports from the risky areas.	No	No
4	Scrapie in Sheep and Goats; Interstate Movement Restrictions and Indemnity Program (Listed in OIRA's database as: Interstate Movement of Sheep and Goats From States That Do Not Quarantine Scrapie-Infected and Source Flocks) Final rule RIN 0579-AA90 OIRA review period: 04/18/2001 to 08/07/2001 Published 08/21/2001 (66 FR 43964)	Other material changes OMB suggested several changes to the preamble that added or clarified descriptions of issues such as (a) the increase in paperwork burden caused by this rule, (b) how to calculate animal and human health risks associated with scrapie, and (c) how to estimate the effectiveness of indemnity as an incentive. OMB also suggested that APHIS clarify how much of the rule's activities could be funded from currently projected agency budgets and how much would require additional funds. According to APHIS, these additional discussions caused no significant changes to the scope of the rule or the benefits it provided. The regulatory language was not changed.	No	No

(Continued From Previous Page)

GAO ID	Executive order review submission	Nature of most significant OMB/OIRA changes	Evidence that OMB/OIRA changes affected costs or benefits	Evidence that outside parties contacted OMB/OIRA
5	Phytosanitary Certificates for Imported Fruits and Vegetables Proposed rule RIN 0579-AB18 OIRA review period: 03/21/2001 to 08/15/2001 Published 08/29/2001 (66 FR 45637)	Other material changes In a memo prepared for GAO, APHIS identified eight specific changes that OMB requested, all in the preamble. These changes mainly provided more specific information, additional examples, and expanded discussions about the economic impacts of this rule.	No The actual costs and benefits did not appear to change as a result of the revisions made at the request of OMB, but the revisions did provide more information on and support for APHIS' analysis of the economic impacts of the rule.	No
6	Plant Pest Regulations; Update of Current Provisions Proposed rule RIN 0579-AA80 OIRA review period: 03/21/2001 to 09/26/2001 Published 10/09/2001 (66 FR 51340)	Other material changes APHIS identified five main changes that OMB requested to the preamble of the rule, such as adding explanations and soliciting comments and alternatives on certain issues, all focused on improving the clarity of the rule. There were no changes to the regulatory language.	No Although the paperwork burden estimates were revised downward in the final version, there is no indication that OIRA was the source of the revisions.	No
7	Mexican Hass Avocado Import Program Final rule RIN 0579-AB27 OIRA review period: 10/23/2001 to 10/29/2001 Published 11/01/2001 (66 FR 55530)	Other material changes Numerous changes were made to the preamble of the rule, especially regarding responses to public comments on the proposed rule and explanations of the agency's actions. APHIS characterized these as changes to make the final rule "more defensible and internally consistent." There were no changes to the regulatory language.	No	No However, OIRA focused many of its comments on suggesting revisions or expansions of the APHIS responses to public comments on the proposed rule, and the OIRA docket included copies of adverse comments submitted on the proposed rule.

(Continued From Previous Page)

GAO ID	Executive order review submission	Nature of most significant OMB/OIRA changes	Evidence that OMB/OIRA changes affected costs or benefits	Evidence that outside parties contacted OMB/OIRA
8	Interstate Movement of Swine Within a Production System Final rule RIN 0579-AB28 OIRA review period: 09/25/2001 to 12/11/2001 Published 12/20/2001 (66 FR 65598)	Other material changes There were inserts in the Federalism and Paperwork Reduction Act sections of the preamble. Inserts in the Paperwork Reduction Act section added information about changes made from proposed rule in terms of paperwork and information collection requirements.	No	No
9	Chronic Wasting Disease in Cervids; Payment of Indemnity (Listed in OIRA's database as: Chronic Wasting Disease in Elk; Interstate Movement Restrictions and Payment of Indemnity) Interim final rule RIN 0579-AB35 OIRA review period: 01/07/2002 to 02/04/2002 Published 02/08/2002 (67 FR 5925)	Significant changes The most significant change made at the suggestion of OMB affected the cost-sharing formula, limiting the federal indemnity payment to 95 percent. Other changes made in response to OMB were related to cost, benefit, and risk data. Both the preamble and the CFR section of the rule were affected by OMB-suggested changes.	Yes OMB changed the 100-percent reimbursement that APHIS had proposed for the indemnity to be 95 percent. OMB also asked APHIS to avoid citing the possible avoidance of a human disease caused by chronic wasting disease as a benefit of this rule because this possibility was considered remote by a Harvard risk analysis.	No

(Continued From Previous Page)

GAO ID	Executive order review submission	Nature of most significant OMB/OIRA changes	Evidence that OMB/OIRA changes affected costs or benefits	Evidence that outside parties contacted OMB/OIRA
10	Animals Destroyed Because of Tuberculosis; Payment of Indemnity Interim final rule RIN 0579-AB29 OIRA review period: 11/13/2001 to 02/11/2002 Published 02/20/2002 (67 FR 7583)	Other material changes Changes were made to the preamble for clarification, particularly regarding APHIS's cost-sharing policy. However, no changes were made to the regulatory language in the CFR amendments section of the rule.	No	No
11	Infectious Salmon Anemia; Payment of Indemnity Interim final rule RIN 0579-AB37 OIRA review period: 03/08/2002 to 04/02/2002 Published 04/11/2002 (67 FR 17605)	Other material changes OMB requested changes related to future (post-2002) funding for the infectious salmon anemia indemnity and a control and eradication program (e.g., clarifying that the administration was examining how the costs of program activities, including the payment of indemnity, are shared among the federal government and others and, therefore, that in the future the indemnity rate provided under this rule might change). OMB further requested that APHIS make clear that all potential indemnity payments were subject to the availability of funding. (An APHIS official also noted that, before the formal review period for this action, OIRA and APHIS agreed to make the federal share of the indemnity 60 percent. Whether this share is any different from what would have been stated in the rule without OIRA's input is not known.)	Unclear The preamble changes suggest that indemnity rates and program funding in a second indemnity/program year might change.	No

(Continued From Previous Page)

GAO ID	Executive order review submission	Nature of most significant OMB/OIRA changes	Evidence that OMB/OIRA changes affected costs or benefits	Evidence that outside parties contacted OMB/OIRA
12	Foot-and-Mouth Disease; Payment of Indemnity (Listed in OIRA's database as: Foot-and-Mouth Disease, Pleuropneumonia, Rinderpest, and Certain Other Communicable Diseases of Livestock or Poultry; Payment of Indemnity) Proposed rule RIN 0579-AB34 OIRA review period: 01/17/2002 to 04/16/2002 Published 05/01/2002 (67 FR 21934)	Significant changes The most substantive changes attributed to OMB affected the regulatory language in the *Code of Federal Regulations* (CFR) amendments section—specifically, eliminating language in the original version of the rule that would have provided compensation for care and feeding of "official vaccinates" (livestock vaccinated as part of a foot-and-mouth eradication program) and compensation "relating to cleaning and disinfecting non-susceptible animals." OMB suggested other changes in the preamble that generally provided additional justifications for the rule and added explanations in the Regulatory Flexibility Act and Executive Order 12866 sections. OMB also requested substantial changes to the economic analysis and APHIS's approach in evaluating the proposed rule's impact.	Yes APHIS made substantial changes to the economic analysis in response to OIRA's suggestion. Further, limiting compensation by not covering the care and feeding of official vaccinates or the cleaning and disinfection of non-susceptible animals lowered the potential costs to the government of the indemnity program. However, according to an APHIS official (and as explained in the preamble of the proposed rule), removing these compensation provisions could impede eradication efforts and, thus, reduce overall benefits to society. This is because official vaccinates may be used as a "fire wall" to prevent the spread of the disease beyond infected animals, and owners would not be compensated for the costs of maintaining the vaccinated animals for the time that might be necessary, and because non-susceptible animals could spread foot-and-mouth disease even if they cannot themselves become infected.	No

(Continued From Previous Page)

GAO ID	Executive order review submission	Nature of most significant OMB/OIRA changes	Evidence that OMB/OIRA changes affected costs or benefits	Evidence that outside parties contacted OMB/OIRA
FDA				
13	Exports; Notification and Recordkeeping Requirements Final rule RIN 0910-AB16 OIRA review period: 08/28/2001 to 11/27/2001 Published 12/19/2001 (66 FR 65429)	Other material changes Some of the OMB-suggested changes in the preamble added or revised information to clarify FDA's responses to public comments on the proposed rule. There were no changes to the regulatory language in the CFR section of the rule.	No	No
14	Additional Criteria and Procedures for Classifying Over-the-Counter Drugs as Generally Recognized as Safe and Effective and Not Misbranded Final rule RIN 0910-AA01 OIRA review period: 09/27/2001 to 12/21/2001 Published 01/23/2002 (67 FR 3060)	Other material changes Most changes were minor editorial revisions in the preamble, but some more substantive changes included (a) repeating information from the analysis of impacts section at the end of the rule on page 2, (b) inserting clarifying material about the General Agreement on Tariffs and Trade and the World Trade Organization to a response to comments on the proposed rule, and (c) inserting a sentence to note that, over the next several years, FDA expects to be able to accept electronic submissions. There were no changes in the regulatory language of the CFR section.	No	No

(Continued From Previous Page)

GAO ID	Executive order review submission	Nature of most significant OMB/OIRA changes	Evidence that OMB/OIRA changes affected costs or benefits	Evidence that outside parties contacted OMB/OIRA
15	Records and Reports Concerning Experience with Approved New Animal Drugs; Interim Final Rule (Listed in OIRA's database at time of GAO's review as: New Animal Drug Approval Process; Implementation of Title I of the Generic Animal Drug and Patent Term Restoration Act (GADPTRA)) Interim final rule RIN 0910-AA02 OIRA review period: 11/29/2001 to 01/08/2002 Published 02/04/2002 (67 FR 5046)	Other material changes Some of the changes to the preamble that were attributed to OMB added new clarifying information or examples to the original text. OMB also revised some of the text on the estimated reporting and recordkeeping burdens, specifically characterizing two sections of the rule as posing new information collection requirements over the existing requirements. The changes attributed to OMB in the regulatory language of the CFR section appeared to be mainly editorial in nature, although the language in one provision on reporting requirements was changed from "must" to "should." (Note: this rule was previously withdrawn. See GAO ID 82.)	Unclear Updated information on the estimated reporting and recordkeeping burdens was included in the revised version of the rule (replacing data from 1999 fiscal year submission reports with data from 2000 fiscal year reports), but the source of this change is not clear in the documentation. FDA, rather than OIRA, might have initiated this change.	No
16	Requirements for Submission of Labeling for Human Prescription Drugs and Biologics in Electronic Format Proposed rule RIN 0910-AB91 OIRA review period: 12/14/2001 to 03/05/2002 Published 05/03/2002 (67 FR 22367)	Other material changes The changes made in response to OIRA included (a) how electronic signatures would be handled and how this would be described in the rule and (b) the treatment and description of the onetime capital costs associated with the reporting burden for this rule. There were also some clarifying changes to the proposed regulatory language in the CFR section.	No Although the OIRA changes affected the categorization and description of the costs of this rule—identifying them as onetime capital costs associated with the reporting burdens of this proposal, where FDA's original text had said there were no capital costs associated with this information collection—this re-categorization did not change FDA's estimate of total costs.	No

(Continued From Previous Page)

GAO ID	Executive order review submission	Nature of most significant OMB/OIRA changes	Evidence that OMB/OIRA changes affected costs or benefits	Evidence that outside parties contacted OMB/OIRA
17	Food Additives: Food Contact Substances Notification System Final rule RIN 0910-AB94 OIRA review period: 02/19/2002 to 05/14/2002 Published 05/21/2002 (67 FR 35724)	Minor editoral changes or no changes Only a few minor changes were attributed to OMB, such as rewording an introductory paragraph regarding comments received on the proposed rule and inserting one sentence in an illustration of how FDA expected its review of notifications to proceed in the future. The Executive Order 12866 statement in the rule was also revised to note that it was a significant regulatory action that was reviewed by OMB, rather than the original statement that it was not. All of these changes were in the preamble; OMB requested no changes in the regulatory language. (However, a substantive FDA change is reflected in the documentation.)	No	No
18	Efficacy Evidence Needed for Products To Be Used Against Toxic Substances When Human Studies Are Unethical or Unfeasible Final rule RIN 0910-AC05 OIRA review period: 03/07/2002 to 05/21/2002 Published 05/31/2002 (67 FR 37988)	Other material changes Additional material was inserted in the preamble to better explain the legal authority and rationale for taking this regulatory action. Other changes were made to FDA's response to some public comments on the proposed version of this rule. However, no changes were made to the regulatory language.	No	No

(Continued From Previous Page)

GAO ID	Executive order review submission	Nature of most significant OMB/OIRA changes	Evidence that OMB/OIRA changes affected costs or benefits	Evidence that outside parties contacted OMB/OIRA
19	Investigational New Drugs; Export Requirements for Unapproved New Drug Products Proposed rule RIN 0910-AA61 OIRA review period: 03/07/2002 to 05/29/2002 Published 06/19/2002 (67 FR 41642)	Other material changes The only changes attributed to OMB were (a) expanding the citations of relevant legal authority in the background section of the preamble and (b) updating references to a previous *Federal Register* notice with a related record keeping requirement—and noting that this particular rule, therefore, would not contain any new record keeping requirements. There were no changes at OMB's request in the regulatory language.	No	No
OSHA				
20	Occupational Injury and Illness Recording and Reporting Requirements Final rule RIN 1218-AC00 OIRA review period: 09/24/2001 to 10/04/2001 Published 10/12/2001 (66 FR 52031)	Minor editoral changes or no changes OIRA did not suggest or recommend any substantive changes to this rule. (However, OSHA initiated a substantive change to delay the effective date of Section 1904.29(b)(7)(vi), and new language was included in the preamble and regulatory text to accomplish this change.)	No No changes were suggested by OIRA.	No

(Continued From Previous Page)

GAO ID	Executive order review submission	Nature of most significant OMB/OIRA changes	Evidence that OMB/OIRA changes affected costs or benefits	Evidence that outside parties contacted OMB/OIRA
21	Procedures for Handling of Discrimination Complaints Under Section 519 of the Wendal H. Ford Aviation Investment and Reform Act for the 21st Century Interim final RIN 1218-AB99 OIRA review period: 12/21/2001 to 03/20/2002 Published 04/01/2002 (67 FR 15454)	Other material changes Three sets of changes were attributed to OIRA. In the preamble of the rule, the changes included (a) adding information and a request for public comment regarding the whistle-blower model that OSHA chose for this rule and (b) identifying this rule as a significant regulatory action (originally labeled "not significant" by OSHA). In the CFR section, language was added to three provisions to clarify that certain procedures would be triggered at the "request of the named person" (the person alleged to have violated the act).	No	No
22	Safety Standards for Signs, Signals, and Barricades Final rule RIN 1218-AB88 OIRA review period: 12/31/2001 to 03/07/2002 Published 04/15/2002 (67 FR 18145)	Minor editoral changes or no changes The only changes attributed to OMB affected two sentences regarding EO 12866 in the preamble—identifying this as a significant regulatory action that was reviewed by OMB, but also noting that the rule was not an economically significant action within the meaning of the executive order.	No	No

(Continued From Previous Page)

GAO ID	Executive order review submission	Nature of most significant OMB/OIRA changes	Evidence that OMB/OIRA changes affected costs or benefits	Evidence that outside parties contacted OMB/OIRA
23	Occupational Injury and Illness Recording and Reporting Requirements; Occupational Hearing Loss Final rule RIN 1218-AC06 Economically significant OIRA review period: 05/24/2002 to 06/25/2002 Published 07/01/2002 (67 FR 44037)	Other material changes OIRA requested an additional explanation of OSHA's method of estimating the number of recordable hearing loss cases. OSHA added a section in the preamble in response to OIRA's request.	No However, the substantive insert in the preamble explained OSHA's estimation of recordable hearing loss cases.	No
24	Occupational Injury and Illness Recording and Reporting Requirements Proposed rule RIN 1218-AC06 Economically significant OIRA review period: 05/24/2002 to 06/25/2002 Published 07/01/2002 (67 FR 44124)	Minor editoral changes or no changes OIRA did not suggest or recommend any substantive changes to this rule. (OSHA initiated the only substantive change made to the rule after it was submitted for OIRA's review, deleting a section on state occupational safety and health plans in the preamble. A section on state plans was later reinserted in the version of the rule that was published in the *Federal Register*. Documentation in the OIRA file for this rule showed that OSHA had informed OIRA before reinserting the state plans section before publication.)	No No changes were suggested by OIRA.	No

(Continued From Previous Page)

GAO ID	Executive order review submission	Nature of most significant OMB/OIRA changes	Evidence that OMB/OIRA changes affected costs or benefits	Evidence that outside parties contacted OMB/OIRA
DOT-FAA				
25	Fees for FAA Services for Certain Flights Final rule RIN 2120-AG17 OIRA review period: 08/01/2001 to 08/06/2001 Published 08/20/2001 (66 FR 43680)	Minor editoral changes or no changes No substantive changes were made to this rule.	No	No
26	Flight Operational Quality Assurance Program Final rule RIN 2120-AF04 OIRA review period: 07/30/2001 to 08/28/2001 Published 10/31/2001 (66 FR 55042)	Minor editoral changes or no changes The only changes made to this rule were minor editorial revisions, such as changing section headings.	No	No
27	Traffic Alert Collision Avoidance System Proposed rule RIN 2120-AG90 OIRA review period: 08/01/2001 to 10/18/2001 Published 11/01/2001 (66 FR 55506)	Other material changes FAA officials provided evidence that indicates that OIRA suggested clarification to the cost-benefit section to be more explicit on how the benefits were determined. Direct questions from OIRA indicate that OIRA wanted the regulation evaluation to be more explicit regarding the rule's likely benefits. According to FAA officials, changes made to the rule were not major, although the rule did receive a postreview letter.	No (However, OIRA did suggest that DOT develop a more transparent analysis of the benefits of the proposal.)	No

(Continued From Previous Page)

GAO ID	Executive order review submission	Nature of most significant OMB/OIRA changes	Evidence that OMB/OIRA changes affected costs or benefits	Evidence that outside parties contacted OMB/OIRA
28	Certification of Pilots, Aircraft, and Repairmen for the Operation of Light Sport Aircraft Proposed rule RIN 2120-AH19 OIRA review period: 12/17/2001 to 01/03/2002 Published 02/05/2002 (67 FR 5368)	Other material changes In response to issues raised by OIRA, FAA added a footnote to this rule that explained consumer surplus benefits and also clarified that specific accident data were not counted more than once. FAA officials characterized these changes as clarifications. (Note that a previous version of this rule was returned by OIRA to FAA for reconsideration [see GAO ID 73 in the table on returned rules].)	No (However, in response to OIRA's review, FAA added information to clarify and explain some of the information on benefits discussed in the rule.)	No
29	Reduced Vertical Separation Minimum in Domestic United States Airspace Proposed rule RIN 2120-AH63 (in the published rule) RIN 2120-AH68 (in OIRA's list of reviewed rules) OIRA review period: 04/12/2002 to 05/03/2002 Published 05/10/2002 (67 FR 31920)	Minor editoral changes or no changes According to FAA officials, only one paragraph was changed in the regulatory evaluation, and FAA officials could not determine whether that change was due to OIRA's suggestion. Further, the one change to the rule was not substantive; it broke out components of a cost estimate without changing the estimate itself.	No	No

(Continued From Previous Page)

GAO ID	Executive order review submission	Nature of most significant OMB/OIRA changes	Evidence that OMB/OIRA changes affected costs or benefits	Evidence that outside parties contacted OMB/OIRA
DOT-FMCSA				
30	Revision of Regulations and Application Form for Mexican-Domiciled Motor Carriers to Operate in U.S. Municipalities and Commercial Zones on the U.S.-Mexico Border Final rule RIN 2126-AA33 OIRA review period: 01/15/2002 to 03/01/2002 Published 03/19/2002 (67 FR 12652)	Minor editoral changes or no changes FMCSA considered the OIRA-suggested changes to be primarily editorial or clarifying in nature and not substantive (such as substituting numbers for percentages in a discussion of the cost-effectiveness of this rule). However, there were substantive changes made by FMCSA.	No (However, FMCSA made changes to the burden-hour estimates for the information collection associated with this rule.)	No
31	Application by Certain Mexican Motor Carriers to Operate Beyond U.S. Municipalities and Commercial Zones on the U.S.-Mexico Border Interim final rule RIN 2126-AA34 OIRA review period: 01/15/2002 to 03/1/2002 Published 03/19/2002 (67 FR 12702)	Other material changes OIRA suggested some revisions or clarifications to descriptions in the preamble and regulatory language of this rule, including noting the applicability of immigration law, revising the rationale in some of FMCSA's explanations or responses to public comments, and clarifying that, under the North American Free Trade Agreement Annex, Mexican-domiciled motor carriers may not provide point-to-point transportation services, including express delivery services, within the United States, other than international cargo. Other OIRA-suggested changes were largely minor editorial changes, such as correcting the title of an application form and substituting numbers for percentages in a discussion of the cost-effectiveness of this rule.	No (However, FMCSA initiated changes to the Paperwork Reduction Act section of the preamble after submission of the draft to OIRA. FMCSA's changes slightly reduced the estimated burden of the information collection associated with this rule.)	No

(Continued From Previous Page)

GAO ID	Executive order review submission	Nature of most significant OMB/OIRA changes	Evidence that OMB/OIRA changes affected costs or benefits	Evidence that outside parties contacted OMB/OIRA
32	Safety Monitoring System and Compliance Initiative for Mexico-Domiciled Motor Carriers Operating in the United States Interim final rule RIN 2126-AA35 OIRA review period: 01/15/2002 to 03/1/2002 Published 03/19/2002 (67 FR 12758)	Other material changes Although most of the changes OIRA suggested were minor (e.g., word choice), one change in the preamble appeared to be material. At OIRA's suggestion, FMCSA added Appendix A to Part 385 for clarification. This new appendix informed Mexico-domiciled motor carriers of the evaluation criteria that FMCSA would use to ensure compliance with the requirements of this rule. A statement in the original draft that the statute requires an examination of each Mexico-domiciled carrier's drivers upon entry was also revised to say that the examination of drivers resulting from the statute provision would allow inspection of each Mexico carrier's drivers upon entry. Changes to the CFR that were attributed to OIRA appeared to be minor, editorial changes (e.g., replacing "oversight program" with "monitoring system"), as well as rewording and reordering of sentences.	No	No
33	Certification of Safety Auditors, Safety Investigators, and Safety Inspectors Interim final rule RIN 2126-AA64 OIRA review period: 01/15/2002 to 03/01/2002 Published 03/19/2002 (67 FR 12776)	Minor editoral changes or no changes The two changes attributed to OIRA were not substantive as they dealt with minor corrections to the rule. One of the suggested changes deleted a redundant statement, and the other corrected the citation of a relevant executive order (changing the citation from Executive Order 12866 to Executive Order 13211).	No OIRA did not suggest or recommend any substantive changes to this rule.	No

(Continued From Previous Page)

GAO ID	Executive order review submission	Nature of most significant OMB/OIRA changes	Evidence that OMB/OIRA changes affected costs or benefits	Evidence that outside parties contacted OMB/OIRA
34	Parts and Accessories Necessary for Safe Operation; Certification of Compliance with Federal Motor Vehicle Safety Standards (FMVSS) Proposed rule RIN 2126-AA69 OIRA review period: 01/15/2002 to 03/01/2002 Published 03/19/2002 (67 FR 12782)	Minor editoral changes or no changes The only change that was attributed as being made at the request of OIRA was the deletion of a redundant statement in the preamble– regarding the boilerplate section on the National Environmental Policy Act.	No	No
35	New Entrant Safety Assurance Process Interim final rule RIN 2126-AA59 Economically significant OIRA review period: 04/12/2002 to 05/06/2002 Published 05/13/2002 (67 FR 31978)	Other material changes The changes attributed to requests by OIRA in the draft rule or the regulatory evaluation included (1) requesting comments on the resource cost to the economy of denying permanent registration, the effect on safety of denying registration, and the assumptions FMCSA made regarding crash rate reductions, (2) attributing designation that this was an economically significant rule to OMB rather than FMCSA, and (3) adding a statement on reimbursement to states of the costs incurred in conducting safety audits (80 percent). There were no changes to the regulatory language.	No Although the OIRA changes added several requests for comments on the potential economic effects and benefits of this rule and also clarified that FMCSA would reimburse states 80 percent of costs incurred conducting safety audits, the changes did not affect the costs or benefits of the rule.	No

(Continued From Previous Page)

GAO ID	Executive order review submission	Nature of most significant OMB/OIRA changes	Evidence that OMB/OIRA changes affected costs or benefits	Evidence that outside parties contacted OMB/OIRA
DOT-NHTSA				
36	Tire Pressure Monitoring Systems Proposed rule RIN 2127-AI33 Economically significant OIRA review period: 07/05/2001 to 07/23/2001 Published 07/26/2001 (66 FR 38982)	Significant changes Changes identified in the material found in the NHTSA docket indicate that OIRA suggested changes to discussions of cost and benefit estimates in the proposed rule, in particular (a) adding statements to the preamble regarding unquantified benefits and costs that might exist, (b) adding estimates of total estimated costs of the two regulatory alternatives in the proposal (original draft only provided estimates of average cost per vehicle), (c) inserting additional information about the calculation of some benefit estimates (e.g., range of injuries and deaths prevented, stopping distance effects, and average tire life increases), and (d) adding a discussion regarding the effect of human factors on the benefits of tire pressure monitoring systems. Many of the OIRA-suggested inserts included a request for public comments. At OIRA's suggestion, NHTSA also deleted draft material about potential unquantified environmental benefits.	Yes At OIRA's suggestion, statements were added that unquantified benefits and costs may exist due to this rule, and public comments were requested on this issue. OIRA also suggested the insertion of (a) additional estimates of some costs and benefits, (b) added clarification or explanation of some economic effects, and (c) requests for public comments on benefits and costs of the proposed regulatory alternatives.	No
37	Light Truck Average Fuel Economy Standard Model Year 2004 Proposed rule 2127-AI68 Economically significant OIRA review period: 01/10/2002 to 01/17/2002 Published 01/24/2002 (67 FR 3470)	Other material changes OIRA suggested the addition of an Energy Impact section. Although NHTSA did not consider the addition of this section to be a substantive change, it met our criteria for classifying the nature of the change in this rule to be an "other material change."	No	No

(Continued From Previous Page)

GAO ID	Executive order review submission	Nature of most significant OMB/OIRA changes	Evidence that OMB/OIRA changes affected costs or benefits	Evidence that outside parties contacted OMB/OIRA
38	Federal Motor Vehicle Improved Tire Safety Standards Proposed rule RIN 2127-AI54 Economically significant OIRA review period: 12/17/2001 to 02/22/2002 Published 03/05/2002 (67 FR 10050)	Minor editoral changes or no changes NHTSA officials could not recall any changes, substantive or nonsubstantive, to this rule during OIRA's review.	No	No
39	Automotive Fuel Economy Manufacturing Incentives for Dual Fuel Vehicles Proposed rule RIN 2127-AI41 Economically significant OIRA review period: 12/19/2001 to 02/22/2002 Published 03/11/2002 (67 FR 10873)	Other material changes Additional information was added to the introduction and background sections of the preamble referring to the Energy Task Force and additional public comments. There were also minor editorial changes throughout the revised draft. Although NHTSA did not consider OIRA's suggested changes to be substantive, we classified the changes made to this rule as an "other material change" to Other material changesbe consistent with our coding of the level of changes observed in other rules.	No	No
40	Federal Motor Vehicle Safety Standards; Child Restraint Systems Proposed rule RIN 2127-AI34 OIRA review period: 02/26/2002 to 04/08/2002 Published 05/01/2002 (67 FR 21806)	Minor editoral changes or no changes NHTSA officials confirmed that OIRA only suggested editorial changes on two or three pages.	No	No

(Continued From Previous Page)

GAO ID	Executive order review submission	Nature of most significant OMB/OIRA changes	Evidence that OMB/OIRA changes affected costs or benefits	Evidence that outside parties contacted OMB/OIRA
EPA-Office of Air and Radiation				
41	Control of Emissions From Nonroad Large Spark-Ignition Engines and Recreational Engines (Marine and Land-Based) Proposed rule RIN 2060-AI11 Economically significant OIRA review period: 08/01/2001 to 09/14/2001 Published 10/05/2001 (66 FR 51098)	Significant changes There were substantive comments and changes from OMB on the preamble, CFR section, and regulatory support document for this rule. The most substantive issue/change was "OMB's desire to not move forward with the marine and highway motorcycle portions of the proposal."	Yes Deleting some of the regulatory scope from the original version of this rule—covering regulation of highway motorcycles and marine engines—would reduce the potential total costs and benefits of the rule as originally submitted for OMB's review. (Note, however, that EPA then covered those engines in a separate rule—see GAO ID 54.)	Yes Many outside parties contacted OIRA regarding this rule, including representatives of several environmental organizations (Natural Trails and Waters Coalition, PIRG, Sierra Club, Bluewater Network, National Parks Conservation Association – meeting held 08/29/2001); the National Marine Maritime Association (meeting held 08/31/2001); the snowmobile industry (Polaris Industries, Arctic Cat, Bombadier, and International Snowmobile Manufacturers Association — meeting held 09/06/2001); and the Motorcycle Riders Association (letter of 09/14/2001; meeting held 10/25/2001). (Representatives of the Vice President's Office, the White House Council of Economic Advisors, and the Small Business Administration also attended these meetings.)

(Continued From Previous Page)

GAO ID	Executive order review submission	Nature of most significant OMB/OIRA changes	Evidence that OMB/OIRA changes affected costs or benefits	Evidence that outside parties contacted OMB/OIRA
42	National Ambient Air Quality Standard for Ozone; Proposed Response to Remand Proposed rule RIN 2060-ZA11 Economically significant OIRA review period: 08/27/2001 to 10/25/2001 Published 11/14/2001 (66 FR 57268)	Minor editoral changes or no changes There were only three minor changes in the preamble attributed to OMB. All three changes appeared to be rewording (rather than deleting or adding information) of statements in the submitted version regarding EPA's views about effects "using plausible but highly uncertain assumptions."	No	No
43	Regulation to Establish New Date Receipt of Summer Grade Reformulated Gasoline at Terminals Proposed rule RIN 2060-AJ79 OIRA review period: 10/24/2001 to 11/16/2001 Published 12/03/2001 (66 FR 60163)	Other material changes Changes were made to the preamble, CFR section, and regulatory support document, although the CFR changes would probably not be considered substantive even using a "possibly substantive" definition. In the preamble, material was added regarding (a) the dates when terminals can receive summer grade reformulated gasoline (RFG), (b) explanations of the costs of producing more summer grade and less winter grade RFG, (c) an explanation of the requirement to petition EPA for approval to transfer dirty blendstocks (with a request for comment on the issue), (d) classification of this rule as a significant regulatory action under EO 12866, and (e) reporting burden comments from the National Petrochemical and Refiners Association in response to a related EPA information collection request. Original material regarding requirements for transferring blendstocks was deleted from the preamble. In the CFR section the only changes were incorporation by reference of a standard test method and some minor edits. The technical support document was changed to specify dates when terminals are required to receive summer grade RFG and to add explanatory details on the costs of producing more summer grade RFG.	No	No

(Continued From Previous Page)

GAO ID	Executive order review submission	Nature of most significant OMB/OIRA changes	Evidence that OMB/OIRA changes affected costs or benefits	Evidence that outside parties contacted OMB/OIRA
44	National Emission Standards for Hazardous Air Pollutants: Organic Liquid Distribution (Non-Gasoline) Proposed rule RIN 2060-AH41 OIRA review period: 06/18/2001 to 09/19/2001 Published 04/02/2002 (67 FR 15674)	Other material changes Changes attributed to OMB in the preamble of the rule included (a) a new section regarding Executive Order 13211, discussing energy effects of the rule, (b) new language reflecting the rule's impact on organic liquid distribution sources, and (c) a request for comments from the public regarding the accuracy of EPA's cost impact estimates. There were also minor editorial changes throughout the preamble. There were no changes to the regulatory language in the CFR section of the proposed rule.	No	No
45	National Emission Standards for Hazardous Air Pollutants: Miscellaneous Organic Chemical Manufacturing and Miscellaneous Coating Manufacturing Proposed rule RIN 2060-AE82 OIRA review period: 06/18/2001 to 09/21/2001 Published 04/04/2002 (67 FR 16154)	Minor editoral changes or no changes EPA docket materials appeared to identify many changes suggested by the Small Business Administration's (SBA) Office of Advocacy, but the only evidence of a change suggested by OMB was an e-mail message suggesting a rewrite of two explanatory sentences in the preamble. (A side-by-side comparison of the submitted and cleared versions of this rule in OIRA's files indicated that there were many changes but without attribution of the sources of those changes.)	No	No Although there was no evidence of OMB/OIRA contacts with outside parties during the formal review period for this proposal, the EPA docket files did document a presentation by industry representatives to OMB and SBA's Office of Advocacy (not attended by EPA) in August 2000.

(Continued From Previous Page)

GAO ID	Executive order review submission	Nature of most significant OMB/OIRA changes	Evidence that OMB/OIRA changes affected costs or benefits	Evidence that outside parties contacted OMB/OIRA
46	NESHAP: Petroleum Refineries; Catalytic Cracking Units, Catalytic Reforming Units and Sulfur Recovery Units Final rule RIN 2060-AF28 OIRA review period: 08/29/2001 to 11/27/2001 Published 04/11/2002 (67 FR 17762)	Minor editoral changes or no changes The EPA docket had an OMB review cover sheet indicating "no substantive changes." The person in charge of developing this rule confirmed that OMB's review resulted in only a few very minor editorial changes.	No	No

(Continued From Previous Page)

GAO ID	Executive order review submission	Nature of most significant OMB/OIRA changes	Evidence that OMB/OIRA changes affected costs or benefits	Evidence that outside parties contacted OMB/OIRA
47	National Emission Standards for Hazardous Air Pollutants; Surface Coating of Metal Furniture (Surface Coating) Proposed rule RIN 2060-AG55 OIRA review period: 06/18/2001 to 10/24/2001 Published 04/24/2002 (67 FR 20206)	Other material changes Changes in the preamble to address OMB comments primarily inserted material for clarification and to request comments. For example, language was added to ask for comments on EPA's maximum achievable control technology (MACT) floor, EPA's conclusion that the creation of subcategories was not warranted for these standards, EPA's decision to reject regulatory options more stringent than the MACT floor, and whether there were alternative means of monitoring performance for add-on controls at source facilities that would be as effective and less expensive than the proposed requirements. In response to OMB's comments, EPA also asked that commenters provide information in support of their comments. More detailed explanations were added regarding (a) the subcategories issue, (b) a requirement to determine the mass of organic hazardous air pollutants in coatings, thinners, and cleaning materials, (c) monitoring systems, and (d) the explanation of the equation for calculating hazardous air pollutant emissions. Changes in the CFR section to address OMB comments included modifying (a) the applicability section of the rule to clarify applicability where a potential overlap may exist with EPA's wood furniture rule and (b) the equation for calculating hazardous air pollutant emissions. (Note that there was also a substantive change regarding the proposed emission limits—which, in turn, affected the estimated costs and benefits of the rule—but the materials in EPA's docket indicated that the change was due to EPA's own reanalysis of emissions data received from firms.)	No (Substantive changes to the potential costs and benefits of the rule were not attributed to a change suggested by OMB but rather to a change EPA made to the proposed emission limits after reanalysis of emissions data submitted by facilities. The revised limits were less stringent than originally proposed, leading to lower costs and lower projected emission reductions.)	No

(Continued From Previous Page)

GAO ID	Executive order review submission	Nature of most significant OMB/OIRA changes	Evidence that OMB/OIRA changes affected costs or benefits	Evidence that outside parties contacted OMB/OIRA
48	Revisions to Regional Haze Rule to Incorporate Sulfur Dioxide Milestones and Backstop Emissions Trading Program for Nine Western States and Eligible Indian Tribes Proposed rule RIN 2060-AJ50 OIRA review period: 11/29/2001 to 02/22/2002 Published 05/06/2002 (67 FR 30418)	Other material changes There were only a few changes in the preamble—for example, deleting some requests for comments and an explanatory section on why EPA was deferring to the Western Regional Air Partnership's (WRAP) judgment on the issue of critical mass and inserting a footnote in response to issues raised in a meeting with the Center for Energy and Economic Development (CEED). There were no changes in the CFR section. (WRAP is a collaborative effort of tribal governments, state governments, and various federal agencies to implement the Grand Canyon Visibility Transport Commission's recommendations and develop tools to comply with EPA's regional haze regulations. CEED is a national, nonprofit organization formed by the nation's coal-producing companies, railroads, a number of electric utilities, equipment manufacturers, and related organizations that advocates on behalf of the long-term viability of coal-based electricity generation in America.)	No	Yes WRAP and CEED sent letters to OIRA on this rule, and CEED requested an EO 12866 meeting with OMB on the rule. The EPA docket included a copy of a 02/05/2002 CEED letter to Dr. Graham (not found in the OIRA files) and an e-mail from OIRA to EPA noting that a meeting had been scheduled at CEED's request on that date (no record found in OIRA's files). A 02/15/2002 letter from WRAP to Dr. Graham appeared in OIRA's docket.
49	Control of Emissions of Air Pollution From New Marine Compression Ignition Engines At or Above 30 Liters/Cylinder Proposed rule RIN 2060-AJ89 OIRA review period: 04/15/2002 to 04/30/2002 Published 05/29/2002 (67 FR 37548)	Significant changes Docket materials indicated that EPA moved from proposing to considering second tier emission standards. Specifically, OIRA edits systematically suggested changing language regarding certain emission [Tier 2] standards from statements "proposing" the adoption of these standards to statements that EPA was only "considering" adoption of the standards.	Unclear Material in the OIRA files indicated that, although the regulatory support document was amended, the revisions did not affect the estimates of costs and benefits for this proposed rule. However, it seems that a shift from actually proposing to just considering adoption of particular emission standards should have had some effect on the rule's potential costs and benefits.	No

(Continued From Previous Page)

GAO ID	Executive order review submission	Nature of most significant OMB/OIRA changes	Evidence that OMB/OIRA changes affected costs or benefits	Evidence that outside parties contacted OMB/OIRA
50	Consolidated Emissions Reporting Rule Final rule RIN 2060-AH25 OIRA review period: 08/27/2001 to 11/26/2001 Published 06/10/2002 (67 FR 39602)	Significant changes Per review of the Paperwork Reduction Act portion of this rule, OMB raised concerns about one portion of the Information Collection Request (ICR). In response, EPA elected to delay compliance with that portion of the ICR, rather than delay the compliance date of the rule. With this change, states would not have to commence reporting point source emissions for two types of emissions until 06/01/2004, or later, if EPA fails to publish an approved revised ICR.	Unclear Delaying commencement of reporting for one subsection of the rule might have a marginal effect on the projected costs and benefits of states' reporting on emissions.	No
51	National Emission Standards for Hazardous Air Pollutants; Surface Coating for Wood Building Products Proposed rule RIN 2060-AH02 OIRA review period: 09/07/2001 to 12/07/2001 Published 06/21/2002 (67 FR 42400)	Significant changes Changes were made in both the preamble and CFR sections of the proposal. The most substantive change attributed to a request from OMB was in the CFR section—delaying the compliance dates in two provisions from 2 years to 3 years after the date of publication of the final rule. At OMB's request, language also was inserted throughout the preamble requesting specific comments on various aspects of products and activities EPA selected for coverage in this rule. Requests were also inserted for data on potential costs and burdens of the rule and how they might differ by subcategories of emission sources.	Yes The most substantive change in the proposed regulatory language would delay compliance dates for two of the rule's provisions. (Note also that some of the changes in the preamble raised questions and solicited comments about the cost-effectiveness of elements of this proposal.)	No

(Continued From Previous Page)

GAO ID	Executive order review submission	Nature of most significant OMB/OIRA changes	Evidence that OMB/OIRA changes affected costs or benefits	Evidence that outside parties contacted OMB/OIRA
52	Proposed Rule for Compliance Program Fees for Light-Duty Vehicles and Engines; Heavy-Duty Vehicles and Engines; and Nonroad Engines and Motorcycles Proposed rule RIN 2060-AJ62 OIRA review period: 02/01/2002 to 04/22/2002 Published 08/07/2002 (67 FR 51402)	Significant changes Lengthy inserts were made to the preamble and the regulatory language in the CFR section. The most substantive change appeared to be the insertion of an entire new section on how to qualify for reduced fees within the regulatory provisions of the CFR section. The changes that appeared to be most substantive in the preamble included: (a) inserting requests for comments regarding many aspects of the proposed fee system (e.g., on minimum fees, alternative ways to adjust fees for inflation, various process questions, and EPA's cost analysis), (b) adding material on special provision fee payments and applications for certain types of manufacturers (and deleting the previous version of the basis for fee schedules), (c) adding clarifying material defining how to calculate a vehicle's average retail value, and (d) adding a Paperwork Reduction Act section.	No The changes primarily affected the explanations of fee payments and application processes, including clarification of how to qualify for reduced fees, but did not change EPA's estimated costs of the proposed rule.	No

(Continued From Previous Page)

GAO ID	Executive order review submission	Nature of most significant OMB/OIRA changes	Evidence that OMB/OIRA changes affected costs or benefits	Evidence that outside parties contacted OMB/OIRA
53	Proposed Non-Conformance Penalties for 2004 and Later Model Year Emission Standards for Heavy-Duty Diesel Engines and Heavy-Duty Diesel Vehicles Proposed rule RIN 2060-AJ73 OIRA review period: 12/10/2001 to 12/20/2001 Published 08/08/2002 (67 FR 51464)	Significant changes The most significant comments and edits conveyed from OIRA to EPA on this rule addressed: (a) rewriting a section about an additional adjustment to "level the playing field" and the assumptions used by EPA (OIRA's position was that this secondary adjustment was not necessary), (b) discount rate (OIRA's position was that, per OMB Circular A-94, it was more appropriate to use a discount rate of 7 percent consistently throughout the rule and regulatory impact analysis—in some instances EPA had used a 3 percent discount rate, citing a recommendation by EPA's Science Advisory Board), (c) fuel prices (OIRA's position was that the estimated fuel price EPA used in its draft was excessive, and OIRA suggested that EPA instead use a 3- to 5-year average of nationwide fuel prices), (d) significance of this proposed rule (OIRA's position was that the proposed rule was significant and potentially economically significant in light of the estimated nonconformance penalties), and (e) cost estimation (OIRA's position was that the basis for the cost estimates was unclear, among other issues, and OIRA suggested that EPA clarify and explicitly discuss its estimation method). (The proposed rule as published solicited comments on use of discount rate other than 7 percent and on using a 5-year average of fuel prices. In the final rule, EPA based its analysis on use of a 7 percent discount rate and a 5-year average for the price of fuel.)	Unclear Overall, the actual economic impact of the rule (and any changes made to it) is unclear because the use of nonconformance penalties by manufacturers is optional. According to EPA, manufacturers are likely to choose whether or not to use nonconformance penalties based on their ability to comply with emissions standards. Nevertheless, changes regarding the discount rate and fuel price could have an effect on the potential costs and benefits of this rule. (A higher discount rate reduces the present value of future costs and benefits compared to more immediate costs and benefits.) In particular, the discount rate changes appeared to result in a slight decrease in the penalty amounts cited in the rule once the discount rate is changed to 7 percent. (As noted in the revised version of the Technical Support Document section, "Penalty Sensitivity to Discount Rate" the net effect of using a smaller discount rate would generally be penalties that were higher.)	Yes OIRA was contacted before the formal review period by industry representatives from Cummins Inc. (letters to OIRA on 09/13/2001, 10/12/2001, and 11/07/2001; meeting with OIRA on 10/01/2001) and Caterpillar Inc. (letter on 10/25/2001 and meeting on 11/14/2001), but there was no evidence of outside contacts within the formal review period for this proposed rule. (There were also many other documents on outside contacts in the dockets for this rulemaking, but they were dated during OIRA's formal review period for the final version of the rule.)

(Continued From Previous Page)

GAO ID	Executive order review submission	Nature of most significant OMB/OIRA changes	Evidence that OMB/OIRA changes affected costs or benefits	Evidence that outside parties contacted OMB/OIRA
54	Control of Emissions from Spark Ignition Marine Vessels and Highway Motorcycles Proposed rule RIN 2060-AJ90 OIRA review period: 01/16/2002 to 04/16/2002 Published 08/14/2002 (67 FR 53050)	Significant changes There were substantive changes in the preamble and the regulatory support document, along with minor editorial changes. However, there did not appear to be any substantive changes in the regulatory language of the CFR section. Substantive changes were made in the regulatory support document regarding some of the cost-benefit, and cost-effectiveness estimates (e.g., cost per motorcycle, cost increases, and fuel savings rates). In the preamble, the sections on regulatory flexibility alternatives and the Paperwork Reduction Act were expanded, while original language was deleted regarding (a) previous standards accomplishing little more than a phase-out of two-stroke engines, (b) the contributions of motorcycles and marine engines to total U.S. emissions, (c) use of catalysts and safety concerns for marine engines, (d) a request for comment on whether banking or trading emission credits should be incorporated into the program, (e) total increased costs per motorcycle, (f) a statement that fuel savings offset cost of emission controls, and (g) a conclusion regarding cost per ton of emission reduction.	Yes The docket materials identified changes in cost-benefit and cost-effectiveness estimates for this rule. In aggregate, the estimated annual cost to manufacturers was reduced by $4 million per year and the estimated annual fuel savings was increased by $4.3 million per year.	Yes Although there was no evidence of direct contact from outside parties during the formal review period for this rule, OMB had meetings with and received letters from several groups (representing both industry and environmental interests) on a previous related rule—GAO ID 41, from which this rule was spun off.

(Continued From Previous Page)

GAO ID	Executive order review submission	Nature of most significant OMB/OIRA changes	Evidence that OMB/OIRA changes affected costs or benefits	Evidence that outside parties contacted OMB/OIRA
EPA-Office of Solid Waste and Emergency Response				
55	Hazardous Waste Management System; Standardized Permit Corrective Action; and Financial Responsibility for RCRA Hazardous Waste Management Facilities Proposed rule RIN 2050-AE44 OIRA review period: 05/10/2001 to 07/19/2001 Published 10/12/2001 (66 FR 52192)	Other material changes Among the revisions attributed to OMB in the preamble were (a) adding several inserts requesting comments on various aspects of the rule (e.g., on ways to reduce the burden and cost of the permitting process), (b) adding a statement that storage of hazardous waste military munitions should continue under the individual permitting program, (c) deleting a short section proposing that "the regulatory agency may itself choose to initiate your conversion to a standardized permit," (d) adding an explanation of current regulatory responsibilities if a generator sends waste off-site for land disposal, (e) adding several paragraphs explaining the option of not requiring a closure plan, (f) deleting much of a paragraph discussing differences between closure cost estimates prepared using EPA's methodology and the estimates from owners and operators (but leaving in a request for actual cost data and a discussion of six options EPA considered for developing cost estimates), (g) adding a reference to an estimation option that has a larger reduction of burden associated with cost estimating but tends to produce higher cost estimates, and (h) adding a paragraph regarding the level of detail required for compliance audits. In the CFR section, the only material change was adding language to clarify which parts of Title 40 CFR section 124.10 apply to the Resource Conservation and Recovery Act (RCRA) standardized permit. There were also minor editorial changes throughout the revised rule.	No	No

(Continued From Previous Page)

GAO ID	Executive order review submission	Nature of most significant OMB/OIRA changes	Evidence that OMB/OIRA changes affected costs or benefits	Evidence that outside parties contacted OMB/OIRA
56	Identification and Listing of Hazardous Waste; Addition of Manganese to Appendix VIII; Inorganic Chemical Manufacturing Waste; and CERCLA Hazardous Substance Designation and Reportable Quantities Final rule RIN 2050-AE49 OIRA review period: 09/26/2001 to 10/31/2001 Published 11/20/2001 (66 FR 58258)	Significant changes Substantive changes were made throughout the preamble and CFR section of the notice in response to OMB's comments. Specifically, the rule as cleared by OMB deferred final action on all elements of the original proposal related to the waste constituent manganese (e.g., adding manganese as a regulated hazardous constituent).	Yes Deferring regulatory action on manganese would also defer potential costs and benefits of the regulatory actions originally proposed by EPA.	Yes OIRA was contacted by industry representatives from the Steel Manufacturers Association and American Iron and Steel Institute (sent letters 09/28/2001 and 10/19/2001; met with OIRA 10/16/2001), Cookson Group (sent letters 09/26/2001 and 10/18/2001), and Eastman (sent letter 10/08/2001). The OIRA files also indicated that OIRA reviewed materials sent by some of these groups to the RCRA Information Center. Cookson Group also requested a meeting with OIRA.
57	Resource Conservation and Recovery Act Burden Reduction Initiative; Office of Solid Waste Burden Reduction Project Proposed rule RIN 2050-AE50 OIRA review period: 08/02/2001 to 10/15/2001 Published 01/17/2002 (67 FR 2518)	Minor editoral changes or no changes EPA told us they made no substantive changes to the rule. The sensitivity analysis requested by OMB also did not result in any changes to the rule.	No	No

(Continued From Previous Page)

GAO ID	Executive order review submission	Nature of most significant OMB/OIRA changes	Evidence that OMB/OIRA changes affected costs or benefits	Evidence that outside parties contacted OMB/OIRA
58	Amendments to the Corrective Action Management Unit [CAMU] Rule Final rule RIN 2050-AE77 OIRA review period: 11/14/2001 to 12/19/2001 Published 01/22/2002 (67 FR 2962)	Other material changes The changes attributed to OMB in the redline/strikeout document were all in the preamble of the rule. In addition to several minor editorial changes (e.g., correcting spelling), changes attributed to OMB included (a) adding a couple of sentences to a paragraph discussing differences between generic minimum national design and operation standards for disposal units and requirements for site-specific clean-ups, (b) rewording and clarifying some statements and responses to public comments regarding a proposed "discretionary kickout provision," (c) clarifying in one sentence, as stated previously in the same section, that the final regulation covers both listed and characteristic wastes, and (d) deleting some of the text explaining why EPA was not further extending the comment period. (Note that the most substantive change from the original draft to the published version of the rule—adding a new provision about allowing disposal of "CAMU-eligible wastes" in off-site hazardous waste landfills—was not attributed to OMB.)	No	No
59	NESHAPS: Standards for Hazardous Air Pollutants for Hazardous Waste Combustors Interim final rule RIN 2050-AE79 OIRA review period: 01/09/2002 to 01/18/2002 Published 02/13/2002 (67 FR 6792)	Minor editoral changes or no changes The only changes marked were in the preamble, and all appeared to be minor. There were no changes in the CFR section of the rule.	No	No

(Continued From Previous Page)

GAO ID	Executive order review submission	Nature of most significant OMB/OIRA changes	Evidence that OMB/OIRA changes affected costs or benefits	Evidence that outside parties contacted OMB/OIRA
60	NESHAPS: Standards for Hazardous Air Pollutants for Hazardous Waste Combustors Final rule RIN 2050-AE79 OIRA review period: 01/09/2002 to 01/18/2002 Published 02/14/2002 (67 FR 6968)	Minor editoral changes or no changes The only two changes clearly marked in the redline/strikeout document were in the preamble and appeared to be minor. There were no changes in the CFR section of the rule.	No	No
61	Gasification of Hazardous Oil-Bearing Secondary Materials from the Petroleum Refining Industry to Produce Synthesis Gas Fuel Proposed rule RIN 2050-AE78 OIRA review period: 10/17/2001 to 01/15/2002 Published 03/25/2002 (67 FR 13684)	Other material changes There were changes on most of the pages in the revised version of the rule. All of the substantive changes were in the preamble, including sizeable insertions of text that provided explanatory information not in the original version of the rule. In particular, there were lengthy inserts requesting comments on a variety of issues and options and also new text regarding the potential economic impacts. There were also many minor editorial changes throughout the preamble and some rewording in the CFR section.	No The changes regarding potential economic impacts just provided more explanation of the potential benefits of this rule. The estimated costs and benefits did not change.	No

(Continued From Previous Page)

GAO ID	Executive order review submission	Nature of most significant OMB/OIRA changes	Evidence that OMB/OIRA changes affected costs or benefits	Evidence that outside parties contacted OMB/OIRA
62	Hazardous Waste Management System; Modification of the Hazardous Waste Program; Cathode Ray Tubes and Mercury-Containing Equipment Proposed rule RIN 2050-AE52 OIRA review period: 12/21/2001 to 02/13/2002 Published 06/12/2002 (67 FR 40508)	Minor editoral changes or no changes According to EPA, the only change made at the suggestion of OMB was that EPA solicited comments on extending the speculative accumulation time of used, broken CRTs to "two or more years" instead of just "two years." A line-by-line comparison of the revised and original versions of the rule in the OIRA docket confirmed only minor changes in the preamble and no changes evident in the CFR section of this rule.	No	No

(Continued From Previous Page)

GAO ID	Executive order review submission	Nature of most significant OMB/OIRA changes	Evidence that OMB/OIRA changes affected costs or benefits	Evidence that outside parties contacted OMB/OIRA
63	Oil Pollution Prevention Regulation: Non-Transportation-Related Onshore and Offshore Facilities; Revisions Final rule RIN 2050-AC62 OIRA review period: 04/27/2001 to 10/15/2001 Published 07/17/2002 (67 FR 47042)	Other material changes The following changes were attributed to OMB in the preamble of the rule: (a) added two sentences to note that EPA will continue to evaluate and intends to request additional data and comments on the issue of modifying secondary containment requirements for small electrical and other types of equipment that use oil for operating purposes, (b) deleted a total of 10 sentences in a section about discretionary provisions in the rule—all appeared to be related to wording changes or additional clarifications in response to comments, (c) expanded a paragraph regarding appropriate methods of secondary containment (e.g., factors to consider in determining whether to install double-walled piping), (d) added a few sentences to a paragraph in which EPA withdrew a proposed 72-hour impermeability standard that was in the proposed rule, (e) added two sentences explaining an editorial change made to one of the rule's provisions (deleting unnecessary words), and (f) added sentences in a response to public comments to note that EPA will continue to evaluate whether provisions for secondary containment found in section 112.7(h)(1) should be modified or revised and that EPA intends to publish a notice asking for additional data and comment on this issue. The only two changed sentences in the CFR section appeared to reflect minor editorial wording changes.	No (However, the docket materials did show that EPA provided OIRA supplemental cost analyses as part of the revised version of the rule.)	No

(Continued From Previous Page)

GAO ID	Executive order review submission	Nature of most significant OMB/OIRA changes	Evidence that OMB/OIRA changes affected costs or benefits	Evidence that outside parties contacted OMB/OIRA
EPA-Office of Water				
64	National Primary Drinking Water Regulations: Arsenic and Clarifications to Compliance and New Source Contaminant Monitoring Proposed rule RIN 2040-AB75 OIRA review period: 06/22/2001 to 07/13/2001 Published 07/19/2001 (66 FR 37617)	Other material changes The significant OMB changes identified by the EPA memo were all in the preamble. (There was no regulatory language associated with this proposal.) EPA made changes to the following seven aspects of the preamble as a result of discussions with OMB: (1) changed questions in the requests for comments to be identical to the language used in the charges to the three review panels, (2) expanded the description of uncertainties in risk analysis, (3) included information specific to the recommendations from the Science Advisory Board on treatment technologies and from a Science Advisory Board advisory committee on latency and income adjustments, (4) expanded the description of latency and other income adjustments, (5) included several clearly worded references to the health date relating primarily to arsenic research at levels above 50 parts per billion (ppb), and the extent to which that affects uncertainties associated with benefits of reducing arsenic below 50 ppb, (6) made editorial changes to the small system section to clearly indicate that EPA identified affordable technologies, so small system variances will not be an option, and (7) included additional wording about providing a small government agency plan under section 203 of the Unfunded Mandates Reform Act.)	No	No (However, the OMB docket did include copies of letters and comments dated prior to the publication of the previous related rulemaking on 01/22/2001.)

(Continued From Previous Page)

GAO ID	Executive order review submission	Nature of most significant OMB/OIRA changes	Evidence that OMB/OIRA changes affected costs or benefits	Evidence that outside parties contacted OMB/OIRA
65	Minimizing Adverse Environmental Impact From Cooling Water Intake Structures at New Facilities Under Section 316(b) of the Clean Water Act, Phase I Final rule RIN 2040-AC34 OIRA review period: 09/10/2001 to 11/08/2001 Published 12/18/2001 (66 FR 65256)	Significant changes Five major changes to the rule were attributed to OIRA, all of which appeared to provide greater flexibility and more alternatives to compliance with requirements and standards in the original draft of the rule. OIRA's five main changes were to (a) add criteria that would allow more facilities to qualify for lower performance standards, (b) change requirements so that facilities withdrawing between 2 million gallons per day (MGD) and 10 MGD did not have to reduce intake flow to a minimum level commensurate with that attained by a closed-cycle recirculating cooling water system, (c) change a requirement so that facilities only needed to use screens to minimize impingement mortality of fish and shellfish if certain criteria were met, (d) add an exception to intake flow requirements regarding cooling water intake structures located in a lake or reservoir, and (e) add "restoration measures" as a compliance alternative under the "Track II" compliance alternative so that intake structure operators may implement measures that "result in increases in fish and shellfish."	Yes OIRA's changes would likely reduce the costs of the rule by providing regulated entities more flexibility and alternatives to compliance with the original standards and requirements of the rule. Their effect on potential benefits is not clear. Changes to the cost estimates were evident in the published version of the rule.	Yes OMB met with Riverkeeper on 09/27/2001, and with representatives from Edison Electric Institute and EOP Group) on 10/29/2001.

(Continued From Previous Page)

GAO ID	Executive order review submission	Nature of most significant OMB/OIRA changes	Evidence that OMB/OIRA changes affected costs or benefits	Evidence that outside parties contacted OMB/OIRA
66	National Primary Drinking Water Regulations: Long-Term 1 Enhanced Surface Water Treatment Rule Final rule RIN 2040-AD18 OIRA review period: 06/13/2001 to 09/24/2001 Published 01/14/2002 (67 FR 1812)	Significant changes Although the EPA docket memo first stated that OMB had no significant comments on this rule, it went on to a long discussion about two major policy issues raised by OMB concerning (a) special primacy requirements for states and (b) the valuation of the cost of Cryptospirdiosis used in the economic analysis accompanying the final rule. The memo noted that both of these issues were elevated to Dr. Graham (OIRA) and Tracy Mehan (EPA Office of Water). OMB agreed to remove their objections to the special primacy requirements in this rule, but indicated intent to raise this issue in subsequent Safe Drinking Water Act regulatory packages. To address OMB's concerns about the valuation issue, the Office of Water and OMB agreed to expand this rule's benefit range by using two cost-of-illness values instead of one. The memo stated that other OMB comments were editorial in nature. (Note that the redline/strikeout document also shows many other changes in the preamble. It was not clear whether these were changes that were not made at the suggestion of OMB or whether the author of EPA's Executive Order 12866 compliance memo did not consider changes to the preamble to be substantive.)	Yes In response to OMB's concern about EPA's valuation of the cost of Cryptospirdiosis used in the economic analysis, OMB and the Office of Water agreed to expand the rule's benefit range by using two cost-of-illness values instead of one. This second COI estimate that was added was lower and only valued lost work time and medical costs associated with Cryptospirdiosis. The other estimate remained the same as EPA's original and valued all loss categories included in the original published study used by EPA (valuing losses for medical costs, work time, productivity, and leisure time).	No
67	Effluent Guidelines and Standards for the Meat Products Point Source Category (Revisions) Proposed rule RIN 2040-AD56 OIRA review period: 12/21/2001 to 01/28/2002 Published 02/25/2002 (67 FR 8582)	Other material changes OMB and SBA suggested changes in two sections of the preamble of the proposed rule. In response to those suggestions, EPA: (a) revised the pretreatment discussion in the preamble to restate the results from EPA's preliminary data collection on meat and poultry product indirect dischargers and related POTW interference events and (b) added a lengthy paragraph in response to OMB's and SBA's request to provide a more thorough explanation of how EPA developed four different production size classifications for each meat and poultry product subcategory.	No	No

(Continued From Previous Page)

GAO ID	Executive order review submission	Nature of most significant OMB/OIRA changes	Evidence that OMB/OIRA changes affected costs or benefits	Evidence that outside parties contacted OMB/OIRA
68	National Pollutant Discharge Elimination System: Proposed Regulations to Establish Requirements for Large Cooling Water Intake Structure at Existing Power Generating Facilities Proposed rule RIN 2040-AD62 Economically significant OIRA review period: 12/28/2001 to 02/28/2002 Published 04/09/2002 (67 FR 17122)	Significant changes EPA identified major changes made at the suggestion or recommendation of OIRA in both the preamble and CFR sections of the proposed rule. Overall, these OIRA changes lowered the performance standard in the rule and made compliance requirements more flexible by allowing, among other things, options for a site-specific approach to minimizing environmental harm. The changes also broadened a restoration option, whereby firms may restore environmental harm rather than comply with the designated performance standard. Many changes to the proposed rule language in eight sections of the proposed CFR amendments were attributed to OIRA. The most extensive changes were to sections 125.94 (10 of 14 major changes in this section were attributed to OIRA) and 125.95 (previously 125.96 – all 7 major changes identified in this section were attributed to OIRA). For example OIRA suggested removing a requirement that facilities in estuaries and tidal waters withdrawing greater than 1 percent of the tidal excursion volume, and oceans withdrawing greater than 500 MGD meet performance standards for reducing mortality and entrainment based on reducing flow commensurate with a closed-cycle, recirculating cooling system and replaced it with a requirement for all facilities in estuaries, tidal rivers, and oceans (regardless of flow) to reduce both impingement mortality and entrainment based on the performance of fish return systems and fine mesh screens. OIRA also suggested broadening the scope of restoration measures to allow use under all compliance alternatives, adding language that allows restoration measures to be used in lieu of design and construction technologies and operational measures to meet performance requirements of the rule.	Yes OIRA recommended that EPA select a regulatory alternative that OIRA believed would yield substantially greater net benefits. The approach that EPA originally proposed would have cost an estimated $610 million per year, with estimated benefits of $890 million per year, yielding net benefits of $280 million. However, OIRA recommended that EPA select another approach that, while having estimated benefits of $735 million, was expected to cost only $280 million, yielding net benefits of $455 million.	Yes Industry groups, such as Edison Electric Institute, EOP Group, and Cinergy, sent letters and provided materials to OIRA. Representatives of those groups and Public Service Electric and Gas, TXU, Progress Energy, Teco Energy, Constellation Energy Group, Allegheny Energy, Minnesota Power, and Migrant Corp. met with OIRA on 02/08/2002. Riverkeeper (an environmental interest group) met with OMB on 02/07/2002.

(Continued From Previous Page)

GAO ID	Executive order review submission	Nature of most significant OMB/OIRA changes	Evidence that OMB/OIRA changes affected costs or benefits	Evidence that outside parties contacted OMB/OIRA
69	Final Revisions to the Clean Water Act Regulatory Definition of "Fill Material" and "Discharge of Fill Material" Final rule RIN 2040-AD51 OIRA review period: 05/01/2002 to 05/02/2002 Published 05/09/2002 (67 FR 31129) (Note that this was a joint rulemaking of the Department of the Army's Corps of Engineers and EPA.)	Significant changes The most substantive change attributed to OIRA in the preamble and regulatory language of the rule revised the definition of fill material as follows – "The term fill material does not include trash~~,~~ or garbage~~, or similar materials unless such materials are to be used to create any structure or infrastructure in waters of the United States, such as an artificial reef or berm~~. (According to an EPA official, the impact of the change was to make the definition clearer so that fill material permit applicants could not ask to use trash or garbage as fill material in creating a structure or infrastructure.) Many of the other OIRA-suggested changes revised discussions of relevant court actions and decisions related to this rulemaking.	Unclear Revising original regulatory language to exclude the possible use of trash, garbage, or similar materials as fill material for some purposes might affect potential costs and environmental benefits.	No There was no evidence of contact before or during OIRA's formal review. However, in a joint letter dated 05/03/2002, one day after OIRA cleared this rule, 10 environmental groups—American Rivers, Clean Water Action, Earthjustice, Friends of the Earth, League of Conservation Voters, Mineral Policy Center, National Audubon Society, National Wildlife Federation, Natural Resources Defense Council, and the Sierra Club—contacted Dr. Graham regarding this rule. (The OIRA files also included a newspaper article that referred to a meeting between the National Mining Association and OMB on 04/06/2001. However, meeting records we reviewed indicated only that EPA attended a meeting with the National Mining Association on that date; there was no mention of whether anyone from OMB also participated.)

(Continued From Previous Page)

GAO ID	Executive order review submission	Nature of most significant OMB/OIRA changes	Evidence that OMB/OIRA changes affected costs or benefits	Evidence that outside parties contacted OMB/OIRA
70	Effluent Limitation Guidelines and New Source Performance Standards for the Construction and Development Category Proposed rule RIN 2040-AD42 Economically significant OIRA review period: 03/01/2002 to 05/15/2002 Published 06/24/2002 (67 FR 42644)	Significant changes There were substantive changes in both the proposed regulatory options in the CFR amendments and the preamble discussion of those regulatory options. At the suggestion or recommendation of OIRA, the proposed regulation no longer included the storm water management or postconstruction regulatory options from the original draft. Also, the active construction options were changed to identify and discuss the following three regulatory options: (1) inspection and certification of construction site erosion and sediment controls, for sites one acre or larger, (2) codification of the Construction General permit plus inspection and certification requirements, for sites five acres or larger, and (3) no regulation. The revisions to the regulatory proposal required corresponding revisions to the preamble.	Unclear The memo in EPA's docket regarding OIRA changes did not directly address whether there were changes in the potential costs and benefits of the rule. The EPA docket did not include sufficient information to allow for a detailed comparison of revised cost and benefit data. However, the nature of the changes made to the regulatory options should have had some effect on the proposed rule's potential costs and benefits.	Yes The OIRA files on this rulemaking included a document from the ELG Working Group (a coalition of interested trade associations) entitled "Issues Raised By The Construction and Development Effluent Limitations Guidelines Working Group Before the White House Office of Management and Budget Office of Information and Regulatory Affairs" (dated 02/04/2002 – about 1 month prior to the formal review period).

(Continued From Previous Page)

GAO ID	Executive order review submission	Nature of most significant OMB/OIRA changes	Evidence that OMB/OIRA changes affected costs or benefits	Evidence that outside parties contacted OMB/OIRA
71	Effluent Limitations Guidelines, Pretreatment Standards, and New Source Performance Standards for the Iron and Steel Manufacturing Point Source Category Final rule RIN 2040-AC90 OIRA review period: 03/29/2002 to 04/30/2002 Published 10/17/2002 (67 FR 64216)	Significant changes At the suggestion of OMB, EPA revised the regulation and supporting preamble discussion for the "water bubble" provision (a voluntary regulatory flexibility mechanism to allow for trading of identical pollutants at any single steel facility with multiple compliance points). This change eliminated an existing minimum net reduction provision that had applied if facilities used the water bubble alternative.	Unclear As described in the existing regulation that this rule was amending, the water bubble provision had a minimum net reduction provision—if a facility used this tool, the amount of the pollutant discharges pursuant to the bubble had to be 10 percent to 15 percent less than the discharges otherwise authorized by the rule without the bubble. At the suggestion of OMB, the revised final rule eliminated this minimum net reduction provision. However, the net effect on costs and benefits of this rule are unclear. While this change eliminated a requirement for additional reductions in pollutant discharges if the water bubble tool is used, it also provided greater flexibility for facilities to use this tool to achieve the overall pollutant reductions required by 40 CFR 420 at the least cost.	Yes Representatives of industry groups contacted OIRA prior to OIRA's formal review period for this rulemaking. On 03/04/2002, representatives of the Steel Manufacturers Association and the Specialty Steel Industry of North America sent a letter to Dr. Graham with comments and a request for a meeting. On 03/19/2002, OIRA held a meeting with steel industry representatives (including those who requested the meeting on March 4). (Note also that the OIRA files on its review of this rule indicated that OIRA had reviewed the substantive comments from the proposed rule stage. The water bubble provision was the subject of some of the public comments on the proposed rule, with industry groups generally supportive of expansions of the water bubble flexibilities and environmental groups supportive of restrictions on the water bubble.)

Source: GAO analysis.

Table 8: Findings and Determinations for Rules Returned to Agency after Submission to OIRA

GAO ID	Executive order review submission	Reason for OIRA's return	Evidence that outside parties contacted or met with OIRA regarding this submission	Evidence of subsequent activity regarding this submission
DOT-FAA				
72	Part 145 Review: Repair Stations Final rule RIN 2120-AC38 OIRA review period: 07/13/2001 to 07/20/2001	OIRA cited concerns from other federal agencies and unease about complicating relations with other countries in its rationale for returning the rule. DOT officials confirmed that the Department of State voiced concerns about the wording of certain provisions. However, they pointed out that FAA had worked out wording changes with the Department of State prior to submitting the rule for OIRA's review. They believed that OIRA's request that FAA withdraw the rule (see GAO ID 84) and OIRA's subsequent return of the resubmitted rule (this case) were based on an OIRA misunderstanding that the Department of State's concerns had not been addressed.	Yes On 07/09/2001—2 days before FAA withdrew the original submission of this rule—the Aeronautical Repair Station Association, the Airline Suppliers Association and other business representatives sent a letter to the OMB Director with a copy to OIRA asking that OIRA send the rule back to FAA with instructions to prepare a Supplemental Notice of Proposed Rulemaking. On 07/26/2001—about 1 week after OIRA returned the rule to FAA and FAA resubmitted to rule to OIRA—OIRA met with representatives from the Aeronautical Repair Station Association, Aerospace Industries Association, Air Transport Association of America, Aircraft Electronics Association, Aircraft Owners and Pilots Association, Airline Suppliers Association, General Aviation Manufacturers Association, National Air Carrier Association, National Air Transport Association, Professional Aviation Maintenance Association, The Boeing Company, General Electric Aircraft Engines, Goodrich, Honeywell, Rockwell Collins, and United Technologies Corporation.	There were a series of activities regarding this rule both before and after this return. On 07/02/2001, FAA submitted a draft of this rule for OIRA's review. On 07/11/2001, FAA withdrew the rule (at OIRA's suggestion according to FAA officials.) (This withdrawal is covered by GAO ID 84.) On 07/13/2001, FAA resubmitted the rule for OIRA's review, and OIRA returned it on 07/20/2001 (the sequence covered by this particular case). That same day FAA resubmitted the rule to OIRA. On 07/30/2001, OIRA completed its review of the rule (with the outcome coded "consistent with no change"). The rule was published on 08/06/2001 (66 FR 41088).

GAO ID	Executive order review submission	Reason for OIRA's return	Evidence that outside parties contacted or met with OIRA regarding this submission	Evidence of subsequent activity regarding this submission
73	Certification of Pilots, Aircraft and Repairmen for the Operation of Light Sport Aircraft Proposed rule RIN 2120-AH19 OIRA review period: 07/06/2001 to 08/09/2001	OIRA returned this rule because of concerns that the regulatory analysis did not adequately support the rule. OIRA noted that FAA used a baseline with which to compare the rule that assumed that, in the absence of this rule, FAA would propose a more stringent set of standards than in the proposal. Although OIRA had no objection to FAA analyzing an alternative that was more stringent than the proposal, OIRA believed that the benefits of the proposal should be compared with a status quo that did not include the artificial "baseline" assumption of increased stringency. OIRA also suggested that, as part of an improved analysis of alternatives, FAA could also consider means of improved compliance and enforcement of regulations currently in place. Given these concerns, OIRA suggested that DOT publish an advanced notice of proposed rulemaking before publishing the specific proposal and returned the rule to DOT for reconsideration.	No	FAA reexamined its regulatory evaluation and resubmitted the rule to OIRA on 12/17/2001. OIRA completed its review of the resubmitted rule on 01/03/2002 (outcome code "consistent with change") (see GAO ID 28). The proposed rule was published on 02/05/2002 (67 FR 5368).
74	Corrosion Control Plan Proposed rule RIN 2120-AE92 OIRA review period: 03/02/2001 to 09/18/2001	OIRA returned this rule because of concerns about the agency's regulatory analysis, primarily related to the cost-benefit analysis. Many of these same concerns applied to the analysis of a related FAA rule on aging aircraft. (See related rule at GAO ID 76.) Although FAA responded to some of these concerns in a revised regulatory evaluation on 07/27/2001, OIRA suggested that a concurrent review of this rule and the aging aircraft rule would help resolve OIRA's concerns and assist in determining the most cost-effective way to detect and correct problems affecting the safety of aging aircraft. Because resolution of these concerns would take additional time, OIRA returned the two rules to DOT and FAA for reconsideration.	No	On 06/18/2002, FAA resubmitted this rule to OIRA. On 09/16/2002, OIRA completed its review of the resubmitted rule (outcome code "consistent with no change"). The proposed rule was published on 10/03/2002 (67 FR 62142).

GAO ID	Executive order review submission	Reason for OIRA's return	Evidence that outside parties contacted or met with OIRA regarding this submission	Evidence of subsequent activity regarding this submission
75	Retrofit of Improved Seats in Air Carrier Transport Category Airplanes Proposed rule RIN 2120-AC84 OIRA review period: 05/14/2002 to 05/16/2002	According to the OIRA database, this rule was returned to FAA because it was an improper submission. However, FAA officials disputed that characterization. They stated that OIRA "had a slew of questions" to which FAA gave a 12-page response. They said that, after the return and an exchange of OIRA suggestions and FAA's response, FAA added language to further explain the plan for improving the seat certification process.	No	On 06/17/2002, FAA resubmitted this rule for OIRA's review. OIRA completed its review of the resubmitted version on 09/24/2002 (outcome code "consistent with change"). The proposed rule was published on 10/04/2002 (67 FR 62294).
76	Aging Airplane Safety Final rule RIN 2120-AE42 OIRA review period: 07/27/2001 to 09/18/2001	OIRA returned this rule due to concerns about the regulatory analysis. Many of these same concerns applied to the analysis of a related FAA corrosion control plan rule (GAO ID 74). Although FAA responded to some of these concerns in a revised regulatory evaluation on 07/27/2001, OIRA believed that a concurrent review of this rule and the corrosion control plan rule would help resolve OIRA's concerns and assist in determining the most cost-effective way to detect and correct problems affecting the safety of aging aircraft. Because resolution of these concerns would take additional time, OIRA returned the two rules to DOT-FAA for reconsideration.	No	On 06/18/2002, FAA resubmitted this rule to OIRA. On 09/24/2002, OIRA completed its review (outcome code "consistent with change"). According to FAA, the changes were to issue this as an interim final rule with a request for comment, instead of as a final rule, and to expand the benefit analysis in the regulatory evaluation. The interim final rule was published on 12/06/2002 (67 FR 72726).

GAO ID	Executive order review submission	Reason for OIRA's return	Evidence that outside parties contacted or met with OIRA regarding this submission	Evidence of subsequent activity regarding this submission
77	Revision of Digital Flight Data Recorder Regulations for Boeing 737 Airplanes and for Part 125 Operators Final rule RIN 2120-AG87 OIRA review period: 06/14/2001 to 09/18/2001	OIRA returned this rule due to concerns about the relative cost-effectiveness of requiring additional flight data recorder parameters, in light of additional steps that would be proposed in a related notice of proposed rulemaking on general flight recorder improvements.	No	The final rule is still pending, according to FAA officials.
DOT-NHTSA				
78	Tire Pressure Monitoring Systems Final rule RIN 2127-AI33 Economically significant OIRA review period: 12/17/2001 to 02/12/2002	OIRA returned this rule because it did not believe the analysis performed by NHTSA adequately demonstrated that the agency selected the best available alternative. Specifically, OIRA returned the rule for reconsideration of two analytic concerns related to safety. First, OIRA identified a regulatory alternative that NHTSA had not explicitly analyzed—considering the impact of regulatory alternatives on the availability of anti-lock brake systems. Second, OIRA said that the technical foundation for NHTSA's estimates of safety benefits needed to be better explained and subjected to sensitivity analysis.	Yes, prior to the formal review period On 10/26/2001, OIRA and DOT officials met with representatives of the Alliance of Automobile Manufacturers and various member companies, including Daimler-Chrysler, Ford, Toyota, and VW of America. (There was also a meeting after the formal review period – on 02/21/2002 – with the Rubber Manufacturers' Association.)	On 05/28/2002, NHTSA submitted a final rule to OIRA that contained the changes suggested by OIRA in the return letter. OIRA completed its review of the rule on 05/29/2002 (outcome code "consistent with no change"). The final rule was published on 06/05/2002 (67 FR 38704). The U.S. Court of Appeals recently held that the rule was contrary to the intent of the tire safety legislation and arbitrary and capricious under the APA. *Public Citizen, Inc. v. Mineta,* No. 02-4237 (2d Cir. Aug. 6, 2003).

GAO ID	Executive order review submission	Reason for OIRA's return	Evidence that outside parties contacted or met with OIRA regarding this submission	Evidence of subsequent activity regarding this submission
EPA-Office of Air and Radiation				
79	FY 2000 Report to Congress on EPA's Implementation of the Waste Isolation Pilot Plant Land Withdrawal Act Proposed rule RIN 2060-ZA12 OIRA review period: 09/13/2001 to 10/17/2001	OIRA returned this item because it was an improper submission.	No	N/A
EPA-Office of Water				
80	Federal Water Quality Standards for Indian Country and Other Provisions Regarding Federal Water Quality Standards Proposed rule RIN 2040-AD46 OIRA review period: 06/29/2001 to 10/02/2001	OIRA's return letter cited a number of concerns about this rule. In particular, the return letter noted that EPA did not provide a quantitative analysis of the costs and benefits that would result from this action. OIRA pointed out that the preamble identified nearly 300 point sources on tribal lands that would be directly affected by the rule and that there might be substantial numbers of nonpoint sources and point sources upstream of tribal lands that could also be affected. OIRA therefore stated that the rule could benefit from further analysis of costs and benefits in order to support informed public comment. OIRA was also concerned with EPA's conclusion that this proposed rule did not have federalism implications. OIRA noted that some of the impacts of this rule on states were likely to be significant (e.g., affecting state permitting activities in upstream waters), but the rule did not appear to contain any requirements for consultation with states. OIRA was also concerned that the rule appeared to establish for the first time EPA jurisdiction over waters whose Indian country status is in dispute.	No	No According to an EPA official, EPA has not resubmitted this rule to OIRA.

Source: GAO analysis.

Table 9: Findings and Determinations for Rules Withdrawn after Submission to OIRA

GAO ID	Executive order review submission	Did the agency withdraw this submission at the suggestion or recommendation of OIRA?	Reason for withdrawal of the submitted rule	Evidence that outside parties contacted or met with OIRA regarding this submission	Evidence of subsequent activity regarding this submission
APHIS					
81	Importation of Clementines From Spain Proposed rule RIN 0579-AB40 OIRA review period: 04/26/2002 to 05/21/2002	The withdrawal was characterized by APHIS as a mutual decision by APHIS and OIRA.	According to APHIS, OIRA and APHIS mutually decided to withdraw this rule to avoid violating the 90-day limit on reviews under Executive Order 12866.	No	APHIS resubmitted the rule to OIRA on 06/28/2002. OIRA completed review of the rule on 07/05/2002 (outcome code "consistent with change"). According to APHIS, OIRA had some changes to better explain the basis for the rule and to address concerns by Spanish clementine exporters. APHIS also noted that some changes were made to the regulatory language in response to the U.S. Trade Representative's Office. The rule was published on 07/11/2002 (67 FR 45922).

GAO ID	Executive order review submission	Did the agency withdraw this submission at the suggestion or recommendation of OIRA?	Reason for withdrawal of the submitted rule	Evidence that outside parties contacted or met with OIRA regarding this submission	Evidence of subsequent activity regarding this submission
FDA					
82	Records and Reports Concerning Experience with Approved New Animal Drugs; Final Rule (Listed in OIRA's database at time of GAO's review as: Records and Reports Concerning Experience with Approved New Animal Drugs; Implementing of Title I of the Generic Animal Drug and Patient [sic] Term Restoration Act) Final rule RIN 0910-AA02 OIRA review period: 08/28/2001 to 11/26/2001	FDA characterized the withdrawal as a mutual decision by FDA and OIRA.	According to FDA, OIRA and FDA made a mutual decision to withdraw the original final rule and reissue it as an interim final rule. Issuing this rule as an interim final rule with an opportunity for public comment was a compromise decision to address OMB's concerns regarding the length of time since publication of the proposed rule (12/17/1991) while not further delaying the rule by reproposing it.	No	FDA resubmitted the rule to OIRA on 11/29/2001. OIRA completed review of the rule on 01/08/2002 (outcome code "consistent with change"). According to FDA, OIRA had some clarifying comments, but these were not substantive (see GAO ID 15 in this appendix for additional details). An interim final rule was published on 02/04/2002 (67 FR 5046). (The interim final rule was published again on 07/31/2002, delaying the effective date indefinitely in order to address Paperwork Reduction Act of 1995 requirements and comments received on the interim final rule.)

GAO ID	Executive order review submission	Did the agency withdraw this submission at the suggestion or recommendation of OIRA?	Reason for withdrawal of the submitted rule	Evidence that outside parties contacted or met with OIRA regarding this submission	Evidence of subsequent activity regarding this submission
83	Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Dietary Ingredients and Dietary Supplements Proposed rule RIN 0910-AB88 Economically significant OIRA review period: 03/28/2001 to 12/19/2001	No The Department of Health and Human Services (HHS) withdrew the rule.	According to FDA, this rule previously had been submitted to OIRA for review but was initially withdrawn in response to the Card memo. Although FDA then resubmitted this rule to OIRA in March 2001, new policy makers in HHS wanted to reconsider the rule. Therefore, HHS decided to again withdraw the rule from OIRA's review.	No	FDA resubmitted a version of this rule to OIRA on 10/04/2002. OIRA completed review of the resubmitted rule on 01/16/2003 (outcome code "consistent with change"). The proposed rule was published on 03/13/2003 (68 FR 12158).

GAO ID	Executive order review submission	Did the agency withdraw this submission at the suggestion or recommendation of OIRA?	Reason for withdrawal of the submitted rule	Evidence that outside parties contacted or met with OIRA regarding this submission	Evidence of subsequent activity regarding this submission
DOT-FAA					
84	Part 145 Review: Repair Stations Final rule RIN 2120-AC38 OIRA review period: 07/02/2001 to 07/11/2001	Yes According to FAA, the agency withdrew the rule at OIRA's suggestion.	FAA officials stated that OIRA suggested the withdrawal due to "concerns from industry and the State department."	Yes On 07/09/2001— 2 days before the withdrawal—the Aeronautical Repair Station Association, the Airline Suppliers Association, and other business representatives sent a letter to OMB Director with a copy to OIRA asking that it send the rule back to FAA with instructions to prepare a Supplemental Notice of Proposed Rulemaking. (On 07/26/2001—after the withdrawal and also after OIRA's 07/20/2001 return of this draft rule—OIRA met with these business representatives.)	(See chronology presented under GAO ID 72, which covers the version of this rule that was returned by OIRA for reconsideration by DOT-FAA.)

GAO ID	Executive order review submission	Did the agency withdraw this submission at the suggestion or recommendation of OIRA?	Reason for withdrawal of the submitted rule	Evidence that outside parties contacted or met with OIRA regarding this submission	Evidence of subsequent activity regarding this submission
DOT-NHTSA					
85	Light Truck Average Fuel Economy Standard Model Year 2004 Final rule RIN 2127-AI68 Economically significant OIRA review period: 11/29/2001 to 12/12/2001	No NHTSA withdrew the rule.	According to NHTSA officials, they withdrew the rule because the agency did not want to promulgate fuel economy standards under the congressional freeze imposed when the rule was drafted, as it appeared that the freeze would soon be lifted (as it was on 12/18/2001).	No	NHTSA resubmitted a proposed rule to OIRA on 01/10/2002. OIRA completed review of the proposed rule on 01/17/2002 (outcome code "consistent with change" – see GAO ID 37 in this appendix for additional information). The proposed rule was published on 01/24/2002. A final rule was published on 04/04/2002 (67 FR 16052).

Source: GAO analysis.

Case Studies on Significantly Affected Rules With Evidence That OIRA Was Contacted by External Parties

The case studies described in this appendix include significantly affected rules that also had evidence of external party contact with OIRA during the review process. For each case, a description of the rule as submitted to OIRA, external party contact with OIRA, and changes ultimately made at OIRA's suggestion are included.

Control of Emissions from Nonroad Large Spark Engines

GAO ID 41
Agency: EPA
RIN: 2060-AI11
Rulemaking stage at time of review: Proposed
Date submitted to OMB for review: August 1, 2001
Date OMB review completed: September 14, 2001
Result of review: Consistent with change

Rule as Submitted to OIRA

On August 2, 2001, OIRA formally received a draft rule from EPA that proposed emission standards for several groups of nonroad engines. These engines include 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 and highway motorcycle engines.

Outside Parties' Contacts with OIRA

In communications with OIRA, marine and highway motorcycle industry representatives objected to being covered by the proposed rule standards. The Motorcycle Riders Foundation sent a letter (dated September 14, 2001) to the OIRA Administrator stating that EPA should defer the proposed rule's coverage of highway motorcycles. According to the letter, "there is no court-ordered deadline for this part of the regulation, and the EPA isn't otherwise under pressure to rush to regulation." The National Marine Manufacturers Association (NMMA) expressed similar concerns. A memo summarizing a meeting with OIRA and EPA on August 31, 2001, indicated that "the key issues raised by NMMA were a federal commitment to delay action on exhaust standards coupled with working with NMMA, Coast Guard and California on catalyst technology."

Changes Made to Rule at OIRA's Suggestion

A redline/strikeout version of the rule in EPA's docket containing "edits representing discussions between EPA and OMB on September 14" reflects deletions of language covering marine vessels with spark engines and

highway motorcycles. Language in the published proposed rule states: "We intended to include in this proposal emission standards for two additional vehicle categories: new exhaust emission standards for highway motorcycles and new evaporative emission standards for marine vessels powered by spark-ignition engines. Proposals for these two categories are not included in the September 14 deadline mandated by the courts, as is the case for the remaining contents that appear in today's proposed rule. We are committed to issue proposals regarding these categories within the next two to three months."

The proposed rule was published in the *Federal Register* October 5, 2001. The marine and highway motorcycle portions of the proposal were covered in a later proposed rulemaking, which was published in the *Federal Register* August 14, 2002.

Proposed Nonconformance Penalties for 2004 and Later Model Year Emission Standards for Heavy-duty Diesel Engines and Heavy-duty Diesel Vehicles

GAO ID 53
Agency: EPA
RIN: 2060-AJ73
Rulemaking stage at time of review: Proposed
Date submitted to OMB for review: December 10, 2001
Date OMB review completed: December 20, 2001
Result of Reviews: Consistent With Change

Rule as Submitted to OIRA

On at least four occasions EPA sent versions of the proposed rule preamble to OIRA previous to OIRA's formal review period. The exchanges began October 30, 2001, and OIRA's official review period was logged as beginning December 10, 2001. In the first draft rule sent to OIRA, EPA proposed that nonconformance penalties (NCP) be made available for the 2004 and later model year nonmethane hydrocarbons and nitrogen oxides standard for heavy-duty diesel engines and vehicles. According to the proposal, the availability of NCPs allows a manufacturer of heavy-duty engines or heavy-duty vehicles whose engines or vehicles fail to conform with certain applicable emission standards, but do not exceed a designated upper limit, to be issued a certificate of conformity upon payment of a monetary penalty. In the technical support document accompanying the rule

preamble, EPA originally used a 3 percent discount rate in calculating certain compliance and fuel costs which were then used in calculating NCP amounts.

Outside Parties' Contacts with OIRA

Regulated parties sent comments to OIRA and met with OIRA officials on several occasions before OIRA's official review of this rule began. From what is available in the OIRA meeting logs, some of the discussions concerned whether the rule would advantage or disadvantage certain engine manufacturers. (Available documents do not indicate that regulated parties suggested OIRA's primary revision to the rule—an increase in the discount rate used in the regulatory impact analysis.) OIRA's contact with external parties regarding the proposed version of this rule is described below.

On September 13, 2001, Cummins Inc. sent a letter to the OIRA Administrator requesting a meeting "to discuss an important regulation which has very serious competitive ramifications for our Company – the 2004 Nonconformance Penalty for Heavy Duty Engines." On October 1, 2001, OIRA, EPA, DOE met with Cummins Inc. to discuss the rule. Several days later (on October 12, 2001) Cummins Inc. sent a letter to the OIRA Administrator thanking him for the October 1, 2001, meeting and requested that the rule not harm engine manufacturers that produce compliant engines. On October 25, 2001, another engine manufacturer (Caterpillar) requested a meeting with OIRA regarding the heavy-duty diesel engine rule; the meeting was held November 14, 2001. On November 7, 2001 Cummins sent additional comments on the rule to the OIRA Administrator urging "expeditious review" of the rule.

Changes Made to Rule at OIRA's Suggestion

OIRA initiated an increase (from 3 percent to 7 percent) in the discount rate used in parts of the regulatory impact analysis for this rule. Some members of EPA's Environmental Economics Advisory Council recommended use of the 3 percent rate. OIRA's suggested change lowered the NCPs levied in the rule from the amounts originally proposed by EPA.

Most of OIRA's suggested changes to the discount rate occurred before OIRA's official review period. However, EPA did not completely switch to the 7 percent discount rate before the official review period began. In a draft submitted December 4, 2001, (about one week before OIRA's official review period began), the 3 percent discounted values remained and a table was added showing certain values if a 7 percent discount rate were used.

Additional language also requested comment on which discount rate would be more appropriate.

OIRA's rationale for increasing the discount rate is offered in the following correspondence with EPA: "We believe that it is more appropriate to use a discount rate of 7% (see OMB circular A-94) consistently throughout the rule, representing the opportunity cost of capital. Since the EPA NCP Cost Survey instructs respondents to discount by 3% and report net present value estimates for the fixed costs, hardware cost, warranty cost, and maintenance/operating cost, please discuss the necessary adjustments used in presenting NPB estimates, in the first version of the proposal, for these cost categories using the 7% discount rate." The rationale for a 7 percent discount rate is also included in a separate fax sent to EPA. By the time the proposed rule was published in the *Federal Register*, all discount rate discussion in the rule used a 7 percent rate. However, the following language is included in the rule regarding potential use of a different rate for portions of the impact analysis and an example of nonconformance penalty parameters using a 3 percent discount rate is included in the technical support document:

"… there is evidence in other contexts that users might apply a different discount rate than seven percent when considering future operating costs during a purchase decision. We request comment on whether there is evidence to support the application of such an alternative discount rate to operating costs in the various segments of the heavy duty engine market. Your comments in support of an alternative discount rate (a higher or lower value) should include a discussion of the supporting economic and business rationale for the alternative rate. We have included an example of the impact on the NCP parameters from using a smaller discount rate (three percent) in the draft Technical Support Document for this proposal."

Identification and Listing of Hazardous Waste (Manganese)

GAO ID 56
Agency: EPA
RIN: 2050-AE49
Rulemaking stage at time of review: Final
Date submitted to OMB for review: September 26, 2001
Date OMB review completed: October 31, 2001
Result of review: Consistent with change

Rule as Submitted to OIRA

On September 26, 2001, EPA submitted a draft final rule to OIRA for review listing manganese and two other wastes generated from inorganic chemical manufacturing processes as "hazardous constituents." EPA said in the

draft rule that it was adding manganese to the list "based on scientific studies demonstrating that manganese has toxic effects on humans." The agency said manganese had long been known to cause neurological effects in occupational settings, a "continuum of dysfunction" with low levels of exposure, and a danger to individuals with a hepatic insufficiency. EPA also cited evidence from epidemiological studies that point to negative health impacts of low-level exposure to manganese in drinking water. After considering public comments on the proposed rule, the agency refuted commenters' claims that manganese is not hazardous and said "we continue to believe that manganese is toxic and clearly poses significant risk to human health." EPA also said that, "based on consultations with individuals knowledgeable in hazardous waste treatment and corrective action, a review of the chemical properties of manganese, and review of Resource Conservation and Recovery Act (RCRA) regulations, the Agency does not believe that there are significant, incremental costs or economic impacts associated with adding manganese to [the list of hazardous constituents]."

Outside Parties' Contacts with OIRA

Also on September 26, 2001, legal counsel for the Cookson Group (an international materials technology organization) sent a letter to OIRA stating that the cost of the final rule to Cookson would be significantly higher than EPA estimated. The letter indicated that Cookson was obligated to manage and dispose of slag materials at a Laredo, Texas smelter that it once owned, and that the rule would classify this slag as hazardous waste—thereby costing the company an additional $29 million to $36 million. The letter also indicated that the "Laredo slag constitutes well over 90 percent of the material that will likely be subject to this rulemaking over the next 30 years." Later, on October 18, 2001, the counsel for the Cookson Group sent another letter to OMB requesting a meeting to discuss the "significant impact of the [rule] on Cookson at a former facility in Laredo, TX, which impact was not known to and considered by EPA when formulating the rule."

On September 28, 2001, counsel for the Steel Manufacturers Association and the American Iron and Steel Institute requested a meeting with the OIRA Administrator to discuss "the failure of [EPA] to conduct any analysis of the impact of the proposal on the steel industry, the country's largest consumer and user of manganese." On October 16, 2001, OIRA and EPA officials met with the organizations' counsels. Three days later, the counsel sent a letter to an OIRA official thanking him for the meeting and stating

that listing manganese as hazardous could harm the steel industry due to increased costs for treating manganese-contaminated waste.[1]

On October 8, 2001, the Eastman chemical company sent a letter to the OIRA Administrator stating that the company "strongly opposes adding manganese to [the listing of hazardous constituents] because of its very low toxicity and the substantial costs it would impose on facilities outside the inorganic chemicals industry, with no resultant environmental or health benefits."

Changes Made to Rule at OIRA's Suggestion

On October 31, 2001, OIRA's review of the rule ended, and the rule was coded as "consistent with change." A memo dated the same day was placed in the EPA docket submitting a "redline/strikeout" version of the rule showing the changes made "in response to comments from OMB." All language in the rule related to listing manganese as hazardous had been deleted. The following language was inserted in the text.

"We received numerous comments related to the risk associated with manganese and the economic impact to many industries, including the steel industry, of adding manganese to the Universal Treatment Standards requirements and to 40 CFR 261. Appendix VIII. Although we continue to believe that manganese poses significant issues that ultimately should be resolved, the court ordered schedule under which we are operating provides us with no flexibility to take additional time to explore these topics more fully. As a result, we have chosen to defer final action on [manganese]."

The final rule was published in the *Federal Register* on November 20, 2001. As of May 30, 2003 EPA had not published a rule regarding manganese.

[1]This letter was not in the EPA docket for the rule, but did appear in the OIRA docket.

Minimizing Adverse Environmental Impact from Cooling Water Intake Structures at New Facilities

GAO ID 65
Agency: EPA
RIN: 2040-AC34
Rulemaking stage at time of review: Final
Date submitted to OMB for review: September 10, 2001
Date OMB review completed: November 8, 2001
Result of review: Consistent with change

Rule as Submitted to OIRA

The draft version of the rule submitted to OIRA on September 10, 2001, implemented section 316 (b) of the Clean Water Act for new facilities (primarily electric power plants) that use water withdrawn from rivers, streams, lakes, reservoirs, estuaries, oceans or other waters of the U.S. for cooling purposes. The draft rule established national technology-based performance requirements applicable to the location, design, construction, and capacity of cooling water intake structures at new facilities. The national requirements also established the best technology available (referred to as a "closed-cycle recirculating cooling water system") for minimizing adverse environmental impacts associated with the use of these structures. The primary adverse environmental impact due to these structures is casualties among aquatic life forms (e.g., fish and shellfish).

The draft rule used a two-track approach to achieve technology based performance requirements. Track I established national intake capacity and velocity requirements as well as location- and capacity-based requirements to reduce intake flows to certain levels. This performance standard was to be commensurate with that produced by a closed-cycle recirculating cooling water system. Track II allowed permit applicants to conduct site-specific studies to demonstrate that alternatives to Track I would result in the same level of reduction of impingement and entrainment at the cooling water intake structure as would be achieved under Track I.

Outside Parties' Contacts with OIRA

Riverkeeper met with OIRA and EPA officials on September 27, 2001, regarding the rule and advocated "dry-cooling" as the technology basis for the final rule.

On October 29, 2001, industry representatives (from EOP Group and Edison Electric Institute) met with OIRA and EPA officials. The industry

representatives recommended that the final rule: (1) use the level of harm reduction in impingement and entrainment as the "point of departure to compare Track I and II," (2) allow different impingement and entrainment performance if the system minimizes total adverse environmental impacts, (3) eliminate the proposal for additional design and construction technologies, (4) allow alternative systems if achieving the Track I system performance is not a cost-effective reduction in adverse environmental impacts.

Changes Made to Rule at OIRA's Suggestion

Five substantive changes were made to the rule due to OIRA's suggestions.

- As originally written, EPA allowed facilities to qualify for alternative performance requirements that were less stringent than those required by the rule. OIRA suggested adding one additional criterion allowing qualification for less stringency if full compliance "would result in significant adverse impacts on local air quality, significant adverse impacts on local water resources not addressed under Section 125.84 (d) (1) (i), or significant adverse impacts on local energy markets." This additional criterion could have the effect of allowing more facilities to qualify for lower performance standards.

- As originally written, facilities withdrawing between 2 million gallons per day (MGD) and 10 MGD had to meet the performance requirements imposed on facilities with higher MGD withdrawal amounts. OIRA suggested changing the requirements so that facilities withdrawing between 2 MGD and 10 MGD did not have to reduce intake flow to a minimum level commensurate with that attained by a closed-cycle recirculating cooling water system. However, all other specifications remained applicable (e.g., through-screen intake velocities and total design intake flow requirements remained the same despite the OIRA change).

- As originally written, intake structures were required to use screens in order to minimize impingement mortality of fish and shellfish. OIRA suggested changing the requirement so that the facilities only needed to use the screens if certain criteria were met (e.g., if there are threatened or endangered species or habitat for these species within the hydraulic zone of the intake structure, if species of interest to fishery management agencies pass through the hydraulic zone, or if the primary performance requirements of the rule would not sufficiently ease stress on protected species or habitat.)

- As originally written, one of the intake flow requirements specified by EPA stated that "for cooling water intake structures located in a lake or reservoir, the total design intake flow must not alter the natural thermal stratification or turnover pattern of the source water." OIRA suggested adding an exception to this requirement by inserting the following language: "…except in cases where the disruption is determined to be beneficial to the management of fisheries for fish and shellfish by any fishery management agency (ies)."

- As originally written, EPA offered "Track II" compliance measures that allowed facility operators to comply with the performance standard of the rule through means other than a closed-cycle recirculating cooling water system. OIRA suggested adding "restoration measures" as a compliance alternative under the "Track II" compliance alternative so that intake structure operators may implement measures that "result in increases in fish and shellfish."

The final rule was published in the *Federal Register* December 18, 2001. Subsequently, on December 26, 2002, EPA published a direct final rule in order to make "minor changes to EPA's final rule published December 18, 2001." However, on March 24, 2003, EPA withdrew the direct final rule "due to adverse comments."

National Pollutant Discharge Elimination System (Existing Intake Structures)

GAO ID 68
Agency: EPA
RIN: 2040-AD62
Rulemaking stage at time of review: Proposed
Date submitted to OMB for review: December 28, 2001
Date OMB review completed: February 28, 2002
Result of review: Consistent with change

Rule as Submitted to OIRA

The proposed rule would have implemented section 316(b) of the Clean Water Act for certain existing power producing facilities that employ a cooling water intake structure and that withdraw 50 million gallons per day or more of water from rivers, streams, lakes, reservoirs, estuaries, oceans, or other waters of the U.S. for cooling purposes. According to the legislative history, section 316(b) "requires the location, design, construction, and capacity of cooling water intake structures of steam-

electric generating plants to reflect the best technology available for minimizing any adverse environmental impacts."

As submitted to OIRA on December 28, 2001, the draft proposed rule required that large facilities in estuaries and tidal rivers meet a uniform, national performance standard commensurate with a closed-cycle, recirculating cooling system that would reduce impingement mortality and entrainment.

Outside Parties' Contacts with OIRA

On January 15, 2002, EPA provided OIRA with a copy of slides from a presentation that the Public Service Electric and Gas (PSEG) Company made to EPA on January 3, 2002, regarding the section 316(b) rulemaking. The slides recommend a "streamlined site-specific approach" for the rule instead of uniform, national standards.

On January 23, 2002, Riverkeeper (an environmental group) sent a letter to the OIRA Administrator requesting a meeting on the rule. February 7, 2002, OIRA and EPA officials met with officials from Riverkeeper, who said Congress mandated that best technology available standards be nationally uniform and technology based—not set on a cases-by-case basis or related to the quality of the water involved. They also said that the use of site-specific best technology available determinations had perpetuated "the most destructive 'once-through' technology." Finally, they argued that leaving best technology available determinations to a case-by-case, site-specific determination "puts a tremendous burden on State regulatory agencies, as well as environmental and citizens groups."

On January 28, 2002, OIRA received an e-mail indicating "PSEG has prepared draft language for implementing Section 316(b) on a site-specific basis." The draft posited that permittees could demonstrate compliance with section 316(b) in any of three ways: (1) a demonstration based on a prior Section 316(b) determination, (2) a demonstration based on a site-specific evaluation of the best technologies or other measures for minimizing adverse effects, or (3) a demonstration to determine the presence of any adverse environmental effects. The draft concluded by saying that "voluntary restoration or conservation measures may be used, in conjunction with or instead of technologies, to demonstrate that a [cooling water intake structure] is not causing (adverse environmental impact)." On January 31, 2002, OIRA received a fax from the EOP Group (a consulting company) containing identical draft section 316(b) regulations "for Site-Specific Permit Renewal Options for Existing Sources."

In February 2002, the Edison Electric Institute prepared a paper advocating a site-specific approach to regulating intake structures that are managed by states. (We discovered the document in the OIRA docket for the rule, although it is not clear how the paper was submitted to OIRA).

On January 31, 2002, Cinergy Corporation sent a letter to the OIRA Administrator requesting a meeting with him on the proposed rule. The Edison Electric Institute sent a similar letter on February 4, 2002. On February 8, 2002, OIRA and EPA officials met with officials from a number of regulated parties, including "TXU" (meaning unclear), Cinergy, Public Service Enterprise Group, Edison Electric Institute, Progress Energy, Teco Energy, Constellation Energy Group, Allegany Energy, Minnesota Power, and Mirant Corporation. Documents submitted at the meeting advocate a "site-specific approach" as "the best means for ensuring cost-effective environmental protection." The documents also indicated that the uniform technology standards "would be based upon performance standards that could only be met by retrofitting to closed cycle cooling for some or all power plants covered under the Phase II rule." In addition, the documents indicated that retrofitting 40 percent of existing open cycle capacity would cost $40 billion, that wide-scale construction outages could affect regional power supplies, and increased air emissions could result from lower-efficiency closed-cycle systems.

On February 27, 2002, OIRA received a fax from the EOP Group forwarding letters that EPA had received from the states and others on the section 316(b) rule. The letters were signed by representatives from the Pennsylvania Department of Environmental Protection, the Marine Mammal Commission, the Texas Natural Resource Conservation Commission, the Office of the Governor of the State of North Carolina, and the Illinois Environmental Protection Agency.

Changes Made to Rule at OIRA's Suggestion

On February 14, 2002, EPA submitted a summary of the revised regulatory proposal to OMB. The summary stated that permittees could chose one of three alternatives for establishing the best technology for minimizing adverse environmental impact at its facility—(1) demonstrate that existing technologies and measures meet regulatory performance standards, (2) demonstrate that technologies and measures selected by the permittee will meet performance standards, and (3) demonstrate that a site-specific determination of best technology available is appropriate. The summary went on to say that restoration could be used in lieu of or in combination with intake technologies and operational measures if the results could be

shown to be comparable to the results obtained from compliance with the regulatory standards.

In its summary of changes made during interagency review, one of the changes that EPA identified as having been suggested by OIRA was "added new regulatory framework that provides three compliance alternatives for the Phase II existing facility rule."

On February 28, 2002, OIRA approved the rule as revised. The rule was published in the *Federal Register* on April 9, 2002.

Effluent Limitation Guidelines and New Source Performance Standards for the Construction and Development Category

GAO ID 70
Agency: EPA
RIN: 2040-AD42
Rulemaking stage at time of review: Proposed
Date submitted to OMB for review: March 1, 2002
Date OMB review completed: May 15, 2002
Result of review: Consistent with change

Rule as Submitted to OIRA

As originally submitted to OIRA, the draft proposed rule would have established effluent limitations for 150,000 construction firms. The draft contained a number of regulatory options to control discharges from active construction sites of one acre or larger (temporary erosion and sediment controls applicable to construction sites while land is being disturbed – three options) and long-term storm water discharges (postconstruction, long-term storm water management options intended as permanent storm water controls – three options). EPA's preferred option combination contained two major provisions. For active construction sites, it would have codified EPA's current construction general permit, along with a design goal of 80 percent reduction in total suspended solids (TSS) discharged from sites and a series of enhanced inspection and certification requirements to improve compliance.[2] EPA's preferred option for management of postconstruction storm water run-off would have established a design goal of an 80 percent reduction in TSS discharge from

[2]TSS are characterized by EPA as conventional pollutants. The primary TSS of concern in this rulemaking is sediment.

finished projects and a requirement to maintain peak runoff levels at pre-construction levels.

Outside Parties' Contacts with OIRA

ELG Working Group (an industry association) met with OIRA and EPA on February 4, 2002 and argued that additional storm water regulations for the construction and development industry are "unnecessary and unwarranted" because construction and development activities "have been subject to federal, state and often local regulations for controlling storm water discharges since 1990." In a document prepared for the meeting, the ELG Working Group suggested that the federal government should encourage state and local flexibility to address water quality issues.

Changes Made to Rule at OIRA's Suggestion

In a memo regarding interagency review, dated May 22, 2002 with no author listed, changes to the rule while under OIRA review are identified, including a change that dropped the postconstruction requirements from the proposed rule. The memo stated that "given the requirement to address postconstruction runoff in the Phase I and Phase II municipal stormwater program, EPA determined that it would be more appropriate to support local communities in developing tailored programs that could better reflect regional and local conditions, and be better integrated into broader local planning efforts."

According to a June 10, 2002, memo (the memo author was not identified), the agency made several changes to the proposed regulation at the suggestion or recommendation of OIRA. The proposed regulation no longer included the storm water management, or postconstruction, regulatory options. Also, the active construction options changed. These changes consisted of identifying and discussing three regulatory options: (1) inspection and certification of construction site erosion and sediment controls, for sites one acre or larger, (2) codification of the Construction General Permit, plus inspection and certification requirements, for sites five acres or larger, and (3) no regulation. These revisions to the regulatory proposal required corresponding revisions to the preamble.

On June 24, 2002, the proposed rule was published in the *Federal Register*.

Effluent Limitations Guidelines for the Iron and Steel Manufacturing Point Source Category

GAO ID 71
Agency: EPA
RIN: 2040-AC90
Rulemaking stage at time of review: Final
Date submitted to OMB for review: March 29, 2002
Date OMB review completed: April 30, 2002
Result of review: Consistent with change

Rule as Submitted to OIRA

The draft rule as submitted to OIRA for review revised technology-based effluent limitations guidelines and standards for certain wastewater discharges associated with metallurgical cokemaking, sintering, and ironmaking operations. In its original form, the rule would have retained an existing minimum net reduction provision in regulations regarding use of a "water bubble" mechanism. According to the rule preamble, the "water bubble" is a regulatory flexibility mechanism that allows trading of identical pollutants at any single steel facility with multiple compliance points to realize cost savings and/or to facilitate compliance. Under the existing regulations, facilities that used the water bubble mechanism were required to reduce the amount of their pollutant discharges pursuant to the bubble to 10 percent to 15 percent less than the discharges otherwise authorized by the regulations without use of the bubble. This additional reduction was referred to as the "minimum net reduction" provision throughout the rule.

Outside Parties' Contacts with OIRA

Counsel for Steel Manufacturers Association and Specialty Steel Industry of North America met with OIRA and EPA officials to discuss this rulemaking on March 19, 2002. In the letter requesting a meeting, the industry counsel argued that "revised effluent limitation guidelines are not technically, economically, or legally justified." The counsel further specified aspects of EPA's cost-benefit analysis that were believed to be flawed, said that the actual cost-benefit ratio for this rule was at least 100:1, and asserted that the rule would be the "most cost-ineffective ELG [effluent limitation guideline] ever promulgated."

Changes Made to Rule at OIRA's Suggestion

The major change in this final rule that was attributed to a request from OIRA eliminated the existing minimum net reduction provision that applied if facilities used a "water bubble" alternative. Because of the elimination of

this minimum net reduction provision, facilities that trade pollutants in accordance with the water bubble mechanism are not required to reduce pollutant discharges to be 10 percent to 15 percent less than the discharges otherwise authorized by the rule without use of the water bubble (as had been required by the existing provision). This water bubble provision was the subject of public comments on EPA's proposed rule, with industry groups generally supportive of the water bubble flexibilities and environmental groups advocating restrictions on the water bubble. The OIRA files on its review of this draft final rule indicated that OIRA had reviewed the substantive comments EPA received on the proposed rule.

On October 17, 2002, the final rule was published in the *Federal Register*.

Tire Pressure Monitoring Systems

GAO ID 78
Agency: DOT-National Highway Traffic Safety Administration (NHTSA)
RIN: 2127-AI33
Rulemaking stage at time of review: Final
Date submitted to OMB for review: December 17, 2001
Date OMB review completed: February 12, 2002
Result of Review: Returned

Rule as Submitted to OIRA

As submitted to OIRA for review, the draft final rule would have established a standard under which all new vehicles would be required to have a tire pressure monitoring system (TPMS). The rule would have allowed automobile manufacturers to use either of two types of systems until October 31, 2006 —a "direct" system that measures the pressure in each tire or an "indirect" system that uses a vehicle's antilock brake system to sense tire pressure differences by monitoring the speed of tire revolution. However, after October 31, 2006, the rule would have required manufacturers to use only the direct monitoring systems.

Outside Parties' Contacts with OIRA

On October 26, 2001—3 months after the Notice of Proposed Rulemaking was published in the *Federal Register* and almost 2 months before the draft final rule was submitted to OIRA for review—OIRA and NHTSA officials met with representatives from the Alliance of Automobile Manufacturers and representatives from individual auto manufacturers (Toyota, Ford, Volkswagen, and Daimler Chrysler). According to a summary of the meeting prepared by NHTSA and placed in the DOT docket, most of the

comments presented by the industry representatives were similar to those in their filed written comments concerning such issues as legislative intent, assumptions about costs and benefits, the validity of test data on stopping distance, the number of vehicles operating with more than one significantly underinflated tire, and the safety benefits of antilock braking systems. In its March 23, 2001, comments on the proposed rule, the Alliance of Automobile Manufacturers said it "believes that both wheel-speed based [indirect] and pressure-sensor based [direct] TPMS have merit, and should be permitted under pending requirements. Our proposal will allow the further development of both types of systems."

On October 31, 2001, the Alliance sent letter to the OIRA Administrator reiterating views regarding the draft final rule. The Alliance expressed concern that the structure of the final rule would have the effect of eliminating indirect tire pressure monitoring systems as a compliance option. According to the letter:

"The Alliance has seen no evidence in the rulemaking record to suggest that real world safety benefits that may accrue from tire pressure monitoring systems will be noticeably different between systems using indirect and direct sensing technologies. Absent such evidence, the Alliance believes that the final rule should be carefully structured to allow, at a minimum, current systems employing either type of sensing technology – indirect or direct – to be used as compliance options. As additional field experience is developed through the implementation of this mandate, NHTSA may in the future exercise its long-standing authority to initiate rulemaking to enhance the performance requirements for tire pressure monitoring systems as may be warranted by valid engineering and performance data. The rule should also be structured to assure the timely and orderly implementation by providing a reasonable phase-in period."

OIRA officials also met with representatives from the Rubber Manufacturers Association regarding the rule on February 21, 2002—9 days after OIRA returned the rule for reconsideration. However, because NHTSA officials did not attend the meeting because of agency policy, there is no summary of the meeting available. An e-mail attached to the OIRA meeting log stated that, according to an OIRA branch chief, "this is not an (Executive Order 12866) meeting, since the rule is no longer here for review." Nevertheless, OIRA listed the meeting on its Web site.

Changes Made to Rule at OIRA's Suggestion

According to the February 12, 2002, return letter, OIRA said "NHTSA needs to provide a stronger analysis of the safety issues and benefits, including a formal analysis of a regulatory alternative that would permit indirect systems after the phase-in period. Moreover, NHTSA could analyze an option that would defer a decision about the ultimate fate of indirect

systems for several more years, until the potential impact on installation of anti-lock brake systems is better understood."

According to a July 24, 2002, NHTSA memo, the agency changed the draft rule at OIRA's suggestion to "permit vehicle manufacturers to use current indirect TPMSs as their means of complying with the standard." The new draft final rule established two compliance options for a period beginning November 1, 2003, and ending October 31, 2006. During this period, automobile manufacturers would be allowed to use either direct or indirect TPMSs. Meanwhile, NHTSA said that it would conduct additional studies and would leave the rulemaking docket open for the submission of new data and analysis. NHTSA said the second part of the rule will be issued by March 1, 2005, and will set performance standards to become effective November 1, 2006. Depending on the data developed during the first period, the performance standards issued in 2005 could require direct monitoring systems (as in the draft final rule as submitted to OIRA), or they could reach some other determination (e.g., continue to allow the use of indirect systems).

On May 28, 2002, NHTSA resubmitted the draft final rule for OIRA review. The next day, OIRA approved the rule "consistent with no change." On June 5, 2002, the final rule was published in the *Federal Register*.[3]

[3] The U.S. Court of Appeals recently held that the rule was contrary to the intent of the tire safety legislation and arbitrary and capricious under the APA. *Public Citizen, Inc. v. Mineta*, No. 02-4237 (2d Cir. Aug. 6, 2003).

Part 145 Review: Repair Stations

GAO IDs 84 and 72
Agency: DOT-FAA
RIN: 2120-AC38
Rulemaking stage at time of review: Final
Dates submitted to OMB for review: July 2, 2001; resubmitted July 13, 2001; resubmitted July 20, 2001
Dates OMB review completed: July 11, 2001 (withdrawn); July 20, 2001 (returned); July 30, 2001 (consistent with no change)
Result of Reviews: Withdrawn, returned, consistent with no change

Rule as Submitted to OIRA

As submitted to OIRA on July 2, 2001, the rule updated and revised the regulations for repair stations. Specifically, the rule reorganized the requirements applicable to repair stations to reduce duplication of regulatory language and eliminate obsolete information. In addition, the rule established new definitions applicable to repair stations and updated requirements relating to repair station certification; housing, facilities, equipment, materials, and data; personnel; and operations. The rule also eliminated, where practicable, distinctions between repair stations based on geographical location.

Outside Parties' Contacts with OIRA

On July 9, 2001, the Aeronautical Repair Station Association (ARSA) and other industry representatives sent a letter to the Director of OMB (with copies to the Deputy Administrator of OIRA and other OIRA officials and staff) requesting that OIRA send the Part 145 rule back to FAA "with instructions to prepare a Supplemental Notice of Proposed Rulemaking (SNPRM) to address all of the issues needed to modernize Part 145."

On July 26, 2001, ARSA and other industry representatives met with OIRA officials and an official from the Department of Commerce (but no one from FAA) to discuss the Part 145 rule. (DOT officials told us that they generally do not attend meetings with industry representatives at OMB.) In their presentation to OIRA, the industry representatives repeated their request that a supplemental notice of proposed rulemaking be issued instead of the final rule. They also requested that guidance material be issued at the same time that the final rule is issued and that a more realistic compliance date be set.

Actions Taken at OIRA's Suggestion

On July 11, 2001, FAA withdrew the rule from OIRA review. An FAA chronology of the rulemaking process stated that OMB "asked FAA to withdraw the final (rule)." That same day, counsel to ARSA testified before the House Subcommittee on Aviation on the FAA rulemaking process, and attached the above-mentioned July 9, 2001, letter to his statement. During our review, the counsel told us that he did not know whether OIRA had requested that FAA withdraw the Part 145 rule, but said any such action on OIRA's part "had nothing to do with us."

On July 13, 2001, FAA resubmitted the rule to OIRA for review. FAA officials told us that the resubmitted rule was identical to the rule submitted to OIRA on July 2, 2001. On July 20, 2001, OIRA returned the rule to FAA for reconsideration. In his return letter, the Deputy Administrator of OIRA said that the Department of State and the Office of the United States Trade Representative indicated that certain language in the rule could be read by other governments as a "needs test" for foreign repair stations that would "raise a significant issue of our compliance with applicable international trade agreements." However, FAA officials told us that they had already addressed the Department of State's concerns. Therefore, they said FAA resubmitted the rule to OIRA (unchanged from its previous submission) on the same day as the return letter—July 20, 2001.

On July 30, 2001, OIRA approved the rule as "consistent with no change," and did not suggest that FAA make the changes that the industry representatives recommended. On August 8, 2001, FAA published the final rule in the *Federal Register*.

Status of 23 High Priority Review Rules

In its May 2001 draft report on the costs and benefits of federal regulations, the Office of Information and Regulatory Affairs (OIRA) within the Office of Management and Budget requested that the public provide it with "suggestions on specific regulations that could be rescinded or changed that would increase net benefits to the public by either reducing costs and/or increasing benefits." In its December 2001 final report, OIRA said it had received 71 suggestions in response to its request. The report also indicated that OIRA had completed an initial review of the suggestions and placed each of the suggestions into one of three categories: (1) "high priority," meaning that OIRA was inclined to agree with and look into the suggestion, (2) "medium priority," meaning that OIRA needed more information about the suggestion, or (3) "low priority," meaning that OIRA was not convinced that the suggestion had merit. OIRA listed 23 of the suggestions in the first category, and said a "prompt letter" might be sent to the responsible agency for its "deliberation and response."

In its December 2002 report, OIRA reported on the status of these 23 high priority suggestions. We used that information and supplemented it with additional information from published sources to determine the status of each of the regulations or issues that were the subject of the 23 suggestions as of May 2003. We then asked OIRA to review our descriptions and provide us with any additional information available. The consolidated information is presented in the table below for each of the 23 suggestions.

Table 10: Status of the 23 High Priority Review Suggestions Identified in OIRA's December 2001 Report on the Costs and Benefits of Federal Regulations

Regulation/issue and concern (as reported by OIRA)	Status
The Mercatus Center said that the Department of Energy's analysis for its central air conditioner and heat pump energy conservation standards did not adequately consider key differences among consumers and may overstate projected energy savings.	As published in January 2001, a Department of Energy final rule would have required that the energy efficiency of new central air conditioners and heat pumps be increased by 30 percent by January 2006. However, in May 2002, the department withdrew the rule and issued a new final rule raising minimum energy efficiency by 20 percent. The department said the withdrawn rule, which never became effective, was "not economically justified under the Energy Policy and Conservation Act."
The Mercatus Center said Department of Health and Human Services (HHS) rule on standards for privacy of individually identifiable health information imposed a costly approach to medical privacy protections while failing to offer tangible benefits.	In August 2002, the department published final revisions to a December 2000 medical privacy rule, clarifying some aspects and modifying others. For example, instead of mandating that direct treatment providers obtain prior written consent to use protected health information before treating a patient, the final rule required them to make a good faith effort to obtain a patient's written acknowledgement that the patient received a notice of privacy rights and practices. The department said the changes were intended to, in part, relieve "unintended administrative burdens created by the Privacy Rule."

(Continued From Previous Page)

Regulation/issue and concern (as reported by OIRA)	Status
The Mercatus Center said that the Food and Drug Administration's (FDA) proposed rule on trans fatty acids in nutrition labeling misled the public by treating trans fats as a subset of saturated fat.	In September 2001, the OIRA administrator sent HHS a prompt letter on the trans fatty acid content of foods, encouraging the agency to give the issue greater priority. FDA submitted the draft final rule to OIRA for review in May 2003.
The Mercatus Center said the costs of the Department of the Interior's (DOI) Bureau of Land Management (BLM) rule on hardrock mining outweighed the benefits.	In March 2001, BLM published a proposed rule to suspend the hardrock mining regulations that took effect in January 2001. In October 2001, BLM published a final rule removing certain provisions and returning others to those in effect before January 2001. For example, the final rule removed a provision granting federal land managers more authority to deny hardrock mining permits and deleted enhanced performance standards for groundwater and site remediation. BLM said the new rule "balances the nation's need to maintain reliable sources of strategic and industrial minerals, while ensuring protection of the environment and natural resources on public lands."
The Mercatus Center said that DOI's National Park Service's rule prohibiting snowmobile use in Rocky Mountain National Park did not allow for different types of users to enjoy the park.	In its December 2002 report, OIRA stated that the January 2001 DOI proposed rule on at issue in this suggestion was undergoing internal departmental review. As of May 2003 no final rule had been issued. However, in response to a lawsuit involving a separate January 2001 final rule that restricted snowmobile use in other parks in the Rocky Mountains, the National Park Service initiated an environmental impact statement that, when completed in February 2003, suggested allowing the use of snowmobiles with access restrictions and limitations on the types of engines. In March 2003, the Park Service approved a record of decision selecting that alternative. Legislation has been introduced in both the House and the Senate that would, if enacted, reinstate the ban on snowmobile use in the parks.
The Mercatus Center said the Department of Labor's (DOL) regulations on "helpers" under the Davis-Bacon Act should attempt to conform to private sector practices. Specifically, Mercatus questioned the department's definition of a "helper," which it said "constrains private sector practices and innovation."	In November 2000, DOL published a final rule allowing contractors on federal and federally assisted construction projects to use "helpers" when that practice prevails in a locality. In December 2002, OIRA noted in its final report on the costs and benefits of regulations that DOL decided that changes to the Davis-Bacon regulations were not appropriate at that time.
The Mercatus Center said the Department of Transportation (DOT) did not present data supporting its conclusions in its rule on the hours of service of drivers that driver fatigue contributes to highway fatalities or that its proposal would address those issues.	In May 2000, DOT's Federal Motor Carrier Safety Administration (FMCSA) published a proposed rule to alter the hours of service for truck and other motor carrier drivers. The agency received more than 50,000 comments on the proposal, which it later characterized as "generally unfavorable." The fiscal year 2002 appropriations bill prohibited the department from moving to a final rule that year. In April 2003, FMCSA published a final rule that changed the scope and certain requirements from the proposal. For example, the final rule exempted buses from its coverage.
The Mercatus Center said that revisions to the Environmental Protection Agency's (EPA) total maximum daily loads program were overly prescriptive and could cost the states billions of dollars.	EPA's July 2000 final rule on the program was intended to resolve issues concerning the identification of impaired waterbodies and to address other issues. However, in an amendment to a fiscal year 2000 appropriations bill, Congress prohibited EPA from implementing the rule. In October 2001 EPA published a notice delaying the effective date of the agency's July 2000 rule until April 2003. In March 2003, EPA published a final rule withdrawing the July 2000 rule. According to OIRA, as of May 2003, a draft of a new proposed rule was undergoing informal interagency review.
The Mercatus Center recommended changes to EPA's guidance on states' use of economic incentive programs to achieve air quality standards.	In its December 2002 report, OIRA said it would "consider further review of the guidance after the States have further experience with the current guidelines."

(Continued From Previous Page)

Regulation/issue and concern (as reported by OIRA)	Status
The Mercatus Center said that EPA's new source review program was a deterrent to investment in new oil refinery and power generation capacity, and that even relatively modest modifications that improve environmental performance could trigger the reviews.	In December 2002, EPA published a final rule revising the Clean Air Act's new source review program that provides industrial facilities with alternatives to the program's requirements to install modern pollution controls whenever they make major modifications that significantly increase emissions. EPA asserts that the rule will remove obstacles to investments in cleaner and more efficient processes, and provide greater certainty and administrative flexibility. Certain environmental groups and state and local governments petitioned EPA to reconsider specific aspects of the rule, and EPA has agreed to reconsider and take public comment on several of the issues raised by these parties. Also in December 2002, EPA published a proposed rule that would revise an exemption from the rule for projects involving routine maintenance, repair, and replacement.
The Mercatus Center said that while concentrated animal feeding operations are a problem in some areas, the benefits of a national rule establishing effluent guidelines do not justify the costs.	In January 2001, EPA published a proposed rule changing the Clean Water Act permitting requirements for concentrated animal feeding operations and strengthening the effluent guidelines for those facilities. In February 2003, EPA published a final rule that OIRA said had been significantly scaled back from the proposal, but would still more than triple the number of operations that would have to obtain permits. However, environmental groups said the new rule weakened the existing standard and said they were considering a lawsuit.
The Mercatus Center and the Association of Metropolitan Water Agencies said the benefits of EPA's rule on arsenic in drinking water did not justify the costs.	EPA's January 2001 final rule lowered the allowable level of arsenic in drinking water from 50 parts per billion to 10 parts per billion. In May 2001, EPA delayed the rule's implementation to review the science and cost factors associated with changing the standard. In September 2001, the National Academy of Sciences published a report indicating that low levels of arsenic can result in higher incidences of cancer. In October 2001, EPA announced that it would publish a final standard at the 10 parts per billion level.
The Mercatus Center said that the Department of Agriculture's Forest Service rule on roadless area conservation would cause unnecessary economic and environmental costs.	A January 2001 Forest Service final rule prohibited road construction, reconstruction, and timber harvesting in inventoried roadless areas on nearly 60 million acres of National Forest System land. In May 2001, the Idaho District Court granted a preliminary injunction enjoining the Forest Service from implementing all aspects of the rule. According to OIRA, in December 2002, the U.S. Court of Appeals for the Ninth Circuit lifted the injunction and remanded the decision to the District Court. As of May 2003 its decision was pending. Also, in July 2003, the Wyoming District Court granted a permanent injunction enjoining the Forest Service from implementing this rule.
The Mercatus Center said the Forest Service's planning procedures polarize the public and are a drain on Forest Service resources.	In December 2002, the Forest Service published a rule proposing changes to its November 2000 rule on forest planning. A review conducted at the direction of the Office of the Secretary concluded that the 2000 rule was "neither straightforward nor easy to implement," and "did not clarify the programmatic nature of land and resource planning." The new proposed rule would, among other things, allow federal land managers to disregard previously established scientific requirements for wildlife protection and expedite the environmental review process when developing plans. According to OIRA, a final rule is expected in the fall of 2003.
Notre Dame University said the Department of Education's regulations under title IV of the Higher Education Act are redundant and place inappropriate administrative burden on institutions of higher education.	In November 2002, the Department of Education published a final rule amending the department's regulations under the Higher Education Act and other statutes. According to the department, the amendments were designed to "reduce administrative burden for program participants, and to provide them with greater flexibility to serve students and borrowers."

(Continued From Previous Page)

Regulation/issue and concern (as reported by OIRA)	Status
The Equal Employment Advisory Council said that DOL's Office of Federal Contract Compliance Programs' (OFCCP) equal opportunity survey is excessively burdensome and ineffective in targeting contractors for compliance audits.	In January 2003, the Employment Standards Administration within DOL announced a "preclearance consultation program" in which the public was allowed to provide comment on the equal opportunity survey. Comments were due by the end of March 2003. The announcement indicated that OFCCP had engaged an outside contractor to study the survey submissions, and that the study would be completed in 2004. In addition, OFCCP requested a 2-year extension to its authorization for the survey under the Paperwork Reduction Act (until the end of March 2005).
The EEAC said the Equal Employment Opportunity Commission's (EEOC) Uniform Guidelines on Employee Selection Procedures should establish a standard definition of a "job applicant" that does not impose undue burden on employers to solicit race and gender information.	DOL said it and the other signatories to the Uniform Guidelines (EEOC, the Department of Justice, and the Office of Personnel Management) have been meeting for more than 3 years on the applicant redefinition issue, particularly as it relates to recordkeeping and reporting requirements. The department also said that reauthorization responsibility rests with EEOC in consultation with the other signatory agencies, and said OMB has requested resolution of this issue by the end of September 2003.
The Employment Policy Foundation (EPF) said that regulations affecting most employment-based immigration cause needless effort and delays, and recommended replacing the certification process with a simpler attestation procedure.	In May 2002, the Employment and Training Administration within DOL published a proposed rule that would, among other things, amend its regulations governing the filing and processing of labor certification applications for the permanent employment of aliens in the United States. In December 2002, OIRA indicated that DOL was in the process of addressing comments and finalizing the rule.
LPA, Inc. said DOL requirements regarding overtime compensation are a disincentive for providing bonuses.	OIRA indicated in its December 2002 report that DOL was considering whether revisions to these regulations would be appropriate.
EPF and the National Partnership for Women and Families said record keeping and notification regulations under the Family Medical Leave Act are burdensome and ambiguous.	In December 2002, OIRA said that DOL was considering whether revisions to these regulations would be appropriate. In February 2003, the Employment Standards Administration within DOL announced that it was conducting a preclearance consultation program (allowing the public and federal agencies to comment) regarding information collections under the Family and Medical Leave Act. The department said it was particularly interested in, among other things, "whether the proposed collection of information is necessary for the proper performance of the functions of the agency."
The American Chemistry Council said that EPA's "mixture and derived from" rule under the Resource Conservation and Recovery Act is necessarily inclusive, and recommended exempting certain waste streams resulting from the treatment of hazardous waste from the requirements.	In April 2003, EPA published a proposed rule adding two chemicals—benzene and 2-ethoxyelthanol—to the list of solvents that can be mixed with wastewater without causing it to be defined as hazardous waste. The proposed rule also would provide flexibility in the way compliance is determined, and would make additional listed hazardous wastes eligible for the *de minimus* exemption.
The City of Austin said EPA needed to improve its cost-benefit estimates for drinking water regulations under the Safe Drinking Water Act in three areas (overly conservative assumptions, inappropriate discount rates, and inadequate consideration of latency) and should change the way fatal risk reduction is valued.	In its December 2002 report, OIRA indicated that it was addressing the issues raised in this suggestion in its new analytic guidance. (See chapter 2 of this report for a discussion of that guidance.)

(Continued From Previous Page)

Regulation/issue and concern (as reported by OIRA)	Status
The American Petroleum Institute said EPA needed to make several changes to its requirements regarding the notification of substantial risk under section 8(e) of the Toxic Substances Control Act (e.g., limit reporting to information that truly meets the statutory standard of substantial risk).	In its December 2002 report, OIRA said EPA was considering several options to address this issue and said EPA had established a new web page that contains guidance, previous submissions, and new submissions posed within 2 weeks of receipt. OIRA also said that EPA was working on a package that would make policy clarifications.

Source: OIRA and GAO analysis of published information.

Comments from the Office of the Information and Regulatory Affairs

ADMINISTRATOR
OFFICE OF
INFORMATION AND
REGULATORY AFFAIRS

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
WASHINGTON, D.C. 20503

SEP 2 2003

Mr. Victor Rezendes
Managing Director
Strategic Issues Team
U.S. General Accounting Office
441 G Street, NW
Washington, DC 20548

Dear Mr. Rezendes:

Thank you for this opportunity to comment on the General Accounting Office's (GAO) draft report on the Office of Management and Budget's (OMB) Office of Information and Regulatory Affairs' (OIRA) regulatory review process ("RULEMAKING: OMB's Role and Transparency of Reviews of Agencies' Draft Rules").

We appreciate GAO's extensive effort to provide a factual analysis of OIRA's regulatory review process. Overall, OIRA believes that the factual foundations of the report are well-grounded. In particular, we are pleased that the draft report takes note of two changes that I have made in the regulatory review process – ensuring that OIRA completes its review of draft rules in a timely manner and increasing the transparency of the regulatory review process.

Regarding the timeliness of OIRA's review, Executive Order No. 12866 (E.O. 12866) states that OIRA's review should generally take no longer than 90 days. However, as GAO notes in its draft report, OIRA during the latter part of the prior Administration (in the late 1990s and in 2000) routinely had many dozens of draft rules pending beyond the 90-day period. One of the first steps that I took, upon becoming OIRA Administrator, was to emphasize to OIRA staff and to the rulemaking agencies the importance of adhering to the 90-day timetable. As I made clear, OIRA reviews should rarely, if ever, extend beyond 90 days. As a result, the number of draft rules pending beyond 90 days quickly plummeted and, as GAO notes in the draft report, OIRA's review has extended past 90 days in only a very few instances during my tenure. We think it is important to note that this dramatic decline in post-90-day rules is not attributable to OIRA's increasing use of "return letters." That is because, as GAO's draft report confirms, the decrease in the number of post-90-day rules far exceeds the number of OIRA return letters (nor is the increasing timeliness of OIRA review due to an increase in the number of agency withdrawals of draft rules; again, the decline in post-90-day-rules far exceeds the number of withdrawals). Instead, this increase in timeliness is due to our commitment to identifying issues that require interagency discussion, and resolving those issues, more expeditiously.

We are also pleased that the draft report identifies the unprecedented level of transparency that OIRA has implemented during my tenure as OIRA Administrator. OIRA is committed to ensuring that the public understands the regulatory review process, and we have increased the transparency of that process under E.O. 12866. (In this regard, we believe that the draft GAO report provides an excellent overview of the regulatory review process, which Members of Congress, their staffs, and the public should find helpful and informative.)

Specifically, OMB has made much greater use of the Internet to increase transparency in its regulatory and paperwork review processes. While certain materials new on the OIRA web page were available previously in OIRA's docket library, this material was difficult to access and, for individuals outside the Washington D.C. area, not accessible at all (other than through the Freedom of Information Act). OIRA's increasing use of the Internet to disseminate information about the regulatory review process has provided the public with quick and easy access to a tremendous amount of material that was previously not available to the public, or not available in one place, or not readily accessible. Information currently provided on OMB's website includes:

- lists of the draft regulations under review (this list is updated daily),
- monthly statistical summaries on reviews completed by OMB,
- copies of review-related letters from OMB-OIRA to agencies (including "prompt" letters, "return" letters, and "post-clearance" letters),
- information on meetings with outside parties concerning draft rules that are under formal or informal OIRA review,
- a list of written correspondence received from outside parties on rules under OIRA review, and
- copies of important policy communications such as the OIRA Administrator's memoranda to the President's Management Council.

In addition, the OIRA Administrator's testimony and speeches are also available on OMB's website.

As GAO notes in its draft report, one of the increases in transparency that OIRA has made during my tenure is not simply to make information that was previously available in OIRA's docket library much more easily available by posting it on OMB's website. Instead, with respect to meetings that outside parties request with OIRA concerning draft rules, OIRA has increased the categories of information that OIRA publicly disseminates. Previously, OIRA's disclosure procedures applied only to the meetings with outside parties that occurred during OIRA's formal review of a draft rule.

Soon after I became OIRA Administrator, I extended the disclosure requirements to cover meetings with outside parties that occur when a draft rule is being "informally" reviewed by OIRA. Such meetings had never before been subject to OIRA's disclosure procedures, but I concluded that this increase in transparency was warranted, and we are pleased that GAO's draft report has acknowledged this change.

OMB has also been making great strides in integrating regulatory and paperwork reviews with OMB's E-government policies, which will further increase the transparency of the regulatory review process. OIRA is developing a new computerized tracking system for OIRA's review of both regulations (under E.O. 12866) and information collection requests (under the Paperwork Reduction Act). The new system will replace an outmoded 20-year old tracking system with electronic capabilities for submission of public comments and dissemination of OIRA documents. The system will allow the public to search for and view information about transactions under review and to review records as they are made public.

OMB continues to explore ways to improve the public's understanding of OIRA's regulatory review process and appreciates GAO's specific recommendations. As GAO recommends in the draft report, we plan to review OIRA's implementation of the transparency requirements. In particular, in accordance with the draft report's recommendation, we will work to indicate more clearly in our meeting log which regulatory action was discussed and the affiliations of the participants in those meetings.

We do not concur with all the recommendations in the report and are concerned that some of them are not well-grounded in the reports' factual foundation. For example, the draft GAO report recommends that OIRA implement additional disclosure requirements that would go beyond the unprecedented level of disclosure that OIRA has already put into place during my tenure. We appreciate GAO's suggestions in this area, but we do not believe that GAO has demonstrated the need or desirability of such changes to the existing – and, again, unprecedented – transparency requirements.

GAO's draft report recommends that OMB disclose changes that the rulemaking agencies make to their draft rules during OIRA's "informal" review of a draft rule. Such disclosures are not required by statute and have not been required by E.O. 12866 or its predecessor, Executive Order No. 12291 (E.O. 12291). We do not believe that it would improve the rulemaking process to disclose these deliberations. As the courts have noted repeatedly over the years, and as Congress recognized in the Freedom of Information Act's protection for deliberative information (in FOIA Exemption 5), it is important for the deliberative process that Executive Branch officials and staff do not operate "in a fishbowl" but instead can explore options and carry on discussions in a confidential manner. Moreover, we do not believe it would be appropriate for OIRA to take it upon itself to waive the deliberative privilege for the rulemaking agencies regarding the draft rules that those agencies are developing.

Similarly, the draft report recommends that we should reexamine the Executive Branch's longstanding practice under E.O. 12866 (and its predecessor, E.O. 12291) that

its disclosure requirements apply to those documents exchanged between the rulemaking agency and OIRA's branch chiefs and higher-level officials. This practice has been followed consistently since the regulatory review disclosure procedures were first put into place in the 1980s; in particular, this practice was followed throughout the prior Administration. The draft GAO report does not explain why this longstanding practice should now be changed, and we continue to believe that the longstanding practice is appropriate.

The draft report also recommends that OIRA or the agencies should disclose the reasons why a rulemaking agency has decided to withdraw its draft rule from OIRA review. Draft rules that are withdrawn are done so at the request of the rulemaking agency. The longstanding, consistent practice under E.O. 12866 (and its predecessor, E.O. 12291) is that agencies do not disclose the reasons why they have decided at some particular point in time to submit a draft rule to OIRA for review, and similarly, agencies have not (at least to our knowledge) disclosed the reasons why they have decided to withdraw a draft rule from OIRA review. The draft GAO report does not explain why this longstanding practice should now be changed, and we continue to believe that the longstanding practice is appropriate. In any event, we do not believe it would be appropriate for OIRA to waive the deliberative privilege for the rulemaking agencies regarding the reasons why they have decided to withdraw a draft rule.

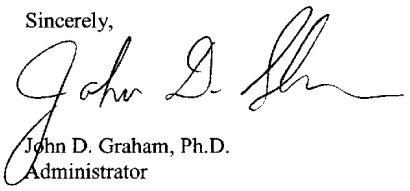
Another draft recommendation concerns the different categories by which OIRA records the outcomes of its reviews. The draft report recommends that OIRA change one of the categories, "consistent with change," so that it differentiates between draft rules that were "substantively" changed at OIRA's suggestion or recommendation and those draft rules that were changed in other ways and for other reasons. Similarly, the draft report reiterates an issue that GAO raised several years ago in its 1998 report (GAO/GGD-98-31); this issue concerns the disclosures that a rulemaking agency makes under E.O. 12866 relating to the "substantive" changes to the draft rule that were made during OIRA review. As OIRA Administrator Sally Katzen explained in her letter of November 10, 1997 (at pages 26-31 of the GAO report), attempting to define what qualifies as a "substantive" change is very difficult and not very helpful. As Administrator Katzen noted: "The same word in the same rule may be viewed by some members of the public as substantive, while others may view it as not substantive." That is why, as did Administrator Katzen, we believe it is better to provide the public with "copies of the various draft regulations reviewed by OIRA"; this enables the person to "identify the changes of interest to that person, and evaluate the nature and importance of the change on its own merits."

Finally, the draft GAO report provides specific recommendations aimed at disclosures that are made by the rulemaking agencies. GAO states in the draft report that it found that rulemaking agencies vary in how they handle their public rulemaking dockets, and GAO encourages agencies to follow "best practices" regarding their documentation. As with the prior set of draft recommendations, this one also appears to reiterate a GAO recommendation from its 1998 report. In her comments on a draft recommendation that OMB issue guidance to agencies on how they should organize their

rulemaking dockets, Administrator Katzen stated that each rulemaking agency had developed its own administrative practices and procedures to fit its own statutes and programs, and she stated that OMB deferred to these rulemaking agency practices. We continue to defer to the rulemaking agencies on this point. We should note, though, that we expect that many of the differences that GAO has identified should be eliminated by the E-Rulemaking project, one of this Administration's 24 E-Government initiatives. When fully implemented by the rulemaking agencies, the initiative will consolidate each agency's public docket into a government-wide docket easily accessible by the public. Ultimately, the system may save as much as $100 million and make it easier for businesses and the public to access the rulemaking process.

Thank you again for this opportunity to comment on the draft report. As I noted earlier, the report provides an excellent overview of the regulatory review process and a careful factual review of how OIRA is operating differently in this Administration.

Sincerely,



John D. Graham, Ph.D.
Administrator

- 5 -

(450138)

GAO's Mission

The General Accounting Office, the audit, evaluation and investigative arm of Congress, exists to support Congress in meeting its constitutional responsibilities and to help improve the performance and accountability of the federal government for the American people. GAO examines the use of public funds; evaluates federal programs and policies; and provides analyses, recommendations, and other assistance to help Congress make informed oversight, policy, and funding decisions. GAO's commitment to good government is reflected in its core values of accountability, integrity, and reliability.

Obtaining Copies of GAO Reports and Testimony

The fastest and easiest way to obtain copies of GAO documents at no cost is through the Internet. GAO's Web site (www.gao.gov) contains abstracts and full-text files of current reports and testimony and an expanding archive of older products. The Web site features a search engine to help you locate documents using key words and phrases. You can print these documents in their entirety, including charts and other graphics.

Each day, GAO issues a list of newly released reports, testimony, and correspondence. GAO posts this list, known as "Today's Reports," on its Web site daily. The list contains links to the full-text document files. To have GAO e-mail this list to you every afternoon, go to www.gao.gov and select "Subscribe to e-mail alerts" under the "Order GAO Products" heading.

Order by Mail or Phone

The first copy of each printed report is free. Additional copies are $2 each. A check or money order should be made out to the Superintendent of Documents. GAO also accepts VISA and Mastercard. Orders for 100 or more copies mailed to a single address are discounted 25 percent. Orders should be sent to:

U.S. General Accounting Office
441 G Street NW, Room LM
Washington, D.C. 20548

To order by Phone: Voice: (202) 512-6000
TDD: (202) 512-2537
Fax: (202) 512-6061

To Report Fraud, Waste, and Abuse in Federal Programs

Contact:

Web site: www.gao.gov/fraudnet/fraudnet.htm
E-mail: fraudnet@gao.gov
Automated answering system: (800) 424-5454 or (202) 512-7470

Public Affairs

Jeff Nelligan, Managing Director, NelliganJ@gao.gov (202) 512-4800
U.S. General Accounting Office, 441 G Street NW, Room 7149
Washington, D.C. 20548

United States
General Accounting Office
Washington, D.C. 20548-0001

Official Business
Penalty for Private Use $300

Address Service Requested

Presorted Standard
Postage & Fees Paid
GAO
Permit No. GI00