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Report to the Chairman, Committee on Oversight and Government Reform, House of Representatives

April 2009

FEDERAL RULEMAKING

Improvements Needed to Monitoring and Evaluation of Rules Development as Well as to the Transparency of OMB Regulatory Reviews

GAO-09-205

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GAO Accountability·Integrity·Reliability

Highlights

Highlights of GAO-09-205, a report to the Chairman, Committee on Oversight and Government Reform, House of Representatives

Why GAO Did This Study

Regulation is one of the principal tools that the government uses to implement public policy. As part of the rulemaking process federal agencies must comply with an increasing number of procedural and analytical requirements. GAO was asked to examine how broadly applicable rulemaking requirements cumulatively have affected (1) agencies' rulemaking processes, in particular including effects of requirements added to the process since 2003, and (2) transparency of the Office of Information and Regulatory Affairs (OIRA) regulatory review process. To address these objectives, GAO reviewed selected rules issued between January 2006 and May 2008 and associated dockets and also interviewed knowledgeable agency and OIRA officials.

What GAO Recommends

GAO recommends that, consistent with internal control standards, the Environmental Protection Agency (EPA), Food and Drug Administration (FDA), and Securities and Exchange Commission (SEC) track and evaluate actual performance versus targeted milestones for developing significant rules to identify process improvement opportunities. GAO also recommends that OMB should provide additional guidance to agencies to improve transparency and documentation of the OIRA review process. In comments on a draft of this report, SEC and OMB generally agreed with our recommendations. EPA and FDA said they believe they already have such tracking systems.

View GAO-09-205 or key components.
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What GAO Found

The agencies GAO reviewed had little data on the time and resources used to comply with regulatory requirements making it difficult to evaluate the effects of these requirements on rulemaking. All the agencies set milestones for regulatory development. During our review, only the Department of Transportation (DOT) provided data showing that it tracked and reported on milestones, but EPA and FDA provided similar information in their agency comments. The agencies GAO reviewed also could provide little systematic data on the resources they used—such as staff hours, contract costs, and other expenses—in developing rules. DOT and SEC have attempted to identify staff time expended on individual rules but are encountering difficulties generating usable and reliable data. Despite the challenges they have encountered in attempting to track time and resources in rulemaking, agency officials identified potential benefits to the management of their processes if they had such information to evaluate. Systematic tracking and reporting by agencies on their schedules and milestones would also be consistent with internal control standards.

Our review of 139 major rules including 16 case-study rules revealed that most triggered analytical requirements under the Paperwork Reduction Act (PRA), Regulatory Flexibility Act (RFA), and Executive Order 12866, but few other requirements. Agency officials reported that requirements added to the rulemaking process by the Office of Management and Budget (OMB) since 2003 sometimes required a learning period when first implemented, but their agencies either already performed the added requirements or recognized the revisions as best practices. The officials instead identified long-standing requirements of the PRA and the RFA as generally requiring a more significant investment of resources. Based on the limited information available, the average time needed to complete a rulemaking across our 16 case-study rules was about 4 years, with a range from about 1 year to nearly 14 years, but there was considerable variation among agencies and rules.

OIRA's reviews of agencies' draft rules often resulted in changes. Of 12 case-study rules subject to OIRA review, 10 resulted in changes, about half of which included changes to the regulatory text. Agencies used various methods to document OIRA's reviews, which generally met disclosure requirements, but the transparency of this documentation could be improved. In particular, some prior issues persist, such as uneven attribution of changes made during the OIRA review period and differing interpretations regarding which changes are "substantive" and thus require documentation. Out of eight prior GAO recommendations to improve the transparency OIRA has implemented only one—to clarify information posted about meetings with outside parties regarding draft rules under OIRA review.

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Abbreviations

ANPRM	Advance Notice of Proposed Rulemaking
APA	Administrative Procedure Act
CAA	Clean Air Act
CAFE	corporate average fuel economy
CDER	Center for Drug Evaluation and Research
CF	Division of Corporation Finance
CFSAN	Center for Food Safety and Applied Nutrition
CRA	Congressional Review Act

DOT	Department of Transportation
EDGAR	Electronic Data Gathering, Analysis, and Retrieval System
EDR	event data recorder
EPA	Environmental Protection Agency
FAA	Federal Aviation Administration
FACA	Federal Advisory Committee Act
FDA	Food and Drug Administration
FRDTS	*Federal Register* Document Tracking System
GACT	generally available control technologies or management practices
ICI	Investment Company Institute
IM	Division of Investment Management
IQA	Information Quality Act
LDR	Labor Distribution Reporting
MACT	maximum achievable control technologies
NEPA	National Environmental Policy Act
NHTSA	National Highway Traffic Safety Administration
NRA	Negotiated Rulemaking Act of 1990
NTTAA	National Technology Transfer and Advancement Act
OAR	Office of Air and Radiation
OIRA	Office of Information and Regulatory Affairs
OMB	Office of Management and Budget
OST	Office of the Secretary of Transportation
OW	Office of Water
PRA	Paperwork Reduction Act
RAPIDS	Rule and Policy Information Development System
RFA	Regulatory Flexibility Act of 1980
RIN	Regulation Identifier Number
SBREFA	Small Business Regulatory Enforcement Fairness Act
SDWA	Safe Drinking Water Act Amendments of 1996
SEC	Securities and Exchange Commission
UMRA	Unfunded Mandates Reform Act of 1995
XBRLe	eXtensible Business Reporting Language

GAO
Accountability * Integrity * Reliability

United States Government Accountability Office
Washington, DC 20548

April 20, 2009

The Honorable Edolphus Towns
Chairman
Committee on Oversight and Government Reform
House of Representatives

Dear Mr. Chairman:

Regulation is one of the principal tools that the government uses to implement public policy. Federal regulations affect many aspects of citizens' lives, whether addressing issues featured in the headlines of the past year, such as the safety of the food supply and the health of the housing and financial markets, or other long-standing goals such as environmental protection and workplace and transportation accident prevention. Regulations also help ensure the effective distribution of funds under a range of programs including Medicare, Medicaid, Social Security, agricultural support, and disaster assistance programs. Underlying federal regulatory actions is the long-standing rulemaking process established by the Administrative Procedure Act (APA).[1]

As part of that process, Congresses and Presidents have required agencies to comply with an increasing number of procedural and analytical requirements prior to issuing a rule. Some requirements apply only to cabinet departments and independent agencies, while others also apply to independent regulatory agencies.[2] The goals of these requirements include promoting public participation in rulemaking, reducing regulatory burdens, requiring more rigorous regulatory analysis, and enhancing oversight of agencies' rulemaking. As we have previously reported, these requirements entail a wide range of procedural, consultative, and

[1]Pub. L. No. 404, 60 Stat. 237 (1946), codified in 1966 in scattered sections of title 5, United States Code.

[2]"Independent agencies" refers to agencies that answer directly to the President but are not part of cabinet departments, such as the Environmental Protection Agency (EPA).

"Independent regulatory agencies" refers to the boards and commissions identified as such in the Paperwork Reduction Act (44 U.S.C. § 3502(5)), such as the Securities and Exchange Commission.

analytical actions on the part of the agencies.[3] For example, the Regulatory Flexibility Act (RFA) requires agencies to examine the impact of their rules on small entities. The Paperwork Reduction Act (PRA) requires agencies to provide public notice, solicit comments, and request approval by the Office of Management and Budget (OMB) before imposing new information collection requirements. Executive Order 12866 directs agencies (other than independent regulatory agencies) to assess costs and benefits of available regulatory alternatives and to submit significant rules to OMB's Office of Information and Regulatory Affairs (OIRA) for review before they are published. (See app. I for a summary of agencies' responsibilities under broadly applicable regulatory requirements relevant to the rules we reviewed for this report.)

In the past, Congress has asked us to review the implementation of specific rulemaking requirements.[4] For this report, you asked us to examine how broadly applicable rulemaking requirements cumulatively have affected (1) agencies' rulemaking processes and (2) the transparency of the OIRA review process.[5] Specifically, you asked us to address the following aspects of the rulemaking process:

- To the extent that information is available, how have changes in requirements since 2003 affected the complexity, cost, and length of the rulemaking process?
- How long do agencies take to issue rules?
- What requirements must an agency comply with to issue a major rule?
- What effect do agency interactions with OMB have on rulemaking?

To address the first and second questions, we primarily relied on reviews of 16 case studies and interviews with officials from regulatory agencies and OMB. We chose a case-study approach because agency officials

[3]See GAO, *Federal Rulemaking: Procedural and Analytical Requirements at OSHA and Other Agencies*, GAO-01-852T (Washington, D.C.: June 14, 2001). See also the Related GAO Products section at the end of this report.

[4]See GAO, *Federal Rulemaking: Past Reviews and Emerging Trends Suggest Issues That Merit Congressional Attention*, GAO-06-228T (Washington, D.C.: Nov. 1, 2005), for a summary of the main findings from reports and testimonies we prepared during the past decade. Although we found benefits associated with individual rulemaking requirements—such as encouraging greater public participation and enhancing the transparency of the rulemaking process—we also found that they were often less effective than intended.

[5]We did not examine the effects of agency- or program-specific requirements on the issuance of regulations, such as EPA's issuance of regulations under the Clean Air Act (see, for example, 42 U.S.C. § 7607).

informed us during initial meetings that little systematic information existed within agencies on the time, staffing, and contracting costs associated with the development of individual rules or the required analyses that support rulemakings. To identify the rules for our case studies, we relied on our Federal Rules Database.[6] The database includes information such as the type of rule (major or nonmajor),[7] priority of the rule (for example, whether it is a significant rule), and the publication date of the rule. We drew a sample from final rules issued from January 2006 through May 2008, to increase the likelihood that the rules chosen were affected by changes in regulatory requirements since 2003 and for which the staff who were involved would be available to discuss the rulemaking process.[8] We randomly selected 16 major or other significant final rules from executive branch agencies responsible for health, safety, and environmental regulations and an independent regulatory agency for purposes of comparison.[9] We examined two case-study rules each from the Department of Transportation's (DOT) Federal Aviation Administration (FAA) and National Highway Traffic Safety Administration (NHTSA), the Environmental Protection Agency's (EPA) Office of Air and Radiation (OAR) and Office of Water (OW), the Food and Drug Administration's (FDA) Center for Drug Evaluation and Research (CDER) and Center for Food Safety and Applied Nutrition (CFSAN), and the Securities and Exchange Commission's (SEC) Division of Corporation Finance (CF) and Division of Investment Management (IM). Although these agencies and offices are not equivalent organizationally, we treated

[6]The Congressional Review Act (CRA) requires agencies to file rules with Congress and the Comptroller General before the rules can become effective. 5 U.S.C. § 801(a)(1)(A). To compile information on all the rules submitted under the CRA, GAO established a database and created a standardized submission form to allow more consistent information collection. The Federal Rules Database is publicly available at www.gao.gov under Legal Products.

[7]As defined by CRA, a major rule is generally a rule that the OIRA Administrator finds has resulted in or is likely to result in (1) an annual effect on the economy of $100 million or more, (2) a major increase in costs or prices, or (3) significant adverse effects on competition, employment, investment, productivity, or innovation. 5 U.S.C. § 804(2). This is similar, but not identical to, the definition of an economically significant rule under Executive Order 12866 on regulatory planning and review.

[8]From January 2006 through May 2008, federal agencies issued over 7,000 rules.

[9]As defined in the *Introduction to The Regulatory Plan and the Unified Agenda of Federal Regulatory and Deregulatory Actions*, "other significant" rules are those that are not economically significant but are considered significant by the agency. This category includes rules that the agency anticipates will be reviewed under Executive Order 12866 or rules that are a priority of the agency head.

them as such for purposes of this report to obtain comparable volumes of major and significant final rules in our selection process. The agencies, offices, and sample of rules that we assessed are not representative of all regulatory agencies and all rules.

We reviewed the agencies' regulatory dockets for each rule selected using a standardized data collection instrument and discussed what we found with knowledgeable agency officials and OMB. We defined "changes in requirements" as changes that OMB identified as significant in its September 2003 revision of OMB Circular No. A-4,[10] which provides guidance on conducting regulatory analysis, and also OMB's December 2004 Final Information Quality Bulletin for Peer Review.[11] These changes were implemented since our 2003 report on OMB's role in the rulemaking process.[12]

To answer the third question, we reviewed the statutory and executive requirements broadly applicable to rulemaking. We also analyzed the 139 major rules, as defined by the Congressional Review Act (CRA), issued from January 2006 through May 2008 to be consistent with the time period used for selection of our case studies. To identify the rules, we again relied on our Federal Rules Database. Based on our tests of the data in the database, including confirming the quality control steps used to ensure completeness of the database and tracing database information back to source documents, we determined that these data were sufficiently reliable for the purposes of this report. To identify the requirements that were discussed and that were triggered by the major rules, we reviewed the relevant GAO major rule report on the rule and the published final rule.[13]

[10]OMB's *New Guidelines for the Conduct of Regulatory Analysis*, which was issued on September 17, 2003, became effective for economically significant proposed rules on January 1, 2004, and for economically significant final rules on January 1, 2005.

[11]Office of Management and Budget, Memorandum for Heads of Departments and Agencies on Issuance of OMB's *Final Information Quality Bulletin for Peer Review* (Dec. 16, 2004).

[12]GAO, *Rulemaking: OMB's Role in Reviews of Agencies' Draft Rules and the Transparency of Those Reviews*, GAO-03-929 (Washington, D.C.: Sept. 22, 2003).

[13]GAO's primary role under CRA is to provide Congress with a report on each major rule containing our assessment of whether the promulgating federal agency's submissions indicate that it has complied with the procedural steps required by various statutes and executive orders governing rulemaking, such as preparation of a cost-benefit analysis, the PRA, the RFA, and Executive Order 12866. 5 U.S.C. § 801(a)(2)(A).

To answer the fourth question, we analyzed the information collected above and reviewed the dockets of the 12 selected case-study rules from DOT, EPA, and FDA relying on the same basic methodology we previously used to report on OMB's role in and affect on rulemaking—reviewing documents from agencies' and OMB's dockets and interviewing officials to obtain information about the regulatory review process for selected rules. We chose these rules because all were subject to review by OMB/OIRA under Executive Order 12866 and the transparency requirements under the order. The other 4 case-study rules were not subject to OIRA review because SEC is an independent regulatory agency. As part of the fourth question, you also asked us to review the status of GAO recommendations from GAO-03-929 on improving the transparency of OIRA's regulatory review process. To report on the status of those recommendations, we relied on information from our annual update of open recommendations and interviews with OMB officials.

For reporting purposes, we discuss our findings on the first three questions in objective one—the effects of rulemaking requirements on agencies' rulemaking processes, including the complexity, cost, and length of their processes. Our findings related to the fourth question and updated findings from our 2003 report are discussed in objective two—the transparency of OMB's role in the regulatory review process. We conducted our review from August 2008 through February 2009 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Results in Brief

During the course of our review, the case-study agencies provided little data on the time and resources required to develop rules or comply with broadly applicable regulatory requirements, making it difficult to evaluate the effects of the requirements on the rulemaking process. During our review, we found that all the agencies set milestones for regulatory development, but only DOT provided data that showed it routinely tracked these milestones. In comments on our draft report, EPA and FDA subsequently provided some documentation and data that showed that these agencies also routinely tracked milestones. Based on the limited information available at the time of our review, the average time needed to complete a rulemaking across our 16 case-study rules was about 4 years, with a range from about 1 year to nearly 14 years, but there was

considerable variation among agencies and rules. The agencies also could provide little systematic data on the resources they use, such as staff hours, contract costs, and other expenses, in developing individual rulemakings. DOT and SEC have attempted to identify staff time expended on individual rules but are encountering difficulties generating usable and reliable data. Despite the challenges they have encountered in attempting to track time and resources in rulemaking, agency officials identified potential benefits to the management of their processes if they had such information. Systematic tracking and reporting by agencies on their schedules and milestones would also be consistent with internal control standards.

When issuing major rules, all agencies must comply with broadly applicable statutory requirements, and agencies other than independent regulatory agencies are also subject to requirements in executive orders. However, an agency may not need to include specific analyses if the substance of the rule or exceptions and thresholds in the requirement lead the agency to determine that a specific rule did not trigger the requirement. Our review of 139 major rules and 16 case-study rules showed that most triggered analytical requirements under the PRA, the RFA, and (except for independent regulatory agencies such as SEC) Executive Order 12866, but few other analytical requirements. Agency officials reported that requirements added to the rulemaking process by OMB since 2003 that include more rigorous assessment of economically significant rules sometimes involved a learning period when first implemented, but their agencies either already performed the added requirements or recognized the revisions as best practices. The officials instead identified the long-standing requirements of the PRA and the RFA as generally requiring a more significant investment of resources.

OIRA's reviews of agencies' draft rules often resulted in changes to the rules, but there are opportunities to improve the transparency of OIRA's reviews. OIRA reviewed 12 of our 16 case-study rules under Executive Order 12866; SEC's rules are not reviewed by OIRA. OIRA's reviews resulted in changes to 10 of the 12 rules. Further, we determined that changes to 4 of the rules (1 DOT, 2 EPA, and 1 FDA) were significant in that they included changes to the regulatory text of the rule. For example, one change to the draft text of a FDA rule on dietary supplements reduced the requirement to save reserve samples from 3 years to 2 years. Agencies used varying methods to document OIRA's review of their draft rules, and their documentation generally met the executive order's requirements to disclose materials they provided to OIRA and substantive changes made during OIRA's review but could be improved for greater transparency. In

particular, there was uneven attribution of the sources of changes made during the OIRA review period and differing interpretations regarding which changes are "substantive" and thus require documentation. We previously made eight recommendations to improve the transparency of the OIRA regulatory review process, but OIRA implemented only one of those recommendations, that is, to clarify information that OIRA posts about meetings with nonfederal parties regarding draft rules under OIRA review. OIRA did not implement the remaining seven recommendations, for example to apply transparency requirements to both formal and informal OIRA review periods and to encourage agencies to use best practice methods to document changes made to rules after submission to OIRA.

To be consistent with internal controls for information in managing agency operations, we recommend that for significant rules FDA and SEC routinely track major milestones in regulatory development and report internally and externally when major milestones are reached against established targets. EPA, FDA, and SEC should also evaluate actual performance versus the targeted milestones and when they are different, determine why. If the administration retains Executive Order 12866 or establishes similar requirements, we recommend that to improve transparency of the review process OIRA should (1) instruct agencies to clearly state in final rules whether the agencies made substantive changes as a result of the OIRA reviews, (2) define what types of changes made as a result of the OIRA review process are "substantive" and need to be publicly identified, (3) direct agencies to clearly attribute those changes made at the suggestion or recommendation of OIRA, and (4) standardize how agencies label documentation of these changes in public rulemaking dockets.

SEC, EPA, FDA, and OMB commented on the recommendations. With regard to the two recommendations directed to the rulemaking agencies, SEC stated that the Commission will consider our recommendations, and both EPA and FDA provided new information on their tracking systems and data. We note, however, that we had requested this information during our review to address our second research question, but the information was not forthcoming. Also, they did not provide this information at the conclusion of our review either in response to our statements of facts to the agencies or at our exit conference with the agencies. Because this information was not provided at the time of our review, we did not have the opportunity to discuss how the information is used, whether it is useful, and, most importantly, if it could be used to respond to our report objectives. We did not audit the new information provided because of an

approaching deadline for OMB to provide recommendations to the President for a new executive order on federal agency regulatory review. With regard to our four recommendations to OMB, the agency stated that these recommendations have merit and warrant further consideration. In particular, OMB stated that it will give full consideration to our recommendations as the agency finalizes its own recommendations to the President for a new executive order on regulatory review.

Background

Regulatory agencies have authority and responsibility for developing and issuing regulations. The basic process by which all federal agencies develop and issue regulations is spelled out in the APA.[14] This act establishes procedures and broadly applicable federal requirements for informal rulemaking, also known as notice and comment rulemaking.[15] Among other things, the APA generally requires agencies to publish a notice of proposed rulemaking in the *Federal Register*.[16] After giving interested persons an opportunity to comment on the proposed rule by providing "written data, views, or arguments," the agency may then publish the final rule. In addition to the requirements under the APA, an agency may also need to comply with requirements imposed by other statutes. The APA has been in place for more than 60 years, but most other statutory requirements on rulemaking have been imposed more recently.

OMB is responsible for the coordinated review of agency rulemaking to ensure that regulations are consistent with applicable law, the President's priorities, and the principles set forth in executive orders, and that decisions made by one agency do not conflict with the policies or actions taken or planned by another agency. OMB also provides guidance to agencies. Some form of centralized review of rules by the Executive Office

[14]Certain rulemakings are governed, however, by agency- or program-specific statutory requirements. For example, certain EPA rulemakings implementing the Clean Air Act are subject to the more specific procedural requirements of the Clean Air Act in lieu of the APA provisions that would otherwise apply. See 42 U.S.C. § 7607.

[15]The APA describes two types of rulemaking, formal and informal. Formal rulemaking includes a trial-type on-the-record proceeding. Most federal agencies use the informal rulemaking procedures outlined in 5 U.S.C. § 553.

[16]The APA includes exceptions to notice and comment procedures for categories of rules such as those dealing with military or foreign affairs and agency management or personnel. 5 U.S.C. § 553(a). APA requirements to publish a proposed rule generally do not apply when an agency finds, for "good cause," that those procedures are "impracticable, unnecessary, or contrary to the public interest." 5 U.S.C. § 553(b).

of the President has existed for over 30 years. OIRA was created within OMB by the PRA and given substantive responsibilities for reviewing and approving agencies' information collection requests. Since 1981, various executive orders also gave OIRA substantive regulatory review responsibilities. OIRA's current regulatory review responsibilities are detailed in Executive Order 12866 related to regulatory planning and review. The order states that OIRA is to be the "repository of expertise concerning regulatory issues."

Under Executive Order 12866, OIRA reviews agencies' significant regulatory actions and is generally required to complete its review within 90 days after an agency formally submits a draft regulation. Each agency provides OIRA a list of its planned regulatory actions, indicating those that the agency believes are significant. After receipt of this list, the Administrator of OIRA may also notify the agency that OIRA has determined that a planned regulation is a significant regulatory action within the meaning of the Executive Order.[17] The order defines significant regulatory actions as those that are 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 Executive Order 12866.

The order further directs executive branch agencies to conduct a regulatory analysis for economically significant regulations (generally those rules that have an annual effect on the economy of $100 million or more).[18] OIRA historical data show that since 1994 (the first full calendar year that Executive Order 12866 was in effect), approximately 15 percent

[17]The Administrator of OIRA may also waive review of any planned regulatory action designated by the agency as significant.

[18]Regulatory analysis, such as benefit-cost analysis, is a tool regulatory agencies use to anticipate and evaluate the likely consequences of rules.

of the rules that OIRA reviewed were economically significant. For other significant rules, the order requires agencies to provide an assessment of the potential costs and benefits of the rule. The executive order also contains several transparency provisions that require both OIRA and agencies to disclose certain information about the OIRA review process. For example, the order requires agencies to publicly identify substantive changes made to the draft at OIRA's suggestion, and it requires OIRA to disclose information about communications between OIRA and persons not employed by the executive branch pertinent to rules under OIRA's review. The transparency requirements are discussed in more detail later in this report.

In addition to the responsibilities that OIRA exercises, OMB also provides guidance to agencies on regulatory requirements. In 2003, for example, OMB issued revised analytical guidelines for agencies to use in assessing the regulatory impact of economically significant regulations in OMB Circular No. A-4.[19] In issuing the guidelines, OMB cited several significant changes from its previous economic guidance. They included placing a greater emphasis on cost-effectiveness analysis, using formal probability analysis to assess uncertainty for rules with more than a billion-dollar annual impact on the economy, and conducting a more systematic evaluation of qualitative as well as quantified benefits and costs.[20] In addition, OMB's guidelines recommend that agencies estimate net benefits using a range of discount rates instead of a single discount rate.[21] In 2004, OMB issued its Final Information Quality Bulletin for Peer Review, which established governmentwide guidance for conducting peer reviews of government science documents. The bulletin directs agencies, including independent regulatory agencies, to subject "influential scientific information," such as original data and formal analytic models used in regulatory impact assessments, to an appropriate level of peer review.

[19]Although independent regulatory agencies, such as SEC, are not subject to Executive Order 12866 and Circular No. A-4, they may be directed to consider the economic effect of their rulemakings by various statutes.

[20]Office of Information and Regulatory Affairs, "Memorandum for The President's Management Council on OMB's Circular No. A-4, *New Guidelines for the Conduct of Regulatory Analysis*" (Mar. 2, 2004).

[21]Discounting is used to make comparable the benefits and costs that occur in different time periods. In general, a higher discount rate gives less weight to benefits and costs occurring in the future compared to the present. The new guidelines recommend that agencies use 7 percent and 3 percent. Previous guidance recommended using 7 percent and encouraged the use of sensitivity analysis to assess the effect of alternative discount rates.

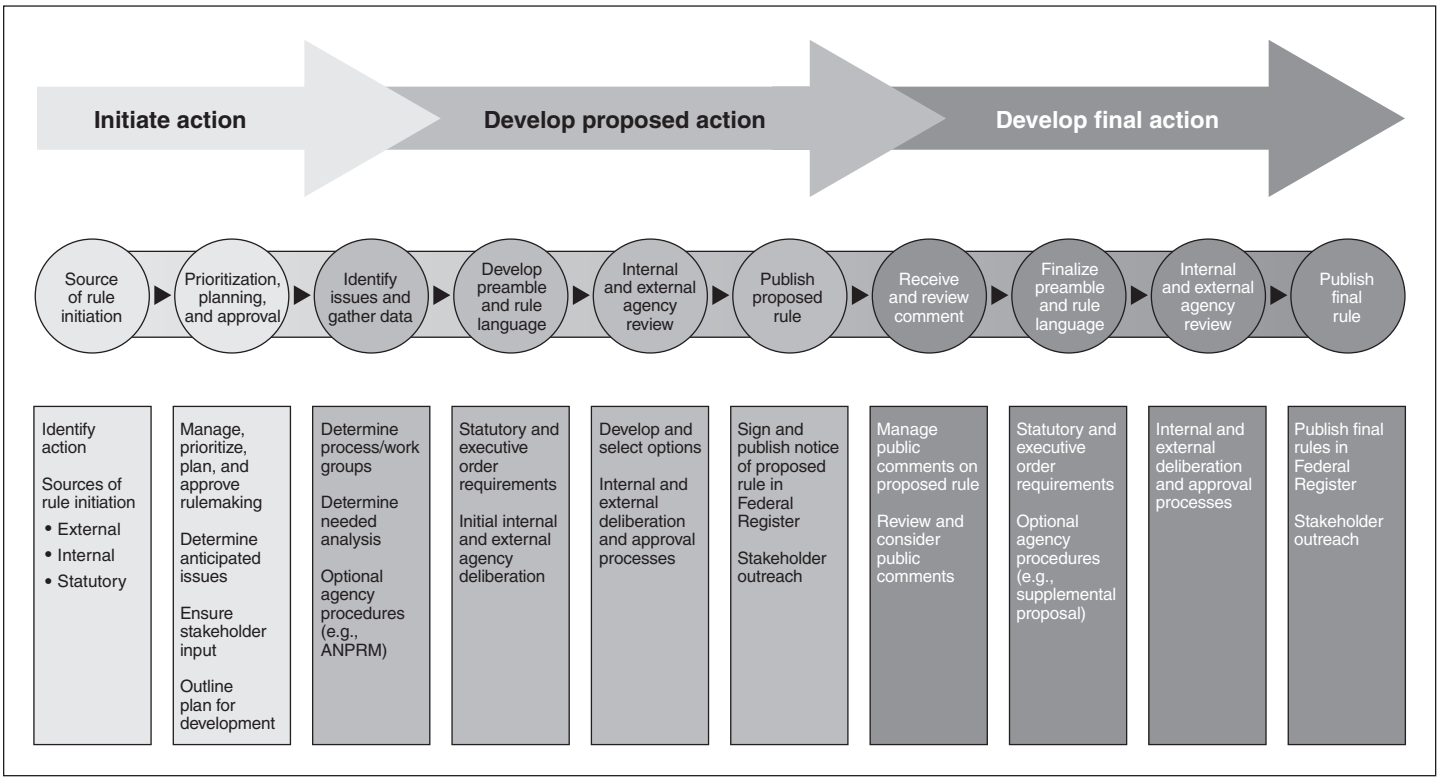
New administrations generally reexamine the rulemaking process and OMB's role in the process. Most recently, in a memorandum of January 30, 2009, President Obama directed the Director of OMB, in consultation with representatives of regulatory agencies, to produce within 100 days a set of recommendations for a new executive order on federal regulatory review.[22] The memorandum stated that the recommendations should offer suggestions for, among other things, the relationship between OIRA and the agencies; provide guidance on disclosure and transparency; encourage public participation in agency regulatory processes; offer suggestions on the role of cost-benefit analysis; address the role of distributional considerations, fairness, and concern for the interests of future generations; identify methods of ensuring that regulatory review does not produce undue delay; clarify the role of the behavioral sciences in formulating regulatory policy; and identify the best tools for achieving public goals through the regulatory process.

Agencies Have Limited Data on the Time and Resources Used to Address Regulatory Requirements in Their Rulemaking Processes

All agencies' rulemaking processes share three basic steps or phases: initiation of rulemaking actions, development of proposed rules, and development of final rules. Built into agencies' rulemaking processes are opportunities for internal and external deliberations and reviews. Figure 1 provides an overview of these regulatory development steps.

[22]74 Fed. Reg. 5977 (Feb. 3, 2009).

Figure 1: Basic Phases of Rulemaking Processes



Source: EPA.

Note: ANPRM is Advance Notice of Proposed Rulemaking.

During initiation, agency officials identify issues that may potentially result in a rulemaking. Potential rulemakings may result from statutory requirements or issues identified through external sources (for example, public hearings or petitions from the regulated community) or internal sources (for example, management agendas). During this phase, agencies gather information that would allow them to determine whether a rulemaking is needed and to identify potential regulatory options. At this time, the agencies will also identify the resources needed for the rulemaking and may draft concept documents to present to agency management that summarize the issues, present the regulatory options,

and identify needed resources.[23] Agency officials reported that this initial work on a rule is of indeterminate length and sometimes constitutes a major portion of the process. While the point at which a rulemaking officially commences may vary by agency and rule, as a general matter, rulemaking begins only after management receives, reviews, and approves the concept document.[24] At the latest, according to OIRA, the rulemaking will officially commence when agency officials assign a Regulation Identifier Number (RIN) for the proposed rule.

The second phase of the rulemaking process starts when an agency begins developing the proposed rule. During this phase, an agency will draft the rule, including the preamble (which is the portion of the rule that informs the public of the supporting reasons and purpose of the final rule) and the rule language. The agency will also begin to address analytical and procedural requirements in this phase. Agency officials pointed out that these initial analyses form the basis for other analyses completed later in the process, including those prepared to address statutory and executive order requirements. Agency officials stated that development of a rule is a coordinated effort, with economists, lawyers, and policy and subject matter experts contributing to individual rulemakings. Also built into this phase are opportunities for internal and external deliberations and reviews, including official management approval. OIRA may be involved informally at any point during the process. For each rule identified by the agency as, or determined by the Administrator of OIRA to be, a significant regulatory action, the agency submits the rule to OIRA for formal review—including the coordination of interagency review. After OIRA completes its review and the agency incorporates resulting changes, the agency publishes the proposed rule in the *Federal Register* for public comments.

In the third phase of the process, the development of the final rule, the agency repeats, as needed, the steps used during the development of the proposed rule. Once the comment period closes, the agency responds to the comments either by modifying the rule to incorporate the comments or by addressing the comments in the final rule. This phase also includes opportunities for internal and external review. Again, if the agency

[23]EPA's concept document is called an analytic blueprint that identifies the types of regulatory analyses needed for the rulemaking and ensures that the agency allocates the resources needed throughout the rulemaking process.

[24]EPA's rulemaking officially begins once the agency assigns a start action number, that is prior to when management receives, reviews, and approves the analytic blueprint.

determines that the rule is significant or at OIRA's request, the agency submits the rule to OIRA for review before publication of the final rule. In the event that OIRA's review results in a change to the final rule, the agency will revise the rule before publishing it in the *Federal Register*. Officials noted that addressing analytical and procedural requirements is faster with a draft of the proposed rule in hand, but analyses may need to be modified if public comments change the rule substantially. The final rule as published in the *Federal Register* includes the date that the rule becomes effective.

While the agencies share these basic process steps, there are inter- and intra-agency variations in the management of the rulemaking process. For example, EPA's OW generally designates one rulemaking team member as the point of contact through the development of the rule. Officials at FDA stated that their point of contact may change during the course of the rulemaking based on the rule's development phase; as the office working on the rule within the agency changes so does the point of contact. Agencies also have differing numbers of required internal reviews, and they may complete tasks within a phase in a different sequence.

Agencies Identified Milestones for Regulatory Development

Officials we met with described agency-specific processes for regulatory development and addressing the procedural and analytical requirements that applied to their respective rulemakings. These included identification of "milestones," significant events or stages in the agency-specific process. Officials also identified some milestones common to the rulemaking process that apply across the federal government, such as publishing the proposed and final rule. In addition, officials at the agencies we spoke with identified the following agency-specific internal milestones in their regulatory development process.

- DOT officials at FAA and NHTSA identified common milestones, including development of a draft concept, management reviews within administrations, review by the Secretary's Office, and external review.
- EPA identified 14 milestones for nonroutine rulemakings from initiation to publication of the proposed rule, including assigning a working group, development and approval of an Analytic Blueprint and management

reviews.[25] After the proposed rule is published, EPA tracks an additional 4 to 5 milestones to develop the final rule.

- FDA officials emphasized that regulatory development is similar throughout FDA. CFSAN and CDER used milestones such as assigning a working group, drafting, and conducting analyses and management clearances.
- SEC officials stated that CF and IM identified as common milestones generation (typically including public input), drafting, and approval by the commissioners.

During the course of our review, only DOT provided us with data that showed it routinely tracked these milestones. In comments on our draft report, EPA and FDA subsequently provided some documentation and data that showed that these agencies also routinely tracked milestones. However, we had requested this information during our review to address our second research question, but the information was not forthcoming. Also, they did not provide this information at the conclusion of our review either in response to our statements of facts to the agencies or at our exit conference with the agencies. Because this information was not provided at the time of our review, we did not have the opportunity to discuss how the information is used, whether it is useful, and, most importantly, if it could be used to respond to our report objectives. We did not audit the new information provided because of an approaching deadline for OMB to provide recommendations to the President for a new executive order on federal agency regulatory review.

DOT sets target dates for major milestones, such as when the rule is scheduled to move to OIRA for review. The agency uses the Rulemaking Management System to monitor both the target and actual dates for these major milestones in the development of rules for internal management decision-making purposes. This allows DOT regulatory development staff and managers to identify a rule's status and determine if the rule is on or behind schedule, based on target dates. Some of the information captured in the system includes the stage of the rulemaking (proposed rule, final rule), a schedule of milestones with target and actual dates, and an explanation for any delay. For significant regulatory actions, DOT makes some milestone tracking information publicly available through the Report on DOT Significant Rulemakings available on the agency's web site.

[25]EPA has three classes, or "tiers," of rulemakings. Only the two higher-priority classes are required to follow this process. Most, but not all, significant rules would go through this process.

Among the objectives that DOT officials attributed to their tracking and reporting efforts were that they provide opportunities to assess their schedule estimates and improve internal and external accountability. An official noted, for example, that tracking and posting the information helped the agency identify best estimates of schedules.

EPA uses an internal tracking database—Rule and Policy Information and Development System (RAPIDS)—that contains both projected and actual dates for meeting major milestones in rule development. This database provides background information and a timetable on each stage of the rulemaking, including a schedule of the milestones with both projected and actual dates. EPA uses the data in RAPIDS to develop management reports used by EPA managers and executives as a planning and tracking tool. The reports also serve as a tool to improve the regulatory development process. EPA makes this tracking information available to the public on a quarterly basis.

FDA also tracks regulatory milestones through its Federal Register Document Tracking System (FRDTS). FRDTS is an internal, Web-based integrated system that allows FDA to track the preparation and approval process of documents to be submitted to the *Federal Register* for publication. Tracking the rulemaking approval process is done for all rulemakings, however the system only tracks milestones for the latter stages of the rulemaking's development and clearing process. FDA management uses the information in FRDTS as one tool in the management of its regulatory development process.

SEC did not have such systematic tracking and reporting of its scheduled and actual regulatory milestones. However, implementing such a system is consistent with standards for internal control.[26] According to the standards, for an agency to run and control its operations, it must have relevant, reliable information relating to external as well as internal events. Moreover, an acknowledged expert on the regulatory process has stated that a myriad of formal requirements and political expectations requires sophisticated management of the rulemaking process.[27] Among other functional requirements, he noted that scheduling and budgeting for

[26]GAO, *Standards for Internal Control in the Federal Government* GAO/AIMD-00-21.3.1 (Washington, D.C.: November 1999).

[27]Cornelius M. Kerwin, *The Management of Regulation Development: Out of the Shadows* (Washington, D.C.: IBM Center for The Business of Government, 2007), 11.

rulemaking are useful tools for officials to manage regulation development and control the resources needed to complete a rule.[28] Monitoring and assessing actual performance against planned targets, identifying reasons for missed targets, and adjusting resource requirements to fit conditions based on actual experience are among the ways that agencies could use their rulemaking plans and milestones as management control and accountability tools.

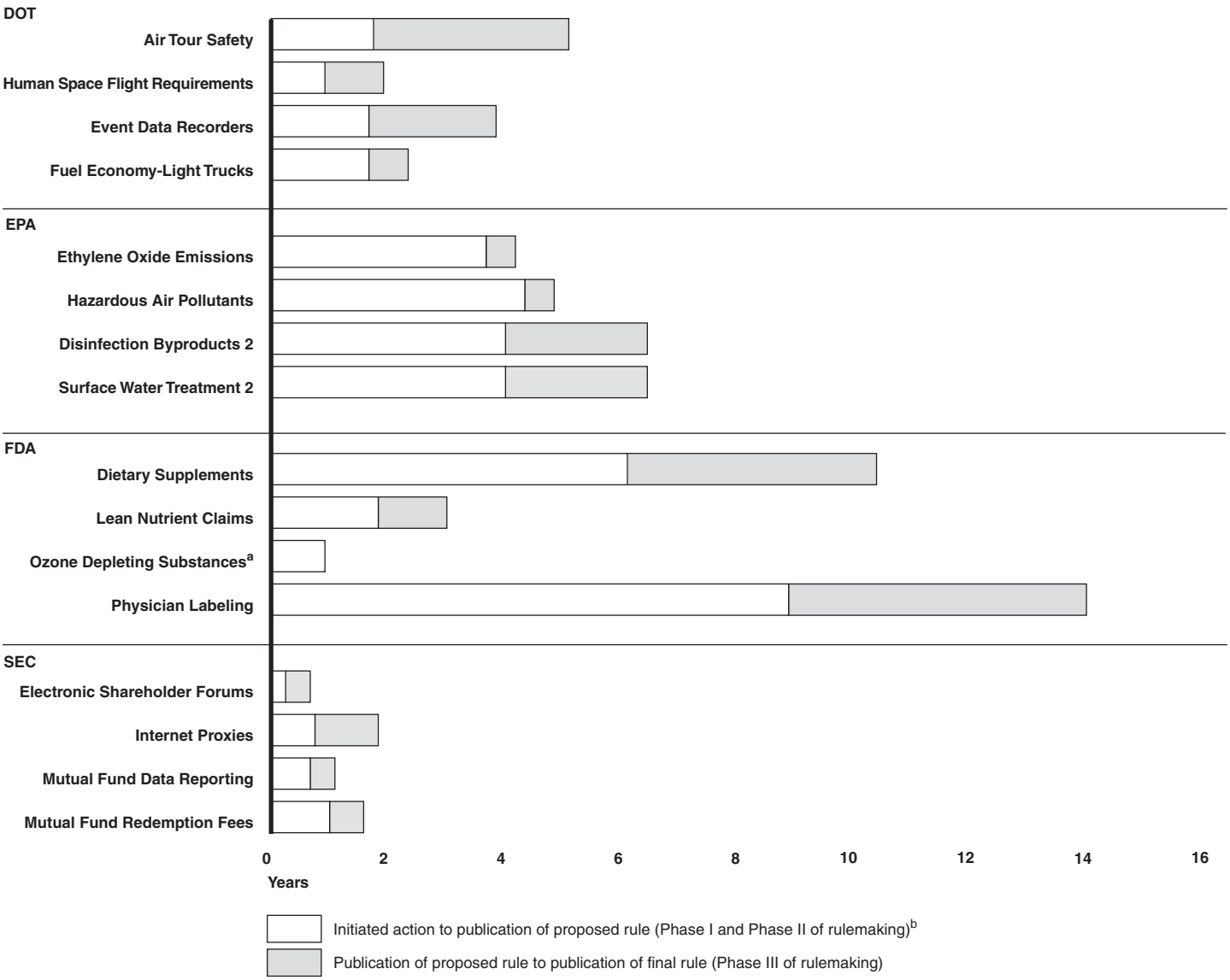
Length of Time Required to Issue a Rule Varies by Agency and Rule with Few Common Characteristics

We found variation in length of time required for the development and issuance of final rules both within and among agencies. In general, agency officials agreed that the publication of the final rule marked the end of the rulemaking process.[29] In contrast, identifying when a rulemaking begins is less definite. All agencies identified milestones that marked the initiation of a rulemaking in their agencies, but also asserted that agency staff sometimes worked on certain issues related to the rulemaking years before commencement of the actual rulemaking, either as part of earlier, related rulemakings or policy development for the rule. Based on agency milestones, officials we spoke with at three of the four agencies provided estimates for the length of time for an average rulemaking. FDA officials estimated that a straightforward rulemaking may take up to 3½ to nearly 4 years from initiation to final publication. DOT officials estimated approximately 1-½ years from the end of the public comment period following the publication of the proposed rule to final rule. SEC officials estimated that some rules are completed within 6 months of publication of a proposed rule to final rule. EPA officials declined to provide an estimate for an average rulemaking at their agency, stating that there is too much variation. However, some agency officials emphasized that the average time required to issue any given rule could vary from these estimates, as illustrated by the 16 case-study rules we reviewed (see fig. 2).

[28]Ibid., p. 20.

[29]OIRA officials pointed out that a rulemaking that is later subject to a judicial challenge may not have "ended" with final publication.

Figure 2: Rulemaking Timelines from Initiation to Final Rule for 16 Case Studies



Source: GAO analysis.

[a]FDA's Ozone Depleting Substances was a direct final rule, and as such, FDA published a proposed and final rule on the same day.

[b]Initiation was based on agencies' best estimates of when they initiated the rules. Also, because of the ambiguity in the early stages of rulemaking—only the end of Phase II of rulemaking, publication of a proposed rule, has a clearly defined milestone—we did not distinguish between the first two phases of rulemaking.

Using two rulemaking milestones common among federal agencies—publication in the *Federal Register* of the proposed rule and publication of the final rule—the length of time for our 16 case-study rules ranged from approximately half a year (SEC's Mutual Fund Data Reporting rule) to nearly 5 years (FDA's Physician Labeling rule). As an illustration of the time investment in regulatory development—as measured from agency-specific internal milestones—the entire rulemaking process for the same two rules ranged from slightly over 1 year to 13 years, respectively. Overall the average time from initiation to final publication of a rule for our 16 case-study rules was just over 4 years, with the average time for the 4 SEC rules just over 1 year, the DOT rules taking an average of just over 3 years, and the EPA and FDA rules taking longer than the overall average at 5-1/2 and 7 years, respectively. For most of our case study rules, the time to develop the proposed rule was at least as much as the time between publication of the proposed and final rules. We also found that the complexity or magnitude of a major rule also did not explain all or most variation, as some case-study rules that were not major took nearly as long or longer to be published. (For more detailed information about the timelines for each of the case-study rules, see app. II.)

During our review we identified multiple factors that influence the time needed to issue a rule, including

- the complexity of the issues addressed by the rulemakings;
- prioritizations set by agency management that can change when other priorities, such as new congressional mandates, arise; and
- the amount of internal and external review required at the different phases of the rulemaking process.

Some agency officials said that rulemaking for complex topics or for rules that raise new issues typically takes longer to complete than for routine rules. Rules that are a management priority or have a statutory or judicial deadline may move more quickly through the rulemaking process, while other rules may be set aside as agency staff members work on other things. Also, rules that require OIRA and interagency review typically need additional time for the external review process and, according to some agency officials, trigger additional internal scrutiny. The priorities and the pace of rulemaking have also been affected during transitions in presidential administrations. Since 1948, the amount of rulemaking activity has increased in the last months of every outgoing administration when the party in control of the White House changed. During every recent transition involving a change in the party controlling the White House since 1981, this has been followed by the incoming administration

recommending that agencies delay effective dates for reconsideration of rules published at the end of the previous administration.[30]

Agencies Have Limited Information on Resources Used in Regulatory Development

There is little rule-specific tracking of resources used in regulatory development. Agency officials were unable to identify the staffing or other resources (such as contracting costs associated with preparing expert analyses or convening public meetings) for regulatory development for all rules or for the limited number of case-study rules. As noted above, internal control standards call for relevant, reliable and timely information. Regarding staffing, such management information was not available from agencies we audited. Officials were able to generally describe how they staff rulemaking, noting that rulemaking is a coordinated effort, with many individuals from throughout the agency contributing to specific rulemakings. However, none of the agencies routinely tracked staff time associated with rulemakings or were able to provide records of staff time devoted to case-study rulemakings or supporting analyses. Moreover, agency officials stated that because many staff within the agencies with different job functions—attorneys, economists, programs staff, as well as regulatory developers—contribute to individual rules, they could not provide after-the-fact estimates.

However, based on their experiences, the agencies' officials identified ways they have explored using existing agency information for purposes of improving management of the rulemaking process. For example, according to a DOT official responsible for rulemaking, having reliable data on how long it takes to publish a proposed rule and identifying where the time is spent is critically important for reengineering the process. The official also pointed out that while the agency knows that the time of some support staff is all devoted to rulemaking, there is no data for tracking core program offices' involvement in technical and lead roles in the rulemaking process. The official noted that these data could help determine how much of certain staff members' time is reasonable and how many additional staff days would be needed to speed up the process. EPA officials stated that they use the tracking information in the agency's RAPIDS system to help identify best practices as well as identify those actions that need corrective measures. FDA officials stated that they track

[30]For the most recent transition, see 74 Fed. Reg. 4435 (Jan. 26, 2009). See also GAO, *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).

the rulemaking process from a project management perspective. According to these officials, this allows the agency to identify areas that appear to "logjam" the process and to develop mechanisms that would improve the rulemaking process. In addition, FDA officials stated that agency management meets to discuss the major milestones reported in the FRDTS to identify areas of improvement in the regulatory development process. SEC officials also track some data from a project management perspective. Officials stated that the former SEC Chairman was interested in knowing how long it takes to conduct economic analyses. During the course of our review, EPA, FDA, and SEC did not document these claims or provide specific examples of how this information was used to improve their rulemaking process. However, in response to our draft report, the EPA and FDA provided both documentation and examples to support the information provided above.

Agency officials described additional details about their tracking efforts and the limitations of this information. One DOT agency, FAA, is working on a system, called Labor Distribution Reporting (LDR) that allows all FAA managers and employees to better understand staff resources required for achieving agency goals and objectives. However, using LDR to assess the staff time devoted to rulemaking has proven challenging for FAA officials responsible for rulemaking activity. Those officials said that the data generated by LDR have not been reliable and the information does not necessarily track rulemaking activity as distinct from other staff responsibilities. Additionally, attempts to aggregate LDR information by rule proved unwieldy as these costs are imbedded in agency-wide systems that capture information at a higher level and for multiple purposes. FAA is reengineering its use of LDR by consolidating and simplifying the codes used with the goal of providing managers with reliable information on how staff time is used and how it contributes to meeting agency performance targets. SEC's CF also tried to do more detailed staff time coding for each rulemaking project but has now instituted more generic tracking by category of activity. A CF official also pointed out that CF's coding does not cover all groups within SEC that contribute to rulemaking projects. Another SEC official from the Division of Trading and Markets identified a similar tracking challenge. Although the division has specific rulemaking offices organized by subject area, not all the work done by these offices is related to rulemaking.

Similarly, there is limited information available regarding contract costs. At three of the agencies in our case study—DOT, FDA, and SEC—analytical and procedural requirements typically are addressed in-house by agency staff. One agency, EPA, regularly supplements in-house staff

responsible for regulatory development by hiring contractors to conduct analyses as part of the regulatory development process. The agency does not track these costs by rulemaking; however, EPA officials were able to identify some of the costs associated with regulatory development for four case-study rules. For the two major OW rules—the Surface Water Treatment 2 rule and the Disinfection Byproducts 2 rule—the costs related to expert advisory panels, public meetings, travel, and regulatory analyses for the microbial pathogens and disinfection byproducts cluster of rules (that includes a total of seven rules including the two case study rules) were more than $13 million. As mentioned above, EPA did not track the costs of each of these rules separately throughout the course of rule development. Identified costs for the two nonmajor rules—the Ethylene Oxide Emissions rule and the Hazardous Air Pollutants rule—were less, $100,000 and $780,000, respectively. EPA officials told us that funding for regulatory analyses comes from a central budget within the program developing the rule.

As stated earlier, while it is difficult to pinpoint when the initiation phase of rulemaking begins, agency officials reported that developing proposed rules constitutes a significant portion of regulatory development, so that much of the resource investment in a rulemaking occurs prior to publication of the proposed rule. For example, NHTSA's Fuel Economy-Light Trucks rule was just one in a series of related rulemakings that dated back to the 1970s, informed by decades of work by that agency. Also, EPA's Disinfection Byproducts 2 rule and the Surface Water Treatment 2 rule were based on the work of an expert panel convened under the Federal Advisory Committee Act years before these rules were proposed. Another example mentioned by EPA officials was a stormwater management rule for the oil and gas industry that supplemented and was partially based on an earlier nationwide, multi-industry rulemaking.

Reviews of published rules or rulemaking dockets provide little information on the resources and level of effort needed for agencies to comply with specific rulemaking requirements. As pointed out by DOT officials, neither the text of the rule nor the materials in the agency's rulemaking docket might indicate all of the resources and the decision-making process that the agency performed to make such determinations. Specifically, they noted that dockets would not necessarily include copies of the underlying analyses if the agency concluded that the rule did not trigger that requirement. Also, each requirement that a rule triggers does not necessarily require preparation of a separate analysis. Agencies can use some analyses to address more than one requirement (for example,

using one benefit-cost analysis to address multiple analytical requirements).

Even if costs and resources were tracked at the individual rule level, the resources used to meet general rulemaking requirements would still need to be captured to provide a complete picture. Rulemaking is an integral part of agency business, and it would be hard to separate all that is done for rulemaking from what also contributes to other operational and policy decisions. Further, given the many other demands on scarce agency resources, the resources that would be needed to develop reliable tracking data on individual rules or requirements must be weighed against other investments.

Many of the Rules GAO Reviewed Triggered Few of the Broadly Applicable Rulemaking Requirements

When issuing major rules, agencies must generally comply with the APA and a number of other broadly applicable procedural and analytical requirements specified in law. However, one statutory requirement, the Unfunded Mandates Reform Act of 1995 (UMRA), does not apply to independent regulatory agencies. EPA and the Occupational Safety and Health Administration must also comply with a requirement to convene a small business advocacy review panel under the Small Business Regulatory Enforcement Fairness Act if their rules would have a significant economic impact on a substantial number of small entities—business or governmental.[31] Further, agencies other than independent regulatory agencies are also subject to requirements in executive orders. In addition to the broadly applicable requirements, agencies may need to comply with agency- or program-specific requirements established by other statutes.

Table 1 lists the 17 broadly applicable statutes and executive orders with rulemaking requirements that were cited by 10 or more major rules that we reviewed for this report.[32] For each we provide a high-level characterization of agencies' responsibilities under the requirement. (App. I provides additional information about these requirements.)

[31]5 U.S.C. § 609.

[32]When discussing or displaying information on multiple requirements in this report, we have followed the convention of listing statutes first followed by executive orders.

Table 1: Rulemaking Requirements Generally Applicable to Major Rules

Source of requirements	Characterization of agencies' responsibilities
Requirements applicable to rules of all agencies	
Administrative Procedure Act	Procedures required for informal rulemaking, also known as notice-and-comment rulemaking
Congressional Review Act	Submission of rules to Congress for review
Endangered Species Act	Analysis of impact on endangered or threatened species
National Environmental Policy Act	Analysis of environmental impacts
National Technology Transfer and Advancement Act	Use of voluntary consensus standards
Paperwork Reduction Act	Analysis of paperwork burden and submission to OIRA for approval of new information collections
Regulatory Flexibility Act	Consideration of regulatory alternatives to lessen the burden on small entities
Requirements applicable to rules of cabinet departments and independent agencies, but not to rules of independent regulatory agencies	
Unfunded Mandates Reform Act	Analysis of costs and benefits of federal mandates and consideration of alternatives
Executive Order 12372	Consultation with state and local elected officials
Executive Order 12630	Analysis of impact on constitutionally protected property rights
Executive Order 12866	Submission of significant rules for OIRA review and analysis of costs, benefits, and regulatory alternatives
Executive Order 12898	Consideration of environmental justice impact on minority and low-income populations
Executive Order 12988	Ensuring clarity of regulatory language regarding legal rights and obligations
Executive Order 13045	Evaluation of environmental health or safety effects on children
Executive Order 13132	Consultation with state and local officials on federalism implications
Executive Order 13175	Consultation with Indian tribal governments
Executive Order 13211	Analysis of effects on energy supply, distribution, or use

Source: GAO.

Our review of the 139 major rules published from January 2006 through May 2008 showed that many of the procedural and analytical requirements that generally apply to the agencies were not triggered by specific rules. An agency may not need to include specific analyses if the substance of the rule or exceptions, exclusions, and thresholds in the requirement lead the agency to determine that the requirement was not triggered by a specific rule. For example, if the substance of a rule includes no new information collections, the agency would not have to estimate burden hours under the PRA. Exceptions and exclusions can be either categorical or statute specific. As an example of a categorical exception, the APA notice-and-comment requirements do not apply to any rule regarding a military or foreign affairs function of the United States. Also, the RFA and UMRA requirements do not apply if a rule was exempt from the APA notice-and-comment requirements. An example of a statute-specific exemption is section 1601(c) of the Farm Security and Rural Investment Act of 2002 that generally exempted rules issued by the Department of Agriculture's Commodity Credit Corporation from the APA and the PRA requirements.[33] The applicability of certain requirements is also limited by threshold provisions. For example, agencies only need to prepare UMRA "written statements" for rules that the agencies believe include a federal intergovernmental or private sector mandate that may result in expenditures of $100 million or more (adjusted for inflation) in any year.[34] Taken as a whole, an agency may need to work through a series of determinations for each rule under each requirement regarding substance, exceptions, and thresholds.[35]

In the 139 major rules we reviewed, the agencies mentioned at least 29 different broadly applicable requirements, but most rules actually triggered only a handful of the requirements. Our review of the major rules showed that in addition to the procedural requirements under the APA and the CRA, the only analytical requirements triggered by 45 percent or more of all rules were the PRA, the RFA, and Executive Order 12866. Collectively, however, the requirements resulted in agencies providing at

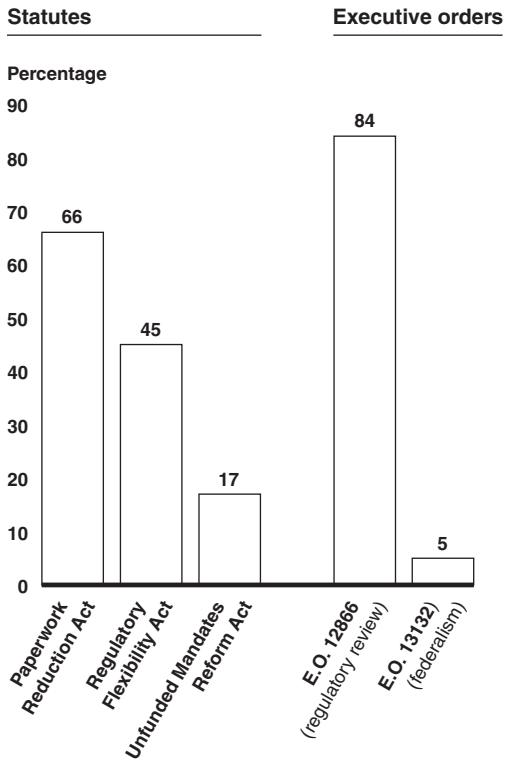
[33]7 U.S.C. § 7991(c).

[34]The dollar threshold for 2008 was approximately $133 million.

[35]See GAO, *Unfunded Mandates: Analysis of Reform Act Coverage*, GAO-04-637 (Washington, D.C.: May 12, 2004), for an illustration of the complex multistep process needed to determine whether UMRA is triggered. In that report, we noted that there are 14 definitional exceptions, exclusions, or other restrictions applicable to the identification of federal mandates in rules.

least some information on the costs, benefits, or both associated with 91 percent of the major rules.[36] Agencies also frequently cited the UMRA and Executive Order 13132 related to federalism, but the rules seldom triggered those requirements. Figure 3 illustrates how often the agencies stated that their rules triggered the most commonly cited analytical requirements, according to our major rules reports.

Figure 3: Percentage of 139 Major Rules That Triggered Rulemaking Requirements



Source: GAO analysis.

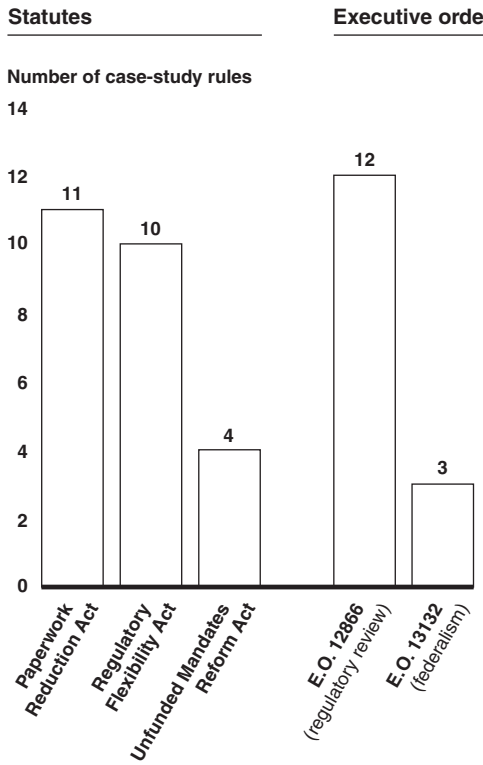
Note: Other requirements were triggered by less than 5 percent of the major rules reviewed.

Similarly, the 16 case-study rules that we reviewed triggered some, but not all, of the broadly applicable requirements. All 16 of the rules discussed requirements under the PRA and the RFA, but only 11 triggered a PRA

[36]Information on the cost-benefit analysis, if any, that was prepared for a rule is one of the mandated elements of our major rule reports under CRA. However, this element reflects requirements from various statutory or executive orders, rather than any one requirement.

analysis and 10 an RFA analysis. Except for the rules promulgated by SEC, all of the rules discussed UMRA and Executive Order 13132 requirements; however, only 4 rules triggered an UMRA analysis and 3 a federalism analysis. The 4 case-study rules from DOT, EPA, and FDA that were economically significant rules also included quantitative cost-benefit analyses required under Executive Order 12866. Figure 4 illustrates how often the agencies stated that the case-study rules triggered the most commonly cited analytical requirements. (See the case studies in app. II for further details on the regulatory requirements addressed by each rule.)

Figure 4: Number of 16 Case-Study Rules That Triggered Rulemaking Requirements



Source: GAO analysis.

Note: UMRA, Executive Order 12866, and Executive Order 13132 do not apply to the 4 SEC rules because SEC is an independent regulatory agency.

Agencies Reported That Recent Regulatory Requirements Presented Some Challenges Initially

Agency officials from case-study agencies reported that in some instances, the new requirements imposed by OMB since 2003 were challenging initially, requiring additional time and resources. However, some officials noted that these recent requirements reflected practices that some agencies had already adopted. For example, FDA had routinely circulated

the regulatory impact analyses of economically significant rules for peer review before submitting the rules to OMB prior to the 2004 issuance of the Peer Review Bulletin and while these regulatory impact analyses are excluded from the requirements of the Bulletin, FDA continues to circulate them for peer review. FDA officials agreed that the revised OMB Circular No. A-4 helped to clarify expectations for their economic analyses and in some cases resulted in less time needed for OMB review and greater confidence in the regulatory choices.

Initially incorporating certain aspects of the new requirement for formal probability analysis to assess uncertainty lengthened the rulemaking process for one agency. NHTSA officials reported that prior to issuance of revised Circular No. A-4—which requires formal probability analysis to assess uncertainty for rules with more than a billion-dollar annual impact on the economy—NHTSA used a simpler form of uncertainty analysis, called sensitivity analysis, rather than the more formal probability analysis. When NHTSA performed its first probability analysis under OMB Circular No. A-4, it took several weeks to complete and required contracting resources outside the agency—not a typical practice for NHTSA. In addition, to meet its statutory deadline, the agency sent the rule to OIRA for review before completing the probability analysis. In contrast, EPA had incorporated probability analysis into its regulatory development process on a case-by-case basis prior to the issuance of Circular No. A-4 and therefore did not find that requirement challenging.

Officials from case-study agencies identified two long-standing analytical and procedural requirements, the PRA regarding information collections and the RFA regarding analysis of rules' effects on small entities, as having had more significant effects on time and resources than the more recent requirements. Some officials said that these requirements add time to the rulemaking process and may even work at cross-purposes during the course of regulatory development. Agency officials at FDA and SEC reported that compliance with the PRA information collection requirements may add a year or more to the timeline of regulatory development. As a result, rather than gather new information to support a rulemaking, agency officials will sometimes rely on existing information, information available from a more limited number of sources, or information gathered through public notices. This can make it more difficult to determine the effect of a regulation on small entities that may not be represented by a small sample of interested parties or respond to public notices. FDA officials stated that the agency posts on its Web site a "Dear Colleague" letter alerting the small business community to the rulemakings listed in the semi-annual Unified Agenda and Regulatory Plan

that may affect small business. This letter explains how to contact the agency and encourages small businesses to become involved early in the rulemaking process. However, it can still be difficult to determine the effect of a regulation on small entities. According to the agency officials, this requires agencies to either move forward with available information or go through time-consuming approvals for information collections under the PRA.

OIRA's Role in the Rulemaking Process Could Be More Transparent

Our review of 12 DOT, EPA, and FDA rules submitted to OIRA for formal review under Executive Order 12866 indicated that for 10 of the 12 rules, the agencies identified OIRA changes to the rules. Using the same basic methodology as in our 2003 report on the effect of OIRA's review process, we used a variety of information sources (such as agency and OIRA docket materials and interviews with agency officials) to classify the most significant level of changes attributed to OIRA's review.[37] For each of the 12 rules, we classified the level of OIRA changes into one of the following three categories:

- Significant changes. Rules in which the most significant changes affected the scope, impact, or estimated costs and benefits of the rules as originally submitted to OIRA. Usually, these changes were made to the regulatory language that would appear in the *Code of Federal Regulations* and is legally binding. For example, in an FDA rule on dietary supplements, OIRA suggested a change in the regulatory language to reduce the number of years required to save a reserve sample. However, revisions to a cost-benefit analysis could also be significant because they affect the reported impact of a rule.
- Other material changes. Rules in which the most significant changes resulted in the addition or deletion of material in the explanatory preamble section of the rule. For example, in a DOT rule on event data recorders, OIRA suggested a change in the explanatory language clarifying that crash investigators and researchers are able to download data from the recorders.
- Minor or no OIRA changes. Rules in which there were no changes made to the draft rule, the most significant changes attributed to OIRA's suggestions resulted in editorial or other minor revisions, or any changes in the rule prior to publication were not at the suggestion of OIRA.

[37] GAO-03-929.

As shown in table 2, we determined that OIRA suggested "significant" changes for 4 of the 12 case-study rules submitted for Executive Order 12866 reviews, "other material" changes for 4 of the rules, and "minor" changes for 2 of the rules. OIRA did not suggest any changes for the remaining 2 rules. Of the 4 rules that had significant changes, 2 were rules developed and promulgated by EPA and 1 each by DOT and FDA. In addition 3 of the 4 rules with significant changes were major rules. (See the case studies in app. II for further details on the changes made to rules reviewed by OIRA.)

Table 2: Classification of OIRA Review Changes to Case-Study Rules

Agency rule	Most significant OIRA review period changes	Examples of OIRA review changes
DOT/FAA Air Tour Safety	Significant changes	Change to regulatory text: Clarification that annual events limit is either four charitable events or nonprofit events, not four of each. Change to preamble: Addition of chart explaining changes proposed by rule from existing regulation. Clarification of difference between "Operation Specification" and "Letter of Authorization."
DOT/FAA Human Space Flight Requirements	Minor or no changes	The agency did not consider OIRA's changes significant.
DOT/NHTSA Fuel Economy-Light Trucks (major rule)	Minor or no changes	The agency did not consider OIRA's changes significant.
DOT/NHTSA Event Data Recorders	Other material changes	Changes to preamble: Language change related to ensuring that crash investigators and researchers are able to download data from the recorders. Addition to the owner's manual of a sentence advising owners that a recorder does not store or collect personal information.
EPA/AR Ethylene Oxide Emissions	Other material changes	Changes to preamble: Language change that mentions how EPA could adopt a "mixed approach and issue generally available control technologies or management practices (GACT) standards for certain emission points and required maximum achievable control technologies (MACT) standards for other emission points. In addition, there is language change regarding cancer risks to individuals exposed to emissions from regulated source.
EPA/AR Hazardous Air Pollutants	Other material changes	Changes to preamble: Related section specifying periodic determinations of pertinent technical factors. Added language to provide a more balanced discussion of rationale for selecting "no control." Requested EPA expand its discussion on risks reduced by emission controls.
EPA/OW Disinfection Byproducts 2 (major rule)	Significant changes	Changes to regulatory text: Changed repeat compliance monitoring to apply only when more than eight monitoring locations were required, rather than four. Removed additional requirements for repeat monitoring.

Agency rule	Most significant OIRA review period changes	Examples of OIRA review changes
EPA/OW Surface Water Treatment 2 (major rule)	Significant changes	Change to regulatory text: Addition of notification of violation requirements for public water systems. Modification of regulatory section on provision of additional circumstances under which data can be grandfathered under state approval. Change to preamble: Indication that regulated systems may assume state approval of monitoring locations if explicit approval is not forthcoming.
FDA/CDER Physician Labeling	Other material changes	Changes to preamble: Deletion of a PRA-related estimate of the number of respondents. Altered the number of affected pharmaceutical firms that could be considered small businesses.
FDA/CDER Ozone Depleting Substances	Minor or no changes	No changes suggested by OIRA.
FDA/CFSAN Dietary Supplements (major rule)	Significant changes	Change to regulatory text: Requirement in the draft rule to save reserve samples for 3 years was changed to 2 years. Change to regulatory impact analysis: Added text justifying the rulemaking and additional description of calculations of costs associated with illness and injury associated with contaminated or mislabeled dietary supplements.
FDA/CFSAN Lean Nutrient Claims	Minor or no changes	No changes suggested by OIRA.

Source: GAO analysis.

Documentation of OIRA Review Was Sometimes Incomplete

Executive Order 12866 requires both agencies and OIRA to disclose to the public certain information about OIRA's regulatory reviews. After the regulatory action has been published in the *Federal Register* or otherwise issued to the public, an agency is required to

1. make available to the public the information provided to OIRA in accordance with the executive order;[38]
2. identify for the public, in a complete, clear, and simple manner, the substantive changes between the draft submitted to OIRA and the action subsequently announced; and
3. identify for the public those changes in the regulatory action that were made at the suggestion or recommendation of OIRA.[39]

[38]For all significant rules this information includes, for example, the text of the draft regulation provided to OIRA and an assessment of the potential costs and benefits. For economically significant rules, the information must also include the underlying analysis of benefits and costs (quantified to the extent feasible).

[39]According to OIRA representatives, the requirement for agencies to document changes made at the suggestion or recommendation of OIRA only applies to changes made after draft rules are formally submitted to OIRA for review.

The order requires OIRA to maintain a publicly available log that includes the following information pertinent to rules under OIRA's review:

1. the status of rules submitted for OIRA review,
2. a notation of all written communications received by OIRA from persons not employed by the executive branch, and
3. information about oral communications between OIRA and persons not employed by the executive branch.

After the rule has been published or otherwise issued to the public (or the agency has announced its decision to not publish or issue the rule), OIRA is required to make available to the public all documents exchanged between OIRA and the agency during the review by OIRA.[40] An OIRA official also pointed out that OIRA does not monitor, on a rule-by-rule basis, compliance by rulemaking agencies with their disclosure obligations under Executive Order 12866.

The case-study agencies generally met the executive order's requirements to disclose materials they provided to OIRA and substantive changes made during OIRA's review. In contrast to our study in 2003, all the agencies we reviewed for this report had documentation of OIRA's reviews. However, the documentation could be improved for greater transparency. 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 on how to do so. Nonetheless, some of the documentation on OIRA's changes was very clear, but in other cases additional efforts were required to interpret the information. As we found in 2003, the agencies did not always clearly attribute changes made at the suggestion of OIRA, and agencies' interpretations were not necessarily consistent regarding what constitutes a substantive change that should be documented to comply with the executive order transparency requirements. For example, different departments within one agency had varied interpretations, with one office only considering those changes made to regulatory text as substantive. Table 3 provides summary information about the type and nature of agencies' documentation to address Executive Order 12866 transparency

[40]According to OIRA representatives, the requirement to make available "all documents exchanged between OIRA and the agency" issuing the regulation only applies to exchanges made by OIRA staff at the branch chief level and above, not documents exchanged between OIRA desk officers and staff in regulatory agencies.

requirements for the 12 case-study rules reviewed by OIRA. (See app. III for examples of agencies' OIRA review documentation.)

Table 3: Documentation of OIRA Reviews for Case-Study Rules

Agency rule	Source of OIRA review documentation	How agency documented OIRA review	Whether publicly available documentation attributed source(s) of changes made to rule
DOT/FAA Air Tour Safety	Online public rulemaking docket (regulations.gov)[a]	Memo to internal file	No
DOT/FAA Human Space Flight Requirements	Testimonial evidence from officials	N/A (no substantive changes)	N/A (no substantive changes)
DOT/NHTSA Fuel Economy – Light Trucks (major rule)	Testimonial evidence from officials	N/A (no substantive changes)	N/A (no substantive changes)
DOT/NHTSA Event Data Recorders	Online public rulemaking docket (regulations.gov)	Memo to file in docket	Yes
EPA/OAR Ethylene Oxide Emissions	Online public rulemaking docket (regulations.gov)	Redline/strikeout document(s) in docket	Yes
EPA/OAR Hazardous Air Pollutants	Online public rulemaking docket (regulations.gov)	Redline/strikeout and e-mails in docket	Yes
EPA/OW Disinfection Byproducts 2 (major rule)	Online public rulemaking docket (regulations.gov)	Redline/strikeout and check box form in docket	No
EPA/OW Surface Water Treatment 2 (major rule)	Online public rulemaking docket (regulations.gov)	Redline/strikeout, check box memo to the file in docket	No
FDA/CDER Physician Labeling Rule	Online public rulemaking docket (regulations.gov)	Redline/strikeout (changed pages consolidated) in docket	Yes
FDA/CDER Ozone Depleting Substances	OIRA regulatory review Web site (www.reginfo.gov)	N/A – Rule classified as "consistent without change"	N/A (no changes)
FDA/CFSAN Dietary Supplements (major rule)	Paper docket at FDA because of difficulties using online docket	Redline/strikeout in docket (62 documents)	No
FDA/CFSAN Lean Nutrient Claims	Online public rulemaking docket (regulations.gov)	Note to file (with an unchanged rule draft)	N/A (no changes)

Source: GAO analysis.

[a]Added to the docket subsequent to our review.

As we also found in 2003, agencies sometimes included more information about OIRA's review than required, and we found such information useful to more clearly explain what had occurred. For example, EPA included copies of messages from OIRA outlining suggested changes to draft rules under review. EPA also included a memo to the docket summarizing the subjects discussed with OIRA at a meeting about one of the case-study rules. In the case of one rule that was unchanged by OIRA, FDA's docket included both an annotated copy of the rule returned to FDA and a memo to the file noting that there were no changes to the draft rule.

In general, compared to our review in 2003, we found it more difficult to find agencies' documentation of OIRA's regulatory reviews, primarily because of difficulties using the search capabilities in the centralized electronic Federal Docket Management System under www.regulations.gov. Using the advanced docket search function as instructed by the Web site user information to first find the rule, we searched by the rule title, the RIN, and the rule Docket ID independently and as they appeared in the published version of the final rule in the *Federal Register*. Using those criteria, we were able to find all four of the DOT case-study rules submitted for OIRA review but only one each of the 4 FDA rules and 4 EPA rules. We chose to use paper dockets when the opportunity presented itself for the FDA case study rules.[41]

Agencies' labeling practices also sometimes made it difficult to find the relevant documentation about OIRA's reviews. Out of 12 dockets, we were able to identify 5 of the 10 changed rules and 1 of the 2 unchanged rules by searching the docket Web pages for "12866," "OIRA," and "OMB." In addition, while the agencies' published rules stated that the rules had been reviewed by OIRA under Executive Order 12866, most of the rules did not identify whether substantive changes had been made during the OIRA review period (and therefore documentation of the changes should be included in the rulemaking docket). Although there is no requirement for agencies to do so, including such additional information would be consistent with how agencies discuss other rulemaking requirements in published rules and potentially help readers navigate the docket. Such information, for example, would more clearly have identified which of our case-study rules' dockets should include documentation of OIRA review changes.

[41]At the time of our review, FDA was transitioning to regulations.gov and had both paper and online dockets available for its rules.

In response to the disclosure requirements placed on OIRA by Executive Order 12866, OIRA's meeting logs indicated that parties not employed by the executive branch initiated meetings with OIRA regarding 7 of the 12 case-study rules, but we do not know what influence meeting discussions had on OIRA recommendations because there is no requirement for OIRA to disclose the substance of the meetings. OIRA logged a total of 10 meetings, but 2 of the meetings each concerned 2 rules. Three of these meetings occurred before formal submission of the draft rule for OIRA review. There were meetings on all 4 EPA case-study rules. As we found during our review in 2003, most of the nonfederal parties appeared to be representatives of regulated entities. In all but 2 of the meetings, the agency issuing the regulation was represented.

OIRA Implemented Only One of Eight Prior GAO Recommendations to Improve Transparency of the Regulatory Review Process

In our 2003 report on the OMB/OIRA regulatory review process, we made eight recommendations to the Director of OMB to improve the transparency of the process.[42] OMB implemented our recommendation to improve the clarity of OIRA's meeting log to better identify participants in OMB meetings with external parties on rules under review by disclosing the affiliations of participants. In some cases, the log also identified the clients represented.

However, OIRA did not agree with the seven remaining recommendations in the 2003 report and did not implement those recommendations. We recommended that OIRA should do the following:

1. Define the transparency requirements applicable to the agencies and OIRA in 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.
2. 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.
3. Reexamine OIRA's current policy that only documents exchanged by OIRA branch chiefs and above need to be disclosed because most of the documents that are exchanged while rules are under review at OIRA are exchanged between agency staff and OIRA desk officers.

[42] GAO-03-929.

4. Establish procedures whereby either OIRA or the agencies disclose the reason why rules are withdrawn from OIRA review.
5. 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 (for example, explanations supporting the choice of one alternative over another and solicitations of comments on the estimated benefits and costs of regulatory options).
6. 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.
7. Encourage agencies to use "best practice" methods of documentation that clearly describe those changes.

We discussed the status of these open recommendations with OIRA representatives annually since 2003 and also as part of this review, and they confirmed that OIRA had not subsequently implemented any of the seven remaining recommendations. As discussed above, our current review indicated that there are still opportunities to improve transparency for some of these topics, such as better identification of when agencies made substantive changes to their rules as a result of the OIRA review process, attributing the sources of changes made during the review period, and clarifying the definition of substantive changes. Other issues covered by our 2003 recommendations—such as OIRA informal reviews and disclosing why rules are withdrawn from OIRA review—did not arise during this review, but this may reflect the nature of the specific rules we reviewed and our more limited sample of case studies.

Conclusions

Federal regulatory agencies issue many rules to ensure public health and safety, protect the environment, and facilitate the effective functioning of financial markets, among other goals. Because these rules can affect so many aspects of citizens' lives, it is crucial that rules be carefully developed and considered and that rulemaking procedures be effective and transparent. To further such goals, Congresses and Presidents have placed many procedural and analytical requirements on the rulemaking process over the years. While we and others have reported on agencies' implementation of individual requirements, there has been little analysis of the cumulative effects these requirements have on agencies' rulemaking processes.

Our study of broadly applicable requirements illustrated the difficulties of evaluating the effects of regulatory requirements on the rulemaking process with limited data. To the extent that agencies had information for selected rules, it showed considerable variation in the time required for issuing final rules that could not be explained by the number of regulatory requirements, few of which were triggered. Moreover, the complexity or magnitude of a major rule also did not explain all or most variation, as some case-study rules were not major and took nearly as long or longer to be published. This raises the question of what factors can account for the variations in rule development. While our findings point to better use of existing estimates and plans to identify opportunities to improve the rulemaking process, agencies also recognized more can be done and, in some cases, have taken steps to answer this question.

We found that early in their rulemaking processes each agency identified the key milestones it needed to accomplish to produce a final rule. During the course of our review, only DOT provided data that it routinely tracked these milestones and reported internally and externally on the status of milestones for development of the agency's significant rules. However, in comments on our draft report, EPA and FDA subsequently provided some documentation and data on their tracking and reporting of milestones. Although there is no right time for how long a rulemaking should take, monitoring actual versus estimated performance enables agency managers to identify steps in the rulemaking process that account for substantial development time and provides information necessary to further evaluate whether the time was well spent. Although not all factors are within an agency's control, some are. Agency officials we spoke with identified several potential benefits to monitoring and reporting, including better scheduling and increased internal and external accountability. This is also consistent with the internal control standard that an agency must have relevant, reliable information relating to external as well as internal events. Additionally, officials in three of the four agencies we audited said they would benefit from a better understanding of how staff resources are used, even though agencies' efforts so far have produced limited results. Information on only one element in the rulemaking process—length of time—cannot answer whether an agency is managing well. However, such information can provide insights into the process, such as when it contributed to our efforts to determine the relative burden of various regulatory requirements.

Our review of major and case-study rules indicated that the majority of the rules triggered only a few of the rulemaking requirements. The requirements that rules most often triggered are among the longest

standing and broadly applicable—the PRA, the RFA, and centralized OIRA review under Executive Order 12866. The PRA and the RFA generally apply to all agencies and rules, and officials from each of the agencies where we conducted case studies cited those requirements as ones that consistently added time to the rulemaking process and required investments of agency resources. Similarly, under Executive Order 12866, we observed that a relatively small portion of rules submitted to OIRA for review have economic consequences significant enough to trigger the most rigorous analytical requirements, so any burden of compliance with those requirements is not very widespread. The majority of rules submitted for OIRA review (around 85 percent historically) are significant for reasons other than their economic impact.

The case-study agencies generally met the executive order's requirements to disclose materials they provided for OIRA's review and substantive changes made during OIRA's review. For those case-study agencies and rules subject to OIRA review, some agency practices were more effective than others in communicating review results. Transparency problems that we identified in the past persist, such as incomplete attribution of changes and inconsistent definitions of substantive changes among and within agencies. Also, unlike when addressing other regulatory requirements—where agencies typically note in the published rule whether the rule triggered the requirements—the agencies did not clearly identify in their final rules when substantive changes had been made during the OIRA review period. OIRA, as the agency responsible for providing oversight and guidance to agencies on regulatory matters, is the principal entity in a position to ensure consistent compliance across agencies if the administration retains transparency requirements regarding regulatory review.

Recommendations for Executive Action

We are making six recommendations to improve the monitoring and evaluation of rules development and the transparency of the review process.

To be consistent with internal controls for information in managing agency operations, we recommend that for significant rules the Commissioner of FDA and the Chairman of SEC routinely track major milestones in regulatory development and report internally and externally when major milestones are reached against established targets. The Administrator of EPA, the Commissioner of FDA, and the Chairman of SEC should each also evaluate actual performance versus the targeted milestones and when they are different determine why.

If the current administration retains Executive Order 12866, or establishes similar transparency requirements, we recommend that the Director of OMB, through the Administrator of OIRA, take the following four actions to more consistently implement the order's requirement to provide information to the public "in a complete, clear, and simple manner":

- define in guidance what types of changes made as a result of the OIRA review process are substantive and need to be publicly identified,
- instruct agencies to clearly attribute those changes "made at the suggestion or recommendation of OIRA,"
- direct agencies to clearly state in final rules whether they made substantive changes as a result of the OIRA reviews, and
- standardize how agencies label documentation of these changes in public rulemaking dockets.

Agency Comments and Our Evaluation

We provided a draft of this report to the Department of Health and Human Services (HHS), DOT, EPA, SEC, and OMB. We received written comments from HHS/FDA, EPA, SEC, and OMB which are summarized below and reprinted in appendices IV through VII. However, because EPA and FDA provided new information as part of agency comments, we did not analyze the information provided and conduct follow-up discussions with agency officials prior to publication of this report. We note that we had asked for this information during our review and the agencies did not provide at that time. Also, they did not provide this information at the conclusion of our review either in response to our statements of facts to the agencies or at our exit conference with the agencies. DOT provided only technical comments. With regard to the two recommendations directed to the rulemaking agencies, SEC stated that the Commission is committed to evaluating and improving all of it processes and will consider our recommendations as part of that process.

With regard to our recommendation that for significant rules agencies routinely track major milestones in regulatory development and report internally and externally when major milestones are reached against established targets, FDA commented that the scope of this recommendation should be more narrow and flexible. Specifically, FDA commented that: (1) the scope of tracking should be limited to only economically significant rules because FDA cannot predict with certainty what rules OMB will consider otherwise significant until close to rule clearance, (2) alternative tracking approaches should be permitted since FDA has the FRDTS that tracks the progress of all its *Federal Register* documents through the latter stages of the agency's development and

clearance process, and (3) routine reporting on when major milestones are met should only be internal because reporting externally may mislead stakeholders and prompt inquiries that draw resources away from the agency's ability to complete regulations.

While we agree that some flexibility is necessary, we disagree about narrowing the scope of our recommendation. For example, regarding FDA's proposal to narrow the scope to only economically significant rules, in this report we note that about 85 percent of all significant rules are not economically significant, so such a limitation would drop the bulk of the agency's regulatory activity. Further, with regard to FDA's point that it is uncertain what rules OMB will deem significant, in this report we stated that under Executive Order 12866 the agency, not OMB, has the primary responsibility to first identify which rules are significant. Therefore, FDA should be aware of many if not most of the rules that are deemed significant in its inventory. For those rules that OMB deems significant only at the latter stages of rulemaking, we recognize that tracking might have to begin at that stage. Regarding FDA's second point, we did not recommend one particular system and recognize that the information in FRDTS provides tracking data on milestones. However, we note that these data are limited to the latter stages of the rulemaking process. Because our review showed that the earlier developmental stages of a rule could be a significant portion of time spent in regulatory development, there is value in also tracking milestones in the earlier stages. Regarding FDA's third point, it is still important to report some information externally as well as internally to improve the transparency and accountability of the agency's rulemaking process. Further, we believe that FDA's concern about the impact that reporting some information externally could have on agency resources is overstated. None of the agencies we met with during this review identified responding to public inquiries as a major factor affecting resources and timeliness. Also, there is nothing that precludes agencies from providing reasons for delays when externally reporting this information to reduce the volume of public inquiries. Therefore, we kept this recommendation addressed to FDA.

With regard to our second recommendation that agencies should also evaluate actual performance versus the targeted milestones, FDA stated that the agency is already engaged in quality improvement efforts for its rulemaking process. Specifically, FDA said that its Policy Council has quarterly meetings with the agency components and the agency periodically reviews its rulemaking processes to see if changes are needed. Also, FDA noted that 12 such reviews have been completed since 1981, and identified two recent pilot projects resulting from these reviews.

However, although FDA said the agency conducted general evaluations and provided some examples, FDA did not provide information showing that the agency had specifically evaluated the issue highlighted in our recommendation. To the extent that FDA has not, we would still recommend that they specifically evaluate the reasons for any discrepancies between projected and actual milestones for their significant rulemakings. Therefore, we kept this recommendation addressed to FDA. We revised the body of the report where appropriate in response to the additional information FDA provided in its comments.

Regarding our recommendation that agencies routinely track major milestones and report internally and externally when major milestones are reached, EPA clarified that the agency currently tracks key milestones associated with the rulemaking process and reports this information internally and externally. Specifically, EPA cited RAPIDS, an internal tracking system that monitors cross-agency involvement and senior management reviews. EPA also cited three primary sources for external reporting, specifically its use of Action Initiation Lists, the Semiannual Regulatory Agenda, and a quarterly report which they subsequently identified as EPA*Stat*.[43]

Based on the new information and subsequent documentation that we requested from EPA in response to the agency's comments, we concur that EPA has a tracking system and internal and external reporting mechanisms that appear to address our recommendation. Therefore, we removed this recommendation to EPA. For example, EPA's RAPIDS tracks information on numerous milestones on all phases of the rulemaking process. Further, RAPIDS tracks information on rules that are both economically significant and significant. Similarly, with regard to internal and external reporting, EPA cited three main sources the agency uses for external reporting of milestones. We modified the body of the report to incorporate the new information. We note, however, that we had requested this information during our review and, because the information was not provided at the time of our review, we did not have the opportunity to discuss how the information is used, whether it is useful, and, most importantly, if it could be used to respond to our report objectives. We did not audit the new information provided because of the

[43]The *Semiannual Regulatory Agenda* is also known as the *Unified Agenda of Federal Regulatory and Deregulatory Actions*.

approaching deadline for OMB to provide recommendations to the President for a new executive order on federal agency regulatory review.

While not specifically addressing our second recommendation that agencies should also evaluate actual performance versus the targeted milestones, EPA comments indicated that agency executives and managers routinely meet to review milestones on key regulations and review program performance. Specifically, EPA noted that actions that are completed on time or early are used by the agency as examples of best practices and actions that are off-track are identified early and corrective steps are taken to expedite their completion. Because we were unaware of this system or its use at the time of our review, we could not determine whether EPA specifically evaluated discrepancies between projected and actual milestones to determine reasons why and took corrective actions. No evidence was provided to draw a conclusion. Therefore, we kept this recommendation addressed to EPA.

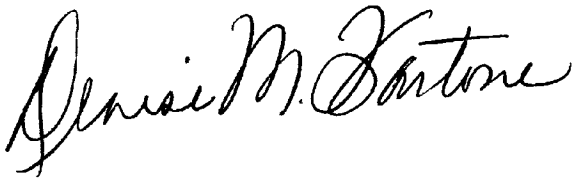
With regard to our four recommendations to OMB to more consistently implement the Executive Order 12866 requirement that agencies provide information to the public in a complete, clear, and simple manner, OMB stated that these recommendations have merit and warrant further consideration. In particular, OMB stated that it will give full consideration to the report and its recommendations as the agency finalizes its recommendations to the President for a new Executive Order on regulatory review. OMB also said that the report will remind rulemaking agencies of their responsibility to identify in a complete, clear, and simple manner the substantive changes between the draft rule submitted to OIRA for review and the action subsequently announced, and to identify those changes in the regulatory action that were made at the suggestion or recommendation of OIRA.

We also received technical comments and clarifications which we incorporated into this report, where appropriate. EPA provided a substantive technical comment regarding our classifications of the level of OIRA changes for three of the case study rules. In light of the clarifying comments EPA provided, we revised our classification of the Ethylene Oxide Emissions rule from “significant changes” to “other material changes.” However we did not reclassify the other two EPA rules because the changes suggested would not be consistent with the methodology and criteria we used in this and prior reviews of the OIRA regulatory review process.

As agreed with your office, unless you publicly announce the contents of this report earlier, we plan no further distribution until 30 days from the report date. At that time, we will send copies to appropriate congressional committees, the Secretary of Health and Human Services, the Secretary of Transportation, the Administrator of EPA, the Chairman of SEC, and the Director of OMB. The report also will be available at no charge on the GAO Web site at http://www.gao.gov.

If you or your staff members have any questions about this report, please contact me at (202) 512-6806 or fantoned@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made major contributions to this report are listed in appendix VIII.

Sincerely yours,



Denise M. Fantone
Director
Strategic Issues

Appendix I: Summary of Common Regulatory Requirements

In this appendix, we provide information on commonly applicable regulatory requirements established by statutes and executive orders. We included those requirements identified by 10 or more of the rules we reviewed for this report or that were relevant to our case-study rules. We list the requirements within each major section (statutory requirements and executive orders) in chronological order. For each requirement, the following paragraphs summarize the general purpose, applicability and requirements imposed by the initiatives that were relevant to the rules we examined for this report.

Statutory Requirements

Administrative Procedure Act

The Administrative Procedure Act (APA) was enacted in 1946 and established the basic framework of administrative law governing federal agency action, including rulemaking.[1] Section 553 of Title 5, United States Code, governs "notice-and-comment" rulemaking, also referred to as "informal" or "APA rulemaking." Section 553 generally requires (1) publication of a notice of proposed rulemaking, (2) opportunity for public participation in the rulemaking by submission of written comments, and (3) publication of a final rule and accompanying statement of basis and purpose not less than 30 days before the rule's effective date. Congresses and Presidents have taken a number of actions to refine and reform this regulatory process since the APA was enacted.

National Environmental Policy Act of 1969

The National Environmental Policy Act (NEPA) requires agencies to consider the potential impact on the environment of federal agency action, including regulations.[2] NEPA directs all agencies of the federal government to include in proposals for "major Federal actions significantly affecting the quality of the human environment" a detailed environmental impact statement addressing certain listed subjects and applying substantive criteria set forth in the Act.[3]

Federal Advisory Committee Act

The Federal Advisory Committee Act (FACA) regulates the formation and operation of advisory committees by federal agencies.[4] Advisory

[1]Pub. L. No. 404, 60 Stat. 237, ch. 324, §§ 1-12 (1946), codified by Pub. L. No. 89-554 (1996) in 5 U.S.C. §§ 551-559, 701-706, 1305, 3105, 3344, 5372, 7521.

[2]Pub. L. No. 91-190, 83 Stat. 852 (1970), codified at 42 U.S.C. §§ 4321-4347.

[3]42 U.S.C. § 4332.

[4]Pub. L. No. 92-463, 86 Stat. 770 (1972) (codified at 5 U.S.C. App. 2).

committees, normally comprising of experts in the regulatory field involved, representatives of affected interest groups, and representatives of federal and state agencies, generally advise agencies on the content of rulemaking or on issues while the rulemaking is in progress. Some statutes require the agencies to use advisory committees, and others authorize but do not require their use.[5]

Endangered Species Act of 1973

The Endangered Species Act seeks to protect species of animals against threats to their continuing existence caused by man.[6] Under section 7 of the Act, each federal agency, "in consultation with and with the assistance of the Secretary" of the Interior shall ensure that any regulation issued by that agency not jeopardize the continued existence of any endangered or threatened species. 16 U.S.C. § 1536(a)(2).

Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) was enacted in response to concerns about the effect that federal regulations can have on small entities.[7] The RFA requires independent and other regulatory agencies to assess the impact of their rules on "small entities," defined as including small businesses, small governmental jurisdictions, and certain small not-for-profit organizations. Under the RFA, an agency must prepare an initial regulatory flexibility analysis at the time proposed rules are issued, unless the head of the agency certifies that the proposed rule would not have a "significant economic impact upon a substantial number of small entities." 5 U.S.C. § 605(b). The analysis must include a consideration of regulatory alternatives that accomplish the stated objectives of the proposed rule and that minimize any significant impact on such entities. However, the RFA only requires consideration of such alternatives and an explanation of why alternatives were rejected; the Act does not mandate any particular outcome in rulemaking. After the comment period on the proposed rule is closed, the agency must either certify a lack of impact, or prepare a final regulatory flexibility analysis, which among other things, responds to issues raised by public comments on the initial regulatory flexibility analysis. The agencies must make the final analysis available to the public and publish the analysis or a summary of it in the *Federal Register*. The Act also requires agencies to ensure that small entities have an

[5]The Occupational Safety and Health Act of 1970, for example, authorizes, but does not require, the use of advisory committees for establishing certain safety and health standards. 29 U.S.C. § 656.

[6]Pub. L. No. 93-205, 87 Stat. 884 (1973).

[7]Pub. L. No. 96-354, 94 Stat. 1164 (1980), codified as amended at 5 U.S.C. §§ 601-612.

opportunity to participate in the rulemaking process and requires the Chief Counsel of the Small Business Administration's Office of Advocacy to monitor agencies' compliance. The RFA applies only to rules for which an agency publishes a notice of proposed rulemaking (or promulgates a final interpretative rule involving the internal revenue laws of the United States), and it does not apply to ratemaking.

Paperwork Reduction Act of 1980

The Paperwork Reduction Act (PRA) requires agencies to justify any collection of information from the public to minimize the paperwork burden they impose and to maximize the practical utility of the information collected.[8] The Act applies to independent and other regulatory agencies. Under the PRA, agencies are required to submit all proposed information collections to the Office of Information and Regulatory Affairs (OIRA) in the Office of Management and Budget (OMB).[9] Information collections generally cover information obtained from more than ten sources.[10] In their submissions, agencies must establish the need and intended use of the information, estimate the burden that the collection will impose on respondents, and show that the collection is the least burdensome way to gather the information. Generally, the public must be given a chance to comment on proposed collections of information. 44 U.S.C. § 3506(c), 5 C.F.R. § 1320.11. At the final rulemaking stage, no additional public notice and opportunity for comment is required, although OMB may direct the agency to publish a notice in the *Federal Register* notifying the public of OMB review.

Negotiated Rulemaking Act of 1990

The Negotiated Rulemaking of 1990 (NRA) established a statutory framework for agency use of negotiated rulemaking to formulate proposed regulations.[11] The NRA supplements the rulemaking provisions of the APA,

[8]The PRA was originally enacted into law in 1980, Pub. L. No. 96-511, 94 Stat. 2812 (1980). It was reauthorized with minor amendments in 1986, Pub. L. No. 99-591, 100 Stat. 3341 (1986), and was reauthorized a second time with more significant changes in 1995, Pub. L. No. 104-13, 109 Stat. 163 (1995). 44 U.S.C. §§ 3501-3520.

[9]44 U.S.C. § 3504.

[10]The PRA generally defines a "collection of information" as the obtaining or disclosure of facts or opinions by or for an agency from ten or more nonfederal persons. 44 U.S.C. § 3502(3). Many information collections, recordkeeping requirements, and third-party disclosures are contained in or are authorized by regulations as monitoring or enforcement tools, while others appear in separate written questionnaires for purposes of developing the regulation.

[11]Pub. L. No. 101-648, 104 Stat. 4969 (1990), codified at 5 U.S.C. §§ 561-570. The NRA was permanently reauthorized by the Administrative Dispute Resolution Act of 1996, Pub. L. No. 104-320, § 11, 110 Stat. 2870, 3873 (1996).

clarifying the authority of federal agencies to conduct negotiated rulemaking. Generally, in a negotiated rulemaking, representatives of the agency and the various affected interest groups get together and negotiate the text of a proposed rule.

Unfunded Mandates Reform Act of 1995

The Unfunded Mandates Reform Act (UMRA) was enacted to address concerns about federal statutes and regulations that require nonfederal parties to expend resources to achieve legislative goals without being provided funding to cover the costs.[12] UMRA generates information about the nature and size of potential federal mandates but does not preclude the implementation of such mandates. UMRA applies to proposed federal mandates in both legislation and regulations, but it does not apply to rules published by independent regulatory agencies. With regard to the regulatory process, UMRA generally requires federal agencies to prepare a written statement containing a "qualitative and quantitative assessment of the anticipated costs and benefits" for any rule that includes a federal mandate that may result in the expenditure of $100 million or more in any 1 year by state, local, and tribal governments in the aggregate, or by the private sector.[13] For such rules, agencies are to identify and consider a reasonable number of regulatory alternatives and from those select the least costly, most cost-effective, or least burdensome alternative that achieves the objectives of the rule (or explain why that alternative was not selected). UMRA also includes a consultation requirement; agencies must develop a process to permit elected officers of state, local, and tribal governments (or their designees) to provide input in the development of regulatory proposals containing significant intergovernmental mandates. UMRA applies only to rules for which an agency publishes a notice of proposed rulemaking.

National Technology Transfer and Advancement Act of 1995

The National Technology Transfer and Advancement Act (NTTAA) directs federal agencies to use voluntary consensus standards in their regulatory activities unless the agency provides Congress, through OMB, with an explanation of why using these standards would be inconsistent with applicable law or otherwise impracticable.[14] Voluntary consensus standards are technical standards (e.g., specifications of materials,

[12]Pub. L. No. 104-4, 109 Stat. 48 (1995) (codified in scattered sections of title 2 of the United States Code).

[13]The dollar thresholds in UMRA are in 1996 dollars and are adjusted annually for inflation.

[14]Pub. L. No. 104-113, 110 Stat. 775 (1995).

performance, design, or operation; test methods; sampling procedures; and related management systems practices) that are developed or adopted by voluntary consensus standards bodies.

Small Business Regulatory Enforcement Fairness Act

Congress amended the RFA in 1996 by enacting the Small Business Regulatory Enforcement Fairness Act (SBREFA).[15] SBREFA included judicial review of compliance with the RFA. SBREFA requires agencies to develop one or more compliance guides for each final rule or group of related final rules for which the agency is required to prepare a regulatory flexibility analysis. SBREFA also requires the Environmental Protection Agency and the Occupational Safety and Health Administration to convene advocacy review panels before publishing an initial regulatory flexibility analysis.

Congressional Review Act

The Congressional Review Act (CRA) was enacted as part of SBREFA in 1996 to better ensure that Congress has an opportunity to review, and possibly reject, rules before they become effective.[16] CRA established expedited procedures by which members of Congress may disapprove agencies' rules by introducing a resolution of disapproval that, if adopted by both Houses of Congress and signed by the President, can nullify an agency's rule. CRA applies to rules issued by independent and other regulatory agencies. CRA requires agencies to file final rules with both Congress and GAO before the rules can become effective. GAO's role under CRA is to provide Congress with a report on each major rule (for example, rules with a $100 million impact on the economy) including GAO's assessment of the issuing agency's compliance with the procedural steps required by various acts and executive orders governing the rulemaking process.

Information Quality Act

In 2000, the Information Quality Act (IQA) was added as an amendment to the PRA.[17] IQA applies to the same agencies that are subject to the PRA; the Act applies to independent and other regulatory agencies. The IQA requires every agency to issue guidelines, with OMB oversight, to ensure and maximize the quality, objectivity, utility, and integrity of information disseminated by the agency. Agencies must also establish administrative

[15]Pub. L. No. 104-121, Title II, 110 Stat. 857(1996) (codified in scattered sections of title 5 of the United States Code).

[16]5 U.S.C. §§ 801-808.

[17]Consolidated Appropriations Act of 2001, Pub. L. No. 106-554, § 515, 114 Stat. 2763, 2763A-152,codified at 44 U.S.C. § 3516 note.

mechanisms allowing affected persons to seek and obtain correction of information maintained and disseminated by the agency.

On December 16, 2004, OMB issued the Information Quality Bulletin for Peer Review under the IQA and other authority.[18] The Bulletin establishes minimum standards for when peer review is required for scientific information, including stricter minimum standards for the peer review of "highly influential" scientific assessments. The Bulletin also establishes the types of peer review that should be considered by agencies in different circumstances. The Bulletin applies to independent and other regulatory agencies. Agencies must conduct any required peer reviews early enough to allow the agency to plan its regulatory approaches. "When an information product is a critical component of rule-making, it is important to obtain peer review before the agency announces its regulatory options so that any technical corrections can be made before the agency becomes invested in a specific approach or the positions of interest groups have hardened." 70 Fed. Reg. 2668. The result of a peer review is a report, which agencies must consider making available to potential commenters in the rulemaking process. "If an agency relies on influential scientific information or a highly influential scientific assessment . . . the agency shall include in the administrative record for that action a certification that explains how the agency has complied with the requirements of this Bulletin." 70 Fed. Reg. 2673.

E-Government Act of 2002

The E-Government Act of 2002 was intended to enhance the management and promotion of electronic government services and processes.[19] With regard to the regulatory process, the Act requires agencies, to the extent practicable, to accept public comments on proposed rules by electronic means and to ensure that publicly accessible federal Web sites contain electronic dockets for their proposed rules, including all comments submitted on the rules and other relevant materials.

Executive Orders

In addition to congressional regulatory reform initiatives enacted in statutes, presidential initiatives have a key role in the regulatory process. In fact, centralized review of agencies' regulations within the Executive Office of the President has been part of the rulemaking process for more than 30 years.

[18]70 Fed. Reg. 2664 (Jan. 14, 2005).

[19]Pub. L. No. 107-347, 116 Stat. 2899 (2002), codified at 44 U.S.C. § 3501 note.

Executive Order 12372 – Intergovernmental Review of Federal Programs

This executive order generally requires federal agencies to consult with state and local elected officials on regulations involving Federal financial assistance or Federal development that would have an impact on State and local finances.[20]

Executive Order 12630 -- Governmental Actions and Interference with Constitutionally Protected Property Rights

This executive order requires agencies to limit interference with private property rights protected under the Fifth Amendment to the Constitution.[21] Agencies must include an analysis of the impact of proposed regulations on property rights in its submissions to OMB.

Executive Order 12866 – Regulatory Planning and Review

The formal process by which OIRA currently reviews agencies' proposed rules and final rules is essentially unchanged since Executive Order 12866 was issued in 1993.[22] Under Executive Order 12866, OIRA reviews significant proposed and final rules from agencies, other than independent regulatory agencies, before they are published in the *Federal Register*.

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 generally select regulatory approaches that maximize net benefits (unless a statute requires another approach). Among other principles, the executive order encourages agencies to tailor regulations to impose the least burden on society needed to achieve the regulatory objectives. The executive order also established agency and OIRA responsibilities in the review of regulations, including transparency requirements. OIRA provides guidance to federal agencies on implementing the requirements of the executive order, such as guidance on preparing economic analyses required for significant rules in OMB Circular No. A-4.

OMB Circular No. A-4

On September 17, 2003, OMB issued OMB Circular No. A-4, *Regulatory Analysis*, which is a guide for preparing the economic analysis of

[20]47 Fed. Reg. 30,959 (July 14, 1982).

[21]53 Fed. Reg. 8859 (Mar. 15, 1988).

[22]58 Fed. Reg. 51,735 (Sept. 30, 1993).

significant regulatory action called for by the Executive Order.[23] OMB designed the guidelines to help agencies conduct "good regulatory analyses" and to standardize the way that benefits and costs of regulations are measured and reported. The guidelines define a good regulatory analysis as one that includes a statement of the need for the proposed regulation, an assessment of alternatives, and an evaluation of the benefits and costs of the alternatives. The guidelines state that the motivation of the evaluation is to learn if the benefits of an action are likely to justify the costs, or discover which of the possible alternatives would be the most cost-effective. According to OIRA, this Circular contains several significant changes from previous OMB guidance, including (1) more emphasis on cost-effectiveness analysis, (2) formal probability analysis for rules with more than a billion-dollar impact on the economy and (3) more systematic evaluation of qualitative as well as quantified benefits and costs.

Executive Order 12898 – Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations

This executive order requires each agency to develop an "environmental justice strategy... that identifies and addresses disproportionately high and adverse human health or environmental effects of its programs, policies, and activities on minority populations and low-income populations."[24] Each agency must identify rules that should be revised to meet the objectives of the executive order.

Executive Order 12988 – Civil Justice Reform

This executive order requires agencies to draft regulations in a manner that will reduce needless litigation by ensuring the clarity of regulatory language regarding legal rights and obligations.[25] For example, the order requires agencies to draft regulations that provide a clear legal standard for affected conduct rather than a general standard, and promote simplification and burden reduction.

Executive Order 13045 – Protection of Children from Environmental Health Risks and Safety Risks

This executive order requires that agencies issuing "economically significant" rules that also concern an environmental health risk or safety risk that an agency has reason to believe may disproportionately affect children must submit to OIRA an evaluation of the environmental health or safety effects of the planned regulation on children.[26] Agencies must also include an explanation of why the planned regulation is preferable to other

[23]Available at http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf.

[24]59 Fed. Reg. 7629 (Feb. 11, 1994).

[25]61 Fed. Reg. 4729 (Feb. 5, 1996).

[26]62 Fed. Reg. 19,885 (Apr. 21, 1997).

potentially effective and reasonably feasible alternatives considered by the agencies.

Executive Order 13132 – Federalism

This executive order requires agencies to prepare a federalism summary impact statement for actions that have federalism implications.[27] Specifically, it provides that "no agency shall promulgate any regulation that has federalism implications, [or] that imposes substantial direct compliance costs on state and local governments," unless the agency (1) has consulted with state and local officials early in the process, (2) submitted to OMB copies of any written communications from such officials, and (3) published in the preamble of the rule "a federalism summary impact statement" describing the consultations, "a summary of the nature of [state and local] concerns and the agency's position supporting the need to issue the regulations, and a statement of the extent to which the concerns of State and local officials have been met."

Executive Order 13175 – Consultation and Coordination with Indian Tribal Governments

This executive order provides that "no agency shall promulgate any regulation that has tribal implications" unless the agency (1) has consulted with tribal officials early in the process, (2) submitted to OMB copies of any written communications from such officials, and (3) published in the preamble of the rule "a tribal summary impact statement" describing the consultations, "a summary of the nature of their concerns and the agency's position supporting the need to issue the regulation, and a statement of the extent to which the concerns of tribal officials have been met."[28] On issues relating to tribal self-government, tribal trust resources, or Indian tribal treaty and other rights, each agency should explore and, where appropriate, use consensual mechanisms for developing regulations, including negotiated rulemaking.

Executive Order 13211 – Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use

This executive order requires agencies to prepare and submit to OMB a "Statement of Energy Effects" for significant energy actions.[29] The statement must cover the regulation's "adverse effects on energy supply, distribution, or use (including a shortfall in supply, price increases, and increased use of foreign supplies)" and reasonable alternatives and their effects. The "Statement of Energy Effects" must be published (or summarized) in the related proposed and final rule.

[27]64 Fed. Reg. 43,255 (Aug. 4, 1999).

[28]65 Fed. Reg. 67,249 (Nov. 6, 2000).

[29]66 Fed. Reg. 28,355 (May 18, 2001).

Appendix II: Case Studies of 16 Selected Rules

This appendix provides case studies on 16 final rules published between January 2006 and May 2008 that we reviewed for this report. At the beginning of each case study the official rule title as published in the *Federal Register* is followed by a short title that we used to identify the rule in the body of our report. The body of each case study includes identifying information, a brief summary or synopsis of the rule, a discussion of the regulatory requirements addressed in the final rule, a summary of the changes to the rule resulting from reviews of the draft rule by the Office of Management and Budget's (OMB) Office of Information and Regulatory Affairs (OIRA) (if applicable), and a timeline of important events in the course of the rulemaking.

- Identifying Information. Identifies the responsible federal agency, and other unique identifying information, such as the Regulation Identifier Number (RIN), the citation in the *Federal Register* of the final rule, and the docket number in www.regulations.gov.
- Rule Synopsis. Provides summary information about the substance and effects of the rule, such as the intent or purpose of the rule, a brief discussion of the rule's origin, rulemaking history, or regulatory authority upon which the rule was created.
- Regulatory Requirements Addressed in the Final Rule. Identifies generally-applicable rulemaking requirements discussed by the agency in the final rule as published in the *Federal Register* and either what additional actions were taken to comply with the triggered requirement or why the requirement was not triggered. For economically significant rules that triggered the requirement under Executive Order 12866, we identified if the agency prepared a cost-benefit analysis, and if applicable, we also summarize the actions the agency took to address recent changes to regulatory requirements made by OMB since 2003.
- Changes Resulting from OIRA Review. Describes changes to rules that were recommended by OIRA during OIRA's review of the rulemaking under Executive Order 12866.
- Timeline. Identifies key dates such as the dates OIRA received and completed its reviews, the publication dates of the proposed and final rules in the *Federal Register*, the date the public comment period ended, and other dates mentioned or tracked by agency officials.

National Air Tour Safety Standards (Air Tour Safety)

Identifying Information

- Agency: Department of Transportation, Federal Aviation Administration

- Rule classification: Other Significant
- RIN: 2120-AF07
- *Federal Register* citation: 72 Fed. Reg. 6884
- Regulations.gov docket number: FAA-1998-4521
- Date of final rule: February 13, 2007

Rule Synopsis

The rule sets safety standards governing commercial air tours. The objective of the rule is to provide a higher and uniform level of safety for all commercial air tours. The rule includes provisions requiring that passengers be briefed on safety procedures, such as opening exits, exiting the aircraft, and using life preservers. It requires that passengers in helicopters and planes operating over open water wear life preservers, and that helicopters operating over open water be equipped to float. It also gives relief from drug and alcohol testing for four air tour charity events per year, and increases the required prior flight time for pilots in those events from 200 to 500 hours. Air tours frequently take place in heavy air traffic and in areas geographically limited in size with dangerous natural obstructions. Better oversight of the industry was recommended by the National Transportation Safety Board, reports of the Department of Transportation (DOT) Inspector General, and GAO.

Regulatory Requirements Addressed in the Final Rule

FAA discussed the following generally-applicable statutes and executive orders in the final rule:

- NEPA: FAA concluded that the rule qualified for a categorical exclusion from NEPA and that the rule does not involve any significant impacts to the human environment.
- PRA: The rule included new information collections for which FAA completed and submitted an Information Collection Request to OIRA for approval.
- RFA: FAA determined that the rule will have a significant economic impact on a substantial number of small entities and prepared a final regulatory flexibility analysis.
- Trade Agreements Act: FAA assessed the potential effect of the rule and determined that it would have only a domestic impact and therefore no effect on any international trade-sensitive activity.
- UMRA: FAA determined that the rule would not result in any 1-year expenditure by state, local, and tribal governments, in the aggregate, or by the private sector that would meet or exceed the relevant threshold of $128.1 million.
- Executive Order 12866 (Regulatory Planning and Review): FAA identified the rule as a significant regulatory action as defined by the executive order

because it raised novel policy issues. FAA conducted an economic analysis and submitted the rule to OIRA for review.

- Executive Order 13132 (Federalism): FAA determined that the rule did not have a substantial direct effect on the states, on the relationship between the national government and the states, or on the balance of power and responsibilities among the various levels of government. Therefore, FAA concluded that the rule did not have federalism implications.
- Executive Order 13211 (Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use): FAA determined that the rule was not a significant energy action under the executive order because it was not likely to have a significant adverse effect on the supply, distribution, or use of energy.

Changes Resulting from OIRA Review

There was a significant change to the regulatory text. The rule language was changed to clarify that four charitable or non-profit events, with no event lasting more than 3 consecutive days, was the limit, rather than four of each in one calendar year. There were also a number of other material changes to the rule. OIRA requested the addition of a chart or matrix explaining the changes made by this rule. OIRA requested the inclusion of an explanation of the policy of a four-event limit on charity and nonprofit event flights. OIRA questioned the source used for support of a requirement that pilots flying charity, nonprofit or community event flights have 500 hours total flying time. FAA added an explanation to the rule. OIRA requested clarification of differences between "Operations Specification" and a "Letter of Authorization." FAA rewrote the rule section to clarify the differences. OIRA requested FAA more fully explain the effect of the rule on operations at the Grand Canyon. FAA added three sentences to the preamble. OIRA changed the rule at both the proposed and final rule stages.

Timeline

- January 2, 2002: Preliminary team concurrence on proposed rule.
- January 2, 2002: Economic evaluation of proposed rule.
- November 2, 2002: Final team concurrence on proposed rule.
- December 9, 2002: Director's concurrence on proposed rule.
- January 8, 2003: First internal level concurrence on proposed rule.
- January 30, 2003: Second FAA internal level concurrence on proposed rule.
- February 5, 2003: Draft proposed rule transmitted to the Office of the Secretary of Transportation (OST).
- July 8, 2003: OST approved draft proposed rule.
- July 10, 2003: OIRA received draft proposed rule.
- October 7, 2003: OIRA completed review of proposed.

- October 9, 2003: Issuance of proposed rule.
- October 22, 2003: Proposed rule published in the *Federal Register*.
- October 21, 2005: Preliminary team concurrence on final rule.
- November 21, 2005: Principal's briefing on final rule.
- January 19, 2006: Economic evaluation of final rule.
- March 27, 2006: Final team concurrence on final rule.
- April 5, 2006: Director's concurrence on final rule.
- April 6, 2006: First internal level concurrence on final rule.
- April 25, 2006: Second FAA internal level concurrence on final rule.
- April 27, 2006: Transmittal to the OST of final rule.
- August 16, 2006: OST approval of draft final rule.
- August 16, 2006: Transmittal to OIRA of final rule.
- September 21, 2006: Meeting between OIRA and nonfederal parties regarding the rule.
- November 7, 2006: OIRA approval of final rule.
- December 22, 2006: Issuance of final rule.
- February 13, 2007: Final rule published in the *Federal Register*.

Human Space Flight Requirements for Crew and Space Flight Participants (Human Space Flight Requirements)

Identifying Information

- Agency: Department of Transportation, Federal Aviation Administration
- Rule classification: Other Significant
- RIN: 2120-AI57
- *Federal Register* citation: 71 Fed. Reg. 75,616
- Regulations.gov docket number: FAA-2005-23449
- Date of final rule: December 15, 2006

Rule Synopsis

The rule establishes requirements for human space flight, with the intent of providing an acceptable level of safety to the general public and ensuring individuals on board are aware of the risks associated with launch and reentry. The rule sets training and medical standards for the crew, and requires the operator to inform each space flight participant in writing of the risks of launch and reentry. Security requirements in the rule prevent participants from carrying certain items on board, and safety

requirements in the rule require participants be trained before flight on how to respond to an emergency situation.

Regulatory Requirements Addressed in the Final Rule

FAA discussed the following generally-applicable statutes and executive orders in the final rule:

- NEPA: FAA concluded that the rule qualified for a categorical exclusion from the requirement for preparation of an environmental assessment or environmental impact statement.
- PRA: The rule included new information collections for which FAA completed and submitted an Information Collection Request to OIRA for approval.
- RFA: The FAA Administrator certified that the rule will not have a significant economic impact on a substantial number of small entities.
- Trade Agreements Act: FAA assessed the potential effect of the rule and determined that it will impose the same costs on domestic and international entities and thus has a neutral trade impact.
- UMRA: FAA determined that the rule would not result in any 1-year expenditure by state, local and tribal governments, in the aggregate, or by the private sector that would meet or exceed the relevant threshold of $120.7 million.
- Executive Order 12866 (Regulatory Planning and Review): FAA identified the rule as a significant regulatory action as defined by the executive order because it raised novel policy issues. FAA conducted an economic analysis and submitted the rule to OIRA for review.
- Executive Order 13132 (Federalism): FAA determined that the rule did not have a substantial direct effect on the states, on the relationship between the national government and the states, or the balance of power and responsibilities among the various levels of government. Therefore, FAA concluded that the rule did not have federalism implications.
- Executive Order 13211 (Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use): FAA determined that the rule was not a significant energy action under the executive order because it was not likely to have a significant adverse effect on the supply, distribution, or use of energy.

Changes Resulting from OIRA Review

There were no substantive changes to this rule resulting from OIRA review.

Timeline

- March 22, 2005: Preliminary team concurrence on proposed rule.
- April 25, 2005: Economic evaluation of proposed rule.

- April 29, 2005: Principal's briefing on proposed rule.
- May 31, 2005: Final team concurrence on proposed rule.
- June 17, 2005: Director's concurrence on proposed rule.
- July 12, 2005: Legal concurrence on proposed rule.
- July 24, 2005: Office of the FAA Administrator concurrence on proposed rule.
- July 28, 2005: Proposed rule transmitted to OST.
- September 23, 2005: OST approval of proposed rule.
- September 28, 2005: OIRA received draft proposed rule.
- December 22, 2005: OIRA completed review of draft proposed rule without change.
- December 22, 2005: Issuance of proposed rule.
- December 29, 2005: Proposed rule published in the *Federal Register*.
- March 24, 2006: Preliminary team concurrence on final rule.
- April 6, 2006: Economic evaluation of final rule.
- April 27, 2006: Final team concurrence on final rule.
- May 5, 2006: Director's concurrence on final rule.
- May 26, 2006: Final rule transmitted to OST.
- August 29, 2006: OST approval of final rule.
- August 29 2006: OIRA received draft final rule.
- November 9, 2006: OIRA completed review of draft final rule without change.
- December 1, 2006: Issuance of final rule.
- December 15, 2006: Final rule published in the *Federal Register*.

Light Trucks, Average Fuel Economy; Model Years 2008-2011 (Fuel Economy-Light Trucks)

Identifying Information

- Agency: Department of Transportation, National Highway Traffic Safety Administration
- Rule classification: Major, Economically Significant
- RIN: 2127-AJ61
- *Federal Register* citation: 71 Fed. Reg. 17,566
- Regulations.gov docket number: NHTSA-2005-22223 (proposed rule); NHTSA-2006-24309 (final rule)
- Date of final rule: April 6, 2006

Rule Synopsis

The rule reforms the structure of the corporate average fuel economy (CAFE) program for light trucks and establishes higher CAFE standards for model years 2008 through 2011. While this rule was proposed in 2005 and finalized in 2006, it was preceded by a series of rules establishing fuel economy standards for light trucks (i.e., non-passenger automobiles) that date back to the 1970s. The rule was mandated by the Energy Policy Conservation Act of 1975.

Regulatory Requirements Addressed in the Final Rule

NHTSA discussed the following generally-applicable statutes and executive orders in the final rule:

- NEPA: NHTSA prepared an environmental assessment for the rule and concluded that the rule will not have a significant effect on the quality of the human environment.
- NTTAA: NHTSA consulted with voluntary consensus standards bodies and incorporated industry standards and definitions, such as an industry standard on light truck footprint.
- PRA: The rule included new information collections for which NHTSA completed and submitted an Information Collection Request to OIRA for approval.
- RFA: NHTSA's Deputy Administrator certified that the rule did not have a significant economic impact on a substantial number of small entities.
- UMRA: NHTSA determined that the rule would not result in any 1-year expenditure by state, local and tribal governments, in the aggregate, of more than $115 million, but would result in the expenditure of that magnitude by the private sector. NHTSA concluded that it was required by statute to set standards at the maximum feasible level achievable by manufacturers, and thus could not consider regulatory alternatives.
- Executive Order 12866 (Regulatory Planning and Review): NHTSA identified the rule as a significant regulatory action as defined by the executive order because of its economic significance. Therefore, NHTSA conducted an economic analysis and submitted the rule to OIRA for review.
- Executive Order 12988 (Civil Justice Reform): NHTSA determined that the rule does not have any retroactive effect.
- Executive Order 13045 (Protection of Children from Environmental Health Risks and Safety Risks): NHTSA determined that the rule does not have a disproportionate effect on children.
- Executive Order 13132 (Federalism): NHTSA stated that the statutory authorization for the rule has a broad preemption provision, and therefore, the agency was required to establish these standards by law.

- Executive Order 13211 (Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use): NHTSA determined that the rule would not have any adverse energy effects.
- OMB Peer Review Bulletin: NHTSA convened a panel of three external experts to review the model used in the rule. The peer review reports and the agency's response to reviews were included in the rulemaking docket.

Recent Analytic Requirements Addressed

NHTSA's regulatory impact analysis addressed two of the four analytical changes in the OMB economic guidelines that GAO reviewed for this study. For example, the agency assessed uncertainty using a formal probability analysis and discounted potential future benefits and costs using discount rates of 7 percent and 3 percent, as directed by the OMB guidelines. Agency officials said that conducting the probability analysis was time-consuming, requiring one full-time analyst about 6 weeks to complete. In addition, the officials said, the probability analysis was conducted after the agency had selected the preferred regulatory alternative, and as a result, the analysis was not used for decision-making purposes. The agency did not evaluate qualitative and quantitative benefits and costs because it monetized all the key impacts and the agency's analysis did not emphasize cost-effectiveness.

Changes Resulting from OIRA Review

NHTSA did not consider substantive any of the changes made to either the draft proposed or draft final rules during the formal review period, and thus did not docket a record of changes made during the OIRA review period.

Timeline

- 1974: DOT/EPA reported to Congress on motor vehicle fuel economy standards.
- 1975: Energy Policy Conservation Act of 1975 enacted.
- December 29, 2003: NHTSA issued an Advanced Notice of Proposed Rulemaking under a different RIN (2127-AJ17) soliciting comments on the structure of the CAFE program and an intent to reform the light truck CAFE program.
- July 26, 2005: OIRA received the draft proposed rule.
- August 22, 2005: OIRA completed review of the draft proposed rule with change.
- August 30, 2005: Proposed rule published in the *Federal Register*.
- March 14, 2006: OIRA staff met with outside parties to discuss this rule.
- March 23, 2006: OIRA received the draft final rule.
- March 28, 2006: OIRA completed review of the draft final rule consistent with change.

- April 6, 2006: Final rule published in the *Federal Register*.

Event Data Recorders

Identifying Information

- Agency: Department of Transportation, National Highway Traffic Safety Administration
- Rule classification: Other Significant
- RIN: 2127-AI72
- *Federal Register* citation: 71 Fed. Reg. 50,998
- Regulations.gov docket number: NHTSA-2004-18029 (proposed rule); NHTSA-2006-25666 (final rule)
- Date of final rule: August 28, 2006

Rule Synopsis

The rule establishes standards for the auto industry practice of installing event data recorders (EDR) in passenger cars and other light vehicles. The intent of the rule is to standardize data obtained through EDRs so that data may be most effective and ensure that EDR infrastructure develops to provide a foundation for automatic crash notification. The rule requires a minimum set of specified data elements, standardizes data format, helps ensure crash survivability of an EDR and its data, and ensures commercial availability of tools necessary to enable crash investigators to retrieve data from the EDR. The rule also requires vehicle manufacturers to describe the function and capability of an EDR in the owner's manual of any vehicle equipped with an EDR to ensure public awareness. NHTSA promulgated the rule following years of study by NHTSA and the National Transportation Safety Board, and after having received three citizen petitions.

Regulatory Requirements Addressed in the Final Rule

NHTSA discussed the following generally-applicable statutes and executive orders in the final rule:

- NEPA: NHTSA determined that the rule will not have any significant impact on the quality of the human environment.
- NTTAA: NHTSA adopted voluntary consensus standards where practicable.
- PRA: The rule did not contain any new information collection requests.
- RFA: NHTSA's Administrator certified that the rule would not have a significant economic impact on a substantial number of small entities.

- UMRA: NHTSA determined that the rule would not result in the expenditure by state, local, or tribal governments, in the aggregate, or by the private sector, of more than the annual threshold of $118 million.
- Executive Order 12866 (Regulatory Planning and Review): NHTSA identified the rule as a significant regulatory action as defined by the executive order. NHTSA conducted an economic analysis and submitted the rule to OIRA for review.
- Executive Order 12988 (Civil Justice Reform): NHTSA stated that the rule specified its preemptive effect in clear language.
- Executive Order 13045 (Protection of Children from Environmental Health Risks and Safety Risks): NHTSA concluded that because the rule is not economically significant and does not involve health and safety risks that disproportionately affect children, no further analysis was necessary under this executive order.
- Executive Order 13132 (Federalism): NHTSA concluded that general principles of preemption law would operate so as to displace any conflicting state law or regulation.

Changes Resulting from OIRA Review

As documented by the agency in memorandums included in the public docket, OIRA suggested changes to both the proposed and final rule that NHTSA officials incorporated into the published versions of the rules. NHTSA incorporated OIRA suggested language to the proposed rule preamble related to ensuring that crash investigators and researchers are able to obtain the capability of downloading data from the EDR. Similarly, NHTSA changed, at OIRA's suggestion, the owner's manual statement in the text of the proposed rule to include a sentence advising owners that an EDR does not store or collect personal information. NHTSA incorporated additional OIRA suggestions to the final rule, adding to or clarifying the policy discussion in the preamble, including adding clarifying language to the federalism discussion. NHTSA incorporated OIRA changes to the owner's manual statement in the final rule text, explaining that parties with special equipment, including law enforcement officials, can access information in an EDR if they have access to the vehicle, and that they may group EDR data with personal information regularly collected in the course of a criminal investigation.

Timeline

- 1991: NHTSA began to examine EDRs as part of the Special Crash Investigations Program.
- November 9, 1998: NHTSA denied petition for rulemaking on EDRs.
- June 2, 1999: NHTSA denied second petition for rulemaking on EDRs.
- 2001: NHTSA received a third petition for rulemaking on EDRs.

- October 11, 2002: NHTSA published request for comment on the future role of EDRs in motor vehicles.
- March 9, 2004: OIRA received the draft proposed rule.
- June 3, 2004: OIRA completed review of draft proposed rule consistent with change.
- December 2003: Preliminary regulatory evaluation completed.
- June 14, 2004: Proposed rule published in the *Federal Register*.
- April 11, 2006: OIRA received draft final rule.
- July 2006: Final regulatory evaluation completed.
- August 17, 2006: OIRA completed review of draft final rule consistent with change.
- August 28, 2006: Final rule published in the *Federal Register*.

Ethylene Oxide Emissions Standards for Sterilization Facilities (Ethylene Oxide Emissions)

Identifying Information

- Agency: Environmental Protection Agency, Office of Air and Radiation
- Rule classification: Other Significant
- RIN: 2060-AK09
- *Federal Register* citation: 71 Fed. Reg. 17,712
- Regulations.gov docket number: EPA-HQ-OAR-2003-0197
- Date of final rule: April 7, 2006

Rule Synopsis

The rule resulted from the periodic evaluation of the emission standards for ethylene oxide emissions from sterilization facilities. In the proposed rule, EPA decided not to impose more stringent emission standards, determining that additional controls at existing sources would achieve, at best, minimal emission reduction at a very high cost. The Clean Air Act requires EPA to assess the risk posed by ethylene oxide emissions and set more stringent standards as it deems necessary within 8 years of initially setting standards, taking into account developments in practices, processes, and control technologies.

Regulatory Requirements Addressed in the Final Rule

EPA discussed the following generally-applicable statutes and executive orders in the final rule:

- CRA: EPA filed the rule with the Congress and the Comptroller General.
- NTTAA: The rule does not involve any technical standards.
- PRA: The rule does not impose any new information collection requests.
- RFA: EPA determined that the rule would not have a significant economic impact on a substantial number of small entities.
- UMRA: EPA determined that the rule would not result in expenditures of $100 million or more to state, local, and tribal governments, in the aggregate, or to the private sector in any one year.
- Executive Order 12866 (Regulatory Planning and Review): OMB deemed the rule a significant regulatory action as defined by the executive order. Therefore, EPA submitted the rule to OMB for review.
- Executive Order 13045 (Protection of Children from Environmental Health Risks and Safety Risks): EPA "did not have reason to believe" that the environmental health or safety risks addressed by this rule presented a disproportionate risk to children.
- Executive Order 13132 (Federalism): EPA determined that the final rule did not have a substantial direct effects on the states, on the national government and the states, or on the distribution of power and responsibilities among the various levels of government. EPA concluded that the rule did not have federalism implications.
- Executive Order 13175 (Consultation and Coordination with Indian Tribal Governments): EPA determined that the rule would not have substantial direct effects on tribal governments, on the relationship between the federal government and Indian tribes, or on the distribution of power and responsibilities between the federal government and Indian tribes.
- Executive Order 13211 (Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use): EPA determined that the rule would not likely have a significant adverse effect on the supply, distribution, or use of energy.

Changes Resulting from OIRA Review

An OIRA-initiated change included generally available control technologies or management practices (GACT) in addition to maximum achievable control technologies or management practices (MACT) for area sources of ethylene oxide. Both are standards EPA can use for controlling emissions of ethylene oxide for area sources. Major sources are required to use MACT to control emissions. In the proposed rule OIRA specified that the CAA provides that "EPA is not required to conduct any review under section 112(f) of the CAA or promulgate any emissions limitations under that subsection for any source listed pursuant to section 112(c)(3), for which EPA has issued GACT standards. Thus, although EPA has

discretion to conduct a residual risk review under section 112(f) for area sources for which it has established GACT, it is not required to do so." OIRA specified that EPA's residual risk review is required for each CAA section 112(d) source category, except area source categories for which EPA issued a GACT standard.

While addressing Executive Order 13045, "Protection of Children from Environmental Health and Safety Risks," EPA stated that "The public is invited to submit or identify peer reviewed studies and data, of which the agency may not be aware, that assessed the results of early life exposure to ethylene oxide commercial sterilization facility emissions." During OIRA review this sentence was deleted.

EPA had written that if cancer risks to individuals exposed to emissions from a regulated source are found above a threshold specified in the CAA, "we must promulgate residual risk standards for the source category (or subcategory) which provide an ample margin of safety." OIRA rewrote the sentence to read "we must decide whether additional reductions are necessary to provide an ample margin of safety." Similarly, EPA wrote that in the same circumstance, "we must also adopt more stringent standards to prevent an adverse environmental effect." The quotation changed during OIRA review to read "we must determine whether more stringent standards are necessary to prevent an adverse environmental effect."

Timeline

- December 6, 1994: Original emission standards rule published.
- 1997: EPA began developing the methodology for conducting a residual risk assessment.
- Late 1990s: EPA convened groups to consider changing the technologies used for ethylene emission control.
- February 13, 2002: EPA assigned a Start Action Number.
- August 3, 2005: OIRA received the draft proposed rule.
- September 27, 2005: OIRA completed review of the draft proposed rule.
- October 24, 2005: The proposed rule is published in the *Federal Register*.
- March 22, 2006: OIRA met with nonfederal parties regarding the rule.
- March 23, 2006: OIRA received the draft final rule.
- March 31, 2006: OIRA completed review of the draft final rule.
- April 7, 2006: The final rule was published in the *Federal Register*.

National Emission Standards for Organic Hazardous Air Pollutants from the Synthetic Organic Chemical Manufacturing Industry (Hazardous Air Pollutants)

Identifying Information

- Agency: Environmental Protection Agency, Office of Air and Radiation
- Rule classification: Other Significant
- RIN: 2060-AK14
- *Federal Register* citation: 71 Fed. Reg. 76,603
- Regulations.gov docket number: EPA-HQ-OAR-2005-0475
- Date of final rule: December 21, 2006

Rule Synopsis

The rule established that the original National Emission Standards for Organic Hazardous Air Pollutants for the synthetic organic chemical manufacturing industry set in 1994 would mostly remain unchanged. Although the rule does not impose further controls on the synthetic organic chemical manufacturing industry, it does amend certain aspects of the existing regulations. The CAA directs EPA to evaluate the remaining risk presented by major sources of emissions of hazardous air pollutants 8 years after promulgation of technology-based standards to determine if the standards provide an ample margin of safety to protect public health. The Act also directs EPA to review all standards regulating hazardous air pollutants every 8 years and revise them as necessary, taking into account developments in practices, processes, and control technologies.

Regulatory Requirements Addressed in the Final Rule

EPA discussed the following generally-applicable statutes and executive orders in the final rule:

- CRA: EPA filed the final rule with Congress and the Comptroller General.
- NTTAA: The rule does not involve any voluntary consensus standards.
- PRA: The rule does not impose any new information collection requests.

- RFA: EPA determined that the rule would not have a significant economic impact on a substantial number of small entities.
- UMRA: EPA determined that the rule does not contain a federal mandate that may result in expenditures of $100 million or more on state, local, and tribal governments, in the aggregate, or the private sector in any one year.
- Executive Order 12866 (Regulatory Planning and Review): OMB deemed the rule a significant regulatory action as defined by the executive order because it raised novel legal and policy issues. Therefore, EPA submitted the rule to OMB for review.
- Executive Order 12898 (Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations): One of EPA's environmental justice priorities is to reduce exposure to air toxics. In the proposed rule, EPA requested comment on the implications of this priority since some regulated facilities are located near minority and low-income populations. EPA received one comment regarding this environmental justice concern that it addressed in the final rule.
- Executive Order 13045 (Protection of Children from Environmental Health and Safety Risks): EPA "did not have reason to believe" that the environmental health or safety risks addressed by the rule presented a disproportionate risk to children.
- Executive Order 13132 (Federalism): EPA determined that the rule did not have a substantial direct effect on the states, on the relationship between the national government and the states, or on the balance of power and responsibilities among the various levels of government. Therefore, EPA concluded that the rule did not have federalism implications.
- Executive Order 13175 (Consultation and Coordination with Indian Tribal Governments): EPA determined that the rule does not have tribal implications.
- Executive Order 13211 (Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use): EPA determined that the rule would not likely have a significant adverse effect on the supply, distribution, or use of energy.

Changes Resulting from OIRA Review

OIRA made several substantive changes to the explanatory text of the preamble. OIRA cut a section specifying periodic determinations of pertinent technical factors. It deleted a statement that assumptions made in the study design did not fully capture the relatively higher exposure seen by children. It requested additional and more balanced discussion of the rationale for selecting "no control," and requested that EPA specify a sample size and expand its discussion on risks reduced by emission controls. It deleted a section describing some costs of the regulation and ways for EPA to avoid those costs. OIRA review resulted in EPA deleting a

sentence asserting that it was required by the CAA under a particular set of circumstances to promulgate residual risk standards.

Timeline

- February 14, 2002: EPA assigned a Start Action Number.
- March 16, 2006: OIRA received draft proposed rule.
- March 22, 2006: OIRA met with nonfederal parties regarding the rule.
- May 31, 2006: OIRA completed review of proposed rule.
- June 14, 2006: Proposed rule published in the *Federal Register*.
- December 11, 2006: OIRA received draft final rule.
- December 14, 2006: OIRA completed review of draft final rule.
- December 21, 2006: Final rule was published in the *Federal Register*.

National Primary Drinking Water Regulations: Stage 2 Disinfectants and Disinfection Byproducts Rule (Disinfection Byproducts 2)

Identifying Information

- Agency: Environmental Protection Agency, Office of Water
- Rule classification: Major, Significant
- RIN: 2040-AD38
- *Federal Register* citation: 71 Fed. Reg. 388
- Regulations.gov docket number: EPA-HQ-OW-2002-0043
- Date of final rule: January 4, 2006

Rule Synopsis

The rule is intended to help public water systems deliver safe water with the benefits of disinfection but with fewer risks from disinfection byproducts. Certain disinfectants used to treat drinking water are known to create byproducts posing potential reproductive, developmental, and cancer risks to humans. Authorized by the Safe Drinking Water Act Amendments of 1996 (SDWA), the rule is one of a series of rules, including the Surface Water Treatment 2 rule, intended to improve the quality of drinking water provided by public water systems throughout the United States. EPA's first rulemaking on disinfection byproducts was

promulgated in 1979. Because of the complex and far-reaching implications of the rule, as well as the relationship between the Disinfection Byproducts 2 rule and the Surface Water Treatment 2 rule, EPA convened a FACA panel to help develop the policies in the rule.

Regulatory Requirements Addressed in the Final Rule

EPA discussed the following generally-applicable statutes and executive orders in the final rule:

- NTTAA: EPA adopted voluntary consensus standards for monitoring the levels of disinfection byproducts.
- PRA: The rule contained new information collection requirements for which EPA completed and submitted an Information Collection Request to OIRA for approval.
- RFA: EPA certified that the rule would not have a significant economic impact on a substantial number of small entities. EPA conducted a SBREFA advocacy review panel.
- UMRA: EPA determined that the rule may contain a mandate resulting in annual expenditures of more than $100 million for state, local, and tribal governments, or the private sector. EPA prepared an UMRA analysis, which included a consideration of the regulatory alternatives.
- Executive Order 12866 (Regulatory Planning and Review): EPA identified the rule as a significant regulatory action as defined by the executive order. Therefore, EPA conducted an economic analysis and submitted the rule to OIRA for review.
- Executive Order 12898 (Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations): EPA consulted with minority and low-income stakeholders. EPA determined that since the rule applies uniformly to all communities, the health protections provided are equal across all minority and income groups served by systems regulated by the rule.
- Executive Order 13045 (Protection of Children from Environmental Health Risks and Safety Risks): EPA concluded that "it has reason to believe that the environmental health or safety risk . . . addressed by this [rule] may have a disproportionate effect on children. EPA believes that the [rule] will result in greater risk reduction for children than for the general population."
- Executive Order 13132 (Federalism): EPA determined that the rule did not have federalism implications because it will not have substantial direct effects on the states, on the relationship between the states and federal government, or the distribution of power and responsibilities among various levels of government.
- Executive Order 13175 (Consultation and Coordination with Indian Tribal Governments): EPA concluded that the final rule may have tribal

implications because it may impose substantial direct compliance costs on tribal governments and the federal government will not provide the funds necessary to pay those costs. A detailed estimate of the tribal impact was included in the rule.

- Executive Order 13211 (Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use): EPA determined that the rule is not likely to have a significant adverse effect on the supply, distribution, or use of energy.

Recent Analytic Requirements Addressed

EPA's regulatory impact analysis addressed the four analytical changes in the OMB economic guidelines that we reviewed for this study. For example, the agency analyzed cost-effectiveness, discounted potential benefits and costs using discount rates of 7 percent and 3 percent, evaluated potential qualitative and quantitative benefits and costs, and conducted a probability analysis to assess the uncertainty associated with some potential impacts. Agency officials said that they assessed the cost-effectiveness of the regulatory alternatives in the rule because the OMB guidelines require it but that the three other analyses were conducted because the agency had already adopted them as best practices. The officials estimated that the cost-effectiveness analysis required from 1 to 2 months to complete, partly because the agency had not yet developed guidance for analyzing the cost-effectiveness of health-related rules. In addition, agency officials said that the cost-effectiveness analysis was only of limited use for selecting a final regulatory alternative.

Changes Resulting from OIRA Review

The copy of the draft final rule in the docket shows changes throughout to both the preamble and the rule text itself. Some appear to be strictly editorial, and others appear to have substantive effect. One significant change to the rule text itself is in the section on compliance monitoring requirements. The requirement to repeat monitoring is changed to apply only when more than eight monitoring locations are required, rather than four required monitoring locations. Additional requirements for repeat monitoring have been removed. Changes to the preamble include the addition of a description of variances and exemptions in place of a statement that the rule would be updated "upon completion of affordability discussions with OMB." EPA's Executive Order 12866 compliance form for the rule, docketed with the OMB review of the draft of the final rule, describes the OMB changes as not substantive.

Timeline

- November 29, 1979: The Total Trihalomethanes Rule, the first regulation of disinfection byproducts, was published.

- Fall 1992: EPA convened an advisory committee to address the issue of disinfection and disinfectant byproducts and pathogen control issues; this led to the first Disinfection Byproducts rule.
- Spring 1993: A Cryptosporidium outbreak in Milwaukee, Wisconsin, sickened over 400,000 people, roughly 50 percent of users of the municipal drinking water system.
- 1996: The SDWA required EPA to establish new standards for treatment of drinking water and the byproducts of the water treatment process.
- 1997: EPA convened a federal advisory committee to finalize SDWA rulemakings, including the Disinfection Byproducts 2 rule and Interim Enhanced Surface Water Treatment rule.
- December 16, 1998: The first Disinfection Byproducts rule was published in the *Federal Register*.
- March 1999 to July 2000: EPA reconvened the federal advisory committee to provide technical input on additional SDWA rulemakings, including the Disinfection Byproducts 2 rule and the Surface Water Treatment 2 rule.
- August 6, 1999: EPA assigned a Start Action Number for the rulemaking.
- Late 1999: EPA initiated the pre-panel stages of a SBREFA advocacy review panel.
- June 23, 2000: Advocacy review panel completed.
- September 2000: Federal advisory committee members signed Agreement in Principle stating consensus of the group.
- December 29, 2000: Federal advisory committee Agreement in Principle was published in the *Federal Register*.
- January 16, 2001: Revisions to the first Disinfection Byproducts rulemaking were published in the *Federal Register*.
- October 17, 2001: EPA published pre-proposal draft of Disinfection Byproducts 2 rule preamble and regulatory language on the agency Web site for public comment on whether the draft was consistent with federal advisory committee recommendations.
- July 2003: The agency completed the regulatory impact analysis for proposed rule.
- August 18, 2003: The proposed rule was published in the *Federal Register*.
- February 2005: EPA received notice of intent to sue.
- April 14, 2005: OMB staff met with outside parties to discuss several rules by the EPA Office of Water, including this rule.
- August 26, 2005: OMB received the draft final rule.
- November 2005: EPA entered into settlement agreement to complete the rule by December 2005.
- November 23, 2005: OMB completed review of draft final rule with change.
- December 2005: EPA completed the regulatory impact analysis for final rule.
- December 15, 2005: EPA Administrator signed the final rule.
- January 4, 2006: The final rule was published in the *Federal Register*.

National Primary Drinking Water Regulations: Long Term 2 Enhanced Surface Water Treatment Rule (Surface Water Treatment 2)

Identifying Information

- Agency: Environmental Protection Agency, Office of Water
- Rule classification: Major, Economically Significant
- RIN: 2040-AD37
- *Federal Register* citation: 71 Fed. Reg. 654
- Regulations.gov docket number: EPA-HQ-OW-2002-0039
- Date of final rule: January 5, 2006

Rule Synopsis

The rule is intended to protect public health against Cryptosporidium and other microbial pathogens in drinking water. Cryptosporidium is highly resistant to chemical disinfectants and can cause acute illness and death for people with weakened immune systems. Authorized by SDWA, the rule was one of a series of rules, including the Disinfection Byproducts 2 rule, intended to improve the quality of drinking water supplied by public water systems throughout the United States. Because of the complex and far-reaching implications of the rule, as well as the relationship between the Disinfection Byproducts 2 rule and the rule, EPA convened a FACA panel to help develop the policies in the rule.

Regulatory Requirements Addressed in the Final Rule

EPA discussed the following generally-applicable statutes and executive orders in the final rule:

- NTTAA: EPA adopted voluntary standards for monitoring the levels of one pathogen.
- PRA: The rule contained new information collection requirements for which EPA completed and submitted an Information Collection Request to OIRA for approval.
- RFA: EPA certified that the rule would not have a significant economic impact on a substantial number of small entities. EPA conducted a SBREFA advocacy review panel.

- UMRA: EPA determined that the rule may contain a mandate resulting in annual expenditures of more than $100 million for state, local, and tribal governments, in the aggregate, or the private sector. EPA prepared an UMRA analysis, which included a consideration of the regulatory alternatives.
- Executive Order 12866 (Regulatory Planning and Review): EPA identified the rule as a significant regulatory action as defined in the executive order because of its economic significance. Therefore, EPA conducted an economic analysis and submitted the rule to OIRA for review.
- Executive Order 12898 (Federal Actions to Address Environmental Justice in Minority Populations or Low-Income Populations): EPA determined that since the rule applies uniformly to all communities, the health protections provided are equal across all minority and income groups served by systems regulated by the rule.
- Executive Order 13045 (Protection of Children from Environmental Health Risks and Safety Risks): EPA determined that the rule was economically significant and that the environmental risks addressed by the rule may have a disproportionate effect on children.
- Executive Order 13132 (Federalism): EPA concluded that the rule may have federalism implications because it may impose substantial direct costs on state or local governments, and the federal government will not provide the funds to pay those costs.
- Executive Order 13175 (Consultation and Coordination with Indian Tribal Governments): EPA concluded that the rule may have tribal implications because it may impose substantial direct compliance costs on tribal governments, and the federal government will not provide the funds necessary to pay those costs.
- Executive Order 13211 (Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use): EPA determined that the rule is not likely to have a significant adverse effect on the supply, distribution, or use of energy.

Recent Analytical Requirement Addressed

EPA's regulatory impact analysis addressed the four analytical changes in the OMB economic guidelines that we reviewed for this study. The agency analyzed cost-effectiveness, discounted potential benefits and costs using discount rates of 7 percent and 3 percent, evaluated potential qualitative and quantitative benefits and costs, and conducted a probability analysis to assess the uncertainty associated with some potential impacts. Agency officials said that they assessed the cost-effectiveness of the regulatory alternatives in the rule because the OMB guidelines require it but that the three other analyses were conducted because the agency had already adopted them as best practices. The officials estimated that the cost-effectiveness analysis required from 1 to 2 months to complete, partly

because the agency had not yet developed guidance for analyzing the cost-effectiveness of health-related rules. In addition, agency officials said that the cost-effectiveness analysis was only of limited use for selecting a final regulatory alternative.

Changes Resulting from OIRA Review

According to OMB's public database, OMB received the draft final rule on March 31, 2005, and review was complete on June 22, 2005. The rule was subsequently published "consistent with change." EPA's Executive Order 12866 compliance form for the rule, docketed with the OMB review of the draft of the final rule, describes the OMB changes as not substantive. The reviewed copy of the draft final rule shows changes throughout the draft rule to both the preamble and the rule text itself. Some appear to be strictly editorial, and others appear to have substantive effect. Two significant changes to the rule text itself are addition of notification of violation requirements for public water systems in section 141.211 of the rule and changes to section 141.703 that provide additional circumstances under which data can be grandfathered under state approval. Changes to the preamble include indication that regulated systems may assume state approval of monitoring locations if explicit state approval is not forthcoming.

Timeline

- Fall 1992: EPA convened an advisory committee to address the issue of disinfection and disinfectant byproducts and pathogen control issues; this led to the first Disinfection Byproducts rule.
- Spring 1993: A Cryptosporidium outbreak in Milwaukee, Wisconsin, sickened 400,000 people, roughly 50 percent of users of the municipal drinking water system.
- August 9, 1999: EPA assigned Start Action Number for the rulemaking.
- 1996: The SDWA authorized EPA to establish new treatment standards for drinking water and byproducts of the water treatment process.
- 1997: EPA convened an issue-specific federal advisory committee to develop SDWA rulemakings, including Stage 1 DBP Rule and Interim Surface Water Treatment Rule.
- December 16, 1998: Interim Enhanced Surface Water Treatment Rule was published in the *Federal Register*.
- March 1999 to September 2000: EPA reconvened the federal advisory committee to provide technical input on additional SDWA rulemakings, including the Long Term 2 Rule.
- Late 1999: EPA initiated the pre-panel stages of a SBREFA advocacy review panel.
- June 23, 2000: Advocacy review panel completed.

- September 2000: Federal advisory committee members signed Agreement in Principle stating consensus of the group.
- December 29, 2000: Federal advisory committee Agreement in Principle was published in the *Federal Register*.
- January 16, 2001: Revisions to Interim Enhanced Surface Water Treatment rulemaking were published in the *Federal Register*.
- October 17, 2001: EPA published pre-proposal draft of Long Term 2 Rule preamble and regulatory language on the agency Web site for public comment.
- January 14, 2002: The Long Term 1 Rule was published in the *Federal Register*.
- December 18, 2002: OIRA received the draft proposed rule.
- March 18, 2003: OIRA completed review of the draft proposed rule with change.
- June 2003: The agency completed the regulatory impact analysis for proposed rule.
- August 11, 2003: The proposed rule was published in the *Federal Register*.
- February 2005: EPA received notice of intent to sue.
- March 31, 2005: OMB received the draft final rule.
- April 14, 2005: OMB staff met with outside parties to discuss several rules by the EPA Office of Water, including this rule.
- June 22, 2005: OMB completed review of draft final rule with change.
- November 2005: EPA entered into settlement agreement to complete the rule by December 2005.
- December 2005: The agency completed the regulatory impact analysis for final rule.
- December 15, 2005: Final rule was signed.
- January 5, 2006: The final rule published in the *Federal Register*.

Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products (Physician Labeling)

Identifying Information

- Agency: Food and Drug Administration, Center for Drug Evaluation and Research
- Rule classification: Other Significant

- RIN: 0910-AA94
- *Federal Register* citation: 71 Fed. Reg. 3922
- Regulations.gov docket number: FDA-2000-N-0044
- Date of final rule: January 24, 2006

Rule Synopsis

The rule revises the requirements for the format and content of labeling for human prescription drugs and biological products, the information physicians use to learn about and prescribe these products. The rule governs physician drug labeling which takes the form of package inserts. Package inserts are used as the basis for a large uniform prescription drug manual called The Physician's Desk Reference. FDA stated that the intent of the rule is to enhance the safe and effective use of prescription drug products and to reduce the number of adverse reactions resulting from medication errors caused by misunderstood or incorrectly applied drug information. Specifically, revisions require the labeling of new and recently approved products to include highlights of prescribing information and a table of contents, exclude less important and include more important content, meet new minimum graphical requirements, be accompanied by all applicable patient labeling approved by FDA, and clarify certain prescribing requirements.

Regulatory Requirements Addressed in the Final Rule

FDA discussed the following generally-applicable statutes and executive orders in the final rule:

- NEPA: FDA determined that the rule does not have a significant effect on the human environment.
- PRA: The rule included new information collections for which FDA completed and submitted an Information Collection Request to OIRA for approval.
- RFA: FDA believes that the final rule would not have a significant impact on most small entities in this industry, but it is possible that a few small firms may be significantly affected by the final rule. FDA included a final regulatory flexibility analysis in the final rule.
- UMRA: FDA determined that the rule would not result in any 1-year expenditure by state, local and tribal governments, in the aggregate, or by the private sector that would meet or exceed the relevant threshold of $115 million.
- Executive Order 12866 (Regulatory Planning and Review): FDA identified the rule as a significant regulatory action as defined by the executive order. FDA conducted an economic analysis and submitted the rule to OIRA for review.

- Executive Order 12988 (Civil Justice Reform): FDA determined that the rule does not have any retroactive effect.
- Executive Order 13132 (Federalism): FDA stated that certain state-level product liability claims would conflict with federal law or frustrate the purpose of federal regulation. FDA described six categories of product liability claims that the agency believed would be preempted by FDA's regulation of prescription drug labeling.

Changes Resulting from OIRA Review

FDA deleted at OIRA's suggestion an estimate of the number of people who would submit applications for new drugs and a table detailing the estimated reporting burden for those subject to FDA's information collection request. FDA at OIRA's suggestion also increased the number of affected pharmaceutical firms that could be considered small. We found in FDA's docket, documentation of OIRA's review for the final rule but not for the proposed rule. We assume none was required for the proposed rule as, according to OIRA's www.reginfo.gov, it was not changed by OIRA review.

Timeline

- Before 1992: CDER received feedback from physicians in the field that prescription drug labeling required revision.
- 1992: CDER convened the first focus group on the issue.
- August 2, 2000: OIRA received draft proposed rule.
- December 14, 2000: OIRA completed review of the draft proposed rule without change.
- December 22, 2000: The proposed rule was published in the *Federal Register*.
- August 2003: The draft final rule approved by CDER.
- October 2003: The rule was sent to the Office of Chief Counsel, which performed a federalism analysis.
- November 2004: The rule received FDA approval and was sent to the Department of Health and Human Services and OMB simultaneously.
- January 10, 2005: OIRA received the draft final rule.
- April 1, 2005: FDA withdrew the rule from OIRA review at OIRA's request.
- April 8, 2005: FDA resubmitted the rule for OIRA review.
- January 17, 2006: OIRA completed its review of the final rule with change.
- January 24, 2006: The final rule was published in the *Federal Register*.

Use of Ozone Depleting Substances; Removal of Essential Use Designations (Ozone Depleting Substances)

Identifying Information

- Agency: Food and Drug Administration, Center for Drug Evaluation and Research
- Rule classification: Other Significant
- RIN: 0910-AF93
- *Federal Register* citation: 71 Fed. Reg. 70,870
- Regulations.gov docket number: FDA-2006-N-0169
- Date of final rule: December 7, 2006

Rule Synopsis

The Clean Air Act required that FDA, in consultation with EPA, determine whether an FDA-regulated product that released ozone-depleting substances was essential. The rule removes the "essential use" designations granted previously by FDA for seven products emitting ozone-depleting substances from pressurized containers. As none of the seven products were being marketed in the United States, the rule removed unnecessary essential use designations. The products were granted the designation by a previous FDA rule, which also stated that if essential use products were no longer marketed in the United States, the designation could be withdrawn.

Regulatory Requirements Addressed in the Final Rule

FDA discussed the following generally-applicable statutes and executive orders in the final rule:

- NEPA: FDA conducted an environmental assessment and considered potential impacts. FDA concluded that an environmental impact statement was not required.
- PRA: The rule does not impose any new information collection requests.
- RFA: FDA certified that the rule would not have a significant economic impact on a substantial number of small entities.
- UMRA: FDA did not expect the rule to result in any 1-year expenditure that would meet or exceed the relevant threshold of $118 million.

- Executive Order 12866 (Regulatory Planning and Review): FDA believed that the rule was not a significant regulatory action as defined by this executive order. However, OMB requested the rule for review because of its international implications.
- Executive Order 13132 (Federalism): FDA determined that the rule did not contain policies that have federalism implications.

Changes Resulting from OIRA Review

Under Executive Order 12866, FDA did not consider the rule significant regulatory action as defined by the executive order. However, FDA believed that OMB would want to review the rule because of the rule's implications to the Montreal Protocol (Treaty) that included agency obligations to EPA as stated in the treaty, and also amendments to the Clean Air Act. OIRA did not suggest any changes to the rule during the formal OMB review period.

Timeline

- Early 2006: CDER began drafting the direct-to-final rule.
- May 2006: CDER approval process began.
- July 2006: Economic analysis completed.
- August 2006: Rule approved by CDER's Office of Regulatory Policy.
- September 2006: Rule approved by CDER Director.
- October 2006: Rule approved by Chief Counsel and management at FDA.
- October 23, 2006: OIRA received draft final rule.
- November 28, 2006: OIRA completed review of draft final rule with no change.
- December 2006: Direct-to-final rule published in the *Federal Register*.

Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements (Dietary Supplements)

Identifying Information

- Agency: Food and Drug Administration, Center for Food Safety and Applied Nutrition
- Rule classification: Major, Economically Significant
- RIN: 0910-AB88
- *Federal Register* citation: 72 Fed. Reg. 34,752
- Regulations.gov docket number: FDA-1996-N-0028
- Date of final rule: June 25, 2007

Rule Synopsis

The rule establishes the minimum current good manufacturing practice for manufacturing, packaging, labeling, and holding dietary supplements.[1] FDA was authorized by the Dietary Supplement Health and Education Act of 1994 to prescribe by regulation good manufacturing practices for dietary supplements. FDA published an Advance Notice of Proposed Rulemaking on February 6, 1997 in the *Federal Register*. 62 Fed. Reg. 5700. FDA published a proposed rule in the *Federal Register* on March 13, 2003.

Regulatory Requirements Addressed in the Final Rule

FDA discussed the following statutory and regulatory requirements in the final rule:

[1]For more information on FDA's dietary supplements program see GAO, *Dietary Supplements: FDA Should Take Further Actions to Improve Oversight and Consumer Understanding*, GAO-09-250 (Washington, D.C.: Jan. 29, 2009).

- NEPA: FDA determined that the final rule did not trigger the requirements of NEPA because the action is of a type that does not individually or cumulatively have a significant effect on the human environment.
- PRA: The rule included new information collections for which FDA completed and submitted an Information Collection Request to OIRA for approval.
- RFA: FDA determined that the rule will have a significant economic impact on a substantial number of small entities and prepared a final regulatory flexibility analysis.
- UMRA: FDA determined that the rule may contain a mandate resulting in annual expenditures of more than $122 million for state, local, and tribal governments, or the private sector. FDA prepared an UMRA analysis, which included a consideration of the rule's effects on future costs.
- Executive Order 12866 (Regulatory Planning and Review): FDA identified the rule as a significant regulatory action as defined by the executive order because of its economic significance. Therefore, FDA conducted an economic analysis and submitted the rule to OIRA for review.
- Executive Order 13132 (Federalism): FDA determined that the rule did not have a substantial direct effect on the states, on the relationship between the national government and the states, or on the balance of power and responsibilities among the various levels of government. FDA concluded that the rule did not have federalism implications.

Recent Analytic Requirements Addressed

FDA's regulatory impact analysis for the final rule included the four analytical changes in OMB Circular No. A-4 that we reviewed for this study. For example, the agency analyzed cost-effectiveness and evaluated some qualitative impacts, discounted future benefits and costs using discount rates of 3 percent and 7 percent, and conducted a probability analysis to assess the uncertainty associated with some potential impacts. FDA officials said that they used the two discount rates because of Circular No. A-4 but added that they have always followed OMB guidelines on discount rates. The officials could not recall whether the cost-effectiveness analysis was conducted specifically because of Circular No. A-4, but indicated that it is currently an agency best practice. The officials added that systematically evaluating qualitative impacts and using probability analysis to analyze uncertainty are also agency best practices. For example, the officials said that they analyzed uncertainty using a probability analysis because it is a best practice when there is a large degree of uncertainty about the estimated benefits and costs. According to these officials, OMB Circular No. A-4 is useful because it made transparent what OMB reviewers expect for analytical support on economically significant rules and, more generally, because it serves as a blueprint for conducting a regulatory impact analysis.

Changes Resulting from OIRA Review

FDA made changes at the suggestion of OIRA to both the preamble and the regulatory text. FDA sent draft versions of the final rule to OIRA twice, once in October 2005 and again in June 2006. FDA staff stated that the rule was not returned by OIRA, but rather as a result of discussions, FDA staff made a number of changes and sent a second draft of the rule to OIRA. Our review of both copies of the draft final rule reviewed by OIRA as docketed by FDA found edits to the rule, both to the preamble and the rule itself. For example, in addition to editorial changes, changes to the draft rule text show that a requirement in the rule to save reserve samples for 3 years was changed to 2 years. This change is also reflected in the preamble language. Changes to the regulatory impact analysis—included with the rule in its entirety in keeping with FDA practice—show additions of text justifying the rulemaking and additional descriptions of calculations of costs associated with illness and injury resulting from contaminated or mislabeled dietary supplements. We found documentation of the final stage of OMB review on both drafts sent to OMB during that stage.

Timeline

- October 25, 1994: Dietary Supplement Health and Education Act of 1994, Pub. L. No. 103-417, was enacted, granting FDA authority to prescribe good manufacturing practices for dietary supplements by regulation.
- November 1995: Industry group requested that FDA consider a rulemaking on good manufacturing practices for dietary supplements.
- February 6, 1997: An Advance Notice of Proposed Rulemaking was published in the *Federal Register*.
- 1998-1999: FDA management considered and committed to a rulemaking.
- 1999: FDA undertook a series of outreach activities, including public meetings and tours of dietary supplement manufacturing facilities.
- October 4, 2002: OIRA received the draft proposed rule.
- January 16, 2003: OIRA completed review of the draft proposed rule with change.
- March 13, 2003: The proposed rule was published in the *Federal Register*.
- October 25, 2005: OIRA received the draft final rule.
- November 29, 2005, October 4, 2006, and November 16, 2006: OIRA staff met with outside parties to discuss this rule.
- May 8, 2007: OIRA completed review of draft final rule with change.
- June 25, 2007: Final rule was published in the *Federal Register*, and FDA published an interim final rule on a process for requesting exemption from the dietary supplement current good manufacturing practices requirement for 100 percent identity testing of dietary ingredients.

Food Labeling: Nutrient Content Claims, Expansion of the Nutrient Content Claim "Lean" (Lean Nutrient Claims)

Identifying Information

- Agency: Food and Drug Administration, Center for Food Safety and Applied Nutrition
- Rule classification: Other Significant
- RIN: 0910-ZA27
- *Federal Register* citation: 72 Fed. Reg. 1455
- Regulations.gov docket number: FDA-2004-P-0008
- Date of final rule: January 12, 2007

Rule Synopsis

The rule amends FDA's food labeling regulations to allow the use of the word "lean" more frequently by including it for use with "mixed dishes not measurable with a cup" that fulfill certain criteria for fat and cholesterol content.[2] The intent was to provide reliable information that would assist consumers in maintaining healthy dietary practices. The rule was promulgated in response to a petition by Nestlé Corporation requesting that the category "mixed dishes not measurable with a cup" be included among those that can be called "lean."

Regulatory Requirements Addressed in the Final Rule

FDA discussed the following generally-applicable statutes and executive orders in the final rule:

- NEPA: FDA determined that the final rule did not trigger the requirements of NEPA because the action is of a type that does not individually or cumulatively have a significant effect on the human environment.
- RFA: FDA certified that the rule would not have a significant economic impact on a substantial number of small entities.

[2]For more information on FDA's food labeling program see GAO, *Food Labeling: FDA Needs to Better Leverage Resources, Improve Oversight, and Effective Use Available Data to Help Consumers Select Healthy Foods*, GAO-08-597 (Washington, D.C.: Sept. 9, 2008).

- PRA: The rule did not contain any new information collection requests.
- UMRA: FDA did not expect the rule to result in any 1-year expenditure by state, local, and tribal governments, in the aggregate, or by the private sector, that would meet or exceed the relevant threshold of $122 million.
- Executive Order 12866 (Regulatory Planning and Review): FDA determined that the rule was not a significant regulatory action as defined by the executive order. However, OMB considered the rule a significant regulatory action. Therefore, FDA submitted the rule to OIRA for review.
- Executive Order 13132 (Federalism): FDA determined that the rule would have a preemptive effect on state law, but concluded that the preemptive effect of the rule is consistent with Executive Order 13132.

Changes Resulting from OIRA Review

After 100 days of formal OMB review, the final rule was not changed by OMB.

Timeline

- January 9, 2004: Nestlé submitted the petition for the rulemaking.
- April 22, 2004: FDA filed the Nestlé petition for comprehensive review.
- November 25, 2005: Proposed rule published in the *Federal Register*.
- February 16, 2006: FDA notified state health commissioners, state agricultural commissioners, food program directors, and FDA field personnel and drug program directors of the intended amendment.
- September 12, 2006: OIRA received draft final rule.
- December 21, 2006: OIRA completed review of the draft final rule with no change.
- January 12, 2007: Final rule published in the *Federal Register*.

Electronic Shareholder Forums

Identifying Information

- Agency: Securities and Exchange Commission, Division of Corporation Finance
- Rule classification: Not applicable
- RIN: 3235-AJ92
- *Federal Register* citation: 73 Fed. Reg. 4450
- Regulations.gov docket number: SEC-2007-1058 (proposed rule); SEC-2008-0133 (final rule)
- Date of final rule: January 25, 2008

Rule Synopsis

The rule encourages the use of online shareholder forums. It removes legal ambiguity and both real and perceived impediments to private sector experimentation with the use of the Internet for communication. SEC stated that such communication technology can potentially better vindicate shareholders' rights, for example, to elect directors and improve discussions on a variety of subjects that are now considered only periodically and indirectly through the proxy process. The rule gives liability protection to parties maintaining or operating an electronic shareholder forum.

Regulatory Requirements Addressed in the Final Rule

SEC discussed the following generally-applicable statutes in the final rule:

- RFA: SEC analyzed whether the rule would have a significant economic impact on a substantial number of small entities and prepared both an initial and final regulatory flexibility analysis.
- PRA: The rule did not include any new information collection requirements.

Changes Resulting from OIRA Review

As an independent regulatory agency, SEC is not subject to OIRA regulatory review under Executive Order 12866.

Timeline

- 2006: Lawsuit resulted in court decision concerning proxies.
- May 7, 24, and 25, 2007: SEC hosted three proxy roundtables to gather information from a wide of variety of parties interested in proxy issues.
- July 12, 2007: Staff formally recommended proposed rule for SEC consideration.
- July 27, 2007: At an open meeting, SEC approved issuance of proposed rule.
- August 3, 2007: Proposed rule was published in the *Federal Register*.
- November 16, 2007: Staff formally recommended adopting final rule to SEC.
- November 28, 2007: At an open meeting, SEC approved issuance of final rule.
- January 25, 2008: Final rule was published in *Federal Register*.

Internet Availability of Proxy Materials (Internet Proxies)

Identifying Information

- Agency: Securities and Exchange Commission, Division of Corporation Finance
- Rule classification: Major
- RIN: 3235-AJ47
- *Federal Register* citation: 72 Fed. Reg. 4148
- Regulations.gov docket number: SEC-2005-0386 (proposed); SEC-2007-0134 (final)
- Date of final rule: January 29, 2007

Rule Synopsis

The rule provides an alternative method of providing proxy materials to shareholders by posting the materials on an Internet site and notifying shareholders of their availability. The rule is voluntary, and issuers of securities are not required to offer shareholders an electronic distribution option.

Regulatory Requirements Addressed in the Final Rule

SEC discussed the following generally-applicable statutory requirements in the final rule:

- PRA: The rule included new information collections for which SEC completed and submitted an Information Collection Request to OIRA for approval.
- RFA: SEC analyzed whether the rule would have a significant economic impact on a substantial number of small entities and prepared an initial and final regulatory flexibility analysis.

Changes Resulting from OIRA Review

As an independent regulatory agency, SEC is not subject to OIRA regulatory review under Executive Order 12866.

Timeline

- Spring 2005: SEC regulatory development staff began drafting the proposed rule.
- November 14, 2005: Staff formally recommended that SEC approve proposed rule.

- November 29, 2005: SEC approved issuance of proposed rule at an open meeting.
- December 15, 2005: The proposed rule was published in the *Federal Register*.
- November 27, 2006: Staff formally recommended adopting final rule for SEC consideration.
- December 13, 2006: SEC approved issuance of final rule at an open meeting.
- January 29, 2007: The final rule was published in the *Federal Register*.

Extension of Interactive Data Voluntary Reporting Program on the EDGAR System to Include Mutual Fund Risk/Return Summary Information (Mutual Fund Data Reporting)

Identifying Information

- Agency: Securities and Exchange Commission, Division of Investment Management
- Rule classification: Not applicable
- RIN: 3235-AJ59
- *Federal Register* citation: 72 Fed. Reg. 39,290
- Regulations.gov docket number: SEC-2007-0220 (proposed rule); SEC-2007-0958 (final rule)
- Date of final rule: July 17, 2007

Rule Synopsis

The rule encourages mutual funds to participate in a voluntary reporting program to tag selected risk/return data in a standard format in eXtensible Business Reporting Language (XBRL). According to the preamble, "[w]ith almost half of all U.S. households owning mutual funds. . .improving the quality of mutual fund disclosure is important to millions of Americans." When tagged in XBRL, the data become interactive and can be retrieved, searched, or analyzed by software applications in an automated fashion. The rule encourages voluntary participation in a program of electronically

tagging risk/return information by mutual funds, so that SEC can evaluate the usefulness of such tagging to interested parties. Information submitted would be included in the Electronic Data Gathering, Analysis, and Retrieval System (EDGAR) filings.

Regulatory Requirements Addressed in the Final Rule

SEC discussed the following generally-applicable statutes in the final rule:

- PRA The rule included new information collections for which SEC completed and submitted an Information Collection Request to OIRA for approval.
- RFA: SEC analyzed whether the rule would have a significant economic impact on a substantial number of small entities and prepared both an initial and final regulatory flexibility analysis.

Changes Resulting from OIRA Review

As an independent regulatory agency, SEC is not subject to OIRA regulatory review under Executive Order 12866.

Timeline

- March 2006: ICI announced an initiative to create a taxonomy of interactive data tags for the risk/return summary.
- June 12, 2006: SEC held a public roundtable on the use of interactive data for mutual funds.
- September 24, 2006: First draft of ICI tags distributed to working group for comment; SEC staff provided comments on draft taxonomy over next several weeks.
- January 4, 2007: ICI released the XBRL tags to the public.
- January 18, 2007: Staff formally recommended proposing release for SEC consideration.
- January 31, 2007: SEC approved issuance of proposed rule.
- February 12, 2007: Proposed rule published in the *Federal Register*.
- May 16, 2007: ICI submitted taxonomy to XBRL International for acknowledgment.
- June 6, 2007: Staff formally recommended adopting final rule for SEC.
- June 20, 2007: SEC approved issuance of final rule at an open meeting.
- July 17, 2007: Final rule was published in the *Federal Register*.

Mutual Fund Redemption Fees Identifying Information (Mutual Fund Redemption Fees)

Identifying Information

- Agency: Securities and Exchange Commission, Division of Investment Management
- Rule classification: Major
- RIN: 3235-AJ51
- *Federal Register* citation: 71 Fed. Reg. 58,257
- Regulations.gov docket number: SEC-2006-0292 (proposed rule); SEC-2006-1284 (final rule)
- Date of final rule: October 3, 2006

Rule Synopsis

The rule amends SEC Rule 22c-2, which permits registered open-end investment companies (funds) to impose a redemption fee of up to 2 percent on the redemption of fund shares. The rule is intended to allow funds to recoup some of the direct and indirect costs of frequent trading and to reduce the dilution of fund shares. The rule also requires that the fund, regardless of whether it imposes a redemption fee, enter into a written agreement with each of its intermediaries (such as broker-dealers or retirement plan administrators) under which the intermediaries must provide the fund, upon request, information about the identity of shareholders and information about their transactions in fund shares. These amendments are designed to address certain technical issues that arose after the rule was adopted and reduce the cost of compliance to both funds and financial intermediaries.

Regulatory Requirements Addressed in the Final Rule

SEC discussed the following generally-applicable statutory requirements in the final rule:

- PRA: The rule included new information collections for which SEC completed and submitted an Information Collection Request to OIRA for approval.

- RFA: SEC analyzed whether the rule would have a significant economic impact on a substantial number of small entities and prepared both an initial and final regulatory flexibility analysis.

Changes Resulting from OIRA Review

As an independent regulatory agency, SEC is not subject to OIRA regulatory review under Executive Order 12866.

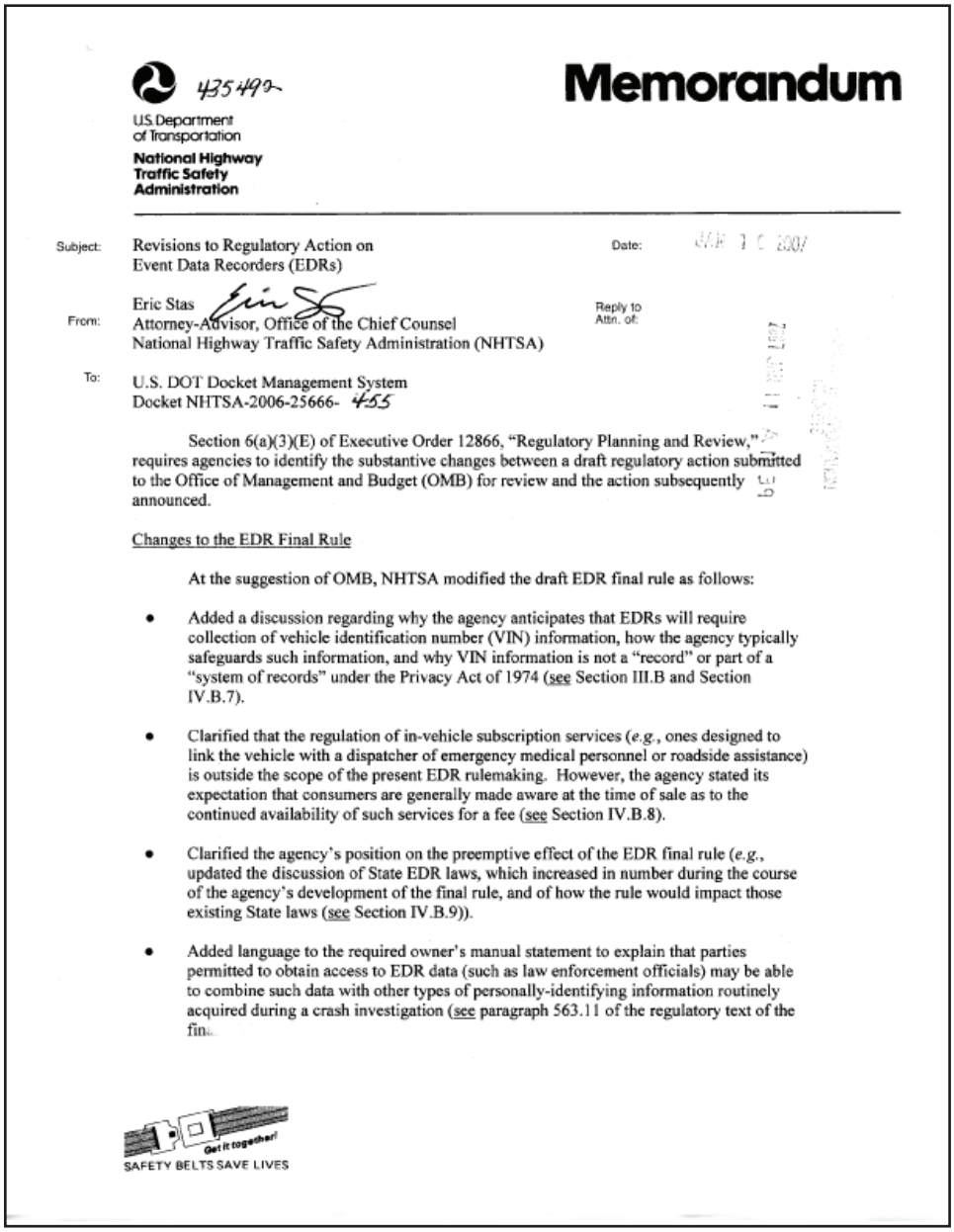
Timeline

- March 11, 2005: SEC adopted rule 22c-2 under the Investment Company Act; in the final notice, SEC solicited additional comment on 22c-2.
- February 3, 2006: Staff formally recommended that SEC amend Rule 22c-2.
- February 28, 2006: SEC approved issuance of proposed amendments to Rule 22c-2.
- March 7, 2006: The proposed amended rule was published in the *Federal Register*.
- September 1, 2006: Staff formally recommended that SEC adopt amended rule.
- September 27, 2006: SEC approved issuance of final rule.
- October 3, 2006: The final rule was published in the *Federal Register*.

This appendix presents examples of different methods that agencies used to document the OIRA review process under Executive Order 12866 in their rulemaking dockets (See figs. 5, 6, and 7.)

Appendix III: Examples of OIRA Review Documentation

Figure 5: NHTSA Summary Memorandum Identifying OIRA Review Changes



435492

Memorandum

U.S. Department of Transportation
National Highway Traffic Safety Administration

Subject: Revisions to Regulatory Action on Event Data Recorders (EDRs)

Date: MAR 1 0 2007

From: Eric Stas
Attorney-Advisor, Office of the Chief Counsel
National Highway Traffic Safety Administration (NHTSA)

Reply to Attn. of:

To: U.S. DOT Docket Management System
Docket NHTSA-2006-25666- 455

Section 6(a)(3)(E) of Executive Order 12866, "Regulatory Planning and Review," requires agencies to identify the substantive changes between a draft regulatory action submitted to the Office of Management and Budget (OMB) for review and the action subsequently announced.

Changes to the EDR Final Rule

At the suggestion of OMB, NHTSA modified the draft EDR final rule as follows:

- Added a discussion regarding why the agency anticipates that EDRs will require collection of vehicle identification number (VIN) information, how the agency typically safeguards such information, and why VIN information is not a "record" or part of a "system of records" under the Privacy Act of 1974 (see Section III.B and Section IV.B.7).
- Clarified that the regulation of in-vehicle subscription services (*e.g.*, ones designed to link the vehicle with a dispatcher of emergency medical personnel or roadside assistance) is outside the scope of the present EDR rulemaking. However, the agency stated its expectation that consumers are generally made aware at the time of sale as to the continued availability of such services for a fee (see Section IV.B.8).
- Clarified the agency's position on the preemptive effect of the EDR final rule (*e.g.*, updated the discussion of State EDR laws, which increased in number during the course of the agency's development of the final rule, and of how the rule would impact those existing State laws (see Section IV.B.9)).
- Added language to the required owner's manual statement to explain that parties permitted to obtain access to EDR data (such as law enforcement officials) may be able to combine such data with other types of personally-identifying information routinely acquired during a crash investigation (see paragraph 563.11 of the regulatory text of the fin

Get it together!
SAFETY BELTS SAVE LIVES

Source: NHTSA.

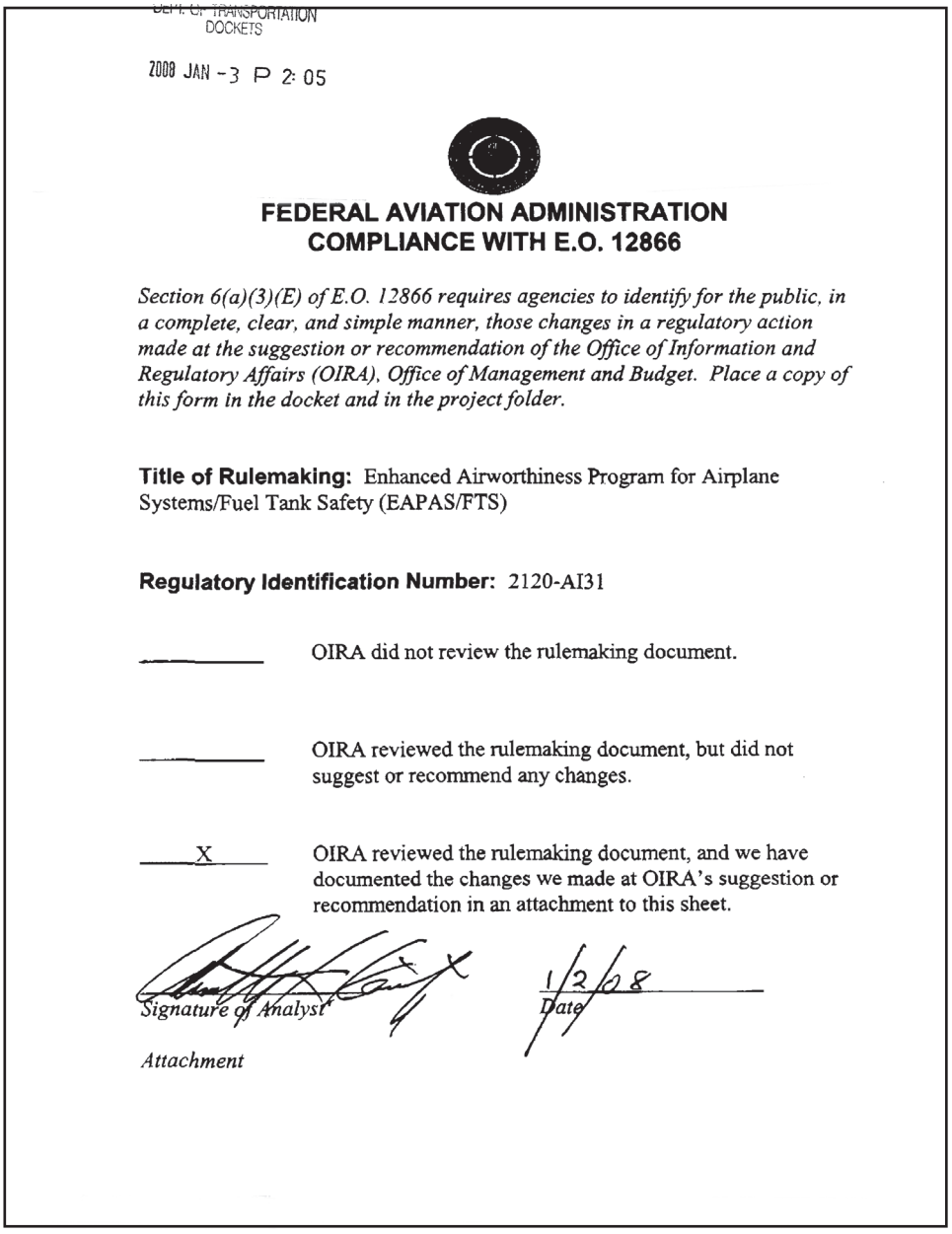
Changes to the EDR Final Regulatory Evaluation (FRE)

At the suggestion of OMB, NHTSA modified the FRE as follows:

- Revised Tables IV-3 and IV-4 to reflect the fact that for some manufacturers whose products do not currently meet all of the requirements of the EDR final rule, there may be certain computer, paperwork, and compliance costs associated with conforming their vehicles to the new requirements. However, the agency continues to believe that those costs would be *de minimis*. Accordingly, for those items, we substituted an estimate of "negligible" cost for the draft final rule's estimate of "$0" (see Chapter IV).

Source: NHTSA.

Figure 6: FAA Standard Form to Indicate the Nature of OIRA Review Changes



DEPT. OF TRANSPORTATION
DOCKETS

2008 JAN -3 P 2:05

FEDERAL AVIATION ADMINISTRATION
COMPLIANCE WITH E.O. 12866

Section 6(a)(3)(E) of E.O. 12866 requires agencies to identify for the public, in a complete, clear, and simple manner, those changes in a regulatory action made at the suggestion or recommendation of the Office of Information and Regulatory Affairs (OIRA), Office of Management and Budget. Place a copy of this form in the docket and in the project folder.

Title of Rulemaking: Enhanced Airworthiness Program for Airplane Systems/Fuel Tank Safety (EAPAS/FTS)

Regulatory Identification Number: 2120-AI31

_____ OIRA did not review the rulemaking document.

_____ OIRA reviewed the rulemaking document, but did not suggest or recommend any changes.

__X__ OIRA reviewed the rulemaking document, and we have documented the changes we made at OIRA's suggestion or recommendation in an attachment to this sheet.

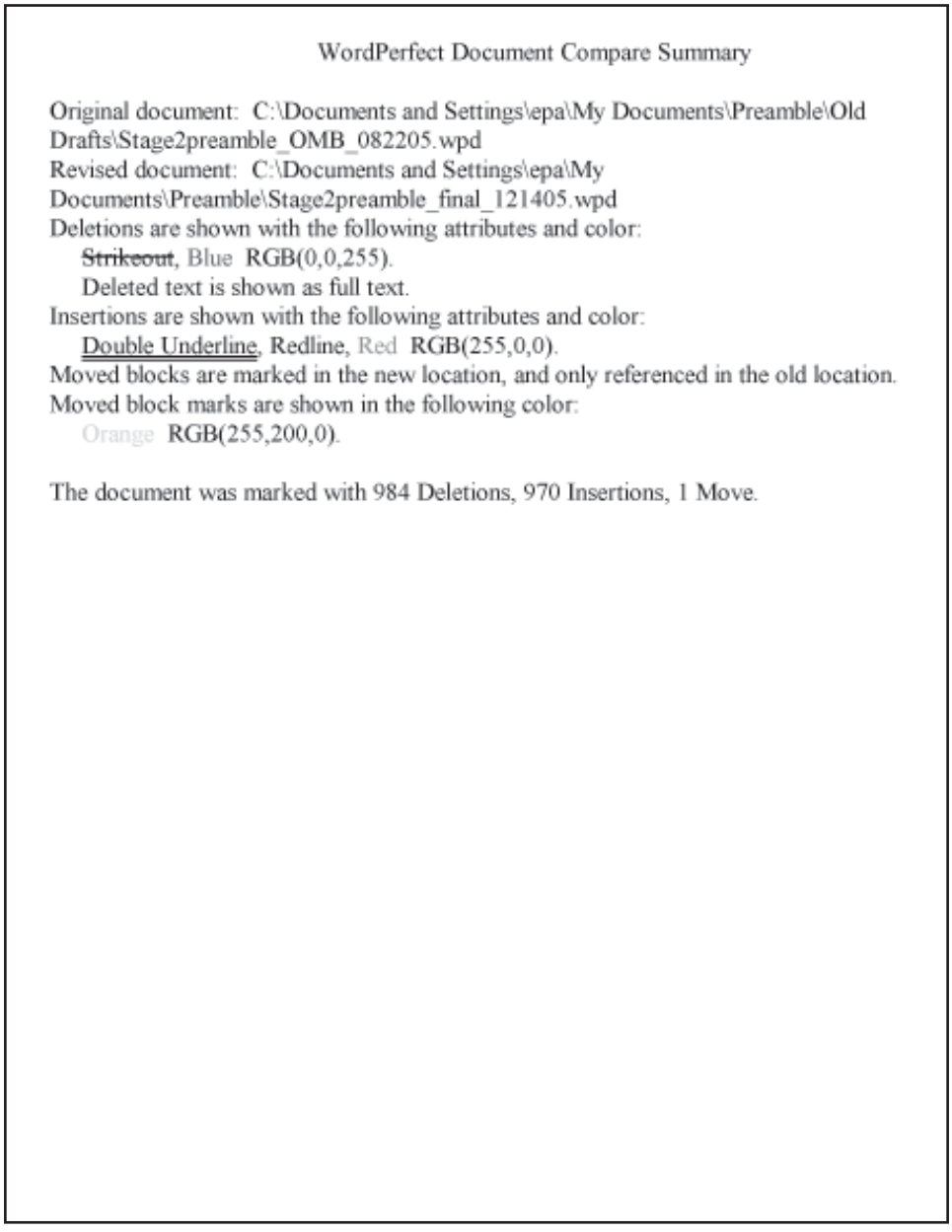
Signature of Analyst

1/2/08
Date

Attachment

Source: FAA.

Figure 7: EPA Use of Redline/Strikeout Method to Document OIRA Review Changes



WordPerfect Document Compare Summary

Original document: C:\Documents and Settings\epa\My Documents\Preamble\Old Drafts\Stage2preamble_OMB_082205.wpd
Revised document: C:\Documents and Settings\epa\My Documents\Preamble\Stage2preamble_final_121405.wpd
Deletions are shown with the following attributes and color:
~~Strikeout~~, Blue RGB(0,0,255).
Deleted text is shown as full text.
Insertions are shown with the following attributes and color:
Double Underline, Redline, Red RGB(255,0,0).
Moved blocks are marked in the new location, and only referenced in the old location.
Moved block marks are shown in the following color:
Orange RGB(255,200,0).

The document was marked with 984 Deletions, 970 Insertions, 1 Move.

Source: EPA.

Source Water Type	Population Size Category	Monitoring Frequency [1]	Distribution System Monitoring Location			
			Total per monitoring period [2]	Highest TTHM Locations	Highest HAA5 Locations	Existing Subpart L Compliance Locations
Subpart H	<500	per year	2	1	1	
	500-3,300	per quarter	2	1	1	
	3,301-9,999	per quarter	2	1	1	
	10,000-49,999	per quarter	4	2	1	1
	50,000-249,999	per quarter	8	3	3	2
	250,000-999,999	per quarter	12	5	4	3
	1,000,000-4,999,999	per quarter	16	6	6	4
	≥ 5,000,000	per quarter	20	8	7	5
Ground Water	<500	per year	2	1	1	
	500-9,999	per year	2	1	1	
	10,000-99,999	per quarter	4	2	1	1
	100,000-499,999	per quarter	6	3	2	1
	≥ 500,000	per quarter	8	3	3	2

[1] All systems must ~~take at least one dual sample set~~monitor during month of highest DBP concentrations.

[2] Systems on quarterly monitoring must take dual sample sets every 90 days at each monitoring location, except for subpart H systems serving 500-3,300.

[3] System~~s~~ on annual monitoring and subpart H systems serving 500-3,300 are required to take individual TTHM and HAA5 samples (instead of a dual sample set) at the locations with the highest TTHM and HAA5 concentrations, respectively. Only one location with a dual sample set per monitoring period is needed if highest TTHM and HAA5 concentrations occur at the same location and month, if monitored annually).

(c) You must recommend subpart V compliance monitoring locations based on standard monitoring results, system specific study results, and subpart L compliance monitoring results. You must follow the protocol in paragraphs (c)(1) through (~~4~~c)(8) of this section. If required to monitor at more than ~~four~~eight locations, you must repeat the protocol as necessary~~, alternating between locations with the highest HAA5 LRAA and the highest TTHM LRAA not previously selected as a subpart V monitoring location for choosing locations under paragraphs (c)(3) and (c)(4)~~. If you do not have existing subpart L compliance

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Source: EPA.

Appendix IV: Comments from the Office of Management and Budget

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

April 7, 2009

Ms. Denise M. Fantone
Director, Strategic Issues
Government Accountability Office
441 G Street, NW
Washington, DC 20548

Dear Ms. Fantone:

Thank you for your letter of February 27, 2009, to Director Orszag in which you provided a draft copy of your report *Federal Rulemaking Improvements Needed to Monitoring and Evaluation of Rules Development as well as to the Transparency of OMB Regulatory Review* (Report), and offered us the opportunity to provide comments on the draft report. Because it is the Office of Information and Regulatory Affairs (OIRA) within the Office of Management and Budget (OMB) that oversees implementation of Executive Order 12866 (EO 12866) governing regulatory review, Director Orszag has asked that I respond to your letter.

We have reviewed the report carefully, particularly those portions pertaining to OMB review of draft regulations pursuant to EO 12866 and the recommendations on how OIRA could make the review process more transparent. Our comments below relate primarily to the report's findings and recommendations regarding OMB's role in the regulatory review process.

First let me say that we appreciate your finding that the rulemaking agencies studied by GAO generally complied with their obligation under EO 12866 to disclose materials that they provided for, and substantive changes to the draft rule that occurred during, OIRA review. (Report at p. 39.) However, we have also noted the concerns in the draft report regarding certain transparency issues related to the disclosures that are made by rulemaking agencies pursuant to EO 12866. (Report at p. 40.) In this regard, OIRA does not monitor, on a rule-by-rule basis, compliance by rulemaking agencies with their disclosure obligations under EO 12866. (As you know, OIRA is subject to its own disclosure requirements under both EO 12866 and OIRA's Memorandum of October 18, 2001 on "OIRA Disclosure.") However, your report will remind rulemaking agencies of their responsibility under EO 12866 – once the regulation has been published in the *Federal Register* or otherwise made available to the public – to identify in a complete, clear, and simple manner the substantive changes between the draft rule submitted to OIRA for review and the action subsequently announced, and to identify those changes in the regulatory action that were made at the suggestion or recommendation of OIRA.

On page 40 of the draft report you recommend that the Director of OMB, through the Administrator of OIRA, take the following four actions to more consistently implement the EO's requirement that the agencies provide information to the public in a complete, clear, and simple manner:

- define in guidance what types of changes made as a result of the OIRA review process are substantive and need to be publicly identified,
- instruct agencies to clearly attribute those changes "made at the suggestion or recommendation of OIRA,"
- direct agencies to clearly state in final rules whether they made substantive changes as a result of the OIRA reviews, and
- standardize how agencies label documentation of these changes in public rulemaking dockets.

We believe these recommendations have merit and warrant further consideration. OIRA takes seriously the disclosure requirements of EO 12866, and OIRA remains committed to a high level of transparency in the regulatory review process.

We would like to bring to your attention that, on January 30, 2009, President Obama issued a Memorandum for the Heads of Executive Departments and Agencies on "Regulatory Review" (74 FR 5977; February 3, 2000). In his Memorandum, the President directed the OMB Director, in consultation with representatives of regulatory agencies, to produce within 100 days a set of recommendations for a new EO on Federal agency regulatory review. The President directed that these recommendations, among other things: "offer suggestions for the relationship between OIRA and the agencies; provide guidance on disclosure and transparency; encourage public participation in agency regulatory processes; offer suggestions on the role of cost-benefit analysis; address the role of distributional considerations, fairness, and concern for the interests of future generations; identify methods of ensuring that regulatory review does not produce undue delay; clarify the role of the behavioral sciences in formulating regulatory policy; and identify the best tools for achieving public goals through the regulatory process."

Since then, OIRA has been reaching out to agencies to solicit recommendations for revising the regulatory review process, consistent with the President's Memorandum. In addition, on February 26, 2009, OMB published a notice in the *Federal Register* (74 FR 8819) inviting public comment on how to improve the regulatory review process and the principles governing the development of regulation. We have received over 100 comments in response to this notice. These comments are available to the public at http://www.reginfo.gov/public/jsp/EO/fedRegReview/publicComments.jsp. In addition, we have also met with various stakeholder groups to obtain their input and have posted a record of these meetings at the same website address (along with any written materials provided at these meetings).

Thank you again for the opportunity to comment on the draft report. We very much appreciate GAO's draft findings and recommendations for improving the regulatory review process, particularly in the area of government transparency, one of the key concerns identified by the President in his January 30 Memorandum. The President also underscored the importance

of transparency in his Memorandum of January 21, 2009, "Transparency and Open Government" (74 FR 4685; January 26, 2009). We will give full consideration to the report and its recommendations as we finalize our recommendations to the President for a new Executive Order on regulatory review.

Sincerely,

Kevin F. Neyland

Kevin F. Neyland
Acting Administrator
Office of Information
and Regulatory Affairs

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Appendix V: Comments from the Securities and Exchange Commission

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

THE CHAIRMAN

March 20, 2009

Timothy A. Bober
Assistant Director, Strategic Issues
United States Government Accountability Office
441 G Street, NW
Washington, DC 20548

Dear Mr. Bober,

Thank you for transmitting the GAO's draft report: "Improvements Needed to Monitoring and Evaluation of Rules Development as well as to the Transparency of OMB Regulatory Reviews." We were happy to participate in your review and appreciate the opportunity to comment. We have transmitted separately a few specific comments on factual portions of the report concerning the SEC that we believe should be amended for accuracy.

The SEC strives for an open and efficient rulemaking process that affords the public a full opportunity to comment. I am committed to evaluating all the Commission's processes and looking for ways in which they can be improved. I appreciate and take seriously any suggestions as to ways in which we can gain efficiencies in our rulemaking process. It is always important for us to think about how we might do a better job, and we will consider your recommendations as part of that evaluation.

Sincerely,

Mary L. Schapiro
Chairman

Appendix VI: Comments from the Department of Health and Human Services, Food and Drug Administration

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

DATE: March 19, 2009

TO: Acting Assistant Secretary for Legislation

FROM: Chief of Staff, FDA

SUBJECT: FDA's General Comments to GAO's Draft Report Entitled, *Federal Rulemaking – Improvements Needed to Monitoring and Evaluation of Rules Development as Well as to the Transparency of OMB Regulatory Reviews* (GAO-09-205)

FDA is providing the attached general comments to the U.S. Government Accountability Office's draft report entitled: *Federal Rulemaking - Improvements Needed to Monitoring and Evaluation of Rules Development as Well as to the Transparency of OMB Regulatory Reviews* (GAO-09-205).

FDA appreciates the opportunity to review and comment on this draft report before it is published.

Susan C. Winckler, R.Ph., Esq.

Attachment

FDA's General Comments to the U.S. Government Accountability Office's (GAO) Draft Report Entitled, *Improvements Needed to Monitoring and Evaluation of Rules Development as Well as to the Transparency of OMB Regulatory Reviews*

The Food and Drug Administration (FDA) welcomes the opportunity to comment on GAO's draft report. This document responds to the three recommendations made by GAO to FDA, the Environmental Protection Agency (EPA), and the Securities and Exchange Commission (SEC).

GAO Recommendations

To be consistent with internal controls for information in managing agency operations, GAO recommends that for significant rules, the Administrator of EPA, the Commissioner of FDA, and the Chairman of SEC take the following actions:

1. Routinely track major milestones in regulatory development

   FDA believes that only "economically significant" rules should be tracked. Even with this more narrow scope, the recommendation would be difficult to implement. FDA cannot predict with certainty which rules OMB considers to be significant until the rule is close to final agency clearance, and FDA does not know the number of rules deemed by OMB to be significant.

   In addition, alternative approaches should be permitted. For example, FDA maintains a database, the Federal Register Document Tracking System (FRDTS), to track the progress of all its Federal Register documents through the latter stages of the agency's development and clearance process. For potentially significant regulations, the agency not only uses the FRDTS, but also develops work plans, and holds quarterly planning meetings with all parties involved in the regulations process, to keep abreast of progress, problems and possible delays. In addition, the agency instituted a Policy Council which is comprised of all senior agency officials involved in the regulations development process. The Policy Council meets once a month, providing the opportunity to report to FDA senior management on the progress of meeting major milestones.

2. Report internally and externally when major milestones are reached against established targets

   FDA already reports internally when major milestones are reached. As mentioned above, FDA holds quarterly and monthly meetings where major milestones are discussed and reported. At its monthly meetings, the FDA Policy Council discusses priorities, resources, and any other issues that impact the agency regulation development process. For example, the Policy Council

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discusses competing priorities and tries to reach consensus on overall agency priorities. The Policy Council serves as a venue to disseminate information on new regulatory requirements such as new statutes and Executive Orders. Moreover, the Policy Council discusses the allocation of agency resources needed for significant regulations.

FDA advises against routinely reporting externally when major milestones are met. Reporting on when major milestones are met as compared to established targets may mislead stakeholders and incorrectly suggest that the agency is not working diligently on the completion of a particular regulation. This reporting may result in follow-up inquiries from interested parties, and responding to such inquiries draws resources away from completing the regulation. Although establishing timeframes upfront for completing a regulation is helpful, it is not uncommon for deadlines to be revisited in light of public health emergencies, changes in priorities in response to public health needs, evolving policy considerations, and the many steps that must be taken to complete and clear a rule, e.g., the various statutory requirements that must be addressed.

3) Evaluate actual performance versus the targeted milestones to determine whether differences are explainable or, if not, if there is a need for further management reviews

FDA already engages in quality improvement efforts for its rulemaking process. In addition to quarterly regulations meetings with each agency component and the FDA Policy Council meetings, FDA periodically reviews its regulations development and clearance process to see if changes are needed to improve the efficiency and timeliness. Since 1981, 12 such reviews have been conducted and recommended improvements implemented. Recent improvements include piloting the use of digital signatures for clearing regulations to reduce the time it takes to clear and publish regulations in the Federal Register, and piloting the use of a standardized questionnaire on a wiki platform to reduce the time it takes to develop an economic analysis for a rule.

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Appendix VII: Comments from the Environmental Protection Agency

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

MAR 20 2009

OFFICE OF
POLICY, ECONOMICS
AND INNOVATION

Ms. Denise M. Fantone
Director, Strategic Issues
United States Government Accountability Office
Washington, D.C. 20548

Dear Ms. Fantone:

Thank you for providing us the opportunity to comment on the final draft report entitled *Federal Rulemaking: Improvements Needed to Monitoring and Evaluation of Rules Development as well as to the Transparency of OMB Regulatory Reviews (GAO-09-205)*. EPA appreciates GAO's efforts, despite the short timeframe for review, to evaluate how changes in broad rulemaking requirements have cumulatively affected: (1) the agencies' rulemaking process; and (2) the transparency of OMB regulatory reviews.

We agree with GAO that the small sample size used in the report may not be representative of all regulatory agencies or all rules within a specific agency. As you know, EPA develops over 450 final regulations in a given year. These regulatory actions vary tremendously from technical amendments consisting of several pages of preamble and rule text to regulations with supporting documents consisting of hundreds of pages. Additionally, the development process itself may differ considerably. Thus, the four EPA case studies are not entirely representative of the range of regulatory development in the agency. For example, two out of the four EPA case studies (Stage 2 Disinfection Byproducts Rule and Longterm 2 Surface Water Treatment Rule) were developed using an "advisory committee process," which involves outside stakeholders in most aspects of developing the rule and supporting data. This approach can result in a long, intense, and very public development process. This advisory committee rule development process is less frequently used than the usual notice and comment rulemaking process. Therefore, drawing recommendations from such a small sample of rules could be misleading.

EPA would like to make several corrections to the current draft report. GAO recommends that agencies routinely track major milestones in regulatory development and report internally and externally when major milestones are reached against established targets. EPA would like to clarify that the agency currently does track key milestones associated with the rulemaking process. This information has been reported internally and externally. The draft report does not reflect the agency's efforts in monitoring the regulatory process. The following data provide information to clarify the systems and processes the Agency uses to track and report on process milestones.

- EPA has a well-established, agency-wide process for rule development, referred to as the **Action Development Process** (ADP). GAO specifically notes on page 15 of the report that EPA tracks 14 milestones as it develops a proposed rule under the ADP. After the proposed rule is published, EPA routinely tracks 4-5 additional milestones to develop the final rule.
- EPA has an internal tracking system, **Rule and Policy Information Development System** (RAPIDS), which monitors cross-Agency involvement and senior management reviews to ensure timely decisions. In RAPIDS, EPA routinely tracks milestones in regulatory development by projecting dates for achieving milestones and subsequently recording actual dates of completion. Actual dates may differ from projected dates for based on a variety of management decisions and resource requirements. The ADP is flexible and programs can adjust milestone dates to address evolving priorities.
- EPA uses data in RAPIDS, complemented by additional information, to develop regulatory management reports that are provided to EPA managers and executives as a forward-looking planning and tracking tool and as a means to improve the flow of communication between and among program managers.
- EPA executives and managers routinely meet to review milestones on key regulations, review program performance, and identify best practices. During the study period, the EPA Deputy Administrator met, at approximately 6-week intervals, with program executives and specifically tracked the attainment of regulation development milestones for several dozen priority actions. Regulations were tracked against an agreed upon schedule for a standard set of development milestones. Actions that are completed on time or early are used by EPA as examples of best practices. Actions that are off-track are identified early and corrective steps are taken to expedite their completion. This data was reviewed weekly at senior staff meetings and reported to the public quarterly.
- As you are aware, twice a year, the Agency publishes all the agency's planned actions which are currently under development or review through **EPA's Semiannual Regulatory Agenda**. This regulatory agenda provides the public updated information on the important external milestones and even highlights those actions in the early pre-rule stages.
- EPA is committed to furthering transparency and has instituted the practice of providing on-line information to the public as soon as the Agency begins development of a new rule. EPA is using **Action Initiation Lists** to notify the public about new rules and other regulatory actions. AILs are posted on the EPA Web site at the end of each month and describe the actions that were approved for commencement. (AILs are found at http://www.epa.gov/lawsregs/search/ail.html).

EPA notes that OMB is currently soliciting comments from agencies and the public on the topic of OMB regulatory review. EPA is developing its response.

Again, we appreciate the opportunity to comment on this report and would be happy to discuss the comments further if needed. Should you have any questions, please contact Bobbie Trent, our GAO liaison at 202-566-0983.

Sincerely,

Louise P. Wise
Acting Associate Administrator
Office of Policy, Economics and Innovation

Enclosure

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Appendix VIII: GAO Contact and Staff Acknowledgments

GAO Contact

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Acknowledgements

In addition to the contact named above, Timothy Bober, Assistant Director; Timothy Guinane; Edward Leslie; Andrea Levine; James McTigue, Susan Offutt, Melanie Pappasian; Jacquelyn Pontious; Robert Powers; Joseph Santiago; Wesley Sholtes; William Trancucci, Michael Volpe; Gregory Wilmoth; and Diana Zinkl made key contributions to this report.

Related GAO Products

Financial Regulation: A Framework for Crafting and Assessing Proposals to Modernize the Outdated U.S. Financial Regulatory System. GAO-09-216. Washington, D.C.: January 8, 2009.

Chemical Assessments: Low Productivity and New Interagency Review Process Limit the Usefulness and Credibility of EPA's Integrated Risk Information System. GAO-08-440. Washington, D.C.: March 7, 2008.

Telecommunications: FCC Should Take Steps to Ensure Equal Access to Rulemaking Information. GAO-07-1046. Washington, D.C.: September 6, 2007.

Reexamining Regulations: Opportunities Exist to Improve Effectiveness and Transparency of Retrospective Reviews. GAO-07-791. Washington, D.C.: July 16, 2007.

Regulatory Flexibility Act: Congress Should Revisit and Clarify Elements of the Act to Improve Its Effectiveness. GAO-06-998T. Washington, D.C.: July 20, 2006.

Federal Rulemaking: Perspectives on 10 Years of Congressional Review Act Implementation. GAO-06-601T. Washington, D.C.: March 30, 2006.

Federal Rulemaking: Past Reviews and Emerging Trends Suggest Issues That Merit Congressional Attention. GAO-06-228T. Washington, D.C.: November 1, 2005.

Electronic Rulemaking: Progress Made in Developing Centralized E-Rulemaking System. GAO-05-777. Washington, D.C.: September 9, 2005.

Regulatory Reform: Prior Reviews of Federal Regulatory Process Initiatives Reveal Opportunities for Improvements. GAO-05-939T. Washington, D.C.: July 27, 2005.

Economic Performance: Highlights of a Workshop on Economic Performance Measures. GAO-05-796SP. Washington, D.C.: July 2005.

Paperwork Reduction Act: New Approach May Be Needed to Reduce Government Burden on Public. GAO-05-424. Washington, D.C.: May 20, 2005.

Unfunded Mandates: Views Vary About Reform Act's Strengths, Weaknesses, and Options for Improvement. GAO-05-454. Washington, D.C.: March 31, 2005.

Unfunded Mandates: Analysis of Reform Act Coverage. GAO-04-637. Washington, D.C.: May 12, 2004.

Rulemaking: OMB's Role in Reviews of Agencies' Draft Rules and the Transparency of Those Reviews. GAO-03-929. Washington, D.C.: September 22, 2003.

Federal Rulemaking: Procedural and Analytical Requirements at OSHA and Other Agencies. GAO-01-852T. Washington, D.C.: June 14, 2001.

Regulatory Flexibility Act: Implementation in EPA Program Offices and Proposed Lead Rule. GAO/GGD-00-193. Washington, D.C.: September 20, 2000.

Federalism: Previous Initiatives Have Little Effect on Agency Rulemaking. GAO/T-GGD-99-131. Washington, D.C.: June 30, 1999.

Regulatory Accounting: Analysis of OMB's Reports on the Costs and Benefits of Federal Regulation. GAO/GGD-99-59. Washington, D.C.: April 20, 1999.

Federal Rulemaking: Agencies Often Published Final Actions Without Proposed Rules. GAO/GGD-98-126. Washington, D.C.: August 31, 1998.

Regulatory Management: Implementation of Selected OMB Responsibilities Under the Paperwork Reduction Act. GAO/GGD-98-120. Washington, D.C.: July 9, 1998.

Regulatory Reform: Agencies Could Improve Development, Documentation, and Clarity of Regulatory Economic Analyses. GAO/RCED-98-142. Washington, D.C.: May 26, 1998.

Regulatory Reform: Implementation of Small Business Advocacy Review Panel Requirements. GAO/GGD-98-36. Washington, D.C.: March 18, 1998.

Unfunded Mandates: Reform Act Has Had Little Effect on Agencies' Rulemaking Actions. GAO/GGD-98-30. Washington, D.C.: February 4, 1998.

Regulatory Reform: Changes Made to Agencies' Rules Are Not Always Clearly Documented. GAO/GGD-98-31. Washington, D.C.: January 8, 1998.

Managing for Results: Regulatory Agencies Identified Significant Barriers to Focusing on Results. GAO/GGD-97-83. Washington, D.C.: June 24, 1997.

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