



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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FEDERAL RULEMAKING

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

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.