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REGULATORY REFORM

Agencies Could Improve Development, Documentation, and Clarity of Regulatory Economic Analyses





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**Resources, Community, and
Economic Development Division**

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The Honorable Fred Thompson
Chairman
The Honorable John Glenn
Ranking Minority Member
Committee on Governmental Affairs
United States Senate

This report responds to your request that we describe the extent to which federal agencies are incorporating the best practices set forth in the Office of Management and Budget's (OMB) guidance for preparing economic analyses in accordance with Executive Order 12866 and the Unfunded Mandates Reform Act of 1995. The report discusses the development, documentation, and use of economic analyses in agencies' regulatory decision-making and contains recommendations to the Director, OMB. The recommendations are designed to enhance the quality and credibility of agencies' economic analyses.

We are sending copies of this report to other appropriate congressional committees; the Director, OMB; the Secretaries of Agriculture and Transportation; the Administrators of the Environmental Protection Agency and the Occupational Safety and Health Administration; and the Commissioner of the Food and Drug Administration. Copies are available to others upon request.

If you or your staff have any questions, please call me at (202) 512-6111. Major contributors to this report are listed in appendix I.

A handwritten signature in black ink, appearing to read 'Peter F. Guerrero', with a long horizontal flourish extending to the right.

Peter F. Guerrero
Director, Environmental
Protection Issues

Executive Summary

Purpose

The last 20 years have seen enormous growth in the number and scope of federal regulations. According to the Office of Management and Budget (OMB), although these regulations have improved public health and safety and environmental quality, their costs are high. In 1996, OMB estimated the costs of federal regulations at \$200 billion annually and the benefits at \$300 billion. To control the costs of regulation, the administration has issued executive orders, including Executive Order 12866, and the Congress has enacted laws, including the Unfunded Mandates Reform Act of 1995 (UMRA). These orders and laws require federal agencies to prepare and use economic analyses—also known as regulatory impact analyses—to assess the benefits and costs of proposed actions before promulgating regulations. These analyses are intended to inform and improve the regulatory process by identifying the likely costs and benefits of feasible alternatives. An interagency group convened by OMB has developed guidance for implementing Executive Order 12866 and UMRA. This guidance sets forth best practices for preparing economic analyses.

To assist the Senate Committee on Governmental Affairs in carrying out its regulatory oversight responsibilities, the Chairman and Ranking Minority Member asked GAO to describe (1) the extent to which federal agencies' economic analyses incorporate the best practices set forth in OMB's guidance and (2) the agencies' use of these analyses in regulatory decision-making.

Background

In 1993, President Clinton issued Executive Order 12866, the most recent of several executive orders requiring federal agencies to conduct economic analyses when developing regulations. Under the order, an agency must conduct an economic analysis of a planned regulation and alternatives to it for an economically significant rule—one that may have an annual effect on the economy of \$100 million or more. In 1995, the Congress enacted UMRA, which imposes a statutory requirement on federal agencies to conduct benefit-cost analyses of planned regulations. UMRA's scope differs slightly from the scope of the executive order. Specifically, the act requires analyses for proposed or final rules that may result in the expenditure of \$100 million or more in any one year, either by state, local, and tribal governments in the aggregate or by the private sector alone. Most recently, Senators Thompson and Levin introduced a bill (S. 981) that would, among other things, require executive summaries and peer reviews for economic analyses. In the past, GAO has recommended executive summaries for economic analyses to enhance their clarity, and peer reviews to enhance their quality and credibility.

In 1996, OMB issued a document describing best practices for preparing economic analyses under Executive Order 12866 and UMRA. These best practices include considering the most important alternative approaches to the problem, analyzing the benefits and costs of these alternatives, and fully disclosing information about the analysis, including the underlying uncertainties and assumptions.

GAO included in this review all economically significant proposed and final rules issued between July 1996 and March 1997 that addressed environmental, health, and safety matters. As a result, GAO reviewed the economic analyses used in promulgating 20 regulations by five agencies—the Departments of Agriculture and Transportation, the Environmental Protection Agency (EPA), the Food and Drug Administration (FDA) within the Department of Health and Human Services, and the Occupational Safety and Health Administration (OSHA) within the Department of Labor. Nine of these regulations involved potential expenditures large enough to bring the regulations within the scope of UMRA.

Results in Brief

Some of the 20 economic analyses that GAO reviewed did not incorporate the best practices set forth in OMB's guidance. For example, 5 of the 20 analyses did not discuss alternatives to the proposed regulatory action, 6 did not assign dollar values to benefits, and 1 did not assign dollar values to costs—all of which are practices recommended by the guidance. OMB's guidance gives agencies the flexibility to decide how thorough their economic analyses should be. At the same time, the guidance stresses the importance of fully disclosing the reasons for omissions, gaps, or other limitations. Although GAO found many instances in which best practices were not followed in the analyses, the reason for not following was disclosed in only one instance. In addition, eight of the economic analyses did not include an executive summary that could help the Congress, decisionmakers, the public, and other users quickly identify key information addressed in the analyses. Finally, only 1 of the 20 analyses received an independent peer review. Because Executive Order 12866 and UMRA establish nearly identical requirements for economic analyses and because agencies typically use the same analyses to comply with both when UMRA is applicable, GAO's findings reflect the extent to which the nine analyses called for under UMRA satisfy the act's as well as the executive order's requirements for economic analyses.

According to agency officials, economic analyses play a valuable role in regulatory decision-making. Twelve of the 20 analyses were used to help identify the most cost-effective of several similar alternatives or to cost-effectively implement health-based regulations. Seven other analyses were used to define a regulation's scope and implementation date, document and defend regulatory decisions, or reduce a health risk at a feasible cost. One analysis played almost no role in decision-making because, according to agency officials, the authorizing statute was so prescriptive that the agency was left with virtually no discretion in developing the implementing regulation.

Principal Findings

Some Economic Analyses Lacked Full Disclosure

For 15 of the 20 regulations that GAO reviewed, the agencies included at least one alternative to the proposed action, but in some instances, the discussion of the alternative was limited. For the five remaining regulations, no evidence was available to show that the agencies had considered alternatives. Agency officials stated that for these five analyses, the agencies either had considered alternatives but had not included them in the analyses or had not considered alternatives at all. Agency officials' reasons for not addressing or considering alternatives included the specificity of the authorizing legislation or the need to issue regulations quickly. Although OMB's guidance states that these can be legitimate reasons for agencies to limit the consideration of alternatives, the guidance also states that even when such limitations apply, agencies should provide some analysis of alternatives to provide decisionmakers with information for judging the consequences of statutory constraints.

Nineteen of the economic analyses assigned dollar values to some costs, and 14 assigned dollar values to some benefits. Similarly, 15 of the analyses discussed the uncertainties associated with the estimates of benefits and costs, but none of the remaining 5 analyses explained why they did not discuss the uncertainty associated with the estimated benefits and costs.

The clarity of the 20 analyses varied, making it difficult at times to determine where or whether elements of OMB's guidance were discussed. Eight of the analyses did not include an executive summary. GAO has previously recommended that EPA's analyses, and S. 981 would require that

all agencies' analyses, contain an executive summary that clearly describes the results of the economic analysis and the key points of the analysis. Only one of the 20 analyses underwent an independent peer review. GAO has previously stated that EPA should use peer review to help ensure the quality and credibility of an analysis. While a similar requirement for peer review for all agencies would entail some costs, as OMB has observed, peer review by independent experts—either internal or external to the agency—could be tailored to reflect the importance, sensitivity, and innovativeness of the analysis and of the associated regulatory decision.

Agencies Often Used Economic Analyses to Identify Cost-Effective Approaches

According to agency officials, the analyses were most frequently used to identify the most cost-effective approach within a fairly narrow range of options. For example, EPA used its economic analysis for a rule on marine engine emissions to examine the costs of different emission levels and to select the most cost-effective level. Four other analyses were used primarily to help agencies better define a rule's coverage or to determine when to implement a rule. For example, EPA's economic analysis for a proposed rule on procedures for testing emissions from motor vehicles incorporated data provided by the automobile industry and led to revisions that gave the industry additional time to implement the final rule. Two analyses were used principally to help agencies document or justify decisions that they had already made. According to agency officials, specific statutory requirements limited their discretion in making regulatory decisions and were a primary reason why economic analyses played a limited role in regulatory decision-making. For example, the Clean Air Act of 1990 directed EPA to review and revise its regulations on motor vehicle testing to better reflect actual driving conditions.

Recommendations

To strengthen the clarity and credibility of the economic analyses required for regulatory decision-making, GAO recommends that the Director, Office of Management and Budget, amend the Office's guidance to include additional elements, two of which are proposed in S. 981. Specifically, GAO recommends that the guidance be amended to provide that economic analyses should

- address all of the best practices identified in OMB's guidance or state the agency's reasons for not addressing them;
- contain an executive summary that briefly and concisely (1) identifies all benefits and costs—both those that can be described quantitatively and those that can be described qualitatively; (2) describes the range of

uncertainties associated with the benefits and costs; and (3) compares the reasonable alternatives considered by the agency; and

- undergo an appropriate level of internal or external peer review by independent experts and state the agency's basis for selecting that level.

Agency Comments

GAO provided a draft of this report to the Office of Management and Budget; the Departments of Agriculture and Transportation, EPA, FDA, and OSHA. GAO received comments from all of these agencies except OSHA, which informed GAO that it had no comments on the draft. The agencies generally agreed with the information presented in the report and concurred with GAO's recommendations calling for economic analyses to address OMB's best practices and to include an executive summary. Although the agencies agreed with GAO that peer review can be beneficial, they suggested that GAO clarify and expand its discussion and recommendation on this issue to more clearly acknowledge that agencies should have discretion in selecting an appropriate level of peer review. FDA urged GAO to delete this recommendation, maintaining that such a requirement would likely make it impossible for the agency to meet other statutory responsibilities. GAO has revised the discussion and recommendation on peer review to clarify that agencies should have such discretion but should also state their basis for selecting a given level of peer review. The agencies offered several technical and/or clarifying comments, which GAO incorporated throughout the report as appropriate.

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Abbreviations

DOT	Department of Transportation
EPA	Environmental Protection Agency
FDA	Food and Drug Administration
OMB	Office of Management and Budget
OSHA	Occupational Safety and Health Administration
UMRA	Unfunded Mandates Reform Act
USDA	U.S. Department of Agriculture

Introduction

Each year, federal agencies establish or revise rules and regulations designed to promote, among other purposes, public health and safety and environmental quality. According to the Office of Management and Budget (OMB), these regulations produce great benefits but also impose great costs. In 1997, OMB estimated annual benefits of about \$300 billion and annual costs of about \$200 billion for federal regulations in effect at that time. Because of the magnitude of these estimated values, as well as the effect of the rules on individuals, firms, industries, and government agencies, the executive branch and the Congress require federal agencies to prepare and use economic analyses—also called regulatory impact analyses—in their regulatory decision-making process. These analyses are intended to inform and improve the regulatory process by estimating the likely benefits and costs of feasible alternatives and identifying the alternative that has the greatest net benefits (benefits minus costs). Although the weight that the analyses should receive in the decision-making process is the subject of some disagreement, the analyses themselves are generally recognized as an important and useful tool.

Executive Branch's Efforts to Improve the Regulatory Process

Since 1971, a series of executive orders and directives by OMB have required federal agencies to consider the benefits and costs associated with individual regulations. In February 1981, President Reagan issued Executive Order 12291, which required federal agencies to prepare economic analyses identifying the benefits, costs, and alternatives for all proposed and final major rules that the agencies issued. A major rule was defined as any regulation that was likely to result in (1) an annual effect on the national economy of \$100 million or more; (2) a major increase in costs or prices for consumers, industries, governments, or geographic regions; or (3) significant adverse effects on competition, employment or investments, productivity, innovation, or the international competitive position of U.S. firms. In September 1993, President Clinton issued Executive Order 12866, replacing Executive Order 12291 and directing federal agencies to assess benefits, costs, and alternatives for all economically significant regulatory actions. Under the order, an economically significant regulatory action is one that is likely to result in a regulation that may 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.

Both executive orders designated OMB as the reviewer of proposed regulations and of the economic analyses supporting them. OMB developed

guidance for implementing both orders. Shortly after President Clinton issued Executive Order 12866, OMB convened an interagency group to review the state of the art for economic analyses. The group was co-chaired by a Member of the Council of Economic Advisers and included representatives of all major regulatory agencies. Over 2 years, the group compiled best practices for preparing economic analyses, which OMB published in January 1996 as guidance for implementing the executive order.

OMB's guidance emphasizes that an economic analysis should provide information to allow decisionmakers to determine that

- there is adequate information indicating the need for and consequences of the proposed action;
- the potential benefits to society justify the potential costs, recognizing that not all benefits and costs can be described in monetary or even quantitative terms, unless otherwise prohibited by statute;
- the proposed action will maximize net benefits to society, unless otherwise prohibited by statute;
- when a statute requires a specific regulatory approach, the proposed action will be the most cost-effective; and
- the agency's decision is based on the best reasonably obtainable scientific, technical, economic, and other information.

The Environmental Protection Agency (EPA) and the Department of Transportation (DOT) developed additional guidance to address unique issues their agencies may face in preparing their economic assessments.

Congressional Efforts to Improve the Regulatory Process

Since the late 1970s, the Congress has taken a number of steps to improve the regulatory process and control the costs of regulation. For example, the Congress has enacted several statutes to reduce the costs and burdens of federal regulations, including the Paperwork Reduction Act of 1980, the Regulatory Flexibility Act, the Small Business Regulatory Enforcement Fairness Act of 1996, and the Unfunded Mandates Reform Act of 1995 (UMRA).

UMRA requires agencies to prepare benefit-cost and other analyses—unless prohibited by law—for any regulations imposing mandates likely to result in expenditures of \$100 million or more in any one year either by state, local, and tribal governments in the aggregate or by the private sector alone. Although UMRA's scope and requirements differ from Executive

Order 12866's, both authorities' provisions on economic analysis are very similar. Accordingly, OMB's guidance for implementing the executive order states that "the economic analysis that the agency prepares should also satisfy the requirements of the Unfunded Mandates Reform Act."

The Congress has also considered—but not enacted—other initiatives to reform the regulatory process. Some of the more comprehensive initiatives proposed to establish regulatory budgets; create deadlines for phasing out regulations, programs, and agencies; revise and expand the judicial review of regulatory actions; and require the federal government to reimburse state and local governments for the costs they incur in complying with federal regulations.

Currently, the Congress is considering S. 981, the Regulatory Improvement Act of 1998. Intended to improve the quality of regulatory decision-making, the bill would, among other things, codify many of the requirements of Executive Order 12866 and establish a requirement for independent peer reviews (critical evaluations of technical work products by independent experts) of economic analyses. To make the regulatory process clearer, or more "transparent," to the public, the bill would require agencies to prepare executive summaries for their economic analyses that would succinctly present, among other things, (1) the benefits and costs expected to result from the rule; (2) the benefits and costs of reasonable alternatives considered by the agency; and (3) the key assumptions and scientific or economic information upon which the agency relied.

Related GAO Reviews

GAO has issued a number of reports on economic analyses, peer review, and unfunded mandates. In 1984, we issued a report on EPA's use of economic analyses.¹ To help agency decisionmakers, we recommended that economic analyses include executive summaries that identify (1) all benefits and costs—that is, both those that can be described quantitatively and those that can be described qualitatively; (2) the range of uncertainties associated with the benefits and costs; and (3) a comparison of all feasible alternatives. In April 1997, we revisited this issue and made a similar set of recommendations to EPA to help agency decisionmakers and the Congress better understand the implications of proposed regulatory actions.² In September 1997, we issued a report on the economic analyses prepared by

¹Cost-Benefit Analysis Can Be Useful in Assessing Environmental Regulations, Despite Limitations (GAO/RCED-84-62, Apr. 6, 1984).

²Air Pollution: Information Contained in EPA's Regulatory Impact Analyses Can Be Made Clearer (GAO/RCED-97-38, Apr. 14, 1997).

the Consumer Product Safety Commission in which we recommended that the Commission develop procedures to ensure that its analyses are comprehensive and reported in sufficient detail.³

In 1996, we issued a report on EPA's implementation of peer review,⁴ in which we recommended wider, more consistent implementation of the agency's policy on peer review to enhance the quality and credibility of the agency's decision-making. In response to questions raised at a March 1997 hearing on this issue, we said that, given the uncertainties associated with predicting the future economic effects of various regulatory alternatives, peer review would help to provide the rigorous independent review of economic analyses needed to enhance the quality, credibility, and acceptability of both the economic analyses and the associated regulatory decisions.

In 1998, we issued a report on the Unfunded Mandates Reform Act of 1995.⁵ That report concluded that UMRA has had little effect on agencies' rulemaking actions because the act's requirements (1) do not apply to many large rulemaking actions; (2) allow agencies not to take certain actions if the agencies determine that the actions are duplicative or infeasible; and (3) direct agencies to take actions that they are already required to take.

Most recently, we provided testimony on S. 981.⁶ In that testimony, we concluded that the passage of S. 981 would provide a statutory foundation for such principles as openness, accountability, and sound science in rulemaking. We cautioned, however, that our reviews of current regulatory requirements suggest that even if S. 981 becomes a law, the Congress will need to carefully oversee its implementation to ensure that the principles embodied in the bill are faithfully implemented.

Objectives, Scope, and Methodology

To assist the Senate Committee on Governmental Affairs in carrying out its regulatory oversight responsibilities, the Chairman and the Ranking Minority Member asked GAO to describe (1) the extent to which federal

³Consumer Product Safety Commission: Better Data Needed to Help Identify and Analyze Potential Hazards (GAO/HEHS-97-147, Sept. 29, 1997).

⁴Peer Review: EPA's Implementation Remains Uneven (GAO/RCED-96-236, Sept. 24, 1996).

⁵Unfunded Mandates: Reform Act Has Had Little Effect on Agencies' Rulemaking Actions (GAO/GGD-98-30, Feb. 4, 1998).

⁶Regulatory Reform: Comments on S. 981—The Regulatory Improvement Act of 1998 (GAO/T-GGD/RCED-98-95, Feb. 24, 1998).

agencies' economic analyses incorporate the best practices set forth in OMB's guidance and (2) the agencies' use of these analyses in regulatory decision-making.

To describe the extent to which federal agencies' economic analyses incorporate the best practices set forth in OMB's guidance, we reviewed all analyses prepared for "economically significant"⁷ proposed and final rules issued between July 1996 and March 1997 that addressed environmental, health, and safety matters. Using these selection criteria, we identified 20 proposed and final rules promulgated by five agencies. Nine of these rules were expected to impose mandates likely to result in expenditures of \$100 million or more annually either by state, local, and tribal governments in the aggregate or by the private sector; therefore, the agencies also used these analyses to satisfy UMRA's requirements for economic analyses. Table 1.1 presents the rules, by agency, together with their dates of publication in the Federal Register and the stages in rulemaking when the economic analyses were published.

Table 1.1: Economically Significant Rules Involving Environmental, Health, or Safety Issues Promulgated Between July 1, 1996 and March 30, 1997

Department or agency and office	Title of rule	Date published in the Federal Register	Rulemaking stage
Department of Agriculture			
Farm Service Agency	Conservation Reserve Program—Long-Term Policy	Sept. 23, 1996 Feb. 19, 1997	Proposed Final
Natural Resources Conservation Service	Environmental Quality Incentives Program	Oct. 11, 1996 May 22, 1997	Proposed Final
Animal and Plant Health Inspection Service	Karnal Bunt Disease: Domestic Plant-Related Quarantine	Aug. 2, 1996 Oct. 4, 1996	Proposed Final
Food Safety and Inspection Service	Pathogen Reduction: Hazard Analysis and Critical Control Point (HACCP) Systems ^a	July 25, 1996	Final
Department of Health and Human Services			
Food and Drug Administration	Food Labeling: Nutrition Labeling, Small Business Exemption	Aug. 7, 1996	Final
	Medical Devices: Current Good Manufacturing Practice (CGMP)	Oct. 7, 1996	Final

(continued)

⁷Under Executive Order 12866, an economically significant regulatory action is a substantive action by an agency that is likely to result in a regulation that may 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.

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Department or agency and office	Title of rule	Date published in the Federal Register	Rulemaking stage
	Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents ^a	Aug. 28, 1996	Final
	Substances Prohibited From Use in Animal Food or Feed; Animal Proteins Prohibited in Ruminant Feed	Jan. 3, 1997 June 5, 1997	Proposed Final
Department of Labor			
Occupational Safety and Health Administration	Occupational Exposure to Methylene Chloride ^a	Jan. 10, 1997	Final
Environmental Protection Agency			
Solid Waste and Emergency Response	Financial Assurance Mechanisms for Local Government Owners and Operators of Municipal Solid Waste Landfill Facilities	Nov. 27, 1996	Final
Air and Radiation	Regulation of Fuels and Fuel Additives; Certification Standards for Deposit Control Gasoline Additives ^a	July 5, 1996	Final
	Acid Rain Programs Nitrogen Oxides Emission Reduction Program ^a	Dec. 19, 1996	Final
	Motor Vehicle Emissions Federal Test Procedure Revisions ^a	Oct. 22, 1996	Final
	National Ambient Air Quality Standards for Ozone ^b	Dec. 13, 1996 July 18, 1997	Proposed Final
	National Ambient Air Quality Standards for Particulate Matter ^b	Dec. 13, 1996 July 18, 1997	Proposed Final
	Emission Standards for Locomotives and Locomotive Engines ^a	Feb. 11, 1997	Proposed
	Air Pollution Control; Gasoline Spark-Ignition Marine Engines: New Nonroad Compression-Ignition and Spark-Ignition Engines, Exemptions ^a	Oct. 4, 1996	Final
Pollution Prevention and Toxics	Lead: Requirements for Lead-Based Paint Activities in Target Housing and Child-Occupied Facilities	Aug. 29, 1996	Final

(continued)

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Introduction**

Department or agency and office	Title of rule	Date published in the Federal Register	Rulemaking stage
Department of Transportation			
National Highway Traffic Safety Administration	Federal Motor Vehicle Safety Standards; Child Restraint Systems; Tether Anchorages for Child Restraint Systems; Child Restraint Anchorage System ^a	Feb. 20, 1997	Proposed
	Federal Motor Vehicle Safety Standards: Occupant Crash Protection (Air Bag Depowering)	Jan. 6, 1997 Mar. 19, 1997	Proposed Final

^aRule also triggers UMRA's requirement for economic analysis. ^bEPA maintains that it was not required to prepare economic analyses under UMRA for these rules even though they come within UMRA's scope because (1) UMRA requires the preparation of economic analyses for covered rules unless otherwise prohibited by law; (2) the Clean Air Act prohibits EPA from considering costs in setting these health-based standards; and (3) the Conference Report for UMRA states that if the agency is prohibited by law from considering the estimate or analysis, it need not prepare one under UMRA.

We reviewed the analyses to describe the extent to which they incorporated the best practices recommended by OMB's guidance. Specifically, we examined the analyses' treatment of alternatives, benefits and costs, uncertainty, and assumptions, as well as of the requirement for full disclosure. We did not, however, verify the accuracy of the data used in the analyses. Although OMB's guidance did not discuss the use of executive summaries or peer review, we also determined whether the analyses contained executive summaries or underwent peer review. We verified our findings through interviews with agency officials who were responsible for preparing the analyses.

To describe how the agencies used the economic analyses in regulatory decision-making, we interviewed agency officials with decision-making responsibility for the 20 rules to obtain more detailed explanations of how the analyses were used. Because our scope involved rules that had already progressed to the proposed or final rulemaking stages, we were unlikely to address situations in which an economic analysis resulted in a determination not to regulate or significantly alter the regulation under consideration. To account for this limitation, we asked agency officials if they were aware of other regulatory actions outside our scope in which an analysis played an important role in withdrawing or significantly altering a regulatory initiative.

We conducted this review between April 1997 and April 1998 in accordance with generally accepted government auditing standards.

Economic Analyses Incorporated Best Practices to Varying Degrees, and Some Lacked Full Disclosure

OMB's guidance sets forth best practices for federal agencies to consider in preparing economic analyses. Although incorporating these best practices can provide valuable information, the guidance recognizes that economic analyses cannot be written according to a formula. Accordingly, it gives agencies the flexibility to use their professional judgment in deciding how thorough their analyses should be. At the same time, the guidance stresses the importance of full disclosure. Therefore, in this review of the extent to which 20 economic analyses incorporated OMB's best practices, we focused not only on which best practices were included but also on whether and how clearly the agencies' methods were explained.⁸

Some of the 20 economic analyses that GAO reviewed did not incorporate the best practices set forth in OMB's guidance. For example, the 20 economic analyses varied in the number and range of alternatives considered; the degree to which benefits and costs were described—in monetary, quantitative, or qualitative terms—for the proposed action and alternatives; the degree to which assumptions and key variables were explained; and the ways in which uncertainty was accounted for in the analyses' conclusions. In some instances, the analyses provided only a limited discussion of alternatives or other best practices. Additionally, when the analyses omitted or only partially incorporated OMB's best practices, they typically did not explain the reasons for these omissions. This lack of explanation is not consistent with the principle of full disclosure. Furthermore, in some instances, the lack of full disclosure obscured the thoroughness of an agency's efforts and/or the constraints on the agency's time or resources. In these instances, full disclosure would have enhanced the reader's understanding and the credibility of the analyses.

The clarity of the 20 analyses varied, making it difficult for readers to determine whether or where OMB's best practices were considered. Some of the analyses contained executive summaries, while others relied on the preambles to the proposed and final rules, published in the Federal Register, to summarize their results. GAO has recommended, and S. 981 would require, the inclusion of an executive summary in an economic analysis to clarify an agency's approach and emphasize the key points of the analysis. Only one of the analyses underwent an independent peer

⁸As mentioned in ch. 1, OMB's guidance applies to economic analyses prepared in response to the requirements of UMRA as well as of Executive Order 12866. Because agencies rarely prepare separate analyses when UMRA is applicable (only one of the nine regulations we selected that came within the scope of UMRA had a separate analysis), our findings reflect the extent to which the nine analyses called for under UMRA satisfy the act's as well as the executive order's requirements for economic analyses.

review. GAO has recommended, and S. 981 would require, the use of peer review to help ensure both the quality and the credibility of an analysis.

Analyses Varied in Incorporating Best Practices and Did Not Always Provide Reasons for Omissions

OMB's guidance describes in detail how economic analyses should consider alternatives, benefits, costs, assumptions, uncertainty, and other factors. This guidance is consistent with standard economic principles, and incorporating its recommended practices into economic analyses could provide valuable information on the benefits and costs of regulatory alternatives. Nonetheless, the guidance also notes that the amount of analysis required depends on the "importance and complexity" of the regulatory issue, as well as on the time available for analysis. In some instances, the need to respond to an emergency or meet a statutory deadline may limit an analysis. The guidance also identifies the "nature of the statutory language and the extent of statutory discretion" as important in determining how much analysis is needed. In particular, the guidance maintains that "a less detailed or intensive analysis of the entire range of regulatory options is needed when regulatory options are limited by statute." For example, the statute directing the Food and Drug Administration (FDA) to exempt small businesses from certain food labeling requirements was so prescriptive that agency officials described the implementing regulations as little more than a photocopy of the law. Nevertheless, the guidance also states that even when such limitations apply, agencies should provide some analysis of alternatives to provide decisionmakers with information for judging the consequences of statutory constraints. Finally, the guidance recognizes that practical considerations, such as constraints on resources, may limit the scope of an analysis.

OMB's guidance allows agencies to exercise their professional judgment in deciding how thorough their analyses should be. At the same time, it stresses the importance of full disclosure in presenting the analyses. Furthermore, when agencies depart from the best practices, the guidance directs them to explain why they have chosen to do so.

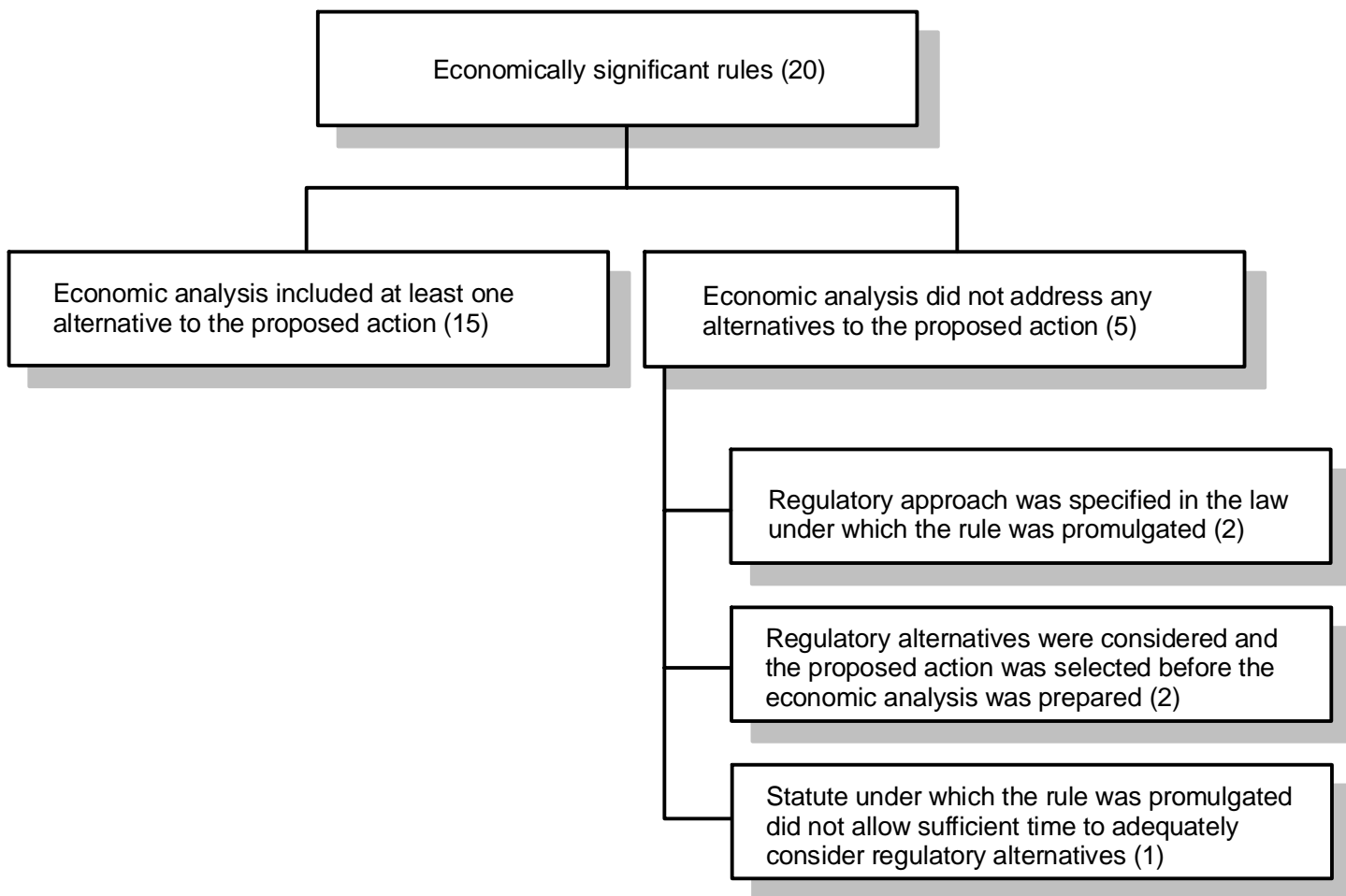
The 20 economic analyses that we reviewed varied in the extent to which they considered alternatives, described benefits and costs, explained key variables, and accounted for uncertainty. Although this variation reflects the flexibility inherent in OMB's guidance, the frequent absence of an agency's rationale for omitting or paying limited attention to certain best practices was not consistent with OMB's guidance.

Analyses Considered
Alternatives to Varying
Degrees

According to OMB, a key goal of an economic analysis in rulemaking is to determine what degree of regulation is needed to maximize net benefits. An economic analysis cannot determine whether net benefits are maximized unless it considers the most important regulatory alternatives or, in the words of the Executive Order, “potentially effective and reasonably feasible alternatives.” Therefore, a complete analysis considers a range of alternatives, measures the benefits and costs of each, and determines which one achieves the greatest net benefits.

In 15 of the 20 analyses that we reviewed, the agencies included at least one alternative to the proposed action, but in some instances, discussion of the alternative was limited. The five other analyses did not indicate why alternatives were not discussed. Agency officials told us that, in preparing two analyses, they considered alternatives but did not discuss them in the analyses. In preparing the three remaining analyses, agency officials told us they did not consider alternatives to the proposed actions either because the authorizing statute (1) specified the regulatory approach to take or (2) did not provide enough time to consider regulatory alternatives. Figure 2.1 summarizes our findings.

Figure 2.1: Economic Analyses' Consideration of Alternatives



Agency officials provided us with reasons for not discussing or considering alternatives in the analyses. These reasons—including the specificity of, or the time constraints imposed by, the authorizing statute—are among those that OMB’s guidance cites as legitimate constraints on an agency’s consideration of alternatives. Although the guidance states that these can be legitimate reasons limiting the consideration of alternatives, it also states that even when such limitations apply, agencies should provide some analysis of alternatives to provide

decisionmakers with information for judging the consequences of statutory constraints. In addition, we noticed that agencies did not always document in their analyses why they did not discuss or consider alternatives in the analyses. For example, for one analysis, EPA initially considered two alternatives for implementing a regulation on certification standards for detergents added to gasoline to reduce emissions. One alternative specified the steps manufacturers should take to comply with the regulation; the other established performance-based standards and allowed the manufacturers to decide how they would achieve the standards. Because Executive Order 12866 and OMB's guidance favor performance-based regulations over command-and-control regulations, EPA dismissed the command-and-control alternative before preparing the analysis and discussed only the performance-based alternative in the analysis. FDA's regulation exempting small businesses from certain food-labeling requirements also included no alternatives and provided no explanation for this departure from OMB's guidance. FDA officials told us, however, that the legislation setting forth the exemptions was so specific that no alternative to the proposed action was feasible.

The 15 analyses that included at least one alternative also varied in the attention given to the alternative or alternatives that were considered and rejected. For example, the analysis for the regulation on adolescents' use of tobacco examined six regulatory alternatives but contained only a few paragraphs on the five that were ultimately rejected. According to the responsible officials, FDA gathered and reviewed data for all six alternatives, and experts evaluated each one before FDA proposed an action. The final economic analysis did not reflect the thoroughness of FDA's review. A more thorough discussion of the alternatives would have enabled the reader to better understand why the agency chose the proposed action.

Analyses Varied in Their Treatment of Benefits and Costs

According to OMB, an economic analysis should measure the benefits and costs of the proposed action and of the alternatives in comparable terms to ensure an accurate determination of net benefits. The benefits and costs should be measured against a baseline, preferably in numerical terms. A baseline generally describes the condition that is expected to exist without the regulation and provides a standard for measuring the incremental benefits and costs of each alternative. When possible, dollar values should be assigned to benefits and costs to enhance the consideration of regulatory alternatives that may produce equal or greater benefits at lower costs. However, if dollar values cannot be assigned, the benefits and costs

should be expressed in consistent quantitative or qualitative terms. Although completeness is desirable, OMB's guidance recognizes that accurate data may not always be available for estimating benefits and costs and that agencies may not have the resources or the time to estimate values for every alternative.

All 20 Analyses Included
Baseline Information

In the 20 economic analyses that we reviewed, the baseline was either explicitly identified or was implicit within the context of the analysis. In these later analyses, the use of a baseline was more difficult to discern but was evident after some review. For example, the analysis for the U.S. Department of Agriculture's (USDA) rule on mandatory controls to reduce foodborne illness from meat and poultry did not explicitly identify a baseline. However, our review of the analysis indicated that costs were indeed measured relative to a baseline because they reflected the costs of the manufacturing controls that would be put in place after the regulation became operative.

FDA's regulation to restrict adolescents' use of tobacco describes the baseline quantitatively in terms of the number of adolescents who, in the absence of additional regulation, would be likely to start smoking each year—estimated to be 1 million under the age of 18. Although the analysis does not assign a dollar value to the costs of the baseline, it does quantify the effects of cutting the number of underage smokers in half, calculating how many fewer adults would smoke, how many deaths would be avoided, and how many life-years would be saved. The analysis then assigns dollar values to these benefits and concludes that the total monetary value of a 50-percent reduction in adolescents' use of tobacco would be between \$28 billion and \$43 billion at a 3-percent discount rate or between \$9 billion and \$10 billion at a 7-percent discount rate.

Analyses Estimated Some
Benefits and Costs

All 20 economic analyses that we reviewed estimated benefits in some terms—whether monetary, quantitative or qualitative. Fourteen⁹ of the analyses assigned dollar values to some benefits. Seven of these analyses assigned dollar values to benefits for both the proposed action and at least one alternative, while the other seven assigned dollar values only for the proposed action. The analyses that did not assign dollar values to benefits did not document their reasons for omitting this element of OMB's

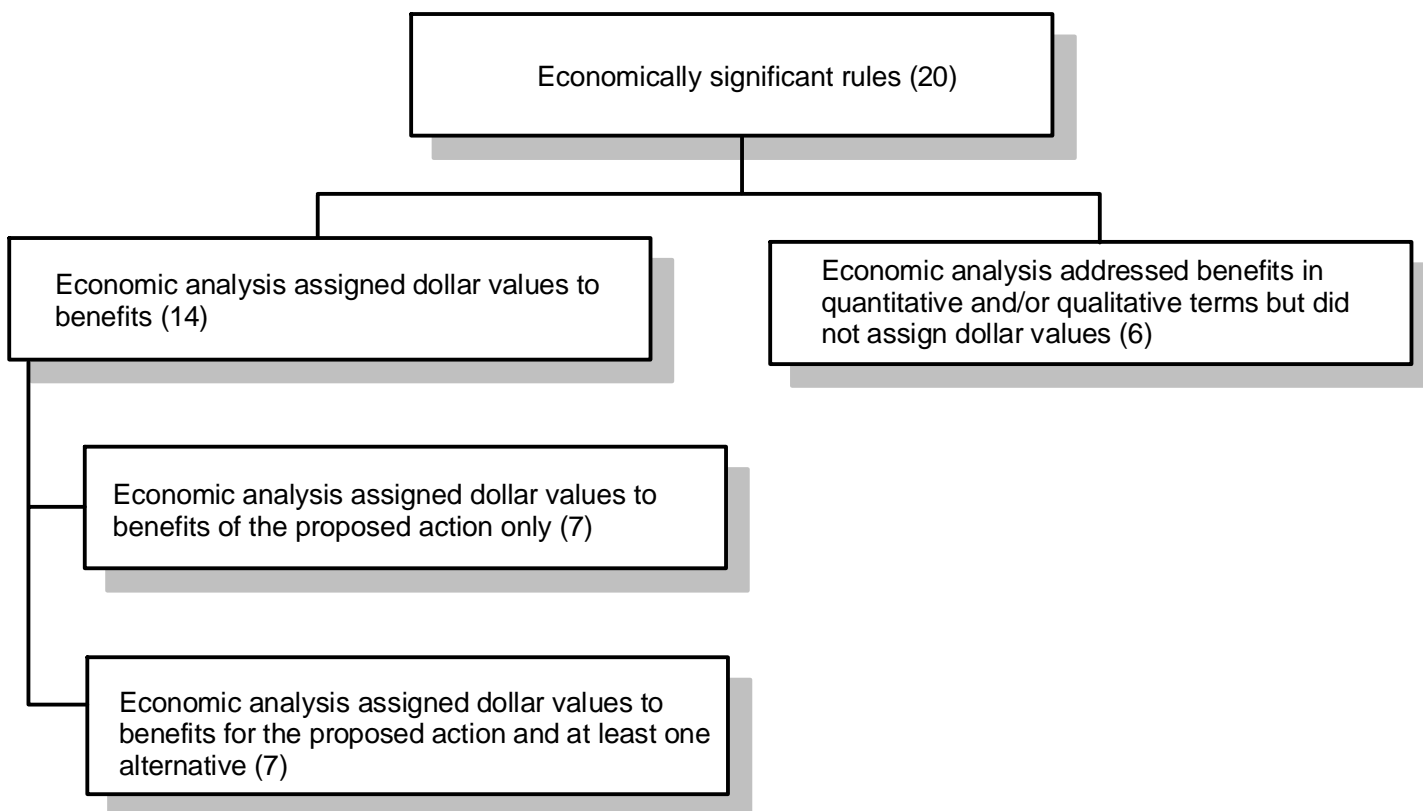
⁹For 1 of these 14 analyses—on lead-based paint abatement activities in certain housing and child-occupied facilities—no data were available to estimate the incremental benefits of the training required for certification and to compare these benefits with the incremental costs of the rule. Consequently, EPA decided to estimate the total benefits of lead paint abatement work and compare these benefits with the incremental costs of the rule in a break-even type of analysis, since these figures were not appropriate for a net benefit analysis.

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guidance. Furthermore, only six analyses specifically identified net benefits (benefits remaining after costs have been accounted for)—a key element in OMB’s guidance. Executive Order 12866 emphasizes that agencies should select approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity), unless a statute requires another regulatory approach.¹⁰

Figure 2.2 shows the extent to which the 20 analyses assigned dollar values to benefits.

Figure 2.2: Economic Analyses’ Assignment of Dollar Values to Benefits



¹⁰Distributive impacts (or equity) indicate how the benefits and costs of a proposed regulatory action are distributed across individual members or groups or classes in society. While recognizing that distributive impacts and equity are important considerations in making decisions, economists sometimes treat them separately from net benefits.

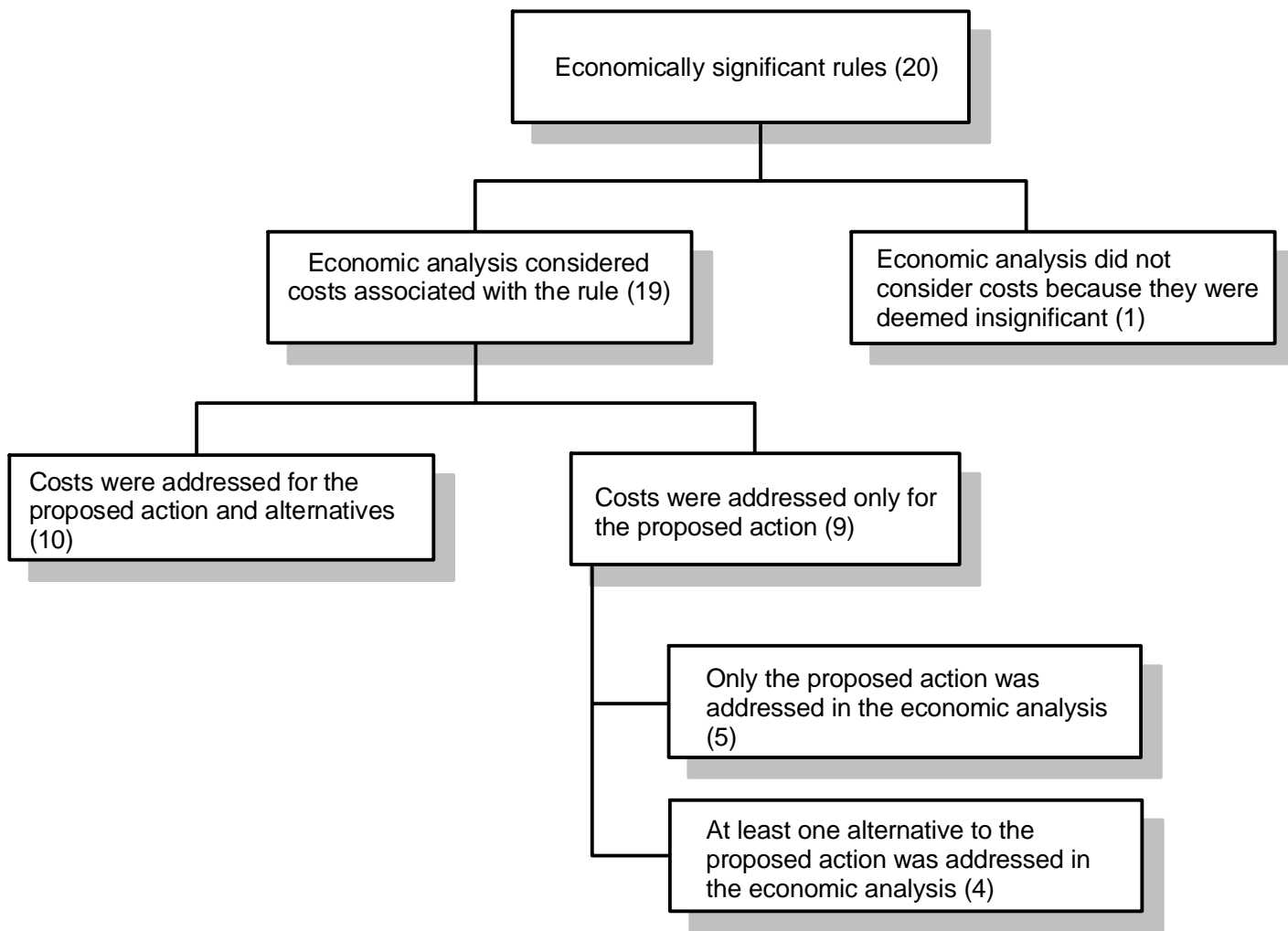
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Agencies assigned dollar values to different types of benefits, including health benefits and costs saved. For example, EPA's analyses for regulations on ozone and particulate matter assigned dollar values to health and other benefits gained through reductions in exposure to these two substances. These benefits included life-years saved and increases in crop yields. EPA's analysis for a regulation on landfills assigned dollar values to the cost savings achieved by using two new, less expensive methods of providing financial assurance. EPA estimated these savings by subtracting the costs of using the new methods from the costs of using the current method and determining the dollar savings. Finally, FDA's analysis for a regulation on ensuring disease-free animal feed assigned dollar values to the costs avoided by not having to destroy cattle.

Agencies' analyses described benefits in quantitative or qualitative terms, sometimes in combination with dollar values. For example, EPA's analysis for a rule on gas certification standards assigned dollar values to fuel consumption benefits, quantified emission reduction benefits, and qualitatively described improvements in maintenance. Four other EPA analyses—those for regulations on federal engine-testing procedures, locomotives, acid rain and nitrogen oxides, and marine engines—also quantified emission reduction benefits. The analysis for the rule on marine engine emissions qualitatively described other improvements in air quality. Other benefits that were described in quantitative or qualitative terms included reductions in fatalities due to accidents, deaths avoided through reductions in exposure to cancer-causing agents, reductions in injuries and impairments, and improvements in health.

Nineteen of the 20 analyses that we reviewed assigned dollar values to some costs. However, nine of the analyses estimated dollar values only for the proposed action. Four of these nine analyses discussed at least one other alternative but did not assign dollar values to them, while the other five did not discuss any alternatives to the proposed action. Figure 2.3 shows how the 20 analyses assigned dollar values to costs.

figure 2.3: Economic Analyses' Assignment of Dollar Values to Costs



Analyses Differed in Treatment of Assumptions and Uncertainty

To determine the present value of future benefits and costs, analysts apply a discount rate. When attempting to estimate the dollar value of benefits for regulations anticipated to extend or save lives, they may use the value of a “statistical life.”¹¹ And to help quantify the effect of uncertainty on benefit and cost estimates, they may use sensitivity or other types of

¹¹A “statistical life” is the product of (1) one minus the estimated probability of death, given no remediation of the problem that the regulation is supposed to correct, and (2) the size of the affected population.

Key Variables Differed, and
Reasons for Differences Were
Not Stated

analyses.¹² Although OMB's guidance provides agencies with flexibility in selecting assumptions and treating uncertainty, the guidance stresses that agencies should explicitly identify the assumptions underlying their economic analyses and the uncertainty associated with the resulting estimates. The economic analyses we reviewed often were not explicit on these matters.

Many economic analyses rely on assumed values of key variables, such as the discount rate and the value of a statistical life, to estimate the benefits and costs of regulations. In economic analyses, the discount rate is the interest rate used to determine the present value of future benefits and costs. The statistical value placed on a human life greatly affects estimates of benefits gained through improvements in safety, reductions in exposure to harmful substances, and other types of health benefits. For analyses that do not estimate values over time, a discount rate is not relevant. Similarly, for analyses that do not consider the impact of regulatory alternatives on human health or safety, the statistical value of a human life is not relevant.

Of the 20 analyses that we reviewed, 15 used one or more discount rates, which ranged from 2.1 percent to 10 percent. While OMB recommends a 7-percent discount rate (adjusted for inflation) for economic analyses, the guidance allows agencies to use different rates if justified. The majority of the 15 analyses that used a discount rate followed OMB's recommendation. The five analyses that did not use a discount rate did not explain why they did not do so. A discount rate was not used because (1) benefits and costs were estimated over only 1 year or (2) dollar values were not assigned to either benefits or costs.

For 6 of the 20 analyses, a reduction in the risk of mortality was a benefit associated with the rule, and a dollar value was, therefore, assigned to a statistical human life for the purpose of calculating benefits. The value of this statistical life varied in the six analyses, ranging from \$1.6 million to \$5.5 million, as indicated in table 2.1. OMB's guidance does not prescribe any particular value for agencies to use and allows for a variety of approaches to estimate the benefits of a reduction in the risk of mortality, including both explicit and implicit valuation methods. In each of the six analyses, the agency fully explained the basis for the assigned value. For the analysis for the lead paint rule, EPA estimated the mean value of a statistical life from 26 selected studies.

¹²A sensitivity analysis assigns a variety of numerical values to key parameters, such as the discount rate, to see how sensitive the benefit and cost estimates are to these different values.

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Table 2.1: Dollar Value Assigned to Human Life

Dollars in millions	
Analysis for rule	Assigned value
Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems	\$1.6
Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents	\$2.5
National Ambient Air Quality Standards for Ozone	\$4.8
National Ambient Air Quality Standards for Particulate Matter	\$4.8
Medical Devices: Current Good Manufacturing Practice	\$5.0 ^a
Lead; Requirements for Lead-Based Paint Activities in Target Housing and Child-Occupied Facilities	\$5.5

^aThe economic analysis for this regulation did not assign a specific value to human life. However, the preamble to the rule published in the Federal Register estimates this value at \$5.0 million.

Of the 14 analyses that did not assign a dollar value to human life, 11 did not identify a reduction in the risk of mortality as a benefit; therefore, a value for life was not applicable. The three other analyses that did have an impact on the risk of mortality were prepared by the National Highway Traffic Safety Administration and the Occupational Safety and Health Administration (OSHA). According to agency officials, the agency does not assign an explicit dollar value to human life or suffering in its analyses because it believes that such a value conveys a false sense of precision and is morally objectionable. Instead, the agencies prefer to describe benefits quantitatively in terms of fewer deaths, injuries, or illnesses.

Majority of Analyses Acknowledged Some Uncertainty

Uncertainty may arise from lack of data, variability in populations or natural conditions, limitations in fundamental scientific knowledge (both social and natural) that result in lack of knowledge about key relationships, or the fundamental unpredictability of certain phenomena. While recognizing that the effects of regulatory actions are often uncertain, OMB's guidance observes that the probability of their occurrence can, in some instances, be predicted through the use of appropriate statistical techniques. In other instances, when different assumptions are plausible, sensitivity analyses can be used to test the impact of the differences.

For 15 of the 20 regulations, the economic analyses or other related documents acknowledged the uncertainty associated with estimates of benefits and/or costs. Seven of the 15 economic analyses used sensitivity

analysis to evaluate the impact of different assumptions on the estimates, and eight of the analyses discussed uncertainties either qualitatively or in terms of ranges of estimates. The five analyses that did not discuss uncertainties did not document the agencies' reasons for not doing so.

FDA's economic analysis for the regulation to restrict adolescents' use of tobacco illustrates the role of sensitivity analysis in regulatory decision-making. For this analysis, FDA assigned dollar values to the health benefits that it estimated would result from reducing, by varying percentages, the number of adolescents who currently use tobacco, assuming a 3-percent discount rate. It estimated that a 50-percent reduction in the number of adolescent smokers would produce annual benefits of \$28.1 billion to \$43.2 billion, while a 5-percent reduction would produce annual benefits of \$2.8 billion to \$4.3 billion. Under either scenario, the estimated annual benefits would vastly outweigh the estimated annual costs of complying with the regulation—\$149 million to \$185 million. Although FDA did not identify a single-value "best estimate" for anticipated net benefits, it did provide a best estimate for reductions in tobacco use from a range of possibilities. Three other analyses also identified some types of best estimates from the range of estimates presented.

Analyses Did Not Provide a Rationale for Omitting Best Practices

While the 20 analyses that we reviewed generally incorporated elements of OMB's guidance to some degree, they seldom accounted for omissions, even when these omissions were consistent with the flexibility inherent in the guidance. As table 2.2 indicates, we found 36 instances in which best practices were not included in the analyses. Although agency officials told us that specific best practices were not relevant in 16 of these instances, these reasons were not provided in the economic analyses themselves. Overall, in only 1 of these 36 instances did the analysis fully disclose why the practice was omitted.

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Table 2.2: Extent to Which Economic Analyses Provided Reasons for Not Incorporating Elements of OMB’s Guidance

Recommended element	Did not incorporate element	Provided reason for not incorporating element
Discuss at least one alternative	5	0
Assign dollar values to some benefits	6	0
Assign dollar values to some costs	1	1
Acknowledge uncertainties	5	0
Assign a value to human life	14 ^a	0
Use a discount rate	5 ^b	0

^aElement was not relevant for 11 of these analyses, and agency’s policy prohibited assigning a value to human life for other 3 analyses.

^bElement was not relevant for these analyses.

Source: GAO’s analysis of 20 economic analyses.

Guidance Could Do More to Ensure Full Disclosure, and Peer Review Could Strengthen Analyses’ Credibility

The clarity of the 20 analyses that we reviewed varied, making it difficult for the reader to determine whether or where particular elements of OMB’s guidance were incorporated. While about half of the analyses included some form of summary, the other half used the preambles to the rules to summarize key information. Because only one of the analyses was submitted for an independent peer review, most of the analyses did not benefit from the enhanced credibility that such a review could have conferred.

Executive Summaries Frequently Not Provided

Twelve of the 20 analyses contained an executive summary that clearly and concisely summarized the reports’ major findings and eight did not. In general, when agencies did not provide an executive summary, they relied on the preamble to the final or proposed rule, published in the Federal Register, to summarize the results of their work. In terms of full disclosure, the preambles were subject to the same limitations as the analyses.

As we have noted in prior reviews of EPA’s economic analyses,¹³ the lack of a summary in an economic analysis restricts the ability of the Congress, the public, and at times the decisionmakers to quickly identify key issues

¹³Cost-Benefit Analysis Can Be Useful in Assessing Environmental Regulations, Despite Limitations (GAO/RCED-84-62, Apr. 6, 1984) and Air Pollution: Information Contained in EPA’s Regulatory Impact Analyses Can Be Made Clearer (GAO/RCED-97-38, Apr. 14, 1997).

and to be fully informed. Accordingly, we recommended to EPA that its economic analyses should, to the extent possible, include executive summaries that identify (1) all benefits and costs—even those that cannot be quantified; (2) the range of uncertainties associated with the benefits and costs; and (3) a comparison of feasible alternatives. S. 981 would require agencies to include an executive summary in the economic analyses. The summary would include, among other things, (1) the benefits and costs expected to result from the rule, (2) the benefits and costs of reasonable alternatives considered by the agency, and (3) the key assumptions and scientific or economic information on which the agency relied.

Analyses Did Not Undergo Peer Review

Only 1 of the 20 analyses that we reviewed was submitted for peer review—independent experts’ critical evaluation of scientific or technical work products. While OMB does not require agencies to submit their analyses for external peer review, the Administrator of OMB’s Office of Information and Regulatory Affairs testified in September 1997¹⁴ that the administration supports peer review but recognizes that it is not cost-free, in terms of an agency’s resources or time. Of the five agencies whose analyses we reviewed, only EPA has a formal peer review policy in place.

GAO is on record in support of peer review for important economic analyses. At a March 1997 hearing on peer review at EPA, we said that “given the uncertainties associated with predicting the future economic impacts of various regulatory alternatives, the rigorous, independent review of economic analyses should help enhance the products’—and the associated agency decisions’—quality, credibility, and acceptability.”

EPA’s peer review policy, issued in 1994, applies to major scientific or technical work products that may affect policy or regulatory decisions. Each office is to develop procedures for implementing the policy that include preparing a list of products for peer review during the upcoming year and documenting the status of products previously nominated. The policy is somewhat flexible, noting that statutory and court-ordered deadlines, resource limitations, and other constraints may limit or even preclude the use of peer review. Accordingly, the policy calls for different levels of peer review, depending upon these constraints, as well as the products’—and associated decisions’—complexity and sensitivity. Factors

¹⁴Statement of Sally Katzen, Administrator, Office of Information and Regulatory Affairs, OMB, before the Senate Committee on Governmental Affairs (Sept. 12, 1997).

to take into account in making decisions about peer review include whether or not the product

- establishes a significant precedent, model or methodology;
- addresses significant controversial issues;
- focuses on significant emerging issues;
- has significant cross-agency/interagency implications;
- involves a significant investment of the agency's resources;
- considers an innovative approach for a previously defined problem/process/methodology; or
- satisfies a statutory or legal mandate for peer review.

Under the policy, soliciting stakeholders' involvement or public comment is not a substitute for peer review, which is intended to solicit the independent, objective views of experts. While these experts may be internal or external to the agency, EPA's revised guidance on peer review¹⁵ states that external peer reviewers are generally preferred. Regardless of their relationship to the agency, the reviewers should be unbiased (i.e. have not contributed to the product's development or have a material stake in the outcome of the review) and have appropriate expertise. The guidance also notes that in some circumstances, peer review may not be needed or may not be possible. For example, products that are primarily based on work that was previously peer reviewed can generally forgo additional peer review. According to the guidance, "in a few instances, statutory and court ordered deadlines and other time constraints may limit or preclude peer review." However, the guidance emphasizes that agency officials should "make every attempt possible to assure that peer review of major work products occurs taking into account these deadlines." The guidance also provides discretion in determining the timing and frequency of peer review, noting that different products warrant differing timing and frequency. A common approach is to have a single peer review when the final draft product becomes available. The guidance also states that the final product should incorporate the peer reviewers' comments or state why these comments are not incorporated.

EPA acknowledges that its implementation of the policy has been uneven, and it has taken steps to better ensure that the policy is understood, used, and considered more seriously. In response to recommendations we made in 1996, EPA has agreed to adopt steps to ensure that all major products are considered for peer review and to identify individual products that are not

¹⁵Science Policy Council Handbook: Peer Review (EPA 100-B-98-001, Jan. 1998).

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selected for review.¹⁶ EPA officials told us that they were considering peer reviews for some economic analyses in the future.

Officials at the agencies we visited acknowledged that peer review could improve the quality and credibility of economic analyses. For example, USDA officials told us that the results of peer reviews provide useful, ongoing guidance for economic analyses prepared for similar types of proposals. However, a number of officials incorrectly identified the process of seeking public comment through the publication of proposed or final rules in the Federal Register as a form of external peer review. Other officials maintained that submitting many of the analyses we reviewed for peer review would have delayed their publication and increased their costs but might not have added value. A common theme among the agencies was that statutory directives, time constraints, and limited resources precluded them from submitting their economic analyses to external experts for peer review. Some officials also believed that they might have difficulty finding independent reviewers with the necessary expertise.

According to a panel of leading economists, peer review should be used for economic analyses supporting regulations with a potentially large impact on the economy. The panelists recommended that the reviewers be selected on the basis of their expertise and reputation. The panel also recommended that agencies use a standard format to present their results, including a summary highlighting key results and uncertainties.¹⁷ A recent report by the Presidential/Congressional Commission on Risk Assessment and Risk Management also supported the use of peer review for key economic documents.¹⁸ In a recent article co-authored by EPA's Associate Assistant Administrator for Policy, Planning, and Evaluation, the authors stressed the importance of conducting economic analyses in a more open manner, involving outside experts and stakeholders. They also suggested that despite time constraints, such outside involvement could occur more often if economic analyses were initiated at the beginning of the rulemaking process.¹⁹

¹⁶Peer Review: EPA's Implementation Remains Uneven (RCED-96-236, Sept. 1996).

¹⁷Arrow, Cropper, et al., Benefit-Cost Analysis in Environmental, Health, and Safety Regulation: A Statement of Principles (1996).

¹⁸Risk Assessment and Risk Management in Regulatory Decision-Making, The Presidential/Congressional Commission on Risk Assessment and Risk Management (1997).

¹⁹"Economic Analysis: Benefits, Costs, Implications," Economic Analyses at EPA: Assessing Regulatory Impact (1997).

Conclusions

Agencies' economic analyses sometimes omitted best practices recommended by OMB's guidance. While agencies have taken advantage of the flexibility that OMB's guidance gives them to use their professional judgment in deciding how thorough their analyses should be, they often have not documented the reasons why they omitted best practices recommended by the guidance—even when their reasons are among those that OMB has identified as legitimate for limiting an analysis. Full disclosure would be consistent with the guidance and would provide decisionmakers with information for judging the consequences of statutory constraints. Thus, full disclosure could generally enhance the credibility of the analyses. Similarly, including executive summaries with the analyses would help to highlight and succinctly present the key points supporting the agency's regulatory decision. Although independent reviews by internal or external experts may not be warranted for all economic analyses, such reviews could enhance both the quality and the credibility of the analyses.

Recommendations

To facilitate full disclosure and add credibility to the economic analyses required for regulatory decision-making, we recommend that the Director, Office of Management and Budget, amend the Office's guidance to include additional elements, the latter two of which are reflected in S. 981. Specifically, we recommend that the guidance be amended to provide that economic analyses should

- address all of the best practices identified in OMB's guidance or state the agency's reasons for not addressing them;
- contain an executive summary that briefly and concisely (1) identifies all benefits and costs—both those that can be described quantitatively and those that can be described qualitatively; (2) describes the range of uncertainties associated with the benefits and costs; and (3) compares the reasonable alternatives considered by the agency; and
- undergo an appropriate level of internal or external peer review by independent experts and state the agency's basis for selecting that level.

Agency Comments

We provided a draft of this report for comment to OMB and the five agencies that prepared the economic analyses we reviewed: USDA, FDA, EPA, DOT, and OSHA. We received comments from all of the agencies except OSHA, which informed us that it had no comments on the draft report. Most of the comments we received involved editorial or technical clarification issues, which we incorporated throughout the report as appropriate.

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The agencies agreed with our findings and recommendations concerning the need for economic analyses to address OMB's best practices and include executive summaries. However, all of the agencies raised issues related to our recommendation on peer review. While USDA agreed with us that peer review is generally appropriate and useful, the Department maintained that using peer reviewers from within the agency is frequently more timely and cost-effective. Accordingly, USDA asked us to clarify what constitutes "an appropriate level of peer review." Similar requests for clarification were raised by OMB and DOT. FDA urged us to delete this recommendation altogether, maintaining that a requirement for peer review by experts external to the agency would have minimal benefits and the resource burden would likely preclude the agency from meeting its statutory requirements.

We acknowledge that peer review imposes some time and resource burdens on agencies and that different types of economic analyses warrant different levels of peer review. We believe that EPA's peer review policy addresses this issue well, providing for either internal or external peer review. However, the policy also emphasizes that, as a general rule, the more important, novel, or sensitive the document and the associated regulatory action, the more rigorous the peer review should be. The policy also emphasizes that whether the review is conducted within or outside the agency, two basic requirements must be met: The reviewers must be unbiased, and they must have appropriate expertise. We have clarified the report's discussion and recommendation on peer review to clarify that agencies should be allowed discretion in the level of peer review selected for individual analyses but should also state the basis for selecting that level.

Agencies Often Used Economic Analyses to Identify Cost-Effective Approaches

According to OMB's guidance, economic analyses should play an important role in agencies' regulatory decision-making. Agency officials said that they generally used the analyses in their decision-making, most frequently to help identify the most cost-effective alternative that would fulfill an authorizing statute's mandate. Because our scope involved rules that had already progressed to the proposed or final rulemaking stages, it was unlikely that any of the 20 analyses we reviewed resulted in the reversal of an agency's decision to regulate or led to major revisions to the proposed action. Nonetheless, agency officials told us analyses conducted early in the rulemaking stages sometimes lead to significant changes in agencies' decisions. Agency officials responsible for making regulatory decisions stated that their decisions to regulate frequently respond to specific statutory mandates or perceived emergencies.

OMB's Guidance Urges Agencies to Use Economic Analyses in Decision-Making

OMB's guidance encourages the use of economic analyses in developing regulations, stressing that "good data and good analysis are critical to inform sound decision-making." However, the guidance recognizes that the same factors that may limit the thoroughness of the analyses may also restrict their use. For example, the need to respond to an emergency, meet a statutory deadline, or comply with specific language in an authorizing statute may limit the use of an analysis. According to the guidance, the most critical of these factors is the extent to which the statute affords discretion in selecting regulatory alternatives. But even when the statute limits an agency's discretion, OMB's guidance urges the agency to "provide some analysis of other regulatory options . . . in order to provide decisionmakers with information for judging the consequences of the statutory constraints."

Most Analyses Were Used to Identify the Most Cost-Effective Approach

According to agency officials, nearly all of the economic analyses we reviewed played some role in regulatory decision-making. However, this role was most often limited to identifying and selecting the most cost-effective approach within a predetermined regulatory approach. The analyses rarely led decisionmakers to select a significantly different alternative or fundamentally revise the regulatory proposal under consideration. Table 3.1 summarizes agency officials' views on the primary uses of the 20 economic analyses.

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Agencies Often Used Economic Analyses to
Identify Cost-Effective Approaches**

Table 3.1: Officials' Views on How Economic Analyses Were Used in Regulatory Decision-Making

Use of analysis	Number of analyses
Identify the most cost-effective approach	10
Implement health-based regulations cost-effectively	2
Define regulation's coverage	3
Define regulation's implementation date	1
Defend/document a regulatory decision	2
Reduce health risks at feasible cost	1
Play no role in the regulatory decision	1

Note: Because some of the analyses fall into more than one category, we categorized them according to their primary use, as defined by agency officials.

Source: GAO's analysis.

The following examples show how agencies have used economic analyses in their regulatory decision-making:

- **Identify the most cost-effective approach:** The economic analysis for EPA's proposed rule on emission standards for marine engines estimated manufacturers' compliance costs for different emission standards. According to EPA officials who prepared the analyses and were involved in the decision-making process, the analysis clearly identified the point at which greater reductions in emissions would come at a dramatically higher cost to industry. The EPA decisionmaker for this rule recalled asking her staff why EPA could not set the standards more stringently and being told that the analysis had demonstrated that the proposed standard was the most cost-effective of several alternatives considered.
- **Implement health-based regulations cost-effectively:** In some instances, according to EPA and the courts, regulatory decisions are to be based on health rather than cost or other considerations. In setting primary air quality standards for ozone and particulate matter, EPA maintained that its first responsibility under the law was "to select standards that protect public health" with "an adequate margin of safety." According to EPA's and the courts' interpretation of the Clean Air Act, the setting of these standards is a health-based decision that specifically is not to be based on cost or other economic considerations. Nevertheless, the agency maintains that economic analyses could help inform decisionmakers on ways to implement these health-based standards cost-effectively. In addition, according to EPA, the analyses can inform the public about the potential costs and benefits of implementing the regulations.
- **Define a regulation's coverage:** The Federal Agriculture Improvement and Reform Act of 1996 authorized the Secretary of Agriculture to combine

into one program the functions of several conservation programs that the act rescinded. According to USDA officials involved in the decision-making process, the economic analysis prepared for the implementing rule played “a tremendous role” in defining the “livestock operations” that are covered by the rule. Because the definition of the rule’s coverage was politically contentious, the analysis also provided the agency with a basis for defending its decision.

- Reduce health risks at feasible cost: According to the preamble to OSHA’s rule on methylene chloride, the agency determined, on the basis of new animal and human data, that current standards place employees at “a significant risk of material impairment of health.” The preamble also states that OSHA’s standards must be “highly protective” as long as they are technologically and economically feasible. The preamble then concludes, on the basis of OSHA’s economic analyses, that “the rule is the most cost-effective alternative for implementation of OSHA’s statutory objective of reducing significant risk to the extent feasible.”
- Define a regulation’s implementation date: EPA’s economic analysis for a proposed rule on procedures for testing emissions from motor vehicles incorporated data provided by the automobile industry and led to revisions that gave the industry additional time to implement the final rule. After EPA published an initial cost analysis as part of a proposed rule, the industry questioned the validity of EPA’s data and provided more current data. EPA then adjusted its cost calculations, dropped one component of its proposal, and extended the deadline for implementing the final rule.
- Defend a regulatory decision: According to FDA officials, the economic analysis for a rule on manufacturing medical devices provided the agency with a credible rebuttal to manufacturers’ complaints that compliance costs would be excessive. USDA officials also told us that they sometimes use their analyses to defend controversial regulatory decisions.
- Play no role in the decision-making process: The economic analysis supporting FDA’s final rule exempting small businesses from food-labeling requirements played virtually no role in the decision-making process. Because the authorizing legislation—the 1993 amendments to the Federal Food, Drug, and Cosmetic Act—was so specific about who would be eligible for the exemption, the analysis was not really necessary, FDA officials said.

Statutes Limited the Use of Economic Analyses

According to agency officials, economic analyses are generally used for the purposes summarized in table 3.1 and are less frequently used for deciding whether or not to regulate or for identifying significantly different regulatory approaches. Agency officials told us that statutory mandates

frequently limited their discretion in deciding whether to regulate and/or in selecting alternative regulatory approaches. In one instance, the statute was so specific that officials described the rule as not much more than a photocopy of the law. In addition, officials cited instances in which the agency believed that it had little discretion or time to react to an emergency situation. The following are some of the other instances cited by agency officials in which the agency issued regulations in response to statutory directives or emergencies:

- In the Clean Air Act Amendments of 1990, the Congress directed EPA, within 18 months, to review and revise as necessary its regulations on testing motor vehicles and engines to ensure that the tests reflect actual, current driving conditions, including conditions related to fuel, temperature, acceleration, and altitude. Because the agency concluded that the current test procedures had shortcomings in representing, among other things, aggressive driving, rapid speed fluctuations, and the use of air conditioning, EPA decided new regulations were warranted.
- The National Highway Traffic Safety Administration Authorization Act of 1991, among other things, directed the Secretary of Transportation to determine whether additional regulations were needed to ensure the safety of child seats used in motor vehicles. In studying this issue, DOT concluded that because so many different types of seat belts were in use, the child restraints were difficult to attach correctly to improve safety. Accordingly, the Department proposed a regulation requiring the use of a specific attachment system. The proposed rule noted that there were data gaps in the economic analyses and stated that if new information became available, DOT would consider other possible alternatives.
- USDA issued emergency quarantine regulations after the Karnal Bunt disease was detected in Arizona and California. The regulations were issued about 6 months before the economic analysis was completed and published. Karnal Bunt is a serious fungal disease that can affect both the yield and quality of wheat. Although it does not present a risk to human or animal health, it makes wheat taste like fish and can dramatically affect wheat sales at home and abroad. Many countries prohibit the import of wheat from countries where Karnal Bunt is known to exist. Although the economic analysis played no role in the initial quarantine, USDA officials told us that it was useful in later decisions about the number and location of acres subject to the quarantine.

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