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REPORT
104–89

COMPREHENSIVE REGULATORY REFORM ACT OF 1995

R E P O R T

OF THE

COMMITTEE ON GOVERNMENTAL AFFAIRS UNITED STATES SENATE

TO ACCOMPANY

S. 343

together with

ADDITIONAL VIEWS

TO REFORM THE REGULATORY PROCESS, AND FOR OTHER PURPOSES

MAY 26 (legislative day, MAY 15), 1995.—Ordered to be printed

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COMPREHENSIVE REGULATORY REFORM ACT OF 1995

MAY 26 (legislative day, MAY 15), 1995.—Ordered to be printed

Mr. ROTH, from the Committee on Governmental Affairs, submitted the following

REPORT

together with

ADDITIONAL VIEWS

[To accompany S. 343]

The Committee on Governmental Affairs, to which was referred the bill (S. 343) to reform the regulatory process, to make Government more efficient and effective, and for other purposes, having considered the same, reports favorably thereon with an amendment in the nature of a substitute and unanimously recommends that the bill as amended do pass.

I. PURPOSE AND SUMMARY

S. 343 is the most comprehensive statutory revision of the regulatory process since the enactment of the Administrative Procedure Act of 1946. This legislation would make substantial changes in the procedural requirements for the issuance of federal regulations. "Major rules" would be subjected to rigorous economic and scientific analysis before they could be issued. Both the Executive and the Judicial Branches would be authorized to compel agency compliance with these requirements. This legislation, with bipartisan and unanimous Committee support, is an effort to achieve meaningful and lasting regulatory reform while ensuring that agencies properly serve the national interest.

This legislation strikes a balance between reducing regulatory costs and still ensuring that needed public protections and benefits are provided. It imposes analytical requirements on the agencies to

produce better-informed decisions, not to slow down the regulatory process or to force irresponsible outcomes.

A brief synopsis of the major provisions of the bill follows:

A. COST-BENEFIT ANALYSIS

Federal agencies would be required to perform a cost-benefit analysis for major rules (imposing costs over $100 million or having a significant impact on the economy). The cost-benefit analysis for major rules would be done at the proposed and final stage and would include:

An estimate of the anticipated benefits of the rule (quantifiable and nonquantifiable);

An estimate of the anticipated costs of the rule (quantifiable and nonquantifiable);

A discussion of an appropriate number of reasonable alternatives to the proposed rule;

Where scientific information is used, a verification of the quality and reliability of the information; and

An explanation of whether the benefits of the rule justify the costs, and whether the rule will achieve the rulemaking objectives in a more cost-effective manner than the alternatives.

Each cost-benefit analysis for a major rule would be subject to peer review by a panel of experts independent of the covered agency. The requirements of this legislation do not override the rulemaking criteria of the underlying statutes.

B. MARKET-BASED MECHANISMS

During the cost-benefit analysis, agencies would be required to assess the feasibility of using ''market-based mechanisms'' (such as emissions trading credits or marketable permits) instead of prescriptive command-and-control regulation.

C. JUDICIAL REVIEW

The legislation would provide for judicial review to compel agencies to conduct required analyses. The cost-benefit analysis and risk assessment would become part of the rulemaking record for purposes of judicial review. However, the analysis or assessment in and of themselves would not be subject to procedural review.

D. REVIEW OF EXISTING RULES

Federal agencies would be required to conduct a comprehensive review of existing regulations to eliminate unnecessary regulations and to reform others. Each covered rule would be reviewed 10 years after its promulgation or the effective date of this legislation, whichever is later. For good cause, the President would be authorized to grant an extension of up to 5 years. Where an agency failed to review a rule within the deadlines, the rule would cease to be enforceable.

E. OPENNESS

The legislation would promote government accountability by expanding public participation in the development and review of regulatory actions and by providing public and agency access to infor-

mation and communications regarding regulatory actions under review.

F. RISK ASSESSMENTS

When developing major rules relating to risks to the environment, human health, or safety, twelve major regulatory agencies would be required to conduct risk assessments following criteria set forth in this legislation. The legislation would require scientifically sound risk estimates based on the available data. The agencies would be required to disclose and explain any assumptions and value judgments made when measuring risks. There would be exemptions from the risk assessment requirements for emergencies and screening analyses. Each risk assessment for a major rule would be subject to peer review by a panel of experts independent of the covered agency. The Office of Management and Budget (OMB), in consultation with the Office of Science and Technology Policy (OSTP), would be required to coordinate the risk assessment practices of all Federal agencies.

G. JUDICIAL REVIEW OF DETERMINATIONS UNDER THE REGULATORY FLEXIBILITY ACT

To ensure that agencies are more sensitive to the burdens of regulation on small businesses and small governments, the legislation would provide for judicial review of analyses required by the Regulatory Flexibility Act. If an agency fails to conduct a Reg-Flex analysis, small entities would have up to one year from the date a rule is issued to seek judicial review.

H. CONGRESSIONAL REVIEW OF RULES

The legislation would provide that no major rule would be effective until after a 45-day period in which Congress, by joint resolution of disapproval (requiring passage by both houses and presentation to the President) could reject those rules. Congressional consideration of the joint resolution of disapproval would be subject to expedited procedures during the 45-day period. If the President agreed with the Congress, or if the Congress had sufficient votes to override a Presidential veto, the rule would be rescinded.

I. COMPARATIVE RISK ANALYSIS

The legislation would require each covered agency to strive to set priorities to address the risks that are the most serious and could be addressed in a cost-effective manner. Each covered agency would be required to incorporate those priorities into its budget, strategic planning, regulatory agenda, enforcement, and research activities. The legislation also would require that an accredited scientific body conduct a study of comparative risk analysis methodologies, as well as a comparative risk analysis, across twelve major regulatory agencies. This study would promote public debate and informed decisionmaking regarding regulatory priorities. The ultimate goal would be to achieve the greatest overall risk reduction at the least cost.

J. REGULATORY ACCOUNTING

Every two years, the President would be required to submit to Congress an accounting statement that estimates the total quantitative and qualitative costs and corresponding benefits of Federal regulations. The President would be required to provide public notice and an opportunity to comment on each accounting statement. When submitting the accounting statement to Congress, the President also would be required to submit an associated report containing: (1) analyses of the impacts of Federal regulation, (2) recommendations for reform, and (3) a summary of any independent analyses of regulatory impacts.

K. EXECUTIVE OVERSIGHT

OMB would supervise and oversee implementation of the requirements of this legislation. To the extent this oversight involves the systematic review of agency regulatory proposals, such review would have to be completed within 90 days.

II. BACKGROUND

Since 1946, the federal regulatory process has been guided by the Administrative Procedure Act (APA), 5 U.S.C. 551–558. The APA was enacted following the dramatic increase in discretionary authority given to Executive Branch agencies stemming from the New Deal. It has served for almost 50 years as the blueprint for how agencies issue regulations. With the dramatic growth of complex and wide-ranging regulatory programs since the late 1960s, the limited procedures of the APA have been outstripped by new demands.[1] These new demands have moved this Committee to produce S. 343, the "Comprehensive Regulatory Reform Act of 1995."

A. GOVERNMENTAL AFFAIRS COMMITTEE ACTION ON REGULATORY REFORM

The Committee has been involved in overseeing the regulatory decisionmaking process for over two decades. Through a variety of studies, hearings, markups of legislative proposals, and oversight of the regulatory process, the Committee has developed a broad-ranging expertise with respect to both the strengths and weaknesses of regulation and proposals for reform. This experience and expertise has contributed to the development of S. 343.

In 1975, the Senate passed a resolution, S. Res. 71, directing the Governmental Affairs Committee to conduct a comprehensive study of Federal Regulations, to assess the impact of regulatory processes and programs, and to analyze the need for change. The Committee spent almost two years carrying out that mandate and concluded with a six volume report on various aspects of the regulatory process, from the organization and effectiveness of regulatory agencies to public participation in the regulatory process, to the role of con-

[1] *See* Testimony of Gary J. Edles, General Counsel of the Administrative Conference of the United States, before the Senate Committee on Governmental Affairs, March 8, 1995, at pp. 3–4.

gressional oversight.[2] The accumulated data and analyses reflected in these volumes constitute the most thorough review of the regulatory process ever conducted by the Congress. The problems identified and solutions proposed have substantially informed subsequent debates over regulatory reform, both within and outside of the Committee, and have influenced the drafting of this legislation. The study emphasizes, for example, that poor, costly and burdensome agency regulations often are a product of defective preliminary analysis which fails to account for costs, the possibility of alternative regulatory solutions, or no regulation at all.[3]

The Committee's Study provided the foundation for extensive hearings in the 96th[4] and 97th[5] Congresses that led to the passage in 1981 of S. 1080, an omnibus regulatory reform bill, by a floor vote of 94–0. Although S. 1080 was overwhelmingly endorsed by the Senate, it died in the House of Representatives.

S. 1080 reflected the increasing public concern that the costs of federal regulation in too many cases do not justify the benefits and that the scientific and policy assumptions underlying regulatory decisions are often questionable. Many of the same elements of S. 1080 are included in the legislation we are reporting, including cost-benefit analysis, review of existing rules, Presidential oversight, and congressional review. S. 343 is rooted in S. 1080 but has been expanded to reflect advances in administrative law and policy over the last 14 years, particularly in risk analysis.

B. EXECUTIVE BRANCH ACTION ON REGULATORY REFORM

The Committee's review of the regulatory process paralleled a growing interest in centralized control and review by the President. The assertion of presidential authority over the rulemaking process began in 1971 when President Richard Nixon established "Quality

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[2] The Governmental Affairs Committee published the following six volumes of the Study on Federal Regulation between January 1977 and December 1978:

1. Senate Committee on Government Operations, 95th Cong., 1st Sess., 1 Study on Federal Regulation, "The Regulatory Appointments Process" (Comm. Print 1977).
2. Senate Committee on Government Operations, 95th Cong., 1st Sess., 2 Study on Federal Regulation, "Congressional Oversight of Regulatory Agencies" (Comm. Print 1977).
3. Senate Committee on Governmental Affairs, S. Doc. 95–71, 95th Cong., 1st Sess., 3 Study on Federal Regulation, "Public Participation in Regulatory Agency Proceedings" (Comm. Print 1977).
4. Senate Committee on Governmental Affairs, S. Doc. 95–72, 95th Cong., 1st Sess., 4 Study on Federal Regulation, "Delay in the Regulatory Process" (Comm. Print 1977).
5. Senate Committee on Governmental Affairs, S. Doc. 95–91, 95th Cong., 2d Sess., 5 Study on Federal Regulation, "Regulatory Organization" (Comm. Print 1977).
6. Senate Committee on Governmental Affairs, S. Doc. 96–13, 96th Cong., 1st Sess., 6 Study on Federal Regulation, "Framework for Regulation" (Comm. Print 1978).

[3] The following conclusion from the 1978 Study rings true today:

The report finds that decisions when and how to regulate all too often are based on insufficient analysis and consideration of alternatives. Simply because a problem exists and, in theory is remediable, does not mean that regulation or other government intervention is desirable. Controls should only be undertaken where there is a clearly identified problem that cannot otherwise be solved, and where the anticipated achievements are significant and not vitiated by projected adverse consequences.

We believe that before Congress or the agency adopts any proposed regulatory scheme, the possible economic justifications for regulation should be scrutinized. The discipline inherent in that procedure is a key element in helping to insure good regulatory decisions. 6 Study on Federal Regulation, pp. xi–xii.

[4] Hearings on Regulatory Legislation, Senate Comm. on Governmental Affairs, 96th Cong., 1st Sess. (1979) (2 parts). These hearings, encompassing 11 days of testimony from 80 witnesses, are summarized in S. Rep. No. 96–1018, part 1, 52–55, 96th Cong., 2d Sess. (1980).

[5] Hearings on Regulatory Reform Legislation of 1981, Senate Comm. on Governmental Affairs, 97th Cong., 1st Sess. 1981. The development of the reform legislation was in close cooperation with the Senate Judiciary Committee. See S. Rep. No. 96–1018, Part 2, 96th Cong., 2d Sess. (1980) (joint report of the Senate Governmental Affairs and Judiciary Committees).

of Life Reviews" for certain U.S. Environmental Protection Agency (EPA) regulations. Every President since Nixon has implemented executive oversight of the regulatory process. President Gerald Ford required agencies to conduct an inflationary impact analysis for major rules. President Jimmy Carter established the Regulatory Analysis Review Group to review important regulations. He also required an economic impact analysis for major rules under Executive Order 12044.

President Ronald Reagan took the most dramatic step over the rulemaking process when he issued Executive Order 12291 in 1981. E.O. 12291 was the logical extension of an evolving centralized review process. E.O. 12291 required that all rules be reviewed by the Office of Information and Regulatory Affairs (OIRA) in the OMB before they were issued as proposed or as final. It also required that each agency analyze the costs and benefits of each major rule and that agencies issue rules, to the extent permitted by law, only if the benefits of the rule outweighed the costs. President Reagan also issued E.O. 12498 in March 1985, directing agencies to prepare a yearly agenda of all significant regulatory actions for the coming year. When he took office in 1989, President George Bush continued President Reagan's Executive Orders.

When President Bill Clinton took office, he rescinded E.O. 12291 but replaced it with Executive Order 12866, which still requires the centralized review of rules. E.O. 12866 applies only to significant rules, not all rules, but it maintains the requirement for a cost-benefit analysis of significant rules—primarily those that have an annual effect on the economy of $100 million or more.

Throughout this period of Executive review, the Committee maintained its long support for improving agency decisionmaking through regulatory review, a mechanism that has the greatest promise to insure more thorough analyses of regulatory proposals, more balanced consideration of diverse interests and opinions, and more effective coordination among agencies—in short, better informed decisionmaking. S. 343, then, may be seen both as a culmination of the Committee's work in regulatory reform, an extension of Executive Branch efforts, and a response to the public demand for a more efficient government.

C. THE NEED FOR REGULATORY REFORM LEGISLATION

The regulatory reform efforts in Congress and the Executive Branch reflect the increasing public concern about the growth of the Federal government and the number and scope of its regulatory programs. In the recent congressional elections, the public sent a clear message that they want a smaller, more efficient, and more effective government. This message reflects a deep and growing concern about the rising costs of federal regulations and their intrusiveness into the lives of many Americans. At the same time, the public continues to desire adequate protections for the environment, health and safety. Rising regulatory costs, limited resources, and a desire to preserve important protections and benefits all necessitate a smarter, more cost-effective approach to regulation.

It is clear that regulatory reform should be a national priority. Although the deregulation of economic regulation in the 1970s and 1980s reduced the burden of economic regulation, the total cost of

regulation is rising, primarily from new regulation of the environment, health, and safety. According to the EPA, by the end of this decade, the United States will spend $160 billion annually just on pollution control.[6] This is almost 90 percent more than was spent in 1987 and constitutes only a fraction of regulatory costs.[7] The total annual costs of all federal regulations has been estimated by Professor Thomas Hopkins at $560 billion for 1992; it is projected to rise another $100 billion by the year 2000.[8] About three-fourths of that cost-increase is expected from upcoming risk regulations—environmental, health and safety standards.[9] The Committee is deeply concerned about the potential adverse impact of the growing regulatory burden on the American public.

The costs of regulation are passed on the American consumer and taxpayer through higher prices, diminished wages, increased taxes, or reduced government services.[10] Those costs have been estimated at $6000 per year for the average American household.[11] Lest these rising costs undermine the confidence of the American public in government, the agencies, the White House and Congress must be more sensitive to cumulative regulatory burden.

Perhaps because most regulatory costs directly impact only businesses and governments, they have not been adequately scrutinized in the past. The decisions to create and impose regulations typically do not include the kind of serious debate about cost that is required to create new on-budget programs. Regulations are created as their need is perceived, without the constraints of a budget or forced tradeoffs with other important priorities. This is too often true not only in the agencies but also in Congress. Indeed, Congress has created many statutes that gave rise to wide-ranging command-and-control regulatory programs. In a time of increasingly limited resources, Congress, the White House, and the agencies must do more to curb the rising costs and inefficiencies of regulation. As the Administration's First Year Report on Executive Order 12866 noted:

> Agencies today face unusual pressure to regulate. With budgetary constraints so tight, and with the difficulty of enacting new legislation in the highly partisan atmosphere that has characterized the last Congress, the only means left for the agencies to implement their initiatives is through regulation.

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[6] Environmental Protection Agency, Environmental Investments: The Cost of a Clean Environment (Nov. 1990); General Accounting Office, Environmental Protection: Meeting Public Expectations With Limited Resources 9 (June 1991).

[7] See id.

[8] Thomas D. Hopkins, "Costs of Regulation: Filling the Gaps" (Rep. Prepared for Reg. Info. Service Center) Table 1 (Aug. 1992); Testimony of Thomas D. Hopkins, Professor of Economics, Rochester Institute of Technology, before the Senate Committee on Government Affairs, March 8, 1995.

[9] See id.

[10] See, *e.g., Public Policies for Environmental Protection*, Resources for the Future (Paul R. Portney, ed. 1990); Thomas D. Hopkins, "Cost of Federal Regulation" 3, reprinted in Regulatory Policy in Canada and the United States (Rochester Inst. Tech. 1992); Steven Pearlstein, "The Myths That Rule Us," The Washington Post, H1, Mar. 5, 1995.

[11] See Thomas D. Hopkins, "Costs of Regulation: Filling the Gaps" (Rep. Prepared for Reg. Info. Service Center) (Aug. 1992); Testimony of Thomas D. Kopkins, Professor of Economics, Senate Committee on Governmental Affairs, March 8, 1995.

This puts inordinate pressure on any attempt to hold steady or reduce the amount of regulation in which they are engaged.[12]

Without significant new controls, the volume of regulations will only grow larger.

The urgency of regulatory reform crystallizes when viewed as part of the larger effort to carefully allocate scarce resources. At a time when the national debt exceeds $4 trillion—$16,000 for every man, woman, and child in America, the Federal government is striving to reduce spending while still maintaining important initiatives, such as reforming education and reducing crime and drug abuse. In the same vein, we need to reduce the regulatory burden on the economy, while still achieving important goals, such as protecting public health, safety, and the environment. Inefficient regulations consume resources that could serve other important purposes.[13]

Despite the laudable goals and successes of many programs, experience has taught us that, too often, regulations have been more costly and less effective than they could have been.[14] There is broad support for regulatory reform and many tools to achieve it, including cost-benefit analysis, market-based mechanisms, risk assessment, and comparative risk analysis. This support comes from such diverse sources as the Clinton Administration,[15] Justice Stephen Breyer,[16] the Administrative Conference of the United States,[17] the Carnegie Commission,[18] Resources for the Future,[19] The Business Roundtable,[20] the National Research Council,[21] The

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[12] "The First Year of Executive Order No. 12866," A Report Prepared by Sally Katzen, Administrator, Office of Information and Regulatory Affairs, Office of Management and Budget (Dec. 20, 1994).

[13] See, e.g., Testimony of Frederick L. Webber, President and Chief Executive Officer, Chemical Manufacturers Association, before the Senate Committee on Governmental Affairs, March 8, 1995, at pp. 2–12; *Public Policies for Environmental Protection*, Resources for the Future, 15 (Paul R. Portney, ed. 1990).

[14] As noted by the President's chief spokesperson on regulatory policy, Sally Katzen: "Regrettably, the regulatory system that has been built up over the past five decades . . . is subject to serious criticism . . . [on the grounds] that there are too many regulations, that many are excessively burdensome, [and] that many do not ultimately provide the intended benefits."

Statement for the Record of Sally Katzen, Administrator of OIRA before the Senate Committee on Governmental Affairs, February 7, 1995, p. 2.

[15] National Performance Review, Creating a Government that Works Better and Costs Less, Washington, D.C. (1993); address by President Bill Clinton, Washington, D.C. (Feb. 21, 1995); National Performance Review, *Improving Regulatory Systems*, Washington, D.C. (Sept. 1993).

[16] Stephen Breyer, Breaking the Vicious Circle: Toward Effective Risk Regulation, Harv. Univ. Press, Cambridge, MA (1993); Stephen Breyer, *Regulation and Its Reform* (1982).

[17] *See, e.g.*, ACUS Recommendation 85–2, "Agency Procedures for Performing Regulatory Analysis of Rules" (1985); ACUS Recommendation 88–9, "Presidential Review of Agency Rulemaking (1988); ACUS recommendation 93–4, "Improving the Environment for Agency Rulemaking" (1993).

[18] Carnegie Commission on Science, Technology, and Government Risk and the Environment: Improving Regulatory Decisionmaking, Washington, D.C. (June 1993).

[19] Paul Portney, Public Policies for Environmental Protection, Resources for the Future, Washington, D.C. (1990); Paul Portney, "Economics and the Clean Air Act," 4 J. Econ. Perspectives 173 (Fall 1990); Worst Things First?: The Debate Over Risk-Based National Environmental Priorities, Resources for the Future, Washington, D.C. (Adam N. Finkel and Dominic Golding, eds. 1994).

[20] The Business Roundtable, Toward Smarter Regulation (1994); The Business Roundtable, Cost of Government Regulation Study (Mar. 1979).

[21] National Research Council, Science and Judgment in Risk Assessment, National Academy Press, Washington, D.C. (1994); National Research Council, Issues in Risk Assessment, National Academy Press, Washington, D.C. (1993); National Research Council, Valuing Health Risks, Costs, and Benefits for Environmental Decision Making, National Academy Press, Washington, D.C. (1990); National Research Council, Improving risk Communication, National Academy Press, Washington, D.C. (1989); National Research Council, Risk Assessment in the Federal Government: Managing the Process, National Academy Press, Washington, D.C. (1983).

Brookings Institution,[22] the American Enterprise Institute,[23] and other think tanks, commissions, and independent scholars throughout the country.[24] The wide consensus on the need for regulatory reform and on many tools to achieve it has contributed to this legislation.

III. Legislative History and Committee Consideration

A. COMMITTEE HEARINGS

On February 7, 1995, the Governmental Affairs Committee began a series of four hearings to explore the merits of regulatory reform. The February 7 hearing provided a forum for Senators to address problems with government regulation and proposals for reform. Testifying at this hearing were Senate Majority Leader Robert Dole as well as Senators Don Nickles, Kay Bailey Hutchinson, Richard Shelby, and Christopher Bond.

The Committee held its second regulatory reform hearing on February 8, 1995. This hearing covered the costs and benefits of regulation and the cumulative regulatory burden. The first two witnesses were Senator Frank Murkowski and John A. Georges, Chairman of the Board and Chief Executive Officer of International Paper and member of The Busness Roundtable Task Force on Government Regulation. Senator George McGovern testified on the second panel. Also testifying were Mike Roush of the National Federation of Independent Business; Dr. Richard Lesher, President of the Chamber of Commerce of the United States; Thomas Hopkins of the Rochester Institute of Technology; Robert Hahn of the American Enterprise Institute; Carl Pope, Executive Director of the Sierra Club; and Paul Portney of Resources for the Future.

A third hearing was held on February 15, 1995. The focus of this hearing was cost-benefit analysis, regulatory accounting, and risk analysis. The first panel included Bob Crandall, Senior Fellow at The Brookings Institution, and Professor Kip Viscusi of Duke University. Also testifying were John Graham, Director of the Harvard Center for Risk Analysis; Jerry Jasinowski, Chairman of the Alliance for Reasonable Regulation and President of the National Association of Manufacturers; Linda Greer, Senior Scientist at the Natural Resources Defense Council; and Don Elliott, Senior Partner at Fried, Frank, Harris, Shriver, and Jacobson.

A fourth and final hearing was held on March 8, 1995. This hearing reviewed the major principles of regulatory reform and solicited

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[22] See, e.g., Lester Lave, The Strategy of Social Regulation, Brookings Institution, Washington, D.C. (1981); Lester Lave, Quantitative Risk Assessment in Regulation, Brookings Institution, Washington, D.C. (1982); Robert W. Crandall, Controlling Industrial Pollution: The Economics and Politics of the Clean Air Act, Brookings Institution, Washington, D.C. (1983).

[23] See, e.g., American Enterprise Institute, Benefit-Cost Analysis of Social Regulation: Case Studies from the Council on Wage and Price Stability, Washington, D.C. (James C. Miller and Bruce Yandle, eds. 1979); M. J. Bailey, Reducing Risks to Life: Measurement of Benefits, American Enterprise Institute, Washington, D.C. (1980); Robert W. Hahn and J. A. Hird, "The Costs and Benefits of Regulation," 8 Yale J. on Reg. 233 (Winter 1991); W. Kip Viscusi, Product-Risk Labelling: A Federal Responsibility, American Enterprise Institute, Washington, D.C. (1993).

[24] Murray L. Weidenbaum, Business and Government in the Global Marketplace, Prentice Hall, Englewood Cliffs, NJ (5th Ed. 1995); W. Kip Viscusi et al., Economics of Regulation and Antitrust, D.C. Heath & Co., Lexington, MA (1992); W. Kip Viscusi, "Pricing Environmental Risks," Policy Study No. 112 (Center for the Study of Am. Bus. June 1992); W. Kip Viscusi, Fatal Tradeoffs: Public and Private Responsibilities for Risk, Oxford Univ. Press, NY (1992); M.K. Landy et al., EPA: Asking the Wrong Questions, Oxford Univ. Press, NY (1990); Cass R. Sunstein, After the Rights Revolution, Harv. Univ. Press, Cambridge, MA (1990).

specific recommendations on major issues, including judicial review, a potential petition process for reviewing rules, a supermandate to inject cost-benefit considerations into existing statutes, as well as market-based mechanisms. Panelists also discussed the merits of cost-benefit analysis, risk assessment, comparative risk analysis, reviewing existing regulations, and regulatory accounting. The first panel included Carol Browner, the Administrator of the Environmental Protection Agency; and Sally Katzen, the Administrator of the Office of Information and Regulatory Affairs in the Office of Management and Budget. Also testifying were C. Boyden Gray, Chairman of Citizens for a Sound Economy and partner, Wilmer, Cutler & Pickering; Frederick L. Webber, President and Chief Executive Officer of the Chemical Manufacturers Association; Gary Edles, General Counsel of the Administrative Conference of the United States; Peter Strauss, Professor at Columbia Law School and Senior Fellow at the Administrative Conference of the United States; David C. Vladeck, Director of the Public Citizen Litigation Group; Alan J. Krupnick, Senior Fellow at Resources for the Future; Joseph Goffman, Senior Attorney at the Environmental Defense Fund; and Jonathan B. Wiener, Professor at Duke University School of Law and the Duke University School of the Environment.

B. AMENDMENTS AND COMMITTEE ACTION

On March 23, 1995, the Committee on Government Affairs marked up and favorably reported S. 291 in the nature of a substitute by vote of 10 to 0. Voting in the affirmative were Senators Roth, Cohen, Thompson, Glenn, Nunn, Levin, Pryor, Lieberman, Akaka, and Smith. In addition, Senators Stevens, Cochran, Grassley, McCain, and Smith voted in the affirmative by proxy. On the same day, the Committee on Governmental Affairs also marked up and favorably reported by voice vote the same text in the nature of a substitute for S. 343.

The Roth-Glenn Manager's Amendment to the Roth Substitute Amendment was approved by voice vote. Moreover, a number of amendments were offered, debated and voted upon. The following were accepted:

(1) Roth amendment for the sunset of "rules that are not reviewed by the agencies in a timely manner" with the exception of removal of paragraph (ii) on p. 17, lines 15–19 (voice vote).

(2) Roth amendment to exempt "the banking institutions and monetary policy of the Fed from the regulatory requirements of the legislation" (voice vote).

(3) Levin amendment strengthening the market mechanisms and performance standards language (without objection).

(4) Levin amendment on establishing an effective date for the bill—180 days after enactment (voice vote).

(5) Levin amendment to strike the word "procedural" from the judicial review section (adopted 8–6). Voting in the affirmative were Senators Thompson, Glenn, Nunn, Levin, Pryor, Lieberman, Akaka, and Dorgan. Negative votes were cast by Senators Roth, Cohen, Cochran (by proxy), Grassley (by proxy), McCain (by proxy), and Smith (by proxy).

(6) Levin amendment to eliminate "a one-time requirement in section 638(a)(1)(B) that agencies report on the status of guidelines they are required to develop" (without objection).

(7) Levin amendment to consolidate "the reporting requirements appearing elsewhere in the bill without deleting any requirements." The amendment "incorporates into section 6(e) the reporting requirements of section 638(b) and section 639(c), and requires that these reports be submitted once, instead of requiring the reports over and over again" (without objection).

IV. SECTION-BY-SECTION ANALYSIS

SECTION 1. SHORT TITLE

The name of the legislation is the "Comprehensive Regulatory Reform Act of 1995".

SECTION 2. DEFINITIONS

This section adds a definition to section 551 of title 5, United States Code. The term "Director" means the Director of the Office of Management and Budget.

SECTION 3. ANALYSIS OF AGENCY RULES

Section 3 substantially amends chapter 6 of title 5, United States Code. Section 3(a) creates three new subchapters, requiring: (1) analysis of agency rules, including cost-benefit analysis and review of existing regulations; (2) risk assessment; and (3) executive oversight. Section 3(b) amends the Regulatory Flexibility Act, heretofore chapter 6 of title 5 (hereafter subchapter I), to provide for judicial review of determinations made under that Act. Section 3(c) is a savings clause, stating that the current legislation does not limit any of the President's constitutional duties. Finally, section 3(d) provides the technical and conforming amendments necessary to reorganize chapter 6 into subchapters, including, for example, moving the Regulatory Flexibility Act to subchapter I of chapter 6.

In amending title 5, United States Code, the Committee-passed bill applies the definition of "agency" under section 551 to subchapters II and III and IV of the bill—the cost-benefit analysis, risk assessment and executive oversight requirements. This definition includes the independent regulatory agencies within the scope of this legislation. Thus, the requirements to identify major rules and perform cost-benefit analyses and risk assessments, where appropriate, would apply not only to departments and other executive agencies, but also to all the independent regulatory agencies, such as the Securities and Exchange Commission, the Federal Trade Commission, the Consumer Product Safety Commission, the Interstate Commerce Commission, etc.

This legislation would also require these independent regulatory agencies, like all other Executive Branch agencies, to be subject to Presidential oversight for compliance with the requirements of this legislation. Such Presidential oversight is likely to include review of proposed and final major rules by the Office of Management and Budget (OMB). Since 1981, OMB's regulatory review authority under Presidential executive order (E.O. 12291, 12498, and 12866) has explicitly exempted independent regulatory agencies and made

their participation in the regulatory review scheme voluntary. This was based on the longstanding tradition of independence from Presidential control for these agencies and the fact that service by the commissioners who head independent regulatory agencies is protected by the good cause removal requirement.

The Committee believes that the provisions of this legislation, especially the requirements for cost-benefit analysis and risk assessment, the review of existing rules, and the congressional review of rules, should apply to all Executive Branch agencies, including the independent regulatory agencies. Subjecting the independent regulatory agencies to these regulatory management tools will improve the regulatory programs of these agencies without violating their independence.

The Committee's decision to subject the independent regulatory agencies to a general Executive Branch-wide cost-benefit analysis and review process is not unprecedented. The Paperwork Reduction Act of 1980 (44 U.S.C. 3507) required OMB to review the information collection proposals of independent regulatory agencies, but empowered the agencies to override an OMB disapproval. In the fourteen-year history of that Act, the independent agency override has been used seven times, according to OMB. The success in incorporating independent agencies into the OMB review process under the Paperwork Reduction Act supports including them in any OMB oversight process.

More importantly, the growing need for more efficient and effective government regulation, as well as for more coherent policy management of the Executive Branch, supports lowering some walls that have separated the independent agencies from other agencies in the Executive Branch.

For these reasons, the Committee believes that independent regulatory agencies should generally be covered by the requirements of this legislation. Specific exemptions are provided within the definition of "major rule" and "rule" to protect the integrity and effectiveness of certain kinds of regulations.

During the Committee's mark-up, however, Chairman Roth and Senator Glenn spoke about and agreed on the importance of protecting the independence of the Federal Reserve. They also agreed to the need to give more attention to the question of the impact of regulatory analysis and review requirements on the unique missions of certain other independent agencies, such as those that oversee the safety and soundness of financial institutions. Committee members will consider this question before the legislation is taken up by the full Senate.

SECTION 3(a)

Section 3(a) creates new subchapters II, III, and IV in chapter 6, title 5, United States Code.

Subchapter II—Analysis of Agency Rules

The first new subchapter in chapter 6 of title 5, United States Code, establishes provisions for new definitions (sec. 621), cost-benefit analysis of agency rules (sec. 622), the scope of judicial review (sec. 623), extension of deadlines to allow adequate time for agencies to perform the required regulatory analyses (sec. 624), agency

review of existing rules (sec. 625), and public disclosure of cost-benefit analysis information (sec. 626).

§ 621. Definitions

This section defines certain terms used in cost-benefit analysis. These definitions are used not only in the new subchapter II, but also are referred to and incorporated into subchapters III and IV.

(1) The term "benefit" means the reasonably identifiable significant favorable effects, including social, environmental and economic benefits, that are expected to result directly or indirectly from implementation of a rule or an alternative to a rule.

The Committee intends to give broad meaning to the term "benefit." Federal agencies issue regulations to assist in the implementation of laws passed by Congress. As such, the value of a regulation is the extent to which it provides the public benefits envisioned by a law. These benefits can be readily apparent, as in economic benefits obtained from standardized hazardous material transportation rules, or in the regained safety of a locality's drinking water supply. These benefits can also be obvious but also very broad, as in the growth of an economic sector or improved nation-wide employment rates. Finally, regulatory benefits can be significant but difficult to quantify, such as the value of increased visibility over the Grand Canyon.

This wide variety of possible benefits must be recognized in the rulemaking process. However, merely because benefits may be varied or difficult to quantify should not relieve agencies from identifying the specific benefits of a rule. One of the basic findings underlying this legislation is that agency action must be based more clearly on identified benefits. The identification of regulatory benefits should enable agencies to improve the effectiveness and efficiency of the regulatory process and to best serve the goals of the enabling statute.

As a part of this broad meaning of "benefit," the Committee requires agencies to consider "direct" as well as the "indirect" benefits. Many benefits, like costs, can be clearly attributed to a regulatory action. Many, however, flow in more tangential ways. The Committee expects agencies to make a reasonably thorough effort at identifying and analyzing all significant benefits that flow from a regulatory action. At the same time, the Committee cautions agencies against speculative attribution of distant outcomes to a regulatory action.

The definition of benefits is not limited to favorable effects which can be quantified. They may include, for example, identifiable and significant but potentially nonquantifiable benefits, such as increased freedom of choice for consumers or enhanced opportunities for public enjoyment of the environment.

Finally, the definition of benefits is limited to those that are "significant." Agencies should not spend valuable resources trying to assess every small, remote benefit of a rule; during the cost-benefit analysis, only significant benefits should be addressed. Equitable considerations, such as whether a rule reduces risks to sensitive subpopulations, whether the risk reduced is involuntary, or whether the rule has a distributional impact on low-income groups, also can play an important role in an agency's decisionmaking process.

(2) The term "cost" means the reasonably identifiable significant adverse effects, including social, environmental, and economic costs that are expected to result directly or indirectly from implementation of, or compliance with, a rule or an alternative to a rule. The concerns expressed above regarding "benefit" apply equally here. As Dr. Paul Portney testified before the Committee:

> It is often alleged that we have a very good idea about how much it costs to comply with federal regulation. I do not believe this to be true. In some cases, we have a good idea about how much a regulated party must spend out-of-pocket to comply with a regulatory requirement. But the sum total of such out-of-pocket expenditures is not identical with "costs" as economists think of them for the purposes of a benefit-cost analysis. This latter concept includes the value of time that people must spend waiting in line for permits, car inspections, etc. It includes the adverse health effects they incur because of the time involved to bring a potentially effective new therapeutic drug to market. It includes the inconvenience they suffer when a product becomes less effective on account of a regulation, or disappears from the market altogether. None of these "costs" involves any out-of-pocket expenditure, but they must all be counted in any serious benefit-cost analysis. To be sure, pollution control expenditures by regulated parties—the out-of-pocket costs referred to above—are an essential ingredient in doing a proper benefit-cost analysis, but the latter requires considerably more sophistication in cost estimation than a mere toting up of who spent what.[25]

As in the case of "benefits," the Committee intends to give broad meaning to the term "cost." At the same time, the definition of costs is limited to those that are "significant."

Agencies must be sensitive to all of the significant costs regulation can impose. While the compliance costs often comprise a substantial portion of total costs, there are other costs of regulation. To name a few, these costs include substitution effects (such as increased risks caused by a regulatory approach), as well as the adverse impacts on consumer choice, technological innovation, wages, productivity, and economic growth. Costs also could include lower employment, even if short-term.

Agencies must identify and evaluate direct and indirect costs, as well as quantitative and non-quantitative costs. Again, agencies should eschew unreliable speculation about costs, as with benefits, but they should try to responsibly identify all "significant" costs imposed by a regulatory action.

(3) The term "cost-benefit analysis" means an evaluation of the costs and benefits of a rule—quantified to the extent feasible and appropriate and otherwise qualitatively described—that is prepared in accordance with the requirements of this subchapter. The legislation adds that this analysis should be performed at the level of detail appropriate and practicable for reasoned decisionmaking on the matter involved, taking into consideration the significance and

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[25] Testimony of Dr. Paul R. Portney, Vice President, Resources for the Future, before the Senate Committee on Governmental Affairs, February 8, 1995, at p. 3.

complexity of the decision and the need for expedition. The Committee intends that the agencies use the best available techniques for these analyses, and tailor the specificity and rigor of the analysis to the consequences of the decision to be made. The Committee recognizes, however, that there is no mechanistic "one size fits all" approach to cost-benefit analysis. Part of the decision-making discretion that Congress delegates to agencies is the responsibility to reasonably determine the degree of detail and rigor necessary to support a rulemaking decision.

(4) The term "major rule" is defined to include two categories of significant rules: economically significant and otherwise significant rules. Because cost-benefit analysis and the periodic review of regulations required by section 625 are costly and time-consuming requirements, the Committee intends that they apply only to those rules that will have a significant impact on the economy. Agencies are required to prepare a cost-benefit analysis only for major rules.

The first category of "major rule" is defined in subsection 621(4)(A)(i) as "a rule or group of closely related rules that the relevant agency, the Director of OMB, or a designee of the President reasonably determines is likely to have an annual effect on the economy of $100,000,000 or more in reasonably quantifiable direct and indirect costs."

The Committee's decision to set the threshold for major rules at $100,000,000 follows the long-standing tradition under centralized executive review of rules. Since President Ford, every President has required the review of regulations under an executive order. An essential component of these orders is a distinction between important rules and those that are more routine. This distinction recognizes that the resources devoted to regulatory analysis should be commensurate with the consequences of the decisions to be made. For over 20 years, that distinction has been drawn where rules impose annual costs on the economy of $100 million or more. Rules of such significance can benefit greatly from detailed analysis. The Committee is concerned that, particularly in this time of budget austerity, setting a lower threshold to trigger the detailed analytical requirements of this legislation would overwhelm the agencies and impair the regulatory process. While cost-benefit analysis can lead to more efficient rules, a careful balance must be struck, lest the costs of the analysis itself outweigh its benefits.

The Committee recognizes that any standard for the definition of major rule will be difficult to apply in practice, even though it may appear on paper to create an objective, "bright line" test. Even the direct, readily quantifiable, costs of a regulation are difficult to calculate accurately and are all the more difficult to quantify before the rule has been proposed.

All significant costs of a rule, even if indirect and difficult to calculate, should be considered and weighed in the cost-benefit and cost-effectiveness determinations of section 622. However, to determine whether a rule is "major" under subsection 621(4)(A)(i), the agency should look to the significant direct and indirect costs that can be identified and quantified with relative certainty.

In determining whether a rule is "major," the agency need only consider the costs of the proposed rule and not its benefits. However, if a proposed "deregulatory" action will reduce the benefits of

a current rule, the reduced benefits should be counted as a regulatory "cost" for purposes of making a major rule determination. Regulations produce both direct and indirect benefits, and, as is the case with costs, only those direct and indirect, readily quantifiable benefits should be used to determine whether the cost of a regulation in reduced benefits reaches the $100,000,000 threshold.

Subsection 621(4)(A)(ii) provides a second prong to the major rule definition to permit agencies and the President in their discretion to subject to cost-benefit analysis those rules which, while not imposing costs of $100,000,000 on the economy, still have a substantial or significant impact on important national goals or on certain sectors of the economy. The Committee recognizes that certain rules while outside of subsection 621(4)(A)(i), still have an important impact on certain economic sectors, such as state and local governments. The Committee encourages agencies or the President to determine that such rules are major under the second prong of the major rule definition, consistent with the availability of resources to prepare regulatory analyses. Subparagraphs (I) through (V) provide guidance for such agency determinations.

Subparagraph (I) allows agencies to determine that a rule is major where it imposes a "substantial increase in costs or prices" on certain groups, government entities, or geographic regions. Subparagraph (V) covers rules with a significant adverse impact on a sector of the economy or a class of persons. Similarly, subparagraph (IV) applies to rules that materially alter the budgetary impact of entitlements, grants, user fees or loan programs, or the rights and obligations of recipients. Regulatory agencies should be sensitive to the disproportionate impact their actions can have on certain groups or sectors of the economy, even if the aggregate effect is not substantial. The Committee encourages agencies to be sensitive to these concerns and use cost-benefit analysis to streamline the regulatory burden, consistent with statutory directives.

Subparagraph (II) provides that a rule may be major where it will have "significant adverse effects" on such important societal interests as wages, economic growth, investment, productivity, innovation, the environment, public health or safety, or the competitiveness of American businesses. There may be situations where the direct, measurable economic effect of a regulation will be slight, but the indirect effects, especially those experienced over the long term can be substantial. In addition, regulatory actions that reduce compliance burdens may, in some cases, have significant adverse effects on the "environment, public health or safety." Therefore, a cost-benefit analysis may be appropriate for such rules. These are among the factors which agencies should consider in making determinations under subparagraph (II).

Subparagraph (III) includes in the definition of major rule a rule that would seriously conflict or interfere with a past or planned action of another agency.

The Committee intends that concerns about agency resources should guide major rule determinations under subsection 621(4)(A)(ii). Thus, agency resources should be devoted to a reasonable number of rules whose impact will be most significant under the narrative criteria set forth in subsection 621(4)(A)(ii).

Subsection 621(4)(A) provides that a "group of closely related rules" ought to be a major rule because the Committee does not want to allow agencies to avoid the analytic requirements of the legislation by breaking up a rule into smaller component parts. The Committee is aware that it may be difficult to identify those separate rules which should be aggregated to determine whether a cost-benefit analysis is required. Where a statutory provision requires an agency to implement a series of regulatory actions directed toward a single goal and affects one industry or sector of the economy, the agency should consider aggregating those discrete actions into a single major rule for the purposes of chapter 6. However, where different agency rules, promulgated pursuant to different enabling statutes or statutory mandates, would all affect one industry, activity or group of persons, aggregation generally would not be appropriate. While such rules might be viewed as closely related by regulated parties, they are totally separate when considered by the agency. The Committee is concerned that aggregation of those rules would impose an unworkable burden on agencies.

Aggregation does not determine how cost-benefit analysis is to be performed. Where closely related rules constitute a major rule, the agency can conduct a cost-benefit analysis for the whole group, or perform individual analyses for each rule, depending on the circumstances. If such a group of closely related rules will be proposed over a period of months, individual analyses may be the most reasonable approach. This should not be construed to obviate a cost-benefit analysis of subsequent rules that independently satisfy major rule criteria, unless the initial analysis for a group of regulations had fully considered all of the potential effects of the subsequent regulations. Thus, an agency might be required to perform a general cost-benefit analysis for each set of regulations that qualifies as a major rule.

The term "major rule" explicitly exempts three categories of rules. First, subparagraph (i) excludes rules involving the Internal Revenue laws. The Committee was concerned that the enormous economic impact of such rules might make an overwhelming number of tax regulations major rules. While many IRS rules have a major economic impact or are otherwise significant, they have this impact because their goal is to raise revenue. Subjecting IRS rules to cost-benefit analysis would interfere with this revenue-raising function, as well as create needless delay and uncertainty.

Second, subparagraph (ii) exempts from "major rule" any rule that authorizes the introduction into, or removal from, commerce, or recognizes the marketable status, of a product. The Committee believes that adequate procedures and safeguards exist to screen out potentially dangerous or undesirable new products or to remove existing ones. The Committee did not want to disturb those procedures or to delay the introduction or removal of products from commerce in accordance with those procedures.

Finally, subparagraph (iii) exempts from the major rule definition any rule that is exempt from notice and public comment procedures under section 553 of title 5 of the United States Code. These include: rules relating to a military or foreign affairs function; interpretative rules; rules relating to grants, benefits, or loans; rules relating to agency management or personnel; and rules relating to

the acquisition, management or disposal of federal property. In some cases, these rules could have a significant impact on the economy. However, the Committee decided to minimize the burdens on the agencies; where notice and comment pursuant to section 553 is not required, a cost-benefit analysis will not be required either.

(5) The term "market-based mechanism" means a regulatory program or requirement that imposes legal accountability for the achievement of a regulatory goal, but affords maximum "market-oriented" flexibility as to how to achieve that goal. Two key elements of this approach are: (1) affording maximum flexibility to each regulated person to comply with mandatory regulatory objectives, such as the opportunity to exchange increments of compliance responsibility for cash or other legal consideration; and (2) allowing regulated persons to respond at their own discretion to changes in general economic conditions pertaining to the regulatory program without undermining the achievement of the program's regulatory mandate or requiring a new rulemaking.

The Committee believes that, where practical, market-based mechanisms can be far more efficient and effective than command-and-control regulation.[26] Where market-based mechanisms can be adequately administered and enforced, they can achieve equivalent or greater benefits at far less cost than command-and-control regulation. The Committee prefers market-based mechanisms because, when practical and enforceable, they enable regulated parties to achieve compliance in the least costly manner, reward innovators who meet or exceed regulatory goals, and adapt to changed circumstances more quickly than traditional command-and-control regulations. Accordingly, whenever agencies consider adopting a major rule, they should always consider whether a market-based mechanism could be used.

The Committee views the success of the program for reducing nationwide sulfur dioxide emissions established under Title IV of the Clean Air Act as a useful and clear-cut example. There, Congress imposed directly on sources of emissions explicit pollution reduction requirements. The sources were forced to meet those requirements through any means they chose, including purchasing credits representing the performance of needed reductions by other sources. This program is achieving greater emissions reductions at about one-tenth of the anticipated costs of command-and-control regulation and is 40 percent ahead of the statutory schedule.[27]

The definition allows regulated entities to respond to both compliance requirements and changing economic circumstances "at their own discretion in an automatic manner." This definition of market-based mechanisms is intended to serve as a benchmark against which an agency should measure any proposal to harness

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[26] The testimony before the Committee strongly supports the view that market-based mechanisms can be far superior to command-and-control regulation. *See* Testimony of Joseph Goffman, Senior Attorney, Environmental Defense Fund, before the Senate Committee on Governmental Affairs, March 8, 1995; Testimony of Alan J. Krupnick, Senior Fellow, Resources for the Future, before the Senate Committee on Governmental Affairs, March 8, 1995; Testimony of Jonathan B. Wiener, Associate Professor, Duke University School of Law and Duke University School of Environment, before the Senate Committee on Governmental Affairs, March 8, 1995; Testimony of C. Boyden Gray, Partner, Wilmer, Cutler & Pickering and Chairman, Citizens for a Sound Economy, March 8, 1995.

[27] Testimony of C. Boyden Gray, Partner, Wilmer, Cutler & Pickering and Chairman, Citizens for a Sound Economy, before the Senate Committee on Governmental Affairs, March 8, 1995, at p. 4.

market forces to achieve program objectives. Where a given regulatory alternative may not fall squarely within the definition of "market-based mechanism," the definition nonetheless would serve as a model against which regulators can judge the inherent limitations of other market incentives, such as using taxes, fees, or charges as regulatory instruments. For example, in a changing economy, fixed charges may afford sources only limited flexibility to respond—in contrast to the latitude sources enjoy in an emissions trading market—and introduce economic distortions that do not enhance the achievement of the program objective. Moreover, agencies should take care not to characterize command-and-control regulation as market-based mechanisms or performance standards. The Committee expects that the definitions of these terms will provide sufficient guidance to the agencies.

(6) The term "performance standard" means a requirement that imposes legal accountability for the achievement of an explicit regulatory objective, such as the reduction of environmental pollutants or of risks to human health, safety, or the environment, on each regulated person. In contrast to command-and-control regulation, performance standards simply establish the ultimate regulatory goal and free regulated parties to meet or exceed that goal as they choose. The Committee's preference for market-based mechanism also extends to performance standards, which have the same elements of accountability, flexibility, and cost-effectiveness.

(7) The term "risk assessment" has the same meaning as such term now is defined under section 632(5) of title 5, United States Code.

(8) The term "rule" has the same meaning as such term is defined in section 551(4) of title 5, United States Code. The definition of "rule," also contains several exclusions. Subparagraph (A) excludes certain rules of "particular applicability" as that phrase is understood in section 551(4) of title 5. These are rules which, while technically within the definition of "rule", are more properly considered as licenses or orders because they apply only to a small group or a single individual. The Committee believes that such rules would not greatly benefit from the cost-benefit analysis and periodic review requirements of this legislation because they are generally developed through complex and lengthy proceeding, which often involve sophisticated economic analysis. Rules of particular applicability also can have a direct impact on individual rights and privileges. Enhancing presidential authority over such rules could allow for its abuse.

Subparagraphs (B) and (C) exclude from the legislation's scope certain rules relating to monetary policy or to the safety or soundness of federally insured depository institutions. Subparagraph (D) excludes certain rules issued by the Federal Election Commission and the Federal Communications Commission. In all of these instances, the Committee felt that the analytic requirements of the legislation would unduly inhibit these rules from achieving their objectives.

§ 622. Rulemaking cost-benefit analysis

A. Background

This section lays out the requirements for agencies to do initial and final cost-benefit analysis when proposing and issuing major rules. The Committee recognizes that many of the problems with the regulatory process can be traced to the failure of agencies to consider all of the potential effects of their rules before promulgation. The cost-benefit analysis is intended to provide a framework for the agency to assess the impact of its rule on the economy and society as a whole. Good analysis is the servant of judgment, not a substitute for it. The Committee intends that the analysis be used by agencies to develop alternative regulatory approaches, to compare the benefits and costs of such approaches, and to produce better informed decisionmaking.[28]

The concept of cost-benefit analysis has developed over the past several administrations to the point where some very sophisticated analyses have been prepared. The Committee is confident that the cost-benefit requirements of this legislation can be implemented consistent with responsible presidential initiatives to improve cost-benefit analysis.

The same requirements that apply to new regulations must also apply to agency action to cut back or rescind existing regulations, and this is especially true of the cost-benefit analysis requirements of this section.

A "rule" is defined in the APA as any "agency statement of general or particular applicability and future effect designed to implement, interpret or prescribe law or policy." 5 U.S.C. 551(4). This definition includes "deregulatory" and regulatory reform actions that reduce or shift compliance burdens. The Committee expects that where such changes rise to the level of being major rules under this legislation, the agency must determine whether the benefits of the deregulatory change will justify the costs and that the action will be adopted in the most cost-effective manner possible.

It is conceivable that some actions designed to reduce compliance costs may impose costs in the form of new risks to public health, safety or the environment. These substitution risks should be viewed as increasing the net cost of the regulatory alternative. Alternatively, reducing the compliance burden imposed on one group or sector of the economy may increase the burden on another; those costs also should be considered. Such analysis should be relevant and technically valid and appropriate. Agencies should not use inappropriate analytic techniques.[29]

A satisfactory cost-benefit analysis would enable independent reviewers to make an informed judgment as to whether the benefits of the rule justify its costs, and whether the rule substantially

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[28] When well used, cost-benefit analysis is a highly effective tool to increase the efficiency of the regulatory process. One EPA study, for example, found that "the return to society from improved environmental regulations is more than one thousand times EPA's investment in cost-benefit analysis." *See* U.S. Environmental Protection Agency, "EPA's Use of Cost-Benefit Analysis: 1981–1986" (Aug. 1987), at p. 5–2.

[29] See Hearing before the Senate Committee on Governmental Affairs, "Risk-Risk Analysis," S. Hearing 102–1144 (Mar. 19, 1992); Hearing before the Senate Committee on Governmental Affairs, "Risk-Risk Analysis: OMB's Review of a Proposed OSHA Rule," GAO/PEMD–92–33 (May 1992).

achieves the statutory objectives in the most cost-effective manner. This determination encompasses the whole rulemaking record.

To fulfull its potential for improving the regulatory process, the preliminary cost-benefit analysis must be made public by the agency to allow comment and criticism by interested parties. As more information is submitted to support or rebut the analysis, it and the final rule will be improved. The preliminary cost-benefit analysis should be summarized in the notice of proposed rulemaking, as should any other preliminary analysis published on the proposed rule. Agencies are encouraged to integrate required documents where feasible to minimize paperwork and delay.

The cost-benefit analysis should be developed by the agency during the development of the rule. The cost-benefit analysis should guide the agency decision-making process, not provide a post hoc rationalization for a decision made before the analysis was prepared. Once completed the final cost-benefit analysis should be made public with the statement of basis and purpose accompanying the rule. A summary of the analysis should be published with the rule in the Federal Register. If the analysis is properly performed, it will provide an excellent brief in support of the agency's factual conclusions and policy choices.

The Committee recognizes that economic analysis should not be the sole standard for all regulatory decisionmaking. Mandating a strict, cost-benefit standard for regulatory decisions under all federal laws would ignore the diversity of enabling legislation dealing with an enormous range of subject matter. The cost-benefit analysis required by this legislation will help to identify questions clearly, to describe assumptions made, and then to clarify the rationale justifying the proposed action so that they may be open for public debate.

B. Framework for Conducting Cost-Benefit Analysis

The first step, outlined in subsection 622(a), is for agencies, before publishing a notice of proposed rulemaking, to determine whether the rule is a major rule under subsection 621(4)(A)(i)—that is, whether the rule is likely to have a gross annual effect on the economy of $100,000,000 or more in reasonably quantifiable direct and indirect costs—and if not, whether the rule is a major rule under the narratives in subsection 621(4)(A)(ii).

If the agencies do not determine a rule to be major, subsection (b) allows the Director of OMB or a designee of the President to exercise the same authority not later than 30 days after the publication of the notice of the proposed rulemaking. This provision is designed to ensure effective Executive Branch oversight of the cost-benefit requirements. A notice of any major rule determination shall be published in the Federal Register, as a part of the notice of proposed rulemaking where possible, and such notice shall include a succinct explanation of the agency's or the President's action.

Both the preliminary and final cost-benefit analysis should address in detail the issues presented by the regulation including the need for the rule, the various alternative approaches (including the potential advantages and disadvantages of each), the legal basis for agency action, and an assessment of the benefits and costs of the

proposed action. The analysis should provide an objective, critical, and impartial discussion of the regulatory problem and of the potential solutions.

Although basically parallel, the preliminary and final cost-benefit analyses differ in several important respects. In most instances, the quality of analysis and data relevant to the analysis will improve between the time a rule is first proposed and when it is finally issued. Preliminary analyses often use simplified methodologies and data sources. In contrast, later estimates typically apply more sophisticated analyses and better data sources, including those provided during public comment. This tends to improve the accuracy and reliability of estimates, often substantially. In some instances, initial estimates may overestimate costs or underestimate benefits. To a large degree, such additional information will be provided by peer review, public comments, or other material developed by the agency. Thus, the later analysis should generally be more complete. In addition, the final analysis should address significant comments submitted on the preliminary analysis. The preliminary cost-benefit and cost-effectiveness evaluations required by subsection 622(c) will be followed by the formal determinations required by the final cost-benefit analysis. The final determinations, of course, should consider any additional data received by the agency since the publication of the preliminary cost-benefit analysis.

C. Content of the Cost-Benefit Analysis

Subsection 622(c) requires the agency to place an initial cost-benefit analysis in the file of a major rule and publish in the Federal Register a summary of such analysis. The agency then must provide an opportunity for interested persons to comment pursuant to section 553 of title 5, United States Code.

According to subsection 622(c)(2), each cost-benefit analysis shall contain eight major components:

(A) An analysis of the benefits of the proposed rule;

(B) An analysis of the costs;

(C) A discussion of an appropriate number of reasonable alternatives;

(D) An assessment of the feasibility of establishing a regulatory program that operates through the application of market-based mechanisms;

(E) An explanation of the extent to which the proposed rule (i) will accommodate differences among geographic regions and among persons with differing levels of resources with which to comply; and (ii) employs voluntary programs, performance standards, or market-based mechanisms that permit greater flexibility in achieving the identified benefits of the proposed rule;

(F) A description of the quality, reliability, and relevance of economic or scientific evaluations of information;

(G) An explanation of whether the identified benefits of the proposed rule justify the identified costs of the proposed rule, and of how the proposed rule is likely to substantially achieve the rulemaking objectives in the most cost-effective manner;

(H) If a major rule addresses risks to human health, safety or the environment—(i) a risk assessment; and (ii) an assessment of incremental risk reduction or other benefits associated with each signifi-

cant regulatory alternative considered by the agency in connection with the rule or proposed rule.

1. Identification Of the problem

Every cost-benefit analysis, whether preliminary or final, should begin with a discussion of the nature of the problem. The agency should identify those persons or national interests that the underlying statute and the regulation is intended to benefit and discuss the nature of the harm that likely will occur if no action is taken. The analysis should identify the cause or causes of the problem and explain whether or not a market-based mechanism would provide an adequate solution. The agency should identify causes, not just symptoms of the problem.

The analysis also should identify the objectives of the rule, and explain how the rule will achieve them. The Committee encourages agencies realistically to discuss any potential shortcomings of the regulation. Agencies should recognize that regulations impose costs and sometimes fail to fully attain their objectives. The agency should bear in mind that, just as market do not function perfectly, neither do regulatory programs. When considering the benefits or regulating, agencies should not compare imperfect markets or externalities with idealized, perfectly functioning regulatory programs. Recognizing these limitations, the agency should make a reasonable attempt to predict the results of the rule in the cost-benefit analysis. The cost-benefit analysis should make the case why the proposed regulation will produce better results than no action.

This legislation requires agencies to identify the statutory authority relied upon by the agency to promulgate the regulation. The agency should briefly explain why its proposal is within its statutory jurisdiction and is consistent with congressional intent. A similar analysis should be done for each significant alternative to help guide the agency to the least costly alternative that is consistent with statutory objectives.

2. Benefits—§ 622(c)(2)(A)

The heart of a cost-benefit analysis is a review and discussion of the benefits and costs of proposed rule and the reasonable alternatives, including an attempt to balance and compare those costs and benefits. Subsection 622(c)(2)(A), (d)(2)(A), and (e)(1) require the agency to analyze and describe the benefits of a rule and its alternatives. Economists have noted that the valuation and calculation of benefits generally pose the greatest problem in preparing a cost-benefit analysis although cost estimates can also be difficult. The benefits of regulation—particularly environmental, safety and health standards, often are substantial, yet difficult to calculate. The Committee does not expect all cost-benefit analyses will assign numerical values to all projected benefits. The agencies should use a rule of reason. When some aspect of a benefit simply cannot be quantified, the agency should describe the benefit in some detail, state what significance it attributes to the nonquantifiable aspects of the benefit, and explain the basis for its conclusion on this point. Those benefits which cannot be quantified need only be described

precisely and succinctly. If the agency provides a monetary or other quantitative estimate, the analysis should include the methodological justification. The ranges of predictions and margins of error should also be specified, as required by subsection 622(e)(1). Subsection 622(e)(2) requires that the agency should rely on cost, benefit, or risk assessment information that is supported by material that would allow the public to assess the accuracy, reliability, and validity of such information. Finally, the agency should clearly articulate the relationship between costs and benefits under subsection 622(e)(2)(B).

3. Costs—§ 622(c)(2)(B)

Subsections 622(c)(2)(B), (d)(2)(A), and (e)(1) make clear that the cost-benefit analysis should address several critical issues in assessing the costs of a regulation. The cost-benefit analysis should look beyond the immediate compliance costs of regulation and attempt to quantify, or at least identify, the indirect costs and adverse effects which may result from the rule. Opportunity costs can be difficult to project but also can be among the most significant costs of regulation. The inefficient use of resources, and investment disincentives can have a significant impact on the economy. The cost-benefit analysis also should, to the extent practical, identify and describe the indirect adverse effects of the regulation on productivity, wages, economic growth, research and innovation, and the environment, public health and welfare. Where these effects are beneficial or neutral, this should be documented as well. Where costs are difficult to quantify, agencies should not expend unreasonable efforts in seeking to calculate all possible costs.

The Committee believes that when estimating direct economic costs, the agency should, where appropriate, consider whether affected groups can bear the expected costs of the regulations. The agency should consider industry structure, revenues, and other characteristics, such as access to capital financing, geographic location, and the possible future effects of other regulatory requirements.

Agencies then should calculate the total direct costs of compliance, including such costs as construction, operation, monitoring, financing, paperwork, and opportunity costs. Agencies also should estimate costs to the government units, including costs of compliance, administration, enforcement, or lost tax revenue.

If a proposed regulation restricts uses of a product or service, the agency should consider that lost benefit as a regulatory cost. Such an evaluation would not require an agency to determine the inherent "value" of a product. The price that consumers are willing to pay for a product or service is the best measure of its value. Where a regulation would ban a product or service, the cost of that regulation would be the difference between the value of the product or service banned and that of its nearest substitute or technical alternative, taking into full consideration other factors affecting product pricing and performance.

4. Alternatives—§ 622(c)(2)(C)

Subsection 622(c)(2)(C) requires the preliminary cost-benefit analysis to contain a brief description of alternative methods for achieving the objectives of the rule, consistent with the underlying statute. Agencies are required to consider not only alternatives proposed by the public, but should make an affirmative effort to develop alternatives that will achieve the statutory objectives in a less costly or more effective manner. In the past, agencies have sometimes adopted rules without seriously considering alternatives that could more effectively achieve the statutory goals or achieve those goals in a less costly manner. This provision is intended to compel agencies to seek out and consider an ''appropriate number'' of such alternative approaches, particularly market-based mechanisms. The legislation focuses the agency's discussion on an ''appropriate number'' of alternatives so that agencies are not forced to engage in limitless or wasteful discussions of possible regulatory alternatives.

Alternatives that achieve substantially all of the benefits of a proposal should be identified and considered, to determine if such alternatives could reduce the net costs of the regulation. Alternative levels and methods of compliance may be appropriate. The alternative of having no regulation should be a starting point in the analysis. There may be existing voluntary, market,[30] judicial, state, or local regulatory mechanisms that could adequately resolve the problem identified by the agency for action. This is not to suggest that a no action alternative may be adopted when a regulation is mandated by the statute under which the agency is acting.

In recent years, as the costs of regulation and the need to reduce this burden have grown, agencies have developed a number of innovative regulatory techniques to make regulatory programs less costly and more effective. For example, performance standards can be used instead of design standards to reduce compliance costs while still meeting regulatory goals. Market-based mechanisms, such as the sale of marketable permits, have been used to reduce the costs of pollution control while meeting or exceeding regulatory goals. Regulations mandating information disclosure or labeling may adequately guide consumer choice and obviate more traditional command-and-control regulation. Pollution prevention initiatives also may reduce the need for regulation and achieve public health, safety, or environmental goals in a cost-effective manner.[31] Indeed, many government agencies and the regulated community are undertaking pollution prevention efforts. Some innovative firms have found a competitive advantage in pollution prevention, reducing compliance costs or creating new value to the firm.

While far from complete, a fundamental shift is taking place in the way federal regulators go about their business, a shift that this legislation is intended to encourage. In the past, agencies too often reached for a single tool, command-and-control regulation, relying

[30] In certain instances, EPA has successfully used voluntary programs, such as the 33/50 Program, to achieve substantial reductions in pollution in a cost-effective, flexible manner. See Testimony of Carol M. Browner, Administrator, U.S. EPA, before the Senate Committee on Governmental Affairs, March 8, 1995, at p. 2.

[31] See Testimony of Carol M. Browner, Administrator, U.S. EPA, before the Senate Committee on Governmental Affairs, March 8, 1995, at p. 2.

on administrative sanctions imposed through formal enforcement procedures, to solve any regulatory problem that arose. Traditional regulation, while necessary and appropriate in some cases, can be time-consuming, costly to both businesses and governments, and can create disincentives to industrial innovation. Command-and-control regulation is usually less effective and more costly than flexible approaches.

5. Analysis of Market-Based Mechanisms—§ 622(c)(2)(C), (D), and (E)

The specific reference in section 622(c)(C)(ii) to market-based mechanisms reflects not only the Committee's preference for the use of market-based mechanisms in the design of regulatory programs, but also the specific steps agencies must follow so that this preference will be consistently considered when formulating major rules. If agencies fulfill the requirement of setting forth the extent to which the designs of proposed regulatory programs incorporate market-based mechanisms, then each rulemaking process, as well as the record created therein, necessarily should reflect discussion and analysis of market-based mechanisms. Since the Committee believes that where practicable and applicable, such alternatives are likely to produce better performing and more cost-effective regulatory programs, then market-based mechanisms will be an important standard against which agency design efforts can be judged. The agency's assessment of the feasibility of establishing a regulatory program that operates through the application of market-based mechanisms must be expressly reflected in the rulemaking record of major rules. Any specific alternatives adopted must be consistent with the statute under which the agency is acting.

6. Scientific or Economic Information or Evaluations—§ 622(c)(2)(F)

Subsection 622(c)(2)(F) is intended to protect against the use of invalid scientific assumptions by requiring an agency to describe what actions have been taken to ensure the reliability of scientific evidence and the conclusions drawn from that evidence. This requirement is intended to ensure the accuracy and scientific validity of the data and studies upon which the agency relies. Many scientific studies already are subjected to peer review before publication in recognized scientific journals. While the Committee stopped short of requiring such reviews in each case, it intends that scientific evaluations and information not previously subjected to such review should be carefully evaluated.

7. Cost-Benefit and Cost-Effectiveness Determinations—§ 622(c)(2)(G), (d)(2)

Subsections 622(c)(2)(G) and 622(d)(2) are the heart of the cost-benefit requirements of this legislation. They take the agencies one step beyond the descriptive exercises of subsections 622(d)(1) and 622(d)(2)(A). Subject to a carefully drawn exception discussed below, subsection 622(d)(2)(B) requires that, in the final cost-benefit analysis for a major rule, the agency must make a twofold determination based on the whole rulemaking record: (1) whether the

benefits of the rule justify its costs; and (2) whether the rule will achieve the rulemaking objectives in a more cost-effective manner than the alternatives presented in the rulemaking proceeding. This requirement parallels that in subsection 622(c)(2)(G) for the preliminary cost-benefit analysis issued in connection with the notice of proposed rulemaking for a major rule.

The choice of the word "justify" is an important one. It signifies two concepts: first, that precise quantification of costs and benefits is not mandated; second, that agencies may bring to bear certain judgmental factors to supplement their numerical analysis in making the required determination.

When pioneering his own regulatory reform proposal, Senator Bennett Johnston elucidated the advantages of "justify" over a more quantitative word:

> Justify was used rather than exceed for two reasons. First, it is often more difficult to estimate the benefits of an environmental regulation than it is to estimate the costs. For example, a clean air regulation may have far-reaching benefits for the environment that are difficult to quantify.
>
> Consequently, I wanted to give the Administrator the latitude to take into account those difficult-to-estimate benefits. . . . All I ask is that the Administrator candidly describe . . . the nonquantifiable benefits that weighed in her determination.
>
> The second season for using justified is that other policy considerations may constitute a benefit of a regulation. For example, the Administrator may conclude that poor children in particular inner-cities may be suffering from exposure to a chemical that poses a human health threat. Even though the quantifiable benefits may not exceed the quantifiable costs, the Administrator may determine that the regulation is nevertheless justified on other policy grounds. Again, I have no objection to these considerations, as long as the Administrator clearly articulates them as part of her certificate.[32]

The second requirement, that the rule "achieve the rulemaking objectives in a more cost-effective manner than the alternatives described in the rulemaking," also is not a purely "objective" quantitative exercise. The agency is not necessarily required to adopt the alternative with the lowest compliance costs where another alternative provides substantially greater benefits. The term "cost-effective" implies a balancing and weighing of not only the cost of each alternative considered, but also the differing degrees of effectiveness of each such alternative.

When testifying before the Committee, Dr. Paul Portney underscored the limits to quantifying all important costs:

> [R]eform legislation should avoid the perils of excessive quantification. It is useful—nay, essential—to make our regulators think hard and analytically about the good their programs will do and the burdens they will impose. Where

[32] 140 Cong. Rec. S. 5877 (daily ed. May 18, 1994).

> these benefits and costs can reasonably be identified and expressed in dollar terms, they should be accompanied by sensitivity analysis to reflect uncertainties. But it makes no sense to me to pretend that we can, at this point in time, at least, make predictions of ecosystem damage analogous to the estimates we can make of expected reductions in cancer cases that might accompany reduced ambient concentrations of a carcinogenic air pollutant. While we should push regulators to be quantitative and precise where they can, they need also to be able to say, "This program will have other good (or bad) effects. While I cannot estimate their likelihood or magnitude at this time, they played a role in the decision I made." [33]

This does not mean that agencies are free to act arbitrarily or in the absence of appropriate record support in making their determinations under subsections 622(c)(2)(G) and 622(d)(2). An agency's cost-benefit and cost-effectiveness determinations must be "reasonable." By imposing this requirement of reasonableness, the Committee intends that the agency will engage in "reasoned decisionmaking." To satisfy this standard, an agency must apply clearly articulated and understandable criteria, and must explain the reasons why it has reached the determinations required under subsections 622(c)(2)(G) and 622(d)(2).

This legislation provides that the evaluations and determinations required by subsections 622(c)(2)(G) and 622(d)(2)(B) are to be made "if not expressly or implicitly" inconsistent with the statute under which the agency is acting.

This language is intended to clarify the relationship between the requirements of the legislation and the substantive provisions of the enabling statutes that govern agency decisionmaking. The language makes clear that the legislation is generic reform legislation providing methodologies for improving regulatory decisions; it does not override the specific substantive provisions of enabling statutes. The language is also intended to reassure the public and members of Congress that the cost-benefit and cost-effectiveness requirements of the legislation would not introduce into the decisionmaking process factors that are inconsistent with Congress' intent in enacting particular regulatory statutes.

The requirement for cost-benefit and cost-effectiveness determinations in the cost-benefit analysis reflects the Committee's judgment that comparative analysis of the cost and benefits of regulatory proposals and alternatives can contribute significantly to the development of more effective and less costly regulations. At the same time, the "where not inconsistent" limitations recognizes that, in certain cases, Congress may have already determined by legislative enactment that cost-benefit and cost-effectiveness analysis does not provide the appropriate test for decisionmaking.

It is not wise to attempt in this report to specify particular statutes that the Committee believes would be inconsistent with the cost-benefit and cost-effectiveness provisions of this legislation. In some cases, such a discussion would place this Committee in a po-

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[33] See Testimony of Paul R. Portney, Vice President of Resources for the Future, before the Senate Committee on Governmental Affairs, February 8, 1995, at pp. 9–10.

sition of appearing to make authoritative interpretations about statutes with which it is not intimately familiar. Such interpretations are the province of reviewing courts or congressional authorizing committees. Further, a discussion that placed certain statutes in a particular category might be interpreted—wrongly—as an implied finding that other analogous statutes omitted from the discussion were not to be afforded similar treatment. The Committee recognizes that the language of subsections 622(c)(2)(G) and 622(d)(2)(B) must be applied on a case-by-case basis by agency officials and, upon challenge, by reviewing courts. However, it is in order for the Committee to make some general comments about how the subsections are expected to apply to different categories of enabling statutes.

Determining whether the requirements of the legislation are consistent with the enabling statutes at hand is to be done according to the generally accepted rules of statutory construction. Thus, the Committee anticipates that when statutory terms are ambiguous, agency officials and courts will give due weight to legislative history, previous court interpretations of related statutory provisions, and other evidence of congressional intent.

The Committee anticipates that regulatory statutes will fall into one of the three categories: (1) their terms, as fleshed out by appropriate tools of statutory construction, may specify that cost factors are, or are not, to be considered interpretations of related provisions, and other evidence of congressional intent.

The Committee anticipates that regulatory statutes will fall into one of the three categories: (1) their terms, as fleshed out by appropriate tools of statutory construction, may specify that cost factors are, or are not, to be considered in reaching a final regulatory decision; (2) while not specifically mentioning costs, the statutory scheme may create a strong implication that the determinations required by subsections 622(c)(2)(G) and 622(d)(2)(B) are, or are not, to be considered; or (3) the terms, after consideration of other aids to statutory construction, may be truly "silent" on the question. The different categories create different problems of interpretation.

An enabling statute whose terms disclaim the relevance of the cost to a regulatory decision clearly would be inconsistent with this legislation. At the other end of the spectrum are statutes in which Congress specified that cost factors were to be an integral part of a regulatory decision. Rules issued under the latter category of statutes should follow the cost-benefit analysis laid out in this legislation.

Some statutes may not expressly mention costs in either of the above ways but may create a strong implication about their relevance. This may be particularly true for statutes that specify that regulations are to be promulgated by means of a certain methodology in light of specific criteria. A statute laying down precise criteria not including costs or establishing a methodology not considering costs may (particularly in light of clarifying legislative history) imply that the requirements of section 622 are inconsistent. To the contrary, for statutes with relatively elastic criteria methodologies, the more reasonable implication is that they are consistent with this legislation.

Finally, the Committee is aware that after a careful attempt to analyze the underlying statute, using accepted rules of statutory construction, the most reasonable interpretation may be that it is truly "silent" on the question of whether cost-benefit and cost-effectiveness considerations can be included in the preliminary and final regulatory analysis. The Committee intends that the requirements of subsections 622(c)(2)(G) and 622(d)(2) apply in such a case. Thus, the Committee in no way intends that application of the requirements depends upon an affirmative statutory confirmation that costs are relevant. This result is fully consistent with the Committee's approach to cost-benefit analysis: as a general matter it can substantially improve decisionmaking and therefore should be a part of that regulatory process where not inconsistent with specific enabling legislation.

8. Risk Assessment and Risk Management—§ 622(c)(2)(H)

Subsection 622(c)(2)(H) requires for each major rule addressing risks to human health, safety, or the environment that the agency conduct a risk assessment as detailed in subchapter III. Moreover, the initial and final cost-benefit analysis must include an assessment of the incremental risk reduction associated with each significant regulatory alternative considered.

9. Quantification and Evaluation of Costs and Benefits—§ 622(e)

Section 622(e) establishes guidelines for the evaluation and description of benefits and costs in the preparation of a cost-benefit analysis. The Committee recognizes that each agency will have to tailor its analytical methodology to meet particular regulatory problems. However, subsection (e) sets forth three basic principles which the Committee intends all agencies to follow.

First, subsection (e) articulates the Committee's realization that in some cases it will not be possible or desirable to attempt to quantify all of the costs or benefits of a regulatory proposal or of the reasonable alternatives to it. Subsection (e) emphasizes that, although nonquantifiable, such costs and benefits are not to be ignored; they should be described in the cost-benefit analysis, identified in "as precise and succinct a manner as possible" and considered in making the determinations required by section 622(d)(2). As a further safeguard against inadequate attention to nonquantifiable costs and benefits, subsection (e) concludes with a statement disclaiming any intention that the cost-benefit and cost-effectiveness evaluations required by subsections 622 (c) and (d) be made primarily on a mathematical or numerical basis.

Second, subsection (e) establishes conditions for the treatment of quantifiable costs and benefits. Where such quantifications are provided, the subsection requires that they be made "in the most appropriate units of measurement" and that they "specify the ranges of predictions" and "explain the margin of error involved in the quantification methods and in the estimates used." For example, a given cost-benefit analysis may describe one of the quantifiable benefits of a regulation as "cases of serious injury reduced." The most precise estimate, consistent with subsection (e), may be the prediction that actual benefits will be within a range of "ten to fifty

cases annually" (this is the "range of prediction"). The probability that the number of cases reduced will actually be within this range may be eighty percent.

By requiring that benefits and costs be quantified "in the most appropriate units of measurement," the Committee intends to emphasize that benefits and costs need not always be expressed in monetary terms. However, reducing all costs and benefits to a common unit of measurement will make the analytical and evaluative exercise more useful and understandable. Hence, efforts should be made to translate costs and benefits into monetary or other concrete terms where appropriate. For example, benefits that consist of reducing or controlling adverse effects on health or the environment could be described in the first instance by estimating, using the risk assessment procedures of this legislation, the degree to which the rule would reduce the risk that such effects would occur. Where meaningful methodologies are available, the agency then might attempt to determine how much society is willing to pay to achieve such a reduction risk.

These requirements recognize that quantification of costs and benefits is far from an exact science. As stated elsewhere in this Report, the Committee intends a reasonable analysis and comparison employing the degree of precision appropriate to each situation. The requirements also recognize that past regulatory analyses have not always adequately disclosed the imprecisions inherent in numerical estimates or the assumptions built into the methodologies used to arrive at them. Subsection (e) requires that assumptions and imprecisions in the analysis be prominently displayed, a requirement paralleling this subsection's directive that the agency's evaluation of cost-benefit relationships be "clearly articulated."

Third, subsection (e) prohibits agencies from relying on cost or benefit information "not accompanied by data, analysis, or other supporting materials that would enable the agency and other persons interested in the rulemaking to assess the accuracy and reliability of such information." This requirement addresses the concern that participants in the regulatory process sometimes make vague, overstated cost or benefit claims not adequately documented at the time nor borne out by subsequent experience. In appropriate cases, the agency should consider whether the cost or benefit information provided is consistent with the provider's representations to other regulatory decision-makers and with data and methodology that have accurately predicted the costs or benefits associated with previous regulations. The nature and extent of information required by the agency should be tempered by the practical limits of economic and scientific analysis. There is always a danger that interested persons may misrepresent the projected costs or benefits of regulation so as to support arguments for a more or less strict regulatory approach. This certainly merits agency scrutiny.

10. Use of data and information—§ 622(g)

Subsection (g) makes clear that it is the responsibility of an officer or employee of the agency to direct the preparation of the cost-benefit analyses. This provision does not preclude a person outside the agency from gathering data or information to be used in preparing the cost-benefit analysis or from providing an explanation

sufficient to permit the agency to analyze such data or information. Agencies also are not precluded from using contractors to perform preliminary and supporting analysis, but agencies maintain ultimate responsibility for such analyses. The agency must identify the data or information gathered or explained and describe the arrangement by which the information was procured by the agency, including the total amount of funds expended for it. Nothing in this subsection precludes the transfer of employees from one agency to another for temporary duty assignments to assist in the preparation of a cost-benefit analysis. The Committee recognizes that certain agencies may have expertise in certain areas, and encourages agencies to share personnel to best accomplish the purposes of this legislation.

11. Savings clause—§ 622(h)

Subsection (h) provides that the cost-benefits requirements not alter the criteria for rulemaking otherwise applicable under other statutes.

§ 623. Judicial review

The central requirement of this legislation is that a cost-benefit analysis and, where relevant, risk assessment, be prepared for major rules. Such analyses, where not inconsistent with the statute under which the agency is proposing the rule, must include determinations as to whether the rule's benefits justify its costs and whether the rule will achieve its objectives in a more cost-effective manner than alternative approaches. The Committee intends that these cost-benefit and risk assessment requirements be subject to limited court scrutiny only as part of the whole administrative record and should guide a reviewing court in evaluating the validity of the rule.

Simply put, the Committee intends to allow sufficient substantive review to ensure that agencies will produce rules based on reasoned analysis pursuant to subchapters II and III. At the same time, the Committee does not want to encourage litigation over procedural technicalities that might ensnare an agency that has made a good-faith effort to perform and consider cost-benefit analysis and risk assessment.

Section 623 imposes significant limits on the role of judicial review in enforcing the risk assessment and cost-benefit requirements of this legislation. This legislation is intended to create a framework for cost-benefit analysis that the Committee believes will lead to improved regulation. It will serve primarily as a blueprint for deliberations by the agency officials who conduct the rulemaking and by any peer review panels that provide an independent look at the agency's reasoning (although the Committee also anticipates input from presidential oversight authorities, members of the public, and, of course, the relevant oversight committees of Congress).

Subchapters II and III are *not* intended to create a detailed code of privately enforceable rights. If the legislation's specifications as to risk assessment and cost-benefit analysis were judicially enforceable in their own right, the court's attention would inevitably be focused on what is really an interim step in the process. Yet, the

question of whether the agency's analysis comports with the specifications of this legislation should never be examined in a vacuum.

The legislation specifically provides for independent and external peer review to help ensure that agencies use technically and scientifically sound techniques for risk assessments and cost-benefit analyses. The comments of the peer review panel, along with the risk assessment or cost-benefit analysis, become part of the administrative record and may be considered during review of the final rule.

The cogency of the agency's cost-benefit analysis conclusions should be considered in light of any peer review panel's comments and the agency's response to those comments in the statement of basis and purpose.

If the independent experts on the peer review panel are satisfied that the risk assessment or cost-benefit analysis is valid, a court might well rely on the panel's endorsement as one reason to sustain the validity of the final rule. Conversely, if the peer review panel found significant reasons to doubt the validity of an agency's assessment or analysis, and the agency simply ignored its comments, that might help a court conclude that the final rule is arbitrary and capricious.

It is the end product—the agency's justification for the rule in light of the entire record—that should be the focus of the court's attention.

Subsection (a) makes clear that compliance or noncompliance by an agency with the provisions of subchapters II and III is subject to judicial review only in connection with the review of the final rule and according to the provisions of section 623.

Subsection (b) prohibits judicial review of a determination of whether a rule is, or is not, a major rule where that determination is made by a designee of the President or the Director under section 622. The authority granted to the Director or other designee by section 622(b) to identify major rules is intended to facilitate presidential management and coordination of the regulatory process. The Director or other designee will be able to focus the attention of agencies on those rules which they believe, consistent with national priorities, should be designated major rules pursuant to section 621(4)(A) and subjected to a more intensive analysis than would normally be the case. Legal challenges to the exercise or failure to exercise this inherently managerial or political authority would be inappropriate and therefore are precluded.

Subsection (c) allows limited judicial review of an agency determination that a rule is, or is not, a major rule under section 621(4)(A)(1) (on grounds that the rule is likely to have a gross annual effect on the economy of $100,000,000 or more in reasonably quantifiable direct and indirect costs). The Committee, however, does not intend to stimulate protracted litigation over an agency's preliminary estimate of a rule's economic impact. Consequently, judicial review is limited to an evaluation of whether an agency properly calculated the economic impact of a rule in light of the information available at the time it performed this analysis. The Committee intends that courts generally will defer to an agency's reasonable, good faith estimate of whether the $100,000,000 threshold has, or has not, been met. A rule only may be set aside based on

a clear and convincing showing that the agency has erred. This heightened evidentiary standard is appropriate in light of the difficulty of projecting ab initio the economic impact of a rule and the extent to which agencies may have to rely on subjective judgments in making cost estimates. Subsection (c) also provides that there is no judicial review of the determination that a rule is, or is not, a major rule under 621(4)(A)(ii). This bar on review is appropriate in light of the complexity and subjectivity of the criteria set out in that subsection, and because agency priority-setting does not readily lend itself to judicial scrutiny.

Section (d) provides that, if the agency has failed to perform the analysis or assessment required under the legislation, the court shall vacate and remand the rule to the agency for further consideration in light of the requirements of this legislation. The subsection specifies that courts are not to review whether analyses or assessments conformed to the particular requirements of this chapter. This subsection also ensures that immaterial procedural flaws in an analysis or assessment shall not be a sufficient basis for overturning a rule.[34] Rather, the analysis and assessment become part of the overall rulemaking record, as provided in subsection 623(e).

Subsection (e) provides that any analysis or assessment prepared under the legislation shall not be subject to an interlocutory challenge separate or apart from review of the agency action to which it relates. Such piecemeal review of agency compliance would delay the rulemaking process. When an action for judicial review of the agency action is instituted, any cost-benefit analysis or risk assessment for such agency action shall constitute part of the whole rulemaking record of agency action for the purposes of judicial review, and shall, to the extent relevant, be considered by a court in determining the legality of the agency action. The analyses and assessments will summarize, analyze, and tie together much of the factual and other support for the rule. As such, the Committee expects that the analysis or assessment will often provide a strong brief in support of the rule and should help justify the rule both to the public and the court, as statements of basis and purpose traditionally have done in agency rulemaking proceedings. The courts should give ample deference to an agency's identification, valuation, and comparison of regulatory costs and benefits. The Committee does not want courts to second-guess agency decisions in this regard. This is an essential limitation, as judges normally lack the technical training in science and economics to conduct in-depth reviews of the adequacies of cost-benefit analyses or risk assessments.

Where the party challenging the rule is able to demonstrate that, in light of the cost-benefit analysis or risk assessment, the rule is arbitrary and capricious, the court may remand the rule to the agency for the development of a more complete record, or for the preparation of a more detailed analysis or risk assessment, or both.

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[34] See Testimony of Peter L. Strauss, Betts Professor of Law, Columbia Law School, before the Senate Committee on Governmental Affairs, March 8, 1995, at pp. 11–12 (stating that allowing judicial review of procedural compliance issues would invite a high reversal rate that is as likely to reflect judicial error as agency error).

§ 624. Deadlines for rulemaking

For a two-year period after the effective date of the legislation, this section extends certain rulemaking deadlines for up to six months to allow agencies time needed to comply with the analytical requirements of the legislation. The affected deadlines include statutory and judicial deadlines for rulemakings, as well as rulemaking deadlines that would create an obligation to regulate through individual adjudications.

The sole purpose of this section is to give agencies some time to make a reasonable effort to faithfully fulfill the requirements of this legislation. The Committee understands that the legislation creates new obligations for agencies in a time of limited budgets. In many cases, these obligations will have to be met without additional resources. The Committee intends that agencies be given a reasonable opportunity to develop policies and procedures adequate to comply with the law. The Committee does not intend this grace period to be used otherwise to delay decisions or to compromise the implementation of legal requirements.

§ 625. Agency review of existing rules

The Committee believes that for regulatory reform to be effective it must not be prospective only. It must also look back and review existing regulations to eliminate outdated, duplicative, or unnecessary rules, and to reform and streamline others. With the passage of time, outmoded government decisions need review and revision. Review is also needed to address the rising cumulative regulatory burden on individuals, businesses, States and local governments, and others. Too many private and public resources are spent on compliance with current Federal regulations to limit regulatory reform to new rules.

Review of existing rules has been required since 1981 under Executive Orders 12291, 12498, and 12866. Yet, getting agencies to review existing rules apparently is much easier said than done. In the first annual report on E.O. 12866, released in November 1994, OIRA Administrator Sally Katzen admitted that bureaucratic incentives make such review a difficult undertaking. While the "lookback" process had begun under E.O. 12866, she said, "it had proven more difficult to institute than we had anticipated. . . . [A]gencies are focused on meeting obligations for new rules, often under statutory or court deadlines, at a time when staff and budgets are being reduced; under these circumstances, it is hard to muster resources for the generally thankless task of rethinking and rewriting current regulatory programs" (p. 36). Much the same point was made in OIRA's May 1, 1994, report to the Vice President on the first six months of implementation of E.O. 12866 (pp. 22 & 25), and in Ms. Katzen's testimony before the Committee on May 19, 1994. After extensive review of the regulatory process, Vice President Gore concluded that "thousands upon thousands of outdated, overlapping regulations remain in place."[35] The long but disappointing record of Executive Branch review efforts necessitates a legislative mandate.

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[35] National Performance Review, *From Red Tape to Results: Creating a Government that Works Better and Costs Less* (1993).

The Committee believes that however bitter the medicine may be, it is time that agencies deliver on the now long-standing requirement to review existing rules. Accordingly, at section 625 of the legislation, the Committee requires agencies to review their current rules. The section sets up a very reasonable timeframe of ten years (with an extension of up to 5 years for good cause) for the review of each rule. To ensure that this requirement is met, the legislation would render unenforceable any rule that is not reviewed as required by the section. The Committee believes that this is a reasonable and effective requirement and finally will set agencies on the road of revisiting forgotten, but still potent, rules.

Section 625(a) requires each agency, within 9 months after the effective date of the legislation, to prepare and publish in the Federal Register a proposed schedule for the review of major rules, as well as other rules selected by the agency. To set priorities for review, the agency must work with the Administrator of OIRA and with the classes of persons affected by the rule, including members from the regulated industries, small businesses, State and local governments, and organizations representing the public. The Committee expects that agencies will solicit comments from these groups and hold public meetings, where useful and appropriate, to discuss priorities for review.

The head of the agency and the OIRA Administrator should base priorities for review on the likelihood that the revision or elimination of a rule would: (1) provide the same or greater benefits at substantially lower costs; (2) achieve substantially greater benefits at the same or lower costs; or (3) replace command-and-control rules with market mechanisms or performance standards that achieve substantially equivalent benefits at lower costs or with greater flexibility.

With each proposed schedule for the review of existing rules, the agency must include: (1) a brief explanation of the reasons why the agency has selected each rule for review; (2) a target date for completion of each review; and (3) a request for public comments on the proposed schedule. The agency should schedule its reviews so that they are reasonable distributed over time, with rules most in need of scrutiny reviewed first.

Agencies should also insure that related rules are reviewed at the same time. The Committee intends that agencies review complete rules or sets of closely related rules as a whole. While rules are often promulgated in the Federal Register in somewhat isolated or distinct form, they are usually incorporated into a large rule or set of rules codified in the Code of Federal Regulations. Thus, for example, a mechanical review of rules based merely on elapsed time since promulgation would most probably obscure the full scope of a rule and confuse those who are interested in it. The Committee expects, therefore, that agencies will schedule rules for review both within the permitted timeframe and in a manner sufficient to include substantively related regulatory matters.

No later than 90 days before publishing the proposed schedule in the Federal Register, each agency shall submit the schedule to the Director of OMB (or other presidential designee), who may select any additional rule for review.

No later than 1 year after the effective date of this section, each agency must publish in the Federal Register a final review schedule, along with its response to comments received concerning the proposed schedule.

Subsection (b)(1) states that the agency shall review: (A) each rule on the schedule; (B) each major rule promulgated, amended, or otherwise continued by an agency after the effective date of this section; and (C) each rule promulgated after the effective date of this section that is selected for review by the President (or the Director or other presidential designee).

The review of a rule required by this section shall be completed no later than the later of: (A) 10 years after the effective date of this section; or (B) 10 years after the date on which the rule is (i) promulgated; or (ii) amended or continued pursuant to this section. These deadlines can be extended only under the provisions of subsection (f) which allow for a one-time extension of up to five years for the review of a rule.

Subsection (c) provides a list of four items that must be included in a notice of proposed action for a rule being reviewed, which would then be published in the Federal Register.

First, the notice must include an identification of the specific statutory authority under which the rule was promulgated and an explanation of whether the agency's interpretation of the statute is expressly required by the current text of that statute or, if not, whether it is within the range of permissible interpretations of the statute.

Second, to the extent practicable, the agency must perform an analysis of the benefits and costs of the rule during the period in which it has been in effect. While the Committee believes the review of a rule would be of little use if some effort was not made to analyze the true costs and benefits of the rule, the Committee is equally concerned that agencies might expend very considerable resources in an overly detailed look back. The review should bring to the fore old rules that need to be eliminated or modified. Analysis sufficient to flag those rules is the goal. Subsequent analysis designed to support new or revised regulations should be more detailed.

Third, agencies should explain the proposed action with respect to the rule, including action to repeal or amend the rule to resolve inconsistencies or conflicts with any other obligation or requirement established by any Federal statute, rule, or other agency statement, interpretation, or action that has the force of law.

Finally, the notice should include a statement that the agency seeks proposals from the public for modifications or alternatives to the rule which may accomplish the objectives of the rule in a more effective or less burdensome manner.

Subsection (d) states that if an agency proposes to repeal or amend a rule under review pursuant to this section, the agency shall, after issuing the notice required by subsection (c), comply with all applicable rulemaking and other procedures that the agency would otherwise have to comply with. In other words, the fact that the rulemaking is initiated to satisfy the review requirements of this legislation does not alter the legal obligations of the agency to comply with all required rulemaking procedures or other deci-

sion-making requirements. Any requirements that the agency would have to comply with if it were repealing or amending the rule for any other reason would also apply to a rulemaking to repeal or amend that rule on account of review undertaken under this section.

Subsection (e) states that if an agency proposes to keep unchanged a rule after review under this section, the agency shall: (1) give interested persons at least 60 days after the publication of the notice required by subsection (c) to comment on the proposed continuation; and (2) publish in the Federal Register notice of the continuation of such rule.

Subsection (f) allows for the extension of the time period in which an agency is to review any particular rule. If an agency reasonably determines that the review of a rule within the 10-year time frame is contrary to an important public interest, the agency may request the President (or the President's designee), to extend the period up to five additional years. Extensions must be published in the Federal Register with an explanation of the reasons. The Committee expects that the ten-year time-frame for review will be complied with in most cases. This subsection's extension will give agencies some flexibility where, for example, resource constraints frustrate otherwise timely review of all rules. For example, as discussed with regard to subsection (a), above, the Committee expects that agencies will schedule the review of rules by related subject matter over a reasonable period of time. Such schedules may lead to the review of a related or commonly codified set of rules, some of which are older than ten years (e.g., distinct sections may have been promulgated at different times). The ability to request and justify an extension would, in such a case, provide for a more meaningful review of the entire set of rules. The Committee intends that, as an exercise of executive oversight, a decision to grant an extension under this subsection shall not be subject to judicial review.

In subsection (g), the Committee included, as an amendment in mark-up, a "sunset" provision, which makes a rule unenforceable if an agency has not conducted its review of that rule within the timeframe allotted. In this way, the Committee ensures that agencies will take seriously the need to review existing rules in a timely fashion. As discussed previously, the Committee wants to ensure that the call to review existing rules will no longer be easily ignored. With a sunset, agencies will have to follow through on the review requirements, or face the loss of a regulation.

Subsection (h) states that nothing in this section shall relieve any agency from its obligation to respond to a petition to issue, amend, or repeal a rule, for an interpretation regarding the meaning of a rule, or for a variance or exemption from the terms of a rule, submitted pursuant to any other provision of law.

§ 626. Public Participation

The efficiency and effectiveness of the Federal regulatory process depends not only on the adequacy of cost-benefit analysis, but also on the transparency of the process. Public participation, regulatory review, judicial review, and congressional oversight all depend to one extent or another on confidence that agencies will consider all relevant information, allow for meaningful public comment on reg-

ulatory proposals, disclose communications that may affect a regulatory decision, and compile a complete rulemaking record.

The current legislation reflects the Committee's concerns on a set of sunshine procedures that can improve public participation and maximize accountability for regulatory decisions without burdening agency decision makers or compromising pre-decisional disclosure or Executive privilege concerns. Section 626 requires rulemaking agencies to take a number of steps to insure accountability for, and public participation in, the development and review of regulatory actions. Section 645 provides parallel requirements for public disclosure of regulatory review-related information by OMB or another regulatory review office. These provisions were included in the managers' amendment introduced in the Committee's mark-up on March 23, 1995. Both sets of provisions, as they now appear in the current legislation, are consistent with recommendations of the Administrative Conference of the United States. (Recommendation 88–9, para. 4–6, 1 C.F.R. 305.88–9).

Section 626 first requires agencies to make all reasonable efforts to provide the public with opportunities for meaningful participation in the regulatory process. Agencies should seek to inform and solicit comments from those who are intended to benefit from and those who are expected to be burdened by any regulatory action.

Second, in promulgating individual rules, agencies must include in their rulemaking notices statements that: (1) summarize steps taken to comply with the cost-benefit analysis and other requirements of this legislation; (2) summarize any cost-benefit analysis performed for the rule; (3) certify that the rule's benefits justify its costs (or explain why such statement cannot be made); and (4) summarize any regulatory review decisions, and the agency's response to such review, including an explanation of any significant resulting changes to the rule.

The certification established by this legislation is a new requirement for the rulemaking notice. It requires that agencies certify that a rule's benefits justify its costs. This provision is in accordance with Section 622's requirement that the initial and final cost-benefit analysis contain an agency determination as to whether the benefits of a rule justify the costs of a rule. The Committee also expects, by the terms of this subsection, that where an agency states that it cannot certify that the benefits justify the costs, the agency will state explicitly why such a determination cannot be made. Such explanation may include a statement that there is insufficient data upon which to base such a determination or that the underlying substantive statute upon which the rule is based precludes the agency from making that determination or requires the issuance of a rule for which the benefits do not justify the costs. In any case, this provision requires the agency to be explicit about any inability to make the required certification.

By "significant," the Committee means any substantive decision or action that affects or relates to the content of an agency rulemaking activity, such as a significant or substantive change or communication. It does not include: stylistic, clerical, or grammatical matters; simple descriptions of a rulemaking activity; or status reports. It does include modifications of agency cost-benefit analyses; suggested changes to or criticisms of a rulemaking activity; as-

sessments of the impact of a rulemaking activity; or suggestions about or criticisms of a milestone, schedule, or date for undertaking a rulemaking activity.

The requirement for explanation of significant changes made to rules as a result of regulatory review parallels the requirement in section 645 that OMB or another regulatory review office explain its review actions. The rulemaking agency should fully explain and justify the reason for any significant change made to a rule based on regulatory review.

Third, to give the public notice about the pendency of regulatory review, agencies must identify, upon request, a regulatory action and the date upon which such action was submitted for any regulatory review established under subchapter IV.

Fourth, to provide the public with a reasonable understanding of the rulemaking decision and its underlying analysis, agencies must disclose any information created or collected in performing any cost-benefit analysis.

Finally, to ensure the compilation of a complete and accurate rulemaking record, agencies must place in the rulemaking record all written communications received from OMB or other designated officer under subchapter IV, or any other person or office relating to regulatory review.

Subchapter III—risk assessment

Risk assessment is a widely recognized tool to structure information for regulatory decisionmaking. The acceptance of risk assessment as a standard tool can be traced back to the seminal report issued by the National Academy of Sciences in 1983: *Risk Assessment in the Federal Government: Managing the Process*. The report presented a conceptually sound and logical approach that has been widely adopted by federal and state agencies to assess environmental, health, and safety risks.

Twelve years after publication of the NAS risk report, there is general agreement that the risk assessment process needs to be refined. The process is not broken, but it does need to be better understood. Risk assessment can be most useful when those who rely on it to inform the risk management process understand the nature and limitations of risk assessment, and use it accordingly. This means that decision makers must at least understand that the process must rely on assumptions and cannot be divorced from assessors' values. They must understand what assumptions were used in the assessment in question, and what values they reflect; that the risk estimate with which they work is expressed as a range, with the level of certainty that the true average is in that range quantified; and, that variability is expressed to the degree that it is known, *i.e.*, how many and what kind of persons (*e.g.*, children) will likely be at significantly higher or lower risk than the hypothetical average individual. Risk managers must take all of these factors into account in making a decision, along with political and economic factors extrinsic to the risk assessment.

In recent years, several studies have documented the use of risk assessment and recommended improvements to the process. In June 1993, the Carnegie Commission on Science, Technology, and Government issued *Risk and the Environment: Improving Regu-*

latory Decision Making. Many of the provisions within the risk assessment subchapter of this bill are strongly supported by findings in the Carnegie Commission report.

The Office of Science and Technology Policy (OSTP) within the Executive Office of the President issued a brief report in March 1995 entitled, *Science, Risk, and Public Policy*. This report also supports many of the concepts addressed in the risk assessment subchapter. Three of the principles in the OSTP report—an open and transparent risk assessment process; scientific peer review; and level of effort commensurate with the severity of risk—are embodied in this risk assessment subchapter.

This subchapter presents: findings and purposes (sec. 631); definitions (sec. 632); applicability (sec. 633); savings provisions (sec. 634); principles for risk assessments (sec. 635); principles for risk characterization (sec. 636); peer review (sec. 637); guidelines, plan for assessing new information, and report (sec. 638); research and training in risk assessment (sec. 639); interagency coordination (sec. 640); plan for review of risk assessments (sec. 640a); judicial review (sec. 640b); and deadlines for rulemaking (sec. 640c).

§ 631. Findings and purposes

This section describes the importance of using realistic and plausible scientific risk assessments in making sound and cost-effective management decisions. Risk assessment has proven to be a useful decisionmaking tool, but improvements are needed in both the quality of the science and the characterization and communication of the findings. In addition, the public stakeholders need to be more fully involved in the decisionmaking process, and they must have access to critical information that is effectively communicated in an objective and unbiased manner.

The purposes of the subchapter are to provide principles and procedures for agencies to follow to ensure that the public and the Executive Branch are presented with the most realistic and plausible information; that relevant data and potential methodologies are fully considered; that significant choices in the risk assessment process are explained; and that consistency in preparing risk assessments and characterizations is enhanced.

§ 632. Definitions

This section defines several key technical terms and lists the agencies covered by the risk assessment requirements. The term "emergency" is defined as a situation that is immediately impending and extraordinary, demanding due attention by the agency to control a risk reasonably expected to cause death, serious illness or severe injury to humans, or substantial endangerment to private property or the environment if no action is taken.

The term "estimates of risk" is defined as numerical representations of the potential magnitude of harm to populations or the probability of harm to individuals. Estimates are derived by considering the range and distribution of estimates of dose-response and exposure, including appropriate statistical representation of the range and most likely exposure levels. When appropriate and practicable, there should be a description of any subpopulations that are likely to experience greater than average exposures.

The term "hazard identification" is defined as the identification of a substance, activity, or condition potentially causing harm to human health, safety or the environment.

Risk assessment is the process by which complex technical data are combined and analyzed to provide decision makers with information useful in making policy decisions. In some decision contexts, such as when evaluating food additives, it is useful to distinguish four steps in the risk assessment: hazard identification, dose-response analysis (which together comprise "hazard assessment"), exposure assessment and risk characterization. In other contexts, such as transportation safety, one or another of the first three steps may not be relevant. "Risk assessment" is defined as identifying, quantifying, where feasible and appropriate, and characterizing hazards and exposures in order to provide structured information on the nature of threats to human health, safety, or the environment. This definition is included because some regulatory activities, such as OSHA's Hazard Communication regulation, are triggered by the hazard identification step, and also because many extra-regulatory consequences also are triggered. It is very important that "hazard identification" related to major rules meet the same quality as any full "risk assessment." Hazard identification should be distinguished as only the first step in the risk assessment process and not be substituted for a full "risk assessment" for the purposes of this legislation.

"Risk characterization" is defined as the integration, synthesis, and organization of hazard identification, dose-response and exposure information that addresses the needs of decisionmakers and interested parties. The characterization should include discussions of the uncertainties, conflicting data, estimates or risks, extrapolations, inferences, and opinions.[36]

A "screening analysis" is defined as a qualitative estimate or bounding estimate[37] of risk that allows risk managers to accept or reject some management options, or allows establishing priorities for agency action. A screening analysis also could include an assessment such as one for a negotiated product restriction or approval, performed by a regulated party and submitted to an agency under a regulatory requirement.[38] The Committee recognizes that screening analyses typically use conservative assumptions for their purposes when assessing the risk.

A "substitution risk" is defined as a reasonably likely increased risk resulting from a regulatory option designed to decrease other risks. The agency should view this increased risk as increasing the

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[36] This definition tracks the Carnegie Report that describes risk characterization as the process "in which the results of the above steps (hazard identification, exposure assessment, and dose-response) are integrated to describe the nature of the adverse effects and the strength of the evidence and to present one or more 'risk numbers'." (p. 77). The definition also follows the evolving views of several recent National Academy of Sciences Committees that have come to regard risk characterization as more than merely a written summary of the risk assessment.

[37] A bounding estimate is an estimate of exposure, dose, or risk that is likely to be significantly higher than that incurred by any person in the population with the highest actual exposure, dose, or risk. Bounding estimates are frequently generated by using high-end values for all of the parameters that are used to calculate exposure, dose, or risk. Bounding estimates are useful in developing statements that an exposure, dose, or risk is "not greater than" the estimated value. Bounding estimates do not characterize actual high-end risks to a population.

[38] See Science, Risk and Public Policy, at p. 3 ("Risk assessments range in depth and complexity from simple screening analyses to major undertakings . . .").

net costs of a regulation and should account for any substitution risks in the risk assessment and cost-benefit analysis.

§ 633. Applicability

This legislation provides guidance on how risk assessments required by the legislation should be conducted. This section recognizes that enforcement of the exact provisions has to be tempered by the circumstances. In particular, the principles and procedures included in the subchapter do not apply when a risk assessment or characterization is performed in respect to an emergency (as determined by the agency head), an environmental inspection or individual facility permitting action, a screening analysis, or product label.

§ 634. Savings provisions

This section states that nothing in the chapter is intended to modify any statutory standard or requirement designed to protect human health, safety, or the environment.

§ 635. Principles for risk assessment

This section presents basic principles that should be followed in conducting a risk assessment. First, the risk assessment should provide a systematic means to structure information.[39] Second, to the maximum extent practicable, policy-driven default assumptions[40] should be used only in the absence of relevant available information. The risk assessment process should also promote involvement from all stakeholders and provide an opportunity for public input.[41]

Although policy-driven default assumptions are inherent in the risk assessment process, subsection 635(a)(2) provides that, to the maximum extent practicable, relevant available information should always be utilized and the policy-driven default assumption modified, based on the available data. As the recent NAS/NRC report *Science and Judgment in Risk Assessment* (1994) clearly acknowledges,

> Over time, the choice of defaults should have decreasing impact on regulatory decision-making. As scientific knowledge increases, uncertainty diminishes. Better data and increased understanding of biological mechanisms should enable risk assessments that are less dependent on default assumptions and more accurate as predictions of human risk. (p. 90).

Subsection 635(a)(5) specifies that risk assessments should be designed so that the degree of specificity and rigor employed is com-

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[39] The 1995 OSTP report states "The concept of risk assessment is attractive as a decision-making tool because it implies rationality, orderliness, and scientific credibility." (p. 4).

[40] Policy-driven default assumptions (sometimes referred to as default options) are a key element of risk assessment as it is practiced today. The 1983 NRC report, Risk Assessment in the Federal Government: Managing the Process, defined default options as "the option chosen on the basis of risk assessment policy that appears to be the best choice in the absence of data to the contrary." As described in the 1994 NRC report, Science and Judgment in Risk Assessment, default options "are generic approaches, based on general scientific knowledge and policy judgment, that are applied to various elements of the risk assessment process when specific scientific information is not available. (p. 28). Default assumptions are necessary to bridge gaps where information is incomplete.

[41] In the Principles in Devising Risk Policy, the 1995 OSTP report states: "The risk assessment process should be as open, transparent, and participatory as possible." (p. 17).

mensurate with the consequences of the decision to be made.[42] Differently stated, the level of effort required for an assessment depends on what is at stake. In some cases, very severe risks can be identified and managed with relatively simple risk assessments because the stakeholders agree that the danger is great enough not to require further analysis. Often, the risks requiring detailed analysis are those that are marginal on a cost-benefit scale: in these cases, credible, detailed analyses can be crucial to satisfying stakeholders.

The risk assessment principles of section 635 and the risk characterization principles of section 636 are broadly written to accommodate the wide range of risk assessments encompassed by the legislation. For example, the Committee does not intend to force agencies looking at safety risks to provide "exposure information," if that term is not applicable to the types of risk assessments that the agency does. In Secretary Peña's testimony before the Senate Environment and Public Works Committee on March 22, 1995, he stated:

> Risk assessment and risk characterization, as defined in S. 291 . . ., have little to do with the Department's safety rulemaking process. Unlike EPA or health agencies, DOT safety rules seldom are based on quantification of the risks of toxicity or exposure for exposed individuals, populations, or resources . . . Much of what we already do to define safety problems is a very real form of risk assessment, but it makes no sense to require the FAA or the Coast Guard to go through an EPA-like risk assessment procedure, using techniques and terminology that are not meaningful in an aviation or maritime safety context. Adding procedural steps makes it less likely that agencies can take the proactive steps necessary to address perceived safety concerns before accidents happen.

The Committee recognizes the variety of risk assessments that would be required under this law, and that in different agencies different terms may be used to denote the same kind of activity. For instance, in accident-prevention studies of the type referred to by Secretary Peña, elaborate event-frequency analyses are carried out, with the express purpose of estimating the probability of different kinds of accidents. These correspond to the complex exposure assessments frequently done by EPA. For safety studies, the hazard part is virtually constant for all similar accidents, so the information useful to decision makers is just the predicted event frequency; for evaluating other risks, both the hazard and exposure may vary from one instance to another, and both need to be understood. The Committee does not intend to deter agencies from using the forms of risk assessment appropriate to their respective regulatory decisions, nor to prescribe the methodology for doing so. It does intend that the methodology be credible and understandable, and its limitations be made known to the public. The Committee

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[42] The OSTP report recognizes that risk assessments can vary from simple screening analyses to "major undertakings that require years of agency effort costing hundreds of thousands of dollars and resulting in detailed, scientifically peer-reviewed documents. (p. 3–4). Accordingly, the OSTP Principles of Devising Risk Policy state: "The level of effort in assessing a risk should be commensurate with the severity of the risks and costs to society." (p. 17).

intends to allow agencies to use the most advanced and scientifically valid techniques for performing the wide variety of risk assessments covered by this legislation.

§ 636. Principles for risk characterization

This section presents basic principles that should be followed when characterizing the results of a risk assessment.[43] Subsection 636(1)(A) requires that the risk characterization include a description of the exposure scenarios used, the natural resources or subpopulations being exposed, and the likelihood of the selected exposure scenarios. Subparagraph (B) goes on to require that when the risk assessor makes significant choices or judgments in the selection of models, assumptions, or inferences, those choices should be identified and explained. Of particular concern are any policy decisions or policy-driven default assumptions made by the risk assessor, as indicated in subparagraph (B)(iii). In describing judgments, the risk assessor should indicate, pursuant to subparagraph (B)(iv), the extent to which a model or other tool has been validated by, or conflicts with, empirical data. Finally, the impact of alternative choices of assumptions, default options or mathematical models should be described pursuant to subparagraph (B)(v).

Subparagraph (C) further requires the risk characterization to include, as appropriate, a description of the major sources of uncertainties in the hazard identification, dose-response and exposure assessment phases of the risk assessment. These first three steps in the risk assessment process include varying degrees of uncertainty based on the assumptions made.[44]

Subsection 636(1)(D) requires that risk assessments, to the extent feasible, include as a component of the risk assessment the range and distribution of exposures and risks[45] used in and generated by the risk assessment.[46] The purpose of this provision is to provide the risk manager with as complete a picture of the risks as possible, avoiding, for example, the simple presentation of a single-point upper-bound exposure or risk estimate.

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[43] These risk characterization principles reflect those enunciated by joint EPA-industry work groups. See American Industrial Health Council, "Improving Risk Characterization," Washington, D.C. (Sept. 1992).

[44] See Science and Judgment in Risk Assessment (pp. 71–72).

[45] See Risk and the Environment: Improving Regulatory Decision Making: "Regulatory agencies should report a range of risk estimates when assessing risk and communicating it to the public. How risk estimates, whether derived from an inventory or not, are conveyed to the public, significantly affects the way citizens perceive those risks. Single-value risk estimates reported to the public do not provide an indication of the degree of uncertainty associated with the estimate. Such numbers do not convey the conservative nature of some risk estimates." (p. 87); see also Science and Judgment in Risk Assessment: "EPA should make uncertainties explicit and present them as accurately and fully as is feasible and needed for risk management decision-making. To the greatest extent feasible, EPA should present quantitative, as opposed to qualitative, representations of uncertainty." (p. 9–24) "The committee endorses the EPA's use of bounding estimates, but only in screening assessments to determine whether further levels of analysis are necessary. For further levels of analysis, the committee supports EPA's development of distributions of exposure values based on available measurements, modeling results, or both." (p. 10–28)

[46] This principle is supported by the Carnegie Commission report which states, "Single-value risk estimates reported to the public do not provide an indication of the degree of uncertainty of risk associated with the estimate. Such numbers do not convey the conservative nature of some risk estimates." (p. 87). The 1995 OSTP report also emphasizes the importance of describing the uncertainties inherent in risk assessments, "Variation in risk estimates also arises from choices of assumptions and methods to address and treat uncertainty in available scientific data. Risk assessors may develop different estimates of risk because they employ different (but equally justifiable) assumptions." (p. 9).

For exposure assessment, the distribution of exposures generally presents a probability or frequency distribution of exposures across the population for which the exposure assessment is being conducted. From this distribution, the risk manager can identify exposures at various percentiles of a population. The distribution of exposures should reflect real differences in exposure that result from different life styles, place of residence, age, and physiological parameters. In certain cases, the distribution of exposures also reflects uncertainty in exposure parameters (*e.g.*, fate and transport parameters). In many cases, there will be sufficient exposure information available to generate a probability distribution, using probabilistic methods, such as Monte Carlo analysis.[47] Risk assessors should resort to combining single-point values to generate estimates of unknown probability only when conducting screening risk assessments. Where, as may often be the case, there is insufficient data to generate a distribution, then multiple-point estimates should be preferred. If a single-point estimates are generated, both most likely and high-end estimates should be presented.

For risk assessments, the distribution of risk estimates relates mainly to uncertainty in the dose-response and exposure assessments, but also could include variability in exposure. The risk estimates entail a number of uncertainties, including applicability of animal toxicity data to humans, choice of model for extrapolating to low doses, and the usually small number of subjects in laboratory tests or epidemiologic studies. Many of these uncertainties are not amendable to representation as a distribution. In such cases, the risk assessor should use expert judgment to describe the qualitative or quantitative likelihood of various assumptions and their impact on the risk estimate. If a distribution cannot be generated, the risk assessor should provide multiple risk estimates that reflect, for example, use of central tendency and high-end estimates.[48]

Finally, this subsection states that when a covered agency provides a risk assessment or risk characterization for a proposed or final regulatory action, such assessment or characterization shall include a statement of any significant substitution risks. While recognizing that it may be difficult for an agency to foresee all substitution risks, the Committee believes it is important to make such evaluations. The Committee is concerned that government has not always been sensitive to risks caused or exacerbated by certain regulatory actions. One such example is the asbestos scare in the early 1980s. Government scientists argued that asbestos exposure could cause thousands of deaths. Public alarm led Congress to pass a sweeping law that led cities and states to spend between $15 and $20 billion to remove asbestos from public buildings. But about three years later, EPA officials confirmed that asbestos removal had been a very costly mistake. Ripping out the asbestos raised the

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[47] Monte Carlo simulation is a mathematical technique for generating a distribution of values for exposure, dose, or risk in a population by using mathematical models of the expected distributions for those parameters that are used to estimate exposure, doses, or risk.

[48] See U.S. Environmental Protection Agency, Policy for Risk Characterization (Mar. 21, 1995): "Information should be presented on the range of exposures derived from exposure scenarios and on the use of multiple risk descriptors (e.g., central tendency, high-end of individual risk population risk, important subgroups, if known) consistent with the terminology in the Guidance on Risk characterization, Agency risk assessment guidelines, and program-specific guidance." (p. 2).

risk to the public because asbestos fibers become airborne during removal.[49] Removing the asbestos also delayed the opening of many schools and other buildings.[50]

§ 637. Peer review

This section specifies that agency heads must develop a systematic program for independent and external peer review of risk assessments and cost-benefit analyses conducted for major rules. Central to the peer review program should be review panels consisting of independent experts from relevant scientific disciplines. Members of the peer review panel should be selected on the basis of their expertise in the sciences relevant to the regulatory decision. The panels should be broadly representative and balanced and, to the extent possible, include experts affiliated with government (but not the covered agency), small business, industry, academia, labor, agriculture, consumers, conservation organizations, and other public interest groups and organizations. Qualified panel candidates should not be excluded on the basis that they represent an entity that may have a potential interest in the outcome, provided that the potential interest is fully disclosed to the agency and the public.

The agency peer review programs must ensure that reviews are conducted on a timely basis and that they contain balanced presentations of all considerations, including minority reports and an agency response to all significant comments. In addition, adequate protection must be provided to ensure that confidential business information and trade secrets are protected.

Subsection 637(b)(1)(B) specifies that the major rule peer review requirement does not pertain to the authorization or approval of any individual substance or product. Subsection 637(b)(2) provides that the Director of the OMB may order that peer review be provided for any risk assessment or cost-benefit analysis that is likely to have a significant impact on public policy decisions or would establish an important precedent.

Subsection 637(c) requires the peer review panel to submit a report to the agency describing the scientific and technical merit of data and methods used for the risk assessment and cost-benefit analyses. In turn, subsection 637(d) requires the head of the covered agency to respond in writing to every peer review and to address the significant points in the review. Under subsection 637(e), the agency response must be made available to the public and be part of the administrative record for purposes of judicial review of any final agency action.[51] Finally, subsection 637(f) exempts from the peer review requirements any data, method, document, or as-

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[49] See U.S. Environmental Protection Agency Advisory from Administrator William K. Reilly (Mar. 6, 1991).

[50] Stephen Breyer, Breaking the Vicious Circle: Toward Effective Risk Regulation 12–13 (1993); Gregg Easterbrook, A Moment on the Earth: The Coming Age of Environmental Optimism 250–53 (1995).

[51] Peer review is a widely accepted component of risk analysis. As stated in the OSTP Principles in Devising Risk Policy, "Appropriate scientific peer review and guidance are essential to the risk assessment process." (p. 17). The Carnegie Commission Report also highlights the importance of external peer review. The report states "A key element in setting risk-based priorities is science advice, both internal (within the agency) and external (through science advisory boards and other mechanisms). External science advisory boards serve a critically important function in providing regulatory agencies with expert advice on a range of issues." (p. 90).

sessment, or any component thereof, that previously has been subjected to peer review.

§ 638. Guidelines, plan for assessing new information, and report

Subsection 638(a) requires agencies to adopt guidelines to implement the risk assessment and risk characterization principles under sections 635 and 636 and the cost-benefit analysis requirements under section 622. Agencies are also required to develop a format for summarizing risk assessment results. Agencies must issue a report on the status of the guidelines no later than 12 months after the effective date of this section. The guidance must include information on technical methodologies and standards for acceptable quality of specific kinds of data as well as address important decisional factors for risk analysis.

Subsection (b) requires that the guidelines, plan and report must be open to public comment. However, the guidelines are not required to be developed as a rule. The Committee was concerned that the APA rulemaking process is too rigid and time-consuming for the development of risk assessment guidelines. The guidelines must allow for flexibility to adapt to differing circumstances. For the same reasons, subsection (d) makes clear that the development, issuance, and publication of risk assessment and risk characterization guidelines developed under this section are not subject to judicial review. Subsection (c) requires the President to review the guidelines at least every 4 years.

§ 639. Research and training in risk assessment

This section requires agency heads to regularly and systematically evaluate risk assessment research and training needs and to develop a strategy and schedule for meeting those needs. Subsection 639(a)(1) requires the evaluation to include the need for research to reduce generic data gaps, to address modelling needs, and to validate default options, particularly those common to multiple risk assessments. Subsection 639(a)(2) also specifies that the evaluation should also identify research that would lead to improvements of methods to quantify and communicate uncertainty and variability among individuals, species, populations, and ecological communities. Under subsection (a)(3), emerging areas of research—including comparative risk and noncancer endpoints—should also be identified and described. Finally, subsection 639(a)(4) provides that the agency evaluations should also identify long-term needs to adequately train individuals in risk assessment techniques. While the Committee believes agencies must improve their risk assessment research and staff capabilities, we do not intend to have agencies waste resources on unnecessarily duplicative efforts. Agencies should work cooperatively to improve the overall ability of the Executive Branch to conduct risk assessment.

§ 640. Interagency coordination

This section is designed to improve the conduct, application and practice of risk assessment across all relevant agencies. Section (a) requires the Office of Management and Budget, in consultation with the Office of Science and Technology Policy, to periodically

survey the manner in which agencies are conducting risk assessments. Such a survey will allow for a determination of the scope and adequacy of risk assessment practices in use by the Federal government. It also will promote the injection of new scientific advances into the risk assessment practices of the Federal agencies. Subsections 640(a)(3) and (a)(4) require OMB to establish with OSTP appropriate interagency mechanisms to promote coordination between agencies and to ensure consistent use of state-of-the-art practices. Finally, subsection (b) requires the President to appoint National Peer Review Panels to submit a report to the President and Congress every 3 years reviewing the progress made by the agencies in implementing provisions of this chapter.

§ 640a. Plan for review of risk assessments

This subsection requires the head of each agency to publish, within 18 months after the effective date of this section, a plan to review and revise risk assessments conducted during the transition between enactment of the act of the 18 month period.

§ 640b. Judicial review

The provisions in section 623 relating to judicial review apply to this subchapter.

§ 640c. Deadlines for rulemaking

The provisions in section 624 relating to deadlines for rulemaking apply to this subchapter.

Subchapter IV. Executive oversight

This subchapter creates a general framework for presidential supervision of the cost-benefit analysis requirements of this legislation. Presidential regulatory review has been in effect in one form or another for twenty years. Since 1981, it has been conducted in a centralized process by the Office of Management and Budget under Executive Order Nos. 12291, 12498, and, most recently, 12866.

The Committee endorses centralized regulatory review. As it has become an integral part of the Federal regulatory process, it should be an explicit element in any regulatory reform legislation. The Committee is mindful that in the past, presidents have argued against regulatory review legislation because of potential inroad on presidential prerogatives. The Committee believes, however, that placing a regulatory review mandate into this legislation will help put to rest arguments about the fundamental nature or need for regulatory review. Nonetheless, respectful of separation of powers, the Committee has only placed into a statute a general framework of executive oversight, limited only by time limits for regulatory review and public disclosure requirements. This allows a President the flexibility to craft the details of any regulatory review scheme, consistent with the legislative substantive cost-benefit analysis requirements.

The subchapter applies the legislation's definitions to this subchapter (sec. 641); authorizes the establishment of regulatory oversight procedures (sec. 642); provides procedures for the promulgation of the oversight rules and establishes deadlines for regulatory

review (sec. 643); delegates primary oversight authority to the Director of OMB (sec. 644); requires public disclosure of regulatory review-related information (sec. 645); and prohibits judicial review of any executive oversight decisions (sec. 646).

§ 641. Definition

The legislation's definitions in sections 551 and 621 apply to the executive oversight provisions created by this subchapter.

§ 642. Procedures

The Director of OMB or other designated officer to whom authority is delegated under section 644 is authorized to: (1) establish procedures for agency compliance with the requirements of the subchapters II and III, *i.e.*, cost-benefit analysis, risk assessment, peer review, and review of current rules; and (2) monitor, review, and ensure agency implementation of such procedures. The Committee expects that OMB will continue to operate its regulatory review process, as currently established by E.O. 12866, with only minor changes to match the requirements of this legislation. Again, the Committee intends to give the President maximum flexibility to structure the regulatory oversight process, consistent with the provisions of this legislation.

§ 643. Promulgation and adoption

To ensure public accountability, and to address some of the complaints about secrecy and special interest access to decisionmakers, the legislation requires that the regulatory oversight procedures established pursuant to section 642 shall be implemented after opportunity for public comment.

Assuming that those procedures include a regulatory review component, though not mandating it our of deference to the prerogatives of the Chief Executive, the time for such review shall not exceed 60 days, although it may be extended for good cause for an additional 30 days. To prevent the use of regulatory review for delay, the legislation requires that any notice of extension be explained and placed in the rulemaking agency's rulemaking file.

§ 644. Delegation of authority

The Committee expects that the President will delegate the authority granted by this subchapter to the Director of the Office of Management and Budget. OMB possesses sufficient resources and clout to perform the function, and the Committee believes OMB should oversee the regulatory process. However, recognizing the prerogatives of the President, the Committee authorizes the delegation of that executive oversight function to an officer within the Executive Office of the President. The legislation only requires that that officer be appointed subject to the advice and consent of the Senate. This ensures accountability to Congress.

§ 645. Public disclosure of information

To provide fair and equal opportunity for the public to participate in the regulatory process, the legislation establishes requirements for public disclosure of regulatory review-related information. The provisions in section 645 parallel those found in section

626, regarding public participation and accountability in agency rulemaking decisions.

The legislation requires that the Director, or other official designated to perform executive oversight of the regulatory process, establish procedures to provide public and agency access to information concerning regulatory review actions. The Committee intends that "regulatory review" be understood broadly to include any review of agency rulemaking that is conducted pursuant to the direction of the President or his designee. Given the development and presumed continued use of a centralized process for the review of Executive Branch regulatory decisions, the term is not meant to apply to ad hoc or informal review or to intra-agency review. It is meant to apply to any ongoing, organized or systematic inter-agency process of presidentially overseen regulatory review. The Committee also intends that the term "review action" be understood to include any review decision made by a regulatory reviewer. This includes not just final review decisions, but any decision, recommendation, comment, suggestion, or direction that the reviewer makes and is in any way communicated to the rulemaking agency.

The public disclosure procedures that are to be established pursuant to this section must include at least three elements. First, they must provide disclosure to the public on an ongoing basis of information regarding the status of regulatory actions undergoing review. This means that the public should be able to learn from the regulatory reviewer what agency regulatory actions are under review. The Committee assumes that this would entail the production of a single monthly listing of all agency regulatory actions under review—as OMB currently prepares pursuant to E.O. 12866. In this way, the legislation would merely create a statutory right to information now provided under presidential executive order.

Second, no later than the date of publication of, or other public notice about, a regulatory action the public must have access to: (A) all written communications, including drafts of all proposals and associated analyses, between the reviewer and the regulatory agency; (B) all written communications between the reviewer and any person not employed by the Executive Branch of the Federal Government relating to the substance of a regulatory action; (C) a record of all oral communications relating to the substance of a regulatory action between the reviewer and any person not employed by the Executive Branch of the Federal Government; and (D) a written explanation of any review action and the date of such action. Again, the Committee expects that this requirement largely will entail the continuation of the current OMB practice of maintaining regulatory review files in a public reading room.

Third, as a counterpart to public disclosure of regulatory review information, a regulatory reviewer must disclose information to the rulemaking agency to ensure full and complete consideration of all information relevant to a rulemaking decision. Accordingly, the reviewer is required to provide the rulemaking agency, on a timely basis: (A) all written communications between the reviewer and any person who is not employed by the Executive Branch of the Federal Government; (B) a description of oral communications, and an invitation to participate in meetings, relating to the substance of a regulatory action between the reviewer and any person not em-

ployed by the Executive Branch of the Federal Government; and (C) a written explanation of any review action. By "explanation," the Committee means a description that should include, but is not limited to a discussion of the ways in which the review action might lead to a provision or proposal different from that proposed by the rulemaking agency; the analytical, scientific, technical, or statistical reasons for the review action; and the basis for and findings of the review action in relation to the statutory mission underlying the proposed rulemaking action.

§ 646. Judicial review

The legislation clearly and unequivocally states that no exercise of authority granted under this subchapter by the Director, the President, or by an officer to whom such authority has been delegated under section 644 shall be subject to judicial review in any manner.

SECTION 3(b). REGULATORY FLEXIBILITY ANALYSIS

The Regulatory Flexibility Act, currently codified as Chapter 6, is renumbered by section 3(d) of this legislation to be Chapter 6, Subchapter I, section 611 of title 5, United States Code. It is also amended to include new provisions on judicial review.

§ 611. Judicial review

Under the Regulatory Flexibility Act, agencies are required to certify that a rule would not have a significant economic impact on a substantial number of small entities. They must prepare a regulatory flexibility analysis that provides alternatives that would accomplish the stated objectives and that would minimize any significant economic impact.

This section allows small entities to seek judicial review of an agency's certification or analysis for regulatory flexibility, giving formal enforcement to this provision. Small businesses have up to one year from the effective date of a rule to file an action if they disagree with an agency's findings. In the case in which a law requires an action challenging a final regulation to be commenced before the expiration of the one-year period, the lesser period will apply to a petition.

There are two avenues that a court can take in making a determination that the agency must revisit a regulatory flexibility analysis: (1) if an agency certifies that a rule would not have a significant economic impact, the court may order the agency to prepare a final regulatory flexibility analysis if it determines that the certification was arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law; or (2) the court may determine that the agency did not comply with the requirements of section 604 (final regulatory flexibility analysis), and therefore, it may order the agency to take corrective action to comply with those requirements.

If, after 90 days, the agency has not taken corrective action or performed the required analysis, the court may stay the rule or grant other relief. In making any determination or granting any relief, the court shall take due account of the rule of prejudicial error.

Judicial review of any regulatory flexibility analysis entails review of the whole record of agency action.

Nothing in this section bars judicial review of any other impact statement or similar analysis required by any other law if judicial review of such statement or analysis is otherwise provided by law.

The effective date for the judicial review section shall only apply to final agency rules issued after the effective date of the legislation. That is, judicial review of regulatory flexibility analysis is only prospective, not retrospective.

Nothing in this legislation shall limit the President's authority and responsibility that the President otherwise possesses under the Constitution and other laws of the United States with respect to regulatory policies, procedures, and programs of departments, agencies, and offices

SECTION 3(d) TECHNICAL AND CONFORMING AMENDMENTS

Section 3(d) provides the technical and conforming amendments to Part I, Chapter 6, of title 5, United States Code. Up to this point, Chapter 6 consisted of regulatory flexibility analysis. With this legislation, Chapter 6 is substantially amended to create Subchapter I, which includes the regulatory flexibility analysis with additional language on judicial review of the Regulatory Flexibility Act. It also creates three new subchapters: Subchapter II—Analysis of Agency Rules; Subchapter III—Risk Assessments; and Subchapter IV—Executive Oversight.

SECTION 4. CONGRESSIONAL REVIEW

As the number of complexity of federal statutory programs has increased over the last fifty years, Congress has come to depend more and more upon Executive Branch agencies to fill out the details of the programs it enacts. As complex as many of the statutory schemes passed by Congress are, the implementing regulations are often more complex by several orders of magnitude. The delegation of legislative rulemaking authority to Executive Branch agencies has been upheld by the courts, unless Congress has failed to establish sufficient standards to guide agency action. *See, e.g., Panama Refining Co.* v. *Ryan,* 293 U.S. 388 (1935). However, as more and more of Congress' legislative functions have been delegated to federal regulatory agencies, may have complained that Congress has effectively abdicated its constitutional role as the national legislature is allowing federal agencies so much latitude in implementing and interpreting congressional enactments.

In many cases this criticism is unjustified. However, there are instances where the criticism is well founded. Our constitutional scheme creates a delicate balance between the appropriate roles of the Congress in enacting laws, and the Executive Branch in implementing those laws. It must not be forgotten that federal regulations have the force and effect of law only because Congress has delegated legislative rulemaking authority to Executive agencies. Section 4 of S. 343 will help to redress the balance, reclaiming for Congress some of its policymaking authority, without at the same time requiring Congress to become a super regulatory agency.

Section 4 of this legislation establishes a government-wide congressional review mechanism for all major rules. This allows Con-

gress the opportunity to review every major rule before it takes effect and to disapprove any rule to which Congress objects. Congress may find a rule to be too burdensome, excessive, inappropriate or duplicative. The bill uses the mechanism of a joint resolution of disapproval which requires passage by both houses of Congress and the President (or veto by the President and a two-thirds' override by Congress) to be effective. In other words, enactment of a joint resolution of disapproval is the same as enactment of a law. However, the bill establishes expedited procedures for consideration of a joint resolution of disapproval relating to a major rule for the 45 day period after the rule is published as final but before it takes effect. That is the unique and all-important feature of this provision.

Congress has considered various proposals for reviewing rules before they take effect for almost twenty years. Use of a simple (one-house), concurrent (two-house), or joint (two houses plus the President) resolution are among the options that have been debated and in some cases previously implemented on a limited basis. In *INS* v. *Chadha,* 462 U.S. 919 (1983), the Supreme Court struck down as unconstitutional any procedure where executive action could be overturned by less than the full process required under the Constitution to make laws—that is, approval by both houses of Congress and presentment to the President. That narrowed Congress' options to use a joint resolution of disapproval. The one-house or two-house legislative veto (as procedures involving simple and concurrent resolutions were previously called), was thus voided.

Because Congress often is unable to anticipate the numerous situations to which the laws it passes must apply, Executive Branch agencies sometimes develop regulatory schemes at odds with congressional expectations. Moreover, during the time lapse between passage of legislation and its implementation, the nature of the problem addressed, and its proper solution, can change. Rules can be surprisingly different from the expectations of Congress or the public. This makes congressional review of rules an important component of regulatory reform. Congressional review gives the public the opportunity to call the attention of politically accountable, elected officials to concerns about proposed rules. If these concerns are sufficiently serious, Congress can stop the rule before any damage is done.

In this section, Part I of title 5, United States Code, is amended to add a new chapter, Chapter 8, congressional review of agency rulemaking. This provision establishes a 45 day period after a major rule is published as final during which Congress, by joint resolution, can disapprove the rule using an expedited procedure.

Section 801(a) limits the application of the congressional review process to major rules as defined in section 621(4) and as determined under section 622 of this bill. This includes rules determined to be major because of the $100 million economic impact and rules determined to be major because of the other factors identified in this bill for that purpose.

Section 801(b) requires that when a major rule is published as final, the rulemaking agency must submit to Congress a copy of the rule, the statement of basis and purpose for the rule and the proposed effective date of the rule. The rule may not take effect: 1) for

45 days from the date on which Congress receives the rule or the date on which the rule is actually published in the Federal Register, whichever is later; or 2) if the President vetoes a joint resolution of disapproval with respect to the rule during the 45 day period, not until the earlier of the date on which one house of Congress fails to override the veto or 30 days expires from the date of the veto.

Section 801(c) states that a major rule shall not take effect if a joint resolution of disapproval is enacted into law.

Section 801(d) provides that a major rule that would otherwise not be able to take effect because of the requirements of this section may take effect if the President determines in writing that the rule is necessary because of an imminent threat to health or safety or other emergency; necessary for the enforcement of criminal laws; necessary for national security. The 45 day period for the expedited consideration of a joint resolution of disapproval would still apply, however.

Section 801(e) provides that major rules promulgated during the period 60 days before Congress adjourns and the date on which the succeeding Congress convenes shall be treated for purposes of this section as though they were published as final on the date the succeeding Congress convenes. Such rule, however, shall take effect as otherwise provided by law.

Section 801(f) provides that a major rule that is disapproved by enactment of a joint resolution shall be treated as though it had never taken effect.

Section 801(g) states that the failure of Congress to enact a joint resolution of disapproval should not be used by a court or agency to infer any intent on the part of Congress with respect to the rule.

Section 801(h) provides that a rule shall cease to be enforceable against any person if the rulemaking agency fails to submit the rule to Congress as required by this section.

Section 801(i) provides the exact language for a joint resolution of disapproval under the terms of this section. It requires that joint resolutions be referred to the appropriate committee of jurisdiction and prohibits such committee from reporting the resolution before eight days have elapsed from the submission of the rule to Congress or its publication in the Federal Register. It is intended that only one committee in each house receive a joint resolution of disapproval. It is also the intent of the Committee that the committee of jurisdiction be the committee with primary jurisdiction over the statute under which the rule is being issued.

This subsection further provides that if the committee to which the joint resolution is referred has not reported such resolution by the end of 20 calendar days after the submission or publication date, then the committee can be discharged by a petition signed by 30 Senators. Upon discharge, the resolution will be placed on the Senate calendar. Although this bill does not establish such procedures for consideration by House committees, it is anticipated that the House will include similar procedures when the bill is considered in conference.

This subsection establishes very strict procedures for consideration of the joint resolution on the floor of the Senate. Any senator may move to proceed to the consideration of the resolution at any

time after it has been placed on the calendar and all points of order against the resolution or against consideration of the resolution are waived. The motion to proceed is privileged and not debatable or amendable. Once a motion to proceed to the consideration of the joint resolution is agreed to, the resolution shall remain the unfinished business of the Senate until it is disposed of.

Debate on the resolution itself is limited to no more than 10 hours, equally divided between proponents and opponents. A motion to further limit debate shall be in order and is not debatable. Amendments and motions to postpone, proceed to the consideration of other business, or to recommit the resolution are not in order, nor is a motion to reconsider the vote on the resolution. The vote on final passage shall immediately follow the debate on the resolution and a single quorum call. All appeals from the decisions of the Chair during these procedures shall be decided without debate. Similar expedited procedures are expected to be developed and added by the House during the conference on this legislation.

If the Senate receives a resolution from the House before the same resolution is passed in the Senate, then the House resolution is not to be referred to committee; the procedure in the Senate applies to the Senate resolution, but when the vote on final passage occurs, it is to be on the resolution of the House.

These procedures are to be enacted as part of the rulemaking power of the Senate, and, when added, the House of Representatives.

Subsection 801(j) states unequivocally that none of the provisions or requirements relating to congressional review of rules is subject to judicial review in any manner.

SECTION 5. STUDIES AND REPORTS

This section directs the Administrative Conference of the United States to conduct two major studies. The first study relates to the operation of the risk assessment requirements of subchapter III. ACUS is required to submit an annual report to the Congress on the findings of the study.

The second study, due no later than December 31, 1996, relates to the operation of chapters 5 and 6 of title 5, United States Code (commonly referred to as the Administrative Procedure Act), as amended by section 3 of this legislation, ACUS must submit a report to the Congress on the findings of the study, including proposals for revision, if any.

These studies will address how subchapter III and other provisions of the APA, as amended, are actually being implemented (or are likely to be implemented) by regulatory agencies, the courts, and other participants in the regulatory process. These studies also will consider how the method of implementation furthers the objectives of this legislation and the public interest. Where necessary, the studies will provide recommendations on how to improve implementation, as well as proposed statutory amendments. Finally, the Committee expects that these studies will cover other sections of the APA and related provisions of law affected by the current legislation.

For example, it will be critically important to determine the effect of this legislation on the agencies themselves—to determine

whether agencies have the capability to carry out the new requirements, and how the new requirements will affect the agencies' ability to fulfill their other statutory obligations. Will agencies have the staff, expertise, and time to do what this legislation requires? Will the development of new regulations, and the review and reform of existing regulations, be unduly delayed by the new requirements? Are the new requirements themselves cost-effective or overly burdensome—*e.g.*, would many regulations come out the same even if the new analyses had not been required? The Committee expects the studies under section 5 to help answer such key questions.

ACUS, which will conduct the studies under section 5, is an independent, non-partisan agency, that includes a diverse group of leading regulatory experts and practitioners from agencies, the judiciary, business, academia, and other sectors. Because ACUS is comprised of respected experts and practitioners representing a wide range of perspectives and interests, and has a record of developing unbiased, practical solutions to regulatory problems, the Committee believes that this agency is well suited to producing the studies and recommendations needed to fulfill the intent of section 5.

SECTION 6. RISK-BASED PRIORITIES

The Committee believes that setting risk-based priorities offers the best opportunity to allocate rationally the resources of both the government and the private sector to provide protections for human health, safety and the environment. With the tool of comparative risk analysis, we can make our health, safety and environmental protection dollars go farther and provide greater overall protection, saving even more lives than the current system. As the blue-ribbon Carnegie Commission panel noted in its report *Risk and the Environment: Improving Regulatory Decision Making*, "The economic burden of regulation is so great and the time and money available to address the many genuine environmental and health threats so limited, that hard resource allocation choices are imperative." (p. 118).

The 1995 National Academy of Public Administration (NAPA) Report to Congress, entitled *Setting Priorities, Getting Results*, recommends that the Environmental Protection Agency use comparative risk analysis to identify priorities and use the budget process to allocate resources to the agency's priorities. The NAPA study commends EPA for having pioneered risk prioritization studies and comparative risk analyses. However, the report states that during the 1995 budgetary process, EPA did not push for shifts in resources to the higher-priority programs. The report recommends that Congress "could enact specific legislation that would require risk-ranking reports every two to three years. Congress should use the information when it passes environmental statutes or reviews EPA's budget proposals." (p. 49).

To prioritize resource use based on risk, the government must systematically evaluate the threats to health, safety and environment that its programs address and determine which of those are the most serious and most amenable to cost-effective amelioration. Section 6 of this legislation requires each designated agency to en-

gage in this evaluation among and within the programs it administers. To better enable the President and Congress to prioritize resources agencies, this section also requires that the risks addressed by all of the designated agencies be evaluated and compared.

The purpose of these analyses is not to dictate how the government uses its resources, but to provide Congress and the President with the information to make more informed choices. We anticipate that, among other things, these analyses will be useful for identifying unaddressed sources of risk, risks borne disproportionately by a segment of the population and research needs. This information also will foster a clearer reasoning for regulating in one area over another or allocating resources to one program over another. Finally, conducted in the public view, these analyses are likely to enhance public debate about these choices and ultimately create greater public confidence in government policy.

Comparative risk analysis is not purely a scientific undertaking. The Committee believes that, while hard data will form the underpinnings of the analysis, public values must also be incorporated when assessing the relative seriousness of the risks and when setting priorities. After all, scientific data alone cannot tell us which of the following is the greater risk or which should be addressed first: neurological damage, heart disease, or birth defects; a plane crash or cancer. The comparative risk analysis should be conducted in such a way that public values are ascertained and considered. This will require including public input in the comparative risk analysis. Nevertheless, when the analysis is completed, it should be clear to the public and policy makers which part of the risk comparison reflects science and which part reflects values.

To encourage the use of risk-based priorities, the Committee is requiring not only that each agency set risk-based priorities for its programs, but also for the OMB to commission a report with an accredited scientific body to study the methodologies of comparative risk analysis and to conduct such an analysis to compare risks across agencies.

This section includes: (a) the purposes of this section; (b) definitions; (c) department and agency goals; (d) comparative risk analysis; (e) reports and recommendations to Congress; and (f) a savings provision and judicial review.

The purposes of this section are to: (1) encourage Federal agencies engaged in regulating risks to human health, safety, and the environment to achieve the greatest risk reduction at the least cost practical; (2) promote the coordination of policies and programs to reduce risks to human health, safety, and the environment; and (3) promote open communication among Federal agencies, the public, the President, and Congress regarding environmental, health, and safety risks, and the prevention and management of those risks. The importance of such a risk-based approach has been advocated

in numerous recent studies and publications[52] and in testimony before the Governmental Affairs Committee.[53]

Subsection (b) provides definitions for the purposes of this section:

(1) "Comparative risk analysis" means a process to systematically estimate, compare, and rank the size and severity of risks to provide a common basis for evaluating strategies for reducing or preventing those risks.[54] This analysis evaluates risks across agencies and ranks dissimilar risks—environmental, health, and safety.

(2) The term "covered agency" includes the same regulatory agencies that are covered under the risk assessment requirements in subchapter III: (A) the Environmental Protection Agency; (B) the Department of Labor; (C) the Department of Transportation; (D) the Food and Drug Administration; (E) the Department of Energy; (F) the Department of the Interior; (G) the Department of Agriculture; (H) the Consumer Product Safety Commission; (I) the National Oceanic and Atmospheric Administration; (J) the United States Army Corps of Engineers; and (K) the Nuclear Regulatory Commission.

(3) "Effect" means a deleterious change in the condition of: (A) a human or other living thing (including, but not limited to, death, cancer, or other chronic illness, decreased reproductive capacity, or disfigurement); or (B) an inanimate thing important to human welfare (including destruction, degeneration, the loss of intended function, and increased costs for maintenance).

(4) "Irreversibility" means the extent to which a return to conditions before the occurrence of an effect are either very slow or will never occur.

(5) "Likelihood" means the estimated probability that an effect will occur.

(6) "Magnitude" means the number of individuals or the quantity of ecological resources or other resources that contribute to human welfare that are affected by exposure to a stressor.

(7) "Seriousness" means the intensity of effect, the likelihood, the irreversibility, and the magnitude.

Subsection (c) specifies that the covered agencies should set priorities and use resources to focus on those risks determined to be most serious and that can be addressed in a cost-effective manner while achieving the greatest overall net reduction in risk. In identifying the greatest risks, agencies should consider the likelihood, irreversibility of the effect, and the scope and magnitude of effect. By identifying both the incremental costs of remedial action and the incremental benefits of risk reduction as factors to prioritize re-

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[52] See, e.g., Carnegie Commission on Science, Technology, and Government, Risk and the Environment: Improving Regulatory Decisionmaking, Washington, D.C. (June 1993); Stephen Breyer, Breaking the Vicious Circle: Toward Effective Risk Regulation, Harv. Univ. Press, Cambridge, MA (1993); Harvard Center for Risk Analysis, Reform of Risk Regulation: Achieving More Protection at Less Cost (Mar. 1995); The Business Roundtable, Toward Smarter Regulation (1994).

[53] See March 8, 1995 testimony of Frederick L. Webber, President and Chief Executive Officer, Chemical Manufacturers Association (quoting Testimony of Stephen Breyer before the Senate Committee on Energy and Natural Resources, November 9, 1993, at p. 2 "Our regulatory system badly prioritizes the health and environmental risks we face.")

[54] This definition is similar to one offered in the OSTP report Science, Risk, and Public Policy. The report defines comparative risk studies as "comprehensive examination of risks, policy trade-offs, and stakeholder concerns. The goal is to conduct a broad examination of governmental policies and expenditures to reduce risk." (p. 11).

sources, the Committee intends that the agencies not devote all their resources to a few risks that, while the most serious, may be extremely expensive to reduce. Rather, agencies should balance both factors and look for opportunities to achieve the greatest protection of human health, safety and the environment with the least resources. Finally, when evaluating cost-effectiveness the agencies should consider both the public and private resoruces required to address the risk.

The priorities identified must be incorporated into the agency budget, strategic planning, regulatory agenda, enforcement, and, as appropriate, research activities. When submitting its budget request to Congress each agency must describe the risk prioritization results and explicitly identify how the requested budget and regulatory agenda reflect those priorities.

Subsection (d) requires the Director of the Office of Management and Budget to: (1) have an accredited scientific body conduct a comparative risk analysis of risks regulated across all agencies; and (2) have an accredited scientific body conduct a study of the methodologies for using comparative risk to rank dissimilar human health, safety, and environmental risks.[55] The comparative risk analysis is to be conducted through an open process, utilizing expertise in toxicology, biology, engineering, medicine, industrial hygiene and environmental effects. The Committee also recognizes that experts in the relevant social sciences may be needed to help incorporate public values into the process. The analysis should be conducted consistent with the risk assessment and characterization principles in sections 635 and 636 of this title. The methodologies and scientific determinations made in the analysis are to be subjected to external peer review and made available for public comment. The results of the comparative risk analysis are to be presented in a manner that distinguishes between the scientific conclusions and any policy or value judgments embodied in the comparisons.[56]

Subsection 6(d)(3) requires that the methodological study and the comparative risk analysis be completed and a report submitted to Congress and the President no later than 3 years after the date of the enactment of the Act. The comparative risk analysis must be revised at least every 5 years thereafter for a minimum of 15 years following the release of the first analysis.

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[55] The need for a national comparative risk analysis was one of the chief recommendations of the Report of the Harvard Group on Risk Management Reform entitled Reform of Risk Regulation: Achieving More Protection at Less Cost (Mar. 1995). The Harvard report states that the purpose of such an analysis would be "to learn how diverse risks should be compared, how ordinary citizens should participate in risk ranking, what inherent limitations to the process might be, and how guidelines can be developed to govern a broad-based process of risk-based priority setting in the federal government." (p. 27).

[56] This provision is supported by the 1993 Carnegie Commission Risk and the Environment report. The report recommends that agencies "experiment with different mechanisms for integrating societal values into the process of setting risk-based regulatory priorities." (p. 89). The report authors believe that value choices should not be made covertly by unaccountable "experts." The report offers that "One possibility is for the experts to make explicit, to the extent possible, all value judgments and their relative weights in the ranking process." (p. 89).

The 1995 NAPA report supports the Carnegie Commission recommendation. THe NAPA report states: "Because comparing risks is a value-laden process as well as a technical challenge, EPA should conduct its comparative risk analyses as policy exercises with the active engagement of the public or its representatives. Doing so would provide legitimate results that would become a base for agency priorities and budget proposals." (p. 49).

Because comparative risk analysis is still a relatively new science, particularly when used to compare dissimilar risks, subsection 6(d)(4) requires that, even while the comparative risk analysis is being conducted; a study be done to improve the methods and use of comparative risk analysis. The study should be sufficient to provide the President and agency heads guidance in allocating resources across agencies and among programs to achieve the greatest degree of risk prevention and reduction. The Committee anticipates that this study will draw upon the experiences of the first comparative risk analysis conducted under this legislation, as well as the analyses already conducted by numerous states.

Subsection 6(e) requires each covered agency to submit a report to Congress and the President no later than 24 months after the date of enactment of the Act, and every 24 months thereafter. The reports should describe how the agencies have complied with subsection (c) and present the reasons for any departure from the requirement to establish priorities. The reports should identify the obstacles to prioritizing their activities and resources in accordance with the priorities identified. At this time, each agency should also recommend those legislative changes to programs or statutory deadlines needed to assist the agency in implementing those priorities.

The Committee views this report back to Congress as the most critical element in readjusting the Federal government's priorities so that we can truly achieve the greatest degree of protection for health, safety and the environment with our resources. Congress needs this information to make the necessary course correction changes to make this possible.

SECTION 7. REGULATORY ACCOUNTING

The Committee is concerned that too little attention has been paid to the cumulative costs of regulation. Unlike tax-and-spend programs, regulatory programs impose costs that are not accounted for in government budget figures. There is an illusion that these costs end with the businesses and governments directly regulated. But inevitably, these costs are passed on to the American consumer and taxpayer in one form or another, including higher prices, lower wages, higher taxes and reduced government services.

Although the circulative regulatory burden is enormous, there currently is no process for establishing priorities and forcing tradeoffs among different regulations and program goals. Government spending programs face some discipline through the budgetary process because, first, costs are documented and, second, spending limits create an incentive to set priorities and spend tax dollars in a cost-effective way. However, there is no formal process for tracking regulatory costs or budgeting those costs. As a result, government is too insensitive to the cumulative costs of regulation and the need to set rational and attainable priorities.[57]

A number of scholars and government officials have been interested in working toward the concept of a "regulatory budget" to address these concerns. Each agency could be limited to a fixed level of regulatory costs that it could impose on the economy each year.

[57] See The Business Roundtable, Toward Smarter Regulation (1994).

If an agency reached its regulatory budget ceiling, the agency could not impose additional regulations until it repealed or modified existing regulations to offset the cost increase from the new regulations. Alternatively, the government could offset the new cost from another agency.

However, the regulatory budget is unworkable today. Simply put, there are not adequate data of the costs and benefits of regulation to construct a regulatory budget. That problem could be overcome by this section because it will require agencies to compile the costs and benefits of regulation. However, questions would remain about the propriety of using overarching ceilings to limit specific actions to implement specific statutory requirements.

While a regulatory budget is unworkable and open to debate, the Committee decided to establish a regulatory accounting system to track the cumulative costs and benefits of regulation. In approving section 7, the Committee does not pass judgment on the regulatory budget. The Committee believes that information on the annual costs and benefits of Federal regulatory programs will be useful in itself for agencies to evaluate their programs and set more rational priorities to achieve the greatest benefits at the least cost. It also will make government more sensitive to the cumulative regulatory burden—estimated by Professor Tom Hopkins to cost the average American household over $6,000 per year. Over time, the information generated from the regulatory accounting system could make a true regulatory budget more technically feasible.

Section 7 includes provisions for: (a) definitions; (b) accounting statement; (c) associated report to Congress; (d) guidance from the Office of Management and Budget; (e) recommendation from the Congressional Budget Office; and (f) judicial review.

Subsection (a) outlines the following definitions:

(1) The term ''agency'' means any executive department, military department, Government corporation, Government controlled corporation, or other establishment in the Executive Branch of the Government (including the Executive Office of the President), or any independent regulatory agency, but shall not include: (A) the General Accounting Office; (B) the Federal Election Commission; (C) the governments of the District of Columbia and of the territories and possessions of the United States, and their various subdivisions; or (D) government-owned contractor-operated facilities, including laboratories engaged in national defense research and production activities. This broad definition reflects the Committee's intent to require an accounting of the wide panoply of regulatory costs and benefits.

(2) The term ''regulation'' means an agency statement of general applicability and future effect design to implement, interpret, or prescribe law or policy or describing the procedures or practice requirements of an agency. The term shall not include: (A) administrative actions governed by sections 556 and 557 of title 5, United States Code; (B) regulations issued with respect to a military or foreign affairs function of the United States; or (C) regulations related to agency organization, management, or personnel. This definition of ''regulation'' differs from that used in the rest of this legislation in a number of important respects, including the following: the regulatory accounting provision covers both major and non-

major rules; it includes tax rules and other rules that create transfer costs; and it includes banking rules, as well as FCC and Federal Election Commission rules.

In subsection (b), the President is required to prepare and submit to Congress every 2 years an accounting statement that estimates the annual costs of Federal regulatory programs and corresponding benefits in accordance with this subsection. Costs and benefits are not specifically defined, and should track the broad definitions in section 621.

The accounting statement should include the following groups of costs: (I) the annual expenditure of national economic resources for each regulatory program, including at least the following categories: private sector costs; Federal sector costs; and State and local government costs; and (II) such other quantitative and qualitative measures of costs as the President considers appropriate.

The accounting statement also should provide a sufficient picture of the many benefits of regulation. Recognizing the inherent difficulty of quantifying and categorizing many benefits, the legislation provides only very general guidance on how to account for benefits. The Committee expects that the agencies will exercise reasonable discretion in implementing this requirement. The object is not to unduly burden the agencies with accounting procedures. The goal is to provide the President, Congress and the public with a statement of program-specific and cumulative regulatory benefits to all for informed debate on where to set our regulatory priorities in light of limited resources and other important priorities.

The estimated benefits should include such quantitative and qualitative measures of benefits as the President considers appropriate. Any estimates of benefits concerning reduction in human health, safety, or environmental risks shall present the most plausible level of risk practical, along with a statement of the reasonable degree of scientific certainty. In short, agencies should attempt to present a clear picture of the risk reduction benefits of social regulations.

Each accounting statement shall cover, at a minimum, the 5 fiscal years beginning on October 1 of the year in which the report is submitted and may cover any fiscal year preceding such fiscal years for purpose of revising previous estimates.

The President shall provide notice and opportunity for comment for each accounting statement. The President may delegate to an agency the requirement to provide notice and opportunity to comment for the portion of the accounting statement relating to that agency.

The President shall propose the first accounting statement under this subsection no later than 2 years after the effective date of this Act and shall issue the first accounting statement in final form no later than 3 years after such effective date. Such statement shall cover, at a minimum, each of the fiscal years beginning after the effective date of this Act.

At the same time as the President submits an accounting statement, OMB shall submit to Congress a report associated with the accounting statement. The associated report shall contain, in accordance with this subsection: (A) analyses of impacts; and (B) recommendations for reform. These recommendations should be sen-

sitive to incremental costs and benefits of regulations or programs, the cumulative regulatory burden, and the importance of other national priorities. The associated report must address a number of issues. First, the report should examine the cumulative economic and social impact on the economy of Federal regulatory programs covered in the accounting statement. Factors to be considered in the report shall include impacts on the following: (i) The ability of State and local governments to provide essential services, including police, fire protection, and education; (ii) Small business; (iii) Productivity; (iv) Wages; (v) Economic growth; (vi) Technological innovation; (vii) Consumer prices for goods and services; (viii) Such other factors considered appropriate by the President.

Again, the Committee does not intend to bog down the agencies in highly prescriptive analytical requirements. The Committee does not intend to mandate that each item in the report be the product of extremely expensive econometric models, if the benefit of more detailed information would not warrant the resources required. On the other hand, great advances in economic modeling have been made, and these models should be used where they would provide valuable information on the costs or benefits of regulation. The underlying goal is to promote better informed decisionmaking and to make government more sensitive to the cumulative regulatory burden. The Committee expects that the agencies and OMB will exercise a rule of reason in fulfilling the requirements of this section. Where valid and accurate analyses are available from outside sources, they should be used. The report should summarize any independent analyses of regulatory impacts prepared by persons commenting during the comment period on the accounting statement.

The report also must include: (A) A summary of recommendations of the President for reform or elimination of any Federal regulatory program or program element that does not represent sound use of national economic resources or otherwise is inefficient; and (B) A summary of any recommendations for such reform or elimination of Federal regulatory programs or program elements prepared by persons commenting during the comment period on the accounting statement.

OMB, in consultation with the Council of Economic Advisers and the agencies, must develop guidance for the agencies: (1) to standardize measures of costs and benefits in accounting statements prepared pursuant to this section and section 3 of this legislation, including: (A) detailed guidance on estimating the costs and benefits of major rules; and (B) general guidance on estimating the costs and benefits of all other rules that do not meet the thresholds for major rules; and (2) to standardize the format of the accounting statements.

After each accounting statement and associated report submitted to Congress, the Director of the Congressional Budget Office shall make recommendations to the President: (1) for improving accounting statements prepared pursuant to this section, including recommendations on level of detail and accuracy; and (2) for improving associated reports prepared pursuant to this section, including recommendations on the quality of analysis.

No requirements under this section shall be subject to judicial review in any manner.

SECTION 8. EFFECTIVE DATE

Except as otherwise provided in this legislation, this Act shall take effect 180 days after the date of the enactment of this Act.

V. REGULATORY IMPACT STATEMENT

Pursuant to paragraph 11(b), rule XXVI of the Standing Rules of the Senate, the Committee, after due consideration, concludes that S. 343 will have a significant regulatory impact.

VI. COST IMPACT

U.S. CONGRESS,
CONGRESSIONAL BUDGET OFFICE,
Washington, DC, May 10, 1995.

Hon. WILLIAM V. ROTH, Jr.,
Chairman, Committee on Governmental Affairs,
United States Senate, Washington, DC.

DEAR MR. CHAIRMAN: The Congressional Budget Office has prepared the enclosed cost estimate for S. 343, the Regulatory Reform Act of 1995. This bill is identical to S. 291, as approved by the Committee on Governmental Affairs on March 22, 1995. Hence, this estimate is identical to CBO's estimate for S. 291, provided on May 8, 1995.

Enactment of S. 343 could affect direct spending. Therefore, pay-as-you-go procedures would apply to the bill.

If you wish further details on this estimate, we will be pleased to provide them.

Sincerely,

JAMES L. BLUM
(For June E. O'Neill).

Enclosure.

CONGRESSIONAL BUDGET OFFICE COST ESTIMATE

1. Bill number: S. 343.
2. Bill title: Regulatory Reform Act of 1995.
3. Bill status: As ordered reported by the Senate Committee on Governmental Affairs on March 22, 1995.
4. Bill purpose: S. 343 would impose additional requirements on federal agencies that issue regulations. These provisions would apply to most agency rules expected to have an effect on the economy of at least $100 million annually. The bill would require all agencies to prepare preliminary as well as final cost-benefit analyses and would require 11 specified agencies to prepare preliminary risk analyses as well as final risk analyses.

S. 343 also would require all agencies to review their major rules within ten years (with a possible extension to fifteen years) of such rules' promulgation. This review would include a cost-benefit analysis of the rule over its lifetime and a determination by the agency as to whether the rule is justified. If an agency fails to meet the

ten-or fifteen-year deadline for a rule, then that rule would become void.

5. Estimated cost to the Federal Government: Few of the agencies that would be affected by this bill have had time to study systematically the additional costs that its implementation would impose. Most agencies already conduct cost-benefit analyses and other analyses for regulations expected to have an economic impact greater than $100 million annually. The bill's additional review requirements, however, would generate new costs.

The cost to the federal government would depend on how the agencies fulfill the bill's requirements. For example, costs to review rules will depend on whether the agencies complete the review within ten years or fifteen years. We do not expect the bill's costs to be very large in the aggregate, however, because some of the requirements imposed by S. 343 are already being done by agencies, at least to some extent. For instance, some of the initial regulatory analysis currently performed by agencies would fulfill the bill's requirements for "preliminary" risk assessments and cost-benefit analyses. Based on limited information from agencies, CBO estimates that the incremental costs of S. 343 would probably range from $10 million to $20 million annually, although they could total up to $50 million annually.

6. Comparison with spending under current law: CBO estimates that enactment of this bill would add $10 million to $20 million annually to the cost of issuing regulations.

7. Pay-as-you-go considerations: Section 252 of the Balanced Budget and Emergency Deficit Control Act of 1985 sets up pay-as-you-go procedures for legislation affecting direct spending or receipts through 1998. Enactment of S. 343 could affect direct spending; therefore, pay-as-you-go procedures would apply to the bill.

Some of the additional regulatory requirements of S. 343 could lead to a delay in the implementation of regulations relating to the collection of user fees or other charges. In addition, regulations that authorize the collection of fees could be voided if agencies fail to meet the review deadline. CBO cannot estimate the potential magnitude of any such effects.

8. Estimated cost to State and local governments: How enactment of S. 343 would affect the budgets of state and local governments is unclear. If regulations that would impose additional requirements on state and local governments are delayed by the enactment of these provisions, then costs to these entities would be less. It is also possible, however, that some regulatory actions that would otherwise provide relief to state and local governments could be delayed, thereby increasing their costs for various activities. CBO has no basis for predicting the direction, magnitude, or timing of such impacts.

9. Estimate comparison: On May 8, 1995, CBO prepared a cost estimate for S. 343, as ordered reported by the Senate Committee on the Judiciary on April 27, 1995. Also on May 8, CBO prepared a cost estimate for S. 291, as ordered reported by the Senate Committee on Governmental Affairs on March 22, 1995. The CBO estimate for S. 343 as ordered reported by the Committee on Governmental Affairs is the same as the estimate for S. 291, since the bills are identical. By comparison, the version of S. 343 approved

by the Judiciary Committee would require agencies to conduct additional analyses for agency rules. CBO estimated that those additional requirements would cost at least $150 million more annually than the provisions contained in S. 291 and S. 343 as approved by the Governmental Affairs Committee.

10. Previous CBO estimate: None.

11. Estimate prepared by: Mark Grabowiz.

12. Estimate approved by: Paul N. Van de Water, Assistant Director for Budget Analysis.

VII. Additional Views of Senators Glenn, Levin, Lieberman, Dorgan, Nunn, Pryor and Akaka

Significant, meaningful regulatory reform is a goal that has been shared by the Members of this Committee for well over a decade. Enactment of this legislation will finally allow us to achieve that goal. We heartily commend the work of the Chairman in continuing the Committee's work on these matters; a number of us were here in 1981 when the Senate approved comparable legislation, S. 1080, by a vote of 94–0. We were all disappointed in the failure of that legislation to be enacted into law, and we are hopeful that this legislation will have a more successful outcome.

We join with Senator Roth and the other Republican members of the Committee in supporting this legislation because we believe it is a tough but fair regulatory reform proposal. It is tough because it requires by law that every proposed major rule be subject to a cost-benefit analysis and, where appropriate, a risk assessment. It requires that each agency assess, where not inconsistent with the statute, whether the benefits of the rule justify the costs of implementing it, and determine how the rule is likely to achieve the objectives of the rulemaking in the most cost-effective manner. The bill is tough because, by statute, it resolves once and for all the role of the President in overseeing the regulatory process. It gives the President the authority to oversee cost-benefit analysis and risk assessment, and it recognizes the significant contribution the President can make to rational rulemaking. The bill is tough because it allows Congress to review and stop any major rule before it takes effect. The bill is tough because the cost-benefit analysis and risk assessment are judicially reviewable as part of the whole rulemaking record. It also provides for judicial review of an agency's determination of whether a rule meets the $100 million economic impact test and for remand of a rule if the agency fails to do the cost-benefit analysis or risk assessment. The bill is tough because it requires agency review of all existing major rules, and renders them unenforceable should the agency fail to review them as required by this legislation.

The bill is fair because it recognizes that many benefits are not quantifiable and that decisions about benefits and costs are by necessity not an exact science but an exercise of agency judgment. The bill is fair because, while it mandates much needed risk assessment, it is not so prescriptive as to micromanage agencies or freeze the further development of scientific methods. It is fair because it requires that to the extent the President oversees the rulemaking process, that oversight must be conducted openly with public accountability. The bill is fair because it does not subject all rules to congressional review, only the significant rules. It is fair because it uses information as a tool for assessing agency performance and makes that information available to everyone to judge

and challenge. The bill is fair because it does not overwhem the rulemaking process by requiring cost-benefit analysis and risk assessment for less than truly significant rules. The bill is fair because, while requiring agency analysis and certification of whether the benefits of the rule justify the costs, it does not override the statutory scheme upon which the rule is based.

We support this legislation, because it is an appropriate blend of strength and reason. It tries to achieve the necessary balance between the public's concern over too much government and the public's strong support for regulations to protect the environment and public health and safety. Whether we have been successful in actually achieving that balance, we will not know until the legislation is implemented. Some of us have concerns that, especially in a time of significant downsizing, we are asking too much of the agencies, beyond what they can deliver and still meet their responsibilities to protect the public and the national interest. Some agencies, for example, may need significant new staff resources to meet the tough requirements of cost-benefit analysis and risk assessment that this bill establishes. We are confident, however, that we have created an open process, and to the extent there are problems, they will be known to the Congress and to the public.

We are also confident that regulation has played a vital role in making our country as liveable a place to call home as it is. Our clean air, clean water, quality food, safe and effective medical devices and medicine, the safety of our children's toys, and the beauty and challenge of our recreational opportunities are all products of the regulatory programs we have established over the past 30 years. We should be proud of that legacy, and we are. At the same time, we are well aware of the excesses of regulation and that too often we in Congress and in the agencies go too far—not without good intentions, but certainly without adequate information and forethought. That is the purpose of this legislation.

In the confusion that may develop in the debate between the regulatory reform bill reported by the Judiciary Committee and this bill reported by our committee, no one should lose sight of the dramatic difference this legislation will make to the regulatory process. Make no mistake about this bill; this is tough reform. Just because it does not try to paralyze the regulatory process does not make it weak. It chooses reform over revolution, and the reform is significant and overarching. Without destroying the positive aspects of government action, this legislation makes the regulatory process more open, more thoughtful, and more effective.

JOHN GLENN.
CARL LEVIN.
JOSEPH LIEBERMAN.
BYRON DORGAN.
SAM NUNN.
DAVID PRYOR.
DANIEL AKAKA.

VIII. CHANGES IN EXISTING LAW

In compliance with paragraph 12 of the rule XXVI of the Standing Rules of the Senate, changes in existing law made by S. 343 as reported are shown as follows (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italic, and existing law in which no change is proposed is shown in roman):

UNITED STATES CODE

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TITLE 5—GOVERNMENT ORGANIZATION AND EMPLOYEES

PART I—THE AGENCIES GENERALLY

[CHAPTER 6—THE ANALYSIS OF REGULATORY FUNCTIONS

CHAPTER 6—THE ANALYSIS OF REGULATORY FUNCTIONS

SUBCHAPTER I—REGULATORY ANALYSIS

SUBCHAPTER I—REGULATORY ANALYSIS

§ 601. Definitions

For purposes of this chapter—

* * * * * * *

[§ 611. Judicial review

[(a) Except as otherwise provided in subsection (b), any determination by an agency concerning the applicability of any of the provisions of this chapter to any action of the agency shall not be subject to judicial review.

[(b) Any regulatory flexibility analysis prepared under sections 603 and 604 of this title and the compliance or noncompliance of the agency with the provisions of this chapter shall not be subject to judicial review. When an action for judicial review of a rule is instituted, any regulatory flexibility analysis for such rule shall constitute part of the whole record of agency action in connection with the review.

[(c) Nothing in this section bars judicial review of any other impact statement or similar analysis required by any other law if judicial review of such statement or analysis is otherwise provided by law.]

§ 611. Judicial review

(a)(1) Except as provided in paragraph (2), no later than 1 year after the effective date of a final rule with respect to which an agency—

(A) certified, pursuant to section 605(b), that such rule would not have a significant economic impact on a substantial number of small entities; or

(B) prepared a final regulatory flexibility analysis pursuant to section 604,

an affected small entity may petition for the judicial review of such certification or analysis in accordance with this subsection. A court having jurisdiction to review such rule for compliance with section 553 of this title or under any other provision of law shall have jurisdiction to review such certification or analysis.

(2)(A) Except as provided in subparagraph (B), in the case of a provision of law that requires that an action challenging a final agency regulation be commenced before the expiration of the 1-year period provided in paragraph (1), such lesser period shall apply to a petition for the judicial review under this subsection.

(B) In a case in which an agency delays the issuance of a final regulatory flexibility analysis pursuant to section 608(b), a petition for judicial review under this subsection shall be filed no later than—

(i) 1 year; or

(ii) in a case in which a provision of law requires that an action challenging a final agency regulation be commenced before the expiration of the 1-year period provided in paragraph (1), the number of days specified in such provision of law,

after the date the analysis is made available to the public.

(3) For purposes of this subsection, the term "affected small entity" means a small entity that is or will be adversely affected by the final rule.

(4) Nothing in this subsection shall be construed to affect the authority of any court to stay the effective date of any rule or provision thereof under any other provision of law.

(5)(A) In a case in which an agency certifies that such rule would not have a significant economic impact on a substantial number of small entities, the court may order the agency to prepare a final regulatory flexibility analysis pursuant to section 604 if the court determines, on the basis of the rulemaking record, that the certification was arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.

(B) In a case in which the agency prepared a final regulatory flexibility analysis, the court may order the agency to take corrective action consistent with section 604 if the court determines, on the basis of the rulemaking record, that the final regulatory flexibility analysis was prepared by the agency without complying with section 604.

(6) If, by the end of the 90-day period beginning on the date of the order of the court pursuant to paragraph (5) (or such longer period as the court may provide), the agency fails, as appropriate—

(A) to prepare the analysis required by section 604; or

(B) to take corrective action consistent with section 604 of this title,

the court may stay the rule or grant such other relief as it deems appropriate.

(7) In making any determination or granting any relief authorized by this subsection, the court shall take due account of the rule of prejudicial error.

(b) In an action for the judicial review of a rule, any regulatory flexibility analysis for such rule (including an analysis prepared or corrected pursuant to subsection (a)(5)) shall constitute part of the whole record of agency action in connection with such review.

(c) Nothing in this section bars judicial review of any other impact statement or similar analysis required by any other law if judicial review of such statement or analysis is otherwise provided by law.

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall take effect on the effective date of this Act, except that the judicial review authorized by section 611(a) of title 5, United States Code (as added by subsection (a)), shall apply only to final agency rules issued after such effective date.

(c) PRESIDENTIAL AUTHORITY.—Nothing in this Act shall limit the exercise by the President of the authority and responsibility that the President otherwise possesses under the Constitution and other laws of the United States with respect to regulatory policies, procedures, and programs of departments, agencies, and offices.

* * * * * * *

SUBCHAPTER II—ANALYSIS OF AGENCY RULES

§ 621. Definitions

For purposes of this subchapter the definitions under section 551 shall apply and—

(1) the term "benefit" means the reasonably identifiable significant favorable effects, including social, environmental and economic benefits, that are expected to result directly or indirectly from implementation of a rule or an alternative to a rule;

(2) the term "cost" means the reasonably identifiable significant adverse effects, including social, environmental, and economic costs that are expected to result directly or indirectly from implementation of, or compliance with, a rule or an alternative to a rule;

(3) the term "cost-benefit analysis" means an evaluation of the costs and benefits of a rule, quantified to the extent feasible and appropriate and otherwise qualitatively described, that is prepared in accordance with the requirements of this subchapter at the level of detail appropriate and practicable for reasoned decisionmaking on the matter involved, taking into consideration the significance and complexity of the decision and any need for expedition;

(4)(A) the term "major rule" means—

(i) a rule or a group of closely related rules that the agency proposing the rule, the Director, or a designee of the President reasonably determines is likely to have a gross annual effect on the economy of $100,000,000 or more in reasonably quantifiable direct and indirect costs; or

(ii) a rule or a group of closely related rules that is otherwise determined to be a major rule by the agency proposing the rule, the Director, or a designee of the President on the ground that the rule is likely to result in—

(I) a substantial increase in costs or prices for wage earners, consumers, individual industries, nonprofit organizations, Federal, State, local, or tribal government agencies, or geographic regions;

(II) significant adverse effects on wages, economic growth, investment, productivity, innovation, the environment, public health or safety, or the ability of enterprises whose principal places of business are in the United States to compete in domestic or export markets;

(III) a serious inconsistency or interference with an action taken or planned by another agency;

(IV) the material alteration of the budgetary impact of entitlements, grants, user fees, or loan programs, or the rights and obligations of recipients thereof; or

(V) a significant impact on a sector of the economy, or disproportionate costs to a class of persons and relatively severe economic, social, and environmental consequences for the class; and

(B) the term "major rule" shall not include—

(i) a rule that involves the internal revenue laws of the United States;

(ii) a rule or agency action that authorizes the introduction into, or removal from, commerce, or recognizes the marketable status, of a product; or

(iii) a rule exempt from notice and public comment procedure under section 553 of this title;

(5) the term "market-based mechanism" means a regulatory program that—

(A) imposes legal accountability for the achievement of an explicit regulatory objective, including the reduction of environmental pollutants or of risks to human health, safety, or the environment, on each regulated person;

(B) affords maximum flexibility to each regulated person in complying with mandatory regulatory objectives, and such flexibility shall, where feasible and appropriate, include the opportunity to transfer to, or receive from, other persons, including for cash or other legal consideration, increments of compliance responsibility established by the program; and

(C) permits regulated persons to respond at their own discretion in an automatic manner, consistent with subparagraph (B), to changes in general economic conditions and in economic circumstances directly pertinent to the regulatory program without affecting the achievement of the program's explicit regulatory mandates under subparagraph (A);

(6) the term "performance standard" means a requirement that imposes legal accountability for the achievement of an explicit regulatory objective, such as the reduction of environ-

mental pollutants or of risks to human health, safety, or the environment, on each regulated person;

(7) the term "risk assessment" has the same meaning as such term is defined under section 632(5); and

(8) the term "rule" has the same meaning as in section 551(4) of this title, and shall not include—

(A) a rule of particular applicability that approves or prescribes for the future rates, wages, prices, services, corporate or financial structures, reorganizations, mergers, acquisitions, accounting practices, or disclosures bearing on any of the foregoing;

(B) a rule relating to monetary policy proposed or promulgated by the Board of Governors of the Federal Reserve System or by the Federal Open Market Committee;

(C) a rule relating to the safety or soundness of federally insured depository institutions or any affiliate of such an institution (as defined in section 2(k) of the Bank Holding Company Act of 1956 (12 U.S.C. 1841(k)); credit unions; the Federal Home Loan Banks; government-sponsored housing enterprises; a Farm Credit System Institution; foreign banks, and their branches, agencies, commercial lending companies or representative offices that operate in the United States and any affiliate of such foreign banks (as those terms are defined in the International Banking Act of 1978 (12 U.S.C. 3101)); or a rule relating to the payments system or the protection of deposit insurance funds or Farm Credit Insurance Fund; or

(D) a rule issued by the Federal Election Commission or a rule issued by the Federal Communications Commission pursuant to sections 312(a)(7) and 315 of the Communications Act of 1934.

§ 622. Rulemaking cost-benefit analysis

(a) Before publishing notice of a proposed rulemaking for any rule (or, in the case of a notice of a proposed rulemaking that has been published on or before the effective date of this subchapter, no later than 30 days after such date), each agency shall determine whether the rule is or is not a major rule within the meaning of section 621(4)(A)(i) and, if it is not, determine whether it is a major rule under section 621(4)(A)(ii). For the purpose of any such determination, a group of closely related rules shall be considered as one rule.

(b)(1) If an agency has determined that a rule is not a major rule, the Director or a designee of the President may, as appropriate, determine that the rule is a major rule no later than 30 days after the publication of the notice of proposed rulemaking for the rule (or, in the case of a notice of proposed rulemaking that has been published on or before the effective date of this subchapter, no later than 60 days after such date).

(2) Such determination shall be published in the Federal Register, together with a succinct statement of the basis for the determination.

(c)(1)(A) When the agency publishes a notice of proposed rulemaking for a major rule, the agency shall issue and place in the

rulemaking file an initial cost-benefit analysis, and shall include a summary of such analysis in the notice of proposed rulemaking.

(B)(i) When the Director or a designee of the President has published a determination that a rule is a major rule after the publication of the notice of proposed rulemaking for the rule, the agency shall promptly issue and place in the rulemaking file an initial cost-benefit analysis for the rule and shall publish in the Federal Register a summary of such analysis.

(ii) Following the issuance of an initial cost-benefit analysis under clause (i), the agency shall give interested persons an opportunity to comment pursuant to section 553 in the same manner as if the draft cost-benefit analysis had been issued with the notice of proposed rulemaking.

(2) Each initial cost-benefit analysis shall contain—

(A) an analysis of the benefits of the proposed rule, including any benefits that cannot be quantified, and an explanation of how the agency anticipates that such benefits will be achieved by the proposed rule, including a description of the persons or classes of persons likely to receive such benefits;

(B) an analysis of the costs of the proposed rule, including any costs that cannot be quantified, and an explanation of how the agency anticipates that such costs will result from the proposed rule, including a description of the persons or classes of persons likely to bear such costs;

(C) an identification (including an analysis of costs and benefits) of an appropriate number of reasonable alternatives allowed under the statute granting the rulemaking authority for achieving the identified benefits of the proposed rule, including alternatives that—

(i) require no government action;

(ii) will accommodate differences among geographic regions and among persons with differing levels of resources with which to comply; and

(iii) employ voluntary programs, performance standards, or market-based mechanisms that permit greater flexibility in achieving the identified benefits of the proposed rule and that comply with the requirements of subparagraph (D);

(D) an assessment of the feasibility of establishing a regulatory program that operates through the application of market-based mechanisms;

(E) an explanation of the extent to which the proposed rule—

(i) will accommodate differences among geographic regions and among persons with differing levels of resources with which to comply; and

(ii) employs voluntary programs, performance standards, or market-based mechanisms that permit greater flexibility in achieving the identified benefits of the proposed rule;

(F) a description of the quality, reliability, and relevance of scientific or economic evaluations or information in accordance with the cost-benefit analysis and risk assessment requirements of this chapter;

(G) if not expressly or implicitly inconsistent with the statute under which the agency is proposing the rule, an explanation of the extent to which the identified benefits of the proposed rule

justify the identified costs of the proposed rule, and an explanation of how the proposed rule is likely to substantially achieve the rulemaking objectives in a more cost-effective manner than the alternatives to the proposed rule, including alternatives identified in accordance with subparagraph (C); and

(H) if a major rule subject to subchapter III addresses risks to human health, safety, or the environment—

(i) a risk assessment in accordance with this chapter; and

(ii) for each such proposed or final rule, an assessment of incremental risk reduction or other benefits associated with each significant regulatory alternative considered by the agency in connection with the rule or proposed rule.

(d)(1) When the agency publishes a final major rule, the agency shall also issue and place in the rulemaking file a final cost-benefit analysis, and shall include a summary of the analysis in the statement of basis and purpose.

(2) Each final cost-benefit analysis shall contain—

(A) a description and comparison of the benefits and costs of the rule and of the reasonable alternatives to the rule described in the rulemaking, including the market-based mechanisms identified under subsection (c)(2)(C)(iii); and

(B) if not expressly or implicitly inconsistent with the statute under which the agency is acting, a reasonable determination, based upon the rulemaking file considered as a whole, whether—

(i) the benefits of the rule justify the costs of the rule; and

(ii) the rule will achieve the rulemaking objectives in a more cost-effective manner than the alternatives described in the rulemaking, including the market-based mechanisms identified under subsection (c)(2)(C)(iii).

(e)(1) The analysis of the benefits and costs of a proposed and a final rule required under this section shall include, to the extent feasible, a quantification or numerical estimate of the quantifiable benefits and costs. Such quantification or numerical estimate shall be made in the most appropriate units of measurement, using comparable assumptions, including time periods, shall specify the ranges of predictions, and shall explain the margins of error involved in the quantification methods and in the estimates used. An agency shall describe the nature and extent of the nonquantifiable benefits and costs of a final rule pursuant to this section in as precise and succinct a manner as possible. An agency shall not be required to make such evaluation primarily on a mathematical or numerical basis.

(2)(A) In evaluating and comparing costs and benefits and in evaluating the risk assessment information developed under subchapter III, the agency shall not rely on cost, benefit, or risk assessment information that is not accompanied by data, analysis, or other supporting materials that would enable the agency and other persons interested in the rulemaking to assess the accuracy, reliability, and uncertainty factors applicable to such information.

(B) The agency evaluations of the relationships of the benefits of a proposed and final rule to its costs shall be clearly articulated in accordance with this section.

(f) As part of the promulgation of each major rule that addresses risks to human health, safety, or the environment, the head of the agency or the President shall make a determination that—

(1) the risk assessment and the analysis under subsection (c)(2)(H) are based on a scientific evaluation of the risk addressed by the major rule and that the conclusions of such evaluation are supported by the available information; and

(2) the regulatory alternative chosen will reduce risk in a cost-effective and, to the extent feasible, flexible manner, taking into consideration any of the alternatives identified under subsection (c)(2) (C) and (D).

(g) The preparation of the initial or final cost-benefit analysis required by this section shall only be performed under the direction of an officer or employee of the agency. The preceding sentence shall not preclude a person outside the agency from gathering data or information to be used by the agency in preparing any such cost-benefit analysis or from providing an explanation sufficient to permit the agency to analyze such data or information. If any such data or information is gathered or explained by a person outside the agency, the agency shall specifically identify in the initial or final cost-benefit analysis the data or information gathered or explained and the person who gathered or explained it, and shall describe the arrangement by which the information was procured by the agency, including the total amount of funds expended for such procurement.

(h) The requirements of this subchapter shall not alter the criteria for rulemaking otherwise applicable under other statutes.

§ 623. Judicial review

(a) Compliance or noncompliance by an agency with the provisions of this subchapter and subchapter III shall not be subject to judicial review except in connection with review of a final agency rule and according to the provisions of this section.

(b) Any determination by a designee of the President or the Director that a rule is, or is not, a major rule shall not be subject to judicial review in any manner.

(c) The determination by an agency that a rule is, or is not, a major rule under section 621(4)(A)(i) shall be set aside by a reviewing court only upon a clear and convincing showing that the determination is erroneous in light of the information available to the agency at the time the agency made the determination. Any determination by an agency that a rule is, or is not, a major rule under section 621(4)(A)(ii) shall not be subject to judicial review in any manner.

(d) If the cost-benefit analysis or risk assessment required under this chapter has been wholly omitted for any major rule, a court shall vacate the rule and remand the case for further consideration. If an analysis or assessment has been performed, the court shall not review to determine whether the analysis or assessment conformed to the particular requirements of this chapter.

(e) Any cost-benefit analysis or risk assessment prepared under this chapter shall not be subject to judicial consideration separate or apart from review of the agency action to which it relates. When an action for judicial review of an agency action is instituted, any regulatory analysis for such agency action shall constitute part of

the whole administrative record of agency action for the purpose of judicial review of the agency action, and shall, to the extent relevant, be considered by a court in determining the legality of the agency action.

§ 624. Deadlines for rulemaking

(a) All deadlines in statutes that require agencies to propose or promulgate any rule subject to section 622 or subchapter III during the 2-year period beginning on the effective date of this section shall be suspended until the earlier of—

(1) the date on which the requirements of section 622 or subchapter III are satisfied; or

(2) the date occurring 6 months after the date of the applicable deadline.

(b) All deadlines imposed by any court of the United States that would require an agency to propose or promulgate a rule subject to section 622 or subchapter III during the 2-year period beginning on the effective date of this section shall be suspended until the earlier of—

(1) the date on which the requirements of section 622 or subchapter III are satisfied; or

(2) the date occurring 6 months after the date of the applicable deadline.

(c) In any case in which the failure to promulgate a rule by a deadline occurring during the 2-year period beginning on the effective date of this section would create an obligation to regulate through individual adjudications, the deadline shall be suspended until the earlier of—

(1) the date on which the requirements of section 622 or subchapter III are satisfied; or

(2) the date occurring 6 months after the date of the applicable deadline.

§ 625. Agency review of rules

(a)(1)(A) No later than 9 months after the effective date of this section, each agency shall prepare and publish in the Federal Register a proposed schedule for the review, in accordance with this section, of—

(i) each rule of the agency that is in effect on such effective date and which, if adopted on such effective date, would be a major rule; and

(ii) each rule of the agency in effect on the effective date of this section (in addition to the rules described in clause (i)) that the agency has selected for review.

(B) Each proposed schedule required under subparagraph (A) shall be developed in consultation with—

(i) the Administrator of the Office of Information and Regulatory Affairs; and

(ii) the classes of persons affected by the rules, including members from the regulated industries, small businesses, State and local governments, and organizations representing the interested public.

(C) Each proposed schedule required under subparagraph (A) shall establish priorities for the review of rules that, in the joint de-

termination of the Administrator of the Office of Information and Regulatory Affairs and the agency, most likely can be amended or eliminated to—

(i) provide the same or greater benefits at substantially lower costs;

(ii) achieve substantially greater benefits at the same or lower costs; or

(iii) replace command-and-control regulatory requirements with market mechanisms or performance standards that achieve substantially equivalent benefits at lower costs or with greater flexibility.

(D) Each proposed schedule required by subparagraph (A) shall include—

(i) a brief explanation of the reasons the agency considers each rule on the schedule to be a major rule, or the reasons why the agency selected the rule for review;

(ii) a date set by the agency, in accordance with subsection (b), for the completion of the review of each such rule; and

(iii) a statement that the agency requests comments from the public on the proposed schedule.

(E) The agency shall set a date to initiate review of each rule on the schedule in a manner that will ensure the simultaneous review of related items and that will achieve a reasonable distribution of reviews over the period of time covered by the schedule.

(2) No later than 90 days before publishing in the Federal Register the proposed schedule required under paragraph (1), each agency shall make the proposed schedule available to the Director or a designee of the President. The President or that officer may select for review in accordance with this section any additional rule.

(3) No later than 1 year after the effective date of this section, each agency shall publish in the Federal Register a final schedule for the review of the rules referred to in paragraphs (1) and (2). Each agency shall publish with the final schedule the response of the agency to comments received concerning the proposed schedule.

(b)(1) Except as explicitly provided otherwise by statute, the agency shall, pursuant to subsections (c) through (e), review—

(A) each rule on the schedule promulgated pursuant to subsection (a);

(B) each major rule promulgated, amended, or otherwise continued by an agency after the effective date of this section; and

(C) each rule promulgated after the effective date of this section that the President or the officer designated by the President selects for review pursuant to subsection (a)(2).

(2) Except as provided pursuant to subsection (f), the review of a rule required by this section shall be completed no later than the later of—

(A) 10 years after the effective date of this section; or

(B) 10 years after the date on which the rule is—

(i) promulgated; or

(ii) amended or continued under this section.

(c) An agency shall publish in the Federal Register a notice of its proposed action under this section with respect to a rule being reviewed. The notice shall include—

(1) an identification of the specific statutory authority under which the rule was promulgated and an explanation of whether the agency's interpretation of the statute is expressly required by the current text of that statute or, if not, whether it is within the range of permissible interpretations of the statute;

(2) an analysis of the benefits and costs of the rule during the period in which it has been in effect;

(3) an explanation of the proposed agency action with respect to the rule, including action to repeal or amend the rule to resolve inconsistencies or conflicts with any other obligation or requirement established by any Federal statute, rule, or other agency statement, interpretation, or action that has the force of law; and

(4) a statement that the agency seeks proposals from the public for modifications or alternatives to the rule which may accomplish the objectives of the rule in a more effective or less burdensome manner.

(d) If an agency proposes to repeal or amend a rule under review pursuant to this section, the agency shall, after issuing the notice required by subsection (c), comply with the provisions of this chapter, chapter 5, and any other applicable law. The requirements of such provisions and related requirements shall apply to the same extent and in the same manner as in the case of a proposed agency action to repeal or amend a rule that is not taken pursuant to the review required by this section.

(e) If an agency proposes to continue without amendment a rule under review pursuant to this section, the agency shall—

(1) give interested persons no less than 60 days after the publication of the notice required by subsection (c) to comment on the proposed continuation; and

(2) publish in the Federal Register notice of the continuation of such rule.

(f) Any agency, which for good cause finds that compliance with this section with respect to a particular rule during the period provided in subsection (b) of this section is contrary to an important public interest may request the President, or the officer designated by the President pursuant to subsection (a)(2), to establish a period longer than 10 years for the completion of the review of such rule. The President or that officer may extend the period for review of a rule to a total period of no more than 15 years. Such extension shall be published in the Federal Register with an explanation of the reasons therefor.

(g) If the agency fails to comply with the requirements of subsection (b)(2), the rule for which rulemaking proceedings have not been completed shall cease to be enforceable against any person.

(h) Nothing in this section shall relieve any agency from its obligation to respond to a petition to issue, amend, or repeal a rule, for an interpretation regarding the meaning of a rule, or for a variance or exemption from the terms of a rule, submitted pursuant to any other provision of law.

§ 626. Public participation and accountability

In order to maximize accountability for, and public participation in, the development and review of regulatory actions each agency

shall, consistent with chapter 5 and other applicable law, provide the public with opportunities for meaningful participation in the development of regulatory actions, including—

(1) seeking the involvement, where practicable and appropriate, of those who are intended to benefit from and those who are expected to be burdened by any regulatory action;

(2) providing in any proposed or final rulemaking notice published in the Federal Register—

(A) a certification of compliance with the requirements of this chapter, or an explanation why such certification cannot be made;

(B) a summary of any regulatory analysis required under this chapter, or under any other legal requirement, and notice of the availability of the regulatory analysis;

(C) a certification that the rule will produce benefits that will justify the cost to the Government and to the public of implementation of, and compliance with, the rule, or an explanation why such certification cannot be made; and

(D) a summary of the results of any regulatory review and the agency's response to such review, including an explanation of any significant changes made to such regulatory action as a consequence of regulatory review;

(3) identifying, upon request, a regulatory action and the date upon which such action was submitted to the designated officer to whom authority was delegated under section 644 for review;

(4) disclosure to the public, consistent with section 634(3), of any information created or collected in performing a regulatory analysis required under this chapter, or under any other legal requirement; and

(5) placing in the appropriate rulemaking record all written communications received from the Director, other designated officer, or other individual or entity relating to regulatory review.

SUBCHAPTER III—RISK ASSESSMENTS

§ 631. Findings and purposes

(a) The Congress finds that:

(1) Environmental, health, and safety regulations have lead to dramatic improvements in the environment and have significantly reduced risks to human health; except—

(A) many regulations have been more costly and less effective than necessary; and

(B) too often, regulatory priorities have not been based upon a realistic consideration of risk, risk reduction opportunities, and costs.

(2) The public and private resources available to address health, safety, and environmental risks are not unlimited. Those resources should be allocated to address the greatest needs in the most cost-effective manner and to ensure that the incremental costs of regulatory options are reasonably related to the incremental benefits.

(3) To provide more cost-effective protection to human health, safety, and the environment, regulatory priorities should be supported by realistic and plausible scientific risk assessments

and risk management choices that are grounded in cost-benefit principles.

(4) Risk assessment has proved to be a useful decisionmaking tool, except—

(A) improvements are needed in both the quality of assessments and the characterization and communication of findings;

(B) scientific and other data must be better collected, organized, and evaluated; and

(C) the critical information resulting from a risk assessment must be effectively communicated in an objective and unbiased manner to decision makers, and from decision makers to the public.

(5) The public stakeholders should be involved in the decisionmaking process for regulating risks. The public has the right to know about the risks addressed by regulation, the amount of risk reduced, the quality of the science used to support decisions, and the cost of implementing and complying with regulations. Such knowledge will allow for public scrutiny and will promote the quality, integrity, and responsiveness of agency decisions.

(b) The purposes of this subchapter are to—

(1) present the public and executive branch with the most realistic and plausible information concerning the nature and magnitude of health, safety, and environmental risks to promote sound regulatory decisions and public education;

(2) provide for full consideration and discussion of relevant data and potential methodologies;

(3) require explanation of significant choices in the risk assessment process that will allow for better public understanding; and

(4) improve consistency within the executive branch in preparing risk assessments and risk characterizations.

§ 632. Definitions

For purposes of this subchapter, the definitions under sections 551 and 621 shall apply and:

(1) The term "covered agency" means each of the following:

(A) The Environmental Protection Agency.

(B) The Department of Labor.

(C) The Department of Transportation.

(D) The Food and Drug Administration.

(E) The Department of Energy.

(F) The Department of the Interior.

(G) The Department of Agriculture.

(H) The Consumer Product Safety Commission.

(I) The National Oceanic and Atmospheric Administration.

(J) The United States Army Corps of Engineers.

(K) The Nuclear Regulatory Commission.

(L) Any other Federal agency considered a covered agency under section 633(b).

(2) The term "emergency" means a situation that is immediately impending and extraordinary in nature, demanding at-

tention due to a condition, circumstance or practice reasonably expected to cause death, serious illness or severe injury to humans, or substantial endangerment to private property or the environment if no action is taken.

(3) The term "estimates of risk" means numerical representations of the potential magnitude of harm to populations or the probability of harm to individuals, including, as appropriate, those derived by considering the range and distribution of estimates of dose-response (potency) and exposure, including appropriate statistical representation of the range and most likely exposure levels, and the identification of the populations or subpopulations addressed. When appropriate and practicable, a description of any populations or subpopulations that are likely to experience exposures at the upper end of the distribution should be included.

(4) The term "hazard identification" means identification of a substance, activity, or condition as potentially causing harm to human health, safety, or the environment.

(5) The term "risk assessment" means—

(A) identifying, quantifying to the extent feasible and appropriate, and characterizing hazards and exposures to those hazards in order to provide structured information on the nature of threats to human health, safety, or the environment; and

(B) the document containing the explanation of how the assessment process has been applied to an individual substance, activity, or condition.

(6) The term "risk characterization" means the integration, synthesis, and organization of hazard identification, dose-response and exposure information that addresses the needs of decision makers and interested parties. The term includes both the process and specific outputs, including—

(A) the element of a risk assessment that involves presentation of the degree of risk in any regulatory proposal or decision, report to Congress, or other document that is made available to the public; and

(B) discussions of uncertainties, conflicting data, estimates of risk, extrapolations, inferences, and opinions.

(7) The term "screening analysis" means an analysis that arrives at a qualitative estimate or a bounding estimate of risk that permits the risk manager to accept or reject some management options, or permits establishing priorities for agency action. Such term includes an assessment performed by a regulated party and submitted to an agency under a regulatory requirement.

(8) The term "substitution risk" means a reasonably likely increased risk to human health, safety, or the environment from a regulatory option designed to decrease other risks.

§ 633. Applicability

(a) Except as provided in subsection (c), this subchapter shall apply to all risk assessments and risk characterizations prepared by, or on behalf of, or prepared by others and adopted by any cov-

ered agency in connection with a major rule addressing health, safety, and environmental risks.

(b)(1) No later than 18 months after the effective date of this section, the President, acting through the Director of the Office of Management and Budget, shall determine whether other Federal agencies should be considered covered agencies for the purposes of this subchapter. Such determination, with respect to a particular Federal agency, shall be based on the impact of risk assessment documents and risk characterization documents on—

(A) regulatory programs administered by that agency; and

(B) the communication of risk information by that agency to the public.

(2) If the President makes a determination under paragraph (1), the provisions of this subchapter shall apply to any affected agency beginning on a date set by the President. Such date may be no later than 6 months after the date of such determination.

(c)(1) This subchapter shall not apply to risk assessments or risk characterizations performed with respect to—

(A) an emergency determined by the head of an agency;

(B) a health, safety, or environmental inspection or individual facility permitting action; or

(C) a screening analysis.

(2) This subchapter shall not apply to any food, drug, or other product label, or to any risk characterization appearing on any such label.

§ 634. Savings provisions

Nothing in this subchapter shall be construed to—

(1) modify any statutory standard or requirement designed to protect human health, safety, or the environment;

(2) preclude the consideration of any data or the calculation of any estimate to more fully describe risk or provide examples of scientific uncertainty or variability; or

(3) require the disclosure of any trade secret or other confidential information.

§ 635. Principles for risk assessment

(a) The head of each covered agency shall ensure that risk assessments and all of the components of such assessments—

(1) provide for a systematic means to structure information useful to decision makers;

(2) provide, to the maximum extent practicable, that policy-driven default assumptions be used only in the absence of relevant available information;

(3) promote involvement from all stakeholders;

(4) provide an opportunity for public input throughout the regulatory process; and

(5) are designed so that the degree of specificity and rigor employed is commensurate with the consequences of the decision to be made.

(b) A risk assessment shall, to the maximum extent practicable, clearly delineate hazard identification from dose-response and exposure assessment and make clear the relationship between the level of risk and the level of exposure to a hazard.

§ 636. Principles for risk characterization

In characterizing risk in any risk assessment document, regulatory proposal, or decision, each covered agency shall include in the risk characterization, as appropriate, each of the following:

(1)(A) A description of the exposure scenarios used, the natural resources or subpopulations being exposed, and the likelihood of those exposure scenarios.

(B) When a risk assessment involves a choice of any significant assumption, inference, or model, the covered agency or instrumentality preparing the risk assessment shall—

(i) identify the assumptions, inferences, and models that materially affect the outcome;

(ii) explain the basis for any choices;

(iii) identify any policy decisions or policy-based default assumptions;

(iv) indicate the extent to which any significant model has been validated by, or conflicts with, empirical data; and

(v) describe the impact of alternative choices of assumptions, default options or mathematical models.

(C) The major sources of uncertainties in the hazard identification, dose-response and exposure assessment phases of the risk assessment.

(D) To the extent feasible, the range and distribution of exposures and risks derived from the risk assessment should be included as a component of the risk characterization.

(2) When a covered agency provides a risk assessment or risk characterization for a proposed or final regulatory action, such assessment or characterization shall include a statement of any significant substitution risks, when information on such risks has been made available to the agency.

§ 637. Peer review

(a) The head of each covered agency shall develop a systematic program for independent and external peer review required under subsection (b). Such program shall be applicable throughout each covered agency and—

(1) shall provide for the creation of peer review panels that—

(A) consist of members with expertise relevant to the sciences involved in regulatory decisions and who are independent of the covered agency; and

(B) are broadly representative and balanced and, to the extent relevant and appropriate, may include persons affiliated with Federal, State, local, or tribal governments, small businesses, other representatives of industry, universities, agriculture, labor consumers, conservation organizations, or other public interest groups and organizations;

(2) shall not exclude any person with substantial and relevant expertise as a panel member on the basis that such person represents an entity that may have a potential interest in the outcome, if such interest is fully disclosed to the agency, and in the case of a regulatory decision affecting a single entity, no peer reviewer representing such entity may be included on the panel;

(3) shall provide for a timely completed peer review, meeting agency deadlines, that contains a balanced presentation of all considerations, including minority reports and an agency response to all significant peer review comments; and

(4) shall provide adequate protections for confidential business information and trade secrets, including requiring panel members to enter into confidentiality agreements.

(b)(1)(A) Except as provided under subparagraph (B), each covered agency shall provide for peer review in accordance with this section of any risk assessment or cost-benefit analysis that forms the basis of any major rule that addresses risks to the environment, health, or safety.

(B) Subparagraph (A) shall not apply to a rule or other action taken by an agency to authorize or approve any individual substance or product.

(2) The Director of the Office of Management and Budget may order that peer review be provided for any risk assessment or cost-benefit analysis that is likely to have a significant impact on public policy decisions or would establish an important precedent.

(c) Each peer review under this section shall include a report to the Federal agency concerned with respect to the scientific and technical merit of data and methods used for the risk assessments or cost-benefit analyses.

(d) The head of the covered agency shall provide a written response to all significant peer review comments.

(e) All peer review comments or conclusions and the agency's responses shall be made available to the public and shall be made part of the administrative record for purposes of judicial review of any final agency action.

(f) No peer review shall be required under this section for any data, method, document, or assessment, or any component thereof, which has been previously subjected to peer review.

§ 638. Guidelines, plan for assessing new information, and report

(a)(1)(A) As soon as practicable and scientifically feasible, each covered agency shall adopt, after notification and opportunity for public comment, guidelines to implement the risk assessment and risk characterization principles under sections 635 and 636, as well as the cost-benefit analysis requirements under section 622, and shall provide a format for summarizing risk assessment results.

(B) No later than 12 months after the effective date of this section, the head of each covered agency shall issue a report on the status of such guidelines to the Congress.

(2) The guidelines under paragraph (1) shall—

(A) include guidance on use of specific technical methodologies and standards for acceptable quality of specific kinds of data;

(B) address important decisional factors for the risk assessment, risk characterization, and cost-benefit analysis at issue; and

(C) provide procedures for the refinement and replacement of policy-based default assumptions.

(b) The guidelines, plan and report under this section shall be developed after notice and opportunity for public comment, and after consultation with representatives of appropriate State agencies and local governments, and such other departments and agencies, organizations, or persons as may be advisable.

(c) The President shall review the guidelines published under this section at least every 4 years.

(d) The development, issuance, and publication of risk assessment and risk characterization guidelines under this section shall not be subject to judicial review.

§ 639. Research and training in risk assessment

(a) The head of each covered agency shall regularly and systematically evaluate risk assessment research and training needs of the agency, including, where relevant and appropriate, the following:

(1) Research to reduce generic data gaps, to address modelling needs (including improved model sensitivity), and to validate default options, particularly those common to multiple risk assessments.

(2) Research leading to improvement of methods to quantify and communicate uncertainty and variability among individuals, species, populations, and, in the case of ecological risk assessment, ecological communities.

(3) Emerging and future areas of research, including research on comparative risk analysis, exposure to multiple chemicals and other stressors, noncancer endpoints, biological markers of exposure and effect, mechanisms of action in both mammalian and nonmammalian species, dynamics and probabilities of physiological and ecosystem exposures, and prediction of ecosystem-level responses.

(4) Long-term needs to adequately train individuals in risk assessment and risk assessment application. Evaluations under this paragraph shall include an estimate of the resources needed to provide necessary training.

(b) The head of each covered agency shall develop a strategy and schedule for carrying out research and training to meet the needs identified in subsection (a).

§ 640. Interagency coordination

(a) To promote the conduct, application, and practice of risk assessment in a consistent manner and to identify risk assessment data and research needs common to more than 1 Federal agency, the Director of the Office of Management and Budget, in consultation with the Office of Science and Technology Policy, shall—

(1) periodically survey the manner in which each Federal agency involved in risk assessment is conducting such risk assessment to determine the scope and adequacy of risk assessment practices in use by the Federal Government;

(2) provide advice and recommendations to the President and Congress based on the surveys conducted and determinations made under paragraph (1);

(3) establish appropriate interagency mechanisms to promote—

(A) coordination among Federal agencies conducting risk assessment with respect to the conduct, application, and practice of risk assessment; and

(B) the use of state-of-the-art risk assessment practices throughout the Federal Government;

(4) establish appropriate mechanisms between Federal and State agencies to communicate state-of-the-art risk assessment practices; and

(5) periodically convene meetings with State government representatives and Federal and other leaders to assess the effectiveness of Federal and State cooperation in the development and application of risk assessment.

(b) The President shall appoint National Peer Review Panels to review every 3 years the risk assessment practices of each covered agency for programs designed to protect human health, safety, or the environment. The Panels shall submit a report to the President and the Congress at least every 3 years containing the results of such review.

§ 640a. Plan for review of risk assessments

(a) No later than 18 months after the effective date of this section, the head of each covered agency shall publish a plan to review and revise any risk assessment published before the expiration of such 18-month period if the covered agency determines that significant new information or methodologies are available that could significantly alter the results of the prior risk assessment.

(b) A plan under subsection (a) shall—

(1) provide procedures for receiving and considering new information and risk assessments from the public; and

(2) set priorities and criteria for review and revision of risk assessments based on such factors as the agency head considers appropriate.

§ 640b. Judicial review

The provisions of section 623 relating to judicial review shall apply to this subchapter.

§ 640c. Deadlines for rulemaking

The provisions of section 624 relating to deadlines for rulemaking shall apply to this subchapter.

SUBCHAPTER IV—EXECUTIVE OVERSIGHT

§ 641. Definition

For purposes of this subchapter, the definitions under sections 551 and 621 shall apply.

§ 642. Procedures

The Director or other designated officer to whom authority is delegated under section 644 shall—

(1) establish procedures for agency compliance with this chapter; and

(2) monitor, review, and ensure agency implementation of such procedures.

§ 643. Promulgation and adoption

(a) Procedures established pursuant to section 642 shall only be implemented after opportunity for public comment. Any such procedures shall be consistent with the prompt completion of rulemaking proceedings.

(b)(1) If procedures established pursuant to section 642 include review of any initial or final analyses of a rule required under this chapter, the time for any such review of any initial analysis shall not exceed 60 days following the receipt of the analysis by the Director, a designee of the President, or by an officer to whom the authority granted under section 642 has been delegated pursuant to section 644.

(2) The time for review of any final analysis required under this chapter shall not exceed 60 days following the receipt of the analysis by the Director, a designee of the President, or such officer.

(3)(A) The times for each such review may be extended for good cause by the President or such officer for an additional 30 days.

(B) Notice of any such extension, together with a succinct statement of the reasons therefor, shall be inserted in the rulemaking file.

§ 644. Delegation of authority

(a) The President shall delegate the authority granted by this subchapter to the Director or to another officer within the Executive Office of the President whose appointment has been subject to the advice and consent of the Senate.

(b) Notice of any delegation, or any revocation or modification thereof shall be published in the Federal Register.

§ 645. Public disclosure of information

The Director or other designated officer to whom authority is delegated under section 644, in carrying out the provisions of section 642, shall establish procedures (covering all employees of the Director or other designated officer) to provide public and agency access to information concerning regulatory review actions, including—

(1) disclosure to the public on an ongoing basis of information regarding the status of regulatory actions undergoing review;

(2) disclosure to the public, no later than publication of, or other substantive notice to the public concerning a regulatory action, of—

(A) all written communications, regardless of form or format, including drafts of all proposals and associated analyses, between the Director or other designated officer and the regulatory agency;

(B) all written communications, regardless of form or format, between the Director or other designated officer and any person not employed by the executive branch of the Federal Government relating to the substance of a regulatory action;

(C) a record of all oral communications relating to the substance of a regulatory action between the Director or other designated officer and any person not employed by the executive branch of the Federal Government; and

(D) a written explanation of any review action and the date of such action; and

(3) disclosure to the regulatory agency, on a timely basis, of—

(A) all written communications between the Director or other designated officer and any person who is not employed by the executive branch of the Federal Government;

(B) a record of all oral communications, and an invitation to participate in meetings, relating to the substance of a regulatory action between the Director or other designated officer and any person not employed by the executive branch of the Federal Government; and

(C) a written explanation of any review action taken concerning an agency regulatory action.

§ 646. Judicial review

The exercise of the authority granted under this subchapter by the Director, the President, or by an officer to whom such authority has been delegated under section 644 shall not be subject to judicial review in any manner.

CHAPTER 8—CONGRESSIONAL REVIEW OF AGENCY RULEMAKING

§ 801. Congressional review of agency rulemaking

(a) For purposes of this chapter, the term—

(1) "major rule" means a major rule as defined under section 621(4) of this title and as determined under section 622 of this title; and

(2) "rule" (except in reference to a rule of the Senate or House of Representatives) is a reference to a major rule.

(b)(1) Upon the promulgation of a final major rule, the agency promulgating such rule shall submit to the Congress a copy of the rule, the statement of basis and purpose for the rule, and the proposed effective date of the rule.

(2) A rule submitted under paragraph (1) shall not take effect as a final rule before the latest of the following:

(A) The later of the date occurring 45 days after the date on which—

(i) the Congress receives the rule submitted under paragraph (1); or

(ii) the rule is published in the Federal Register.

(B) If the Congress passes a joint resolution of disapproval described under subsection (i) relating to the rule, and the President signs a veto of such resolution, the earlier date—

(i) on which either House of Congress votes and fails to override the veto of the President; or

(ii) occurring 30 session days after the date on which the Congress received the veto and objections of the President.

(C) The date the rule would have otherwise taken effect, if not for this section (unless a joint resolution of disapproval under subsection (i) is approved).

(c) A major rule shall not take effect as a final rule if the Congress passes a joint resolution of disapproval described under sub-

section (i), which is signed by the President or is vetoed and overridden by the Congress.

(d)(1) Notwithstanding any other provision of this section (except subject to paragraph (2)), a major rule that would not take effect by reason of this section may take effect if the President makes a determination and submits written notice of such determination to the Congress that the major rule should take effect because such major rule is—

(A) necessary because of an imminent threat to health or safety, or other emergency;

(B) necessary for the enforcement of criminal laws; or

(C) necessary for national security.

(2) An exercise by the President of the authority under this subsection shall have no effect on the procedures under subsection (i) or the effect of a joint resolution of disapproval under this section.

(e)(1) Subsection (i) shall apply to any major rule that is promulgated as a final rule during the period beginning on the date occurring 60 days before the date the Congress adjourns sine die through the date on which the succeeding Congress first convenes.

(2) For purposes of subsection (i), a major rule described under paragraph (1) shall be treated as though such rule were published in the Federal Register (as a rule that shall take effect as a final rule) on the date the succeeding Congress first convenes.

(3) During the period between the date the Congress adjourns sine die through the date on which the succeeding Congress first convenes, a rule described under paragraph (1) shall take effect as a final rule as otherwise provided by law.

(f) Any rule that takes effect and later is made of no force or effect by the enactment of a joint resolution under subsection (i) shall be treated as though such rule had never taken effect.

(g) If the Congress does not enact a joint resolution of disapproval under subsection (i), no court or agency may infer any intent of the Congress from any action or inaction of the Congress with regard to such major rule, related statute, or joint resolution of disapproval.

(h) If the agency fails to comply with the requirements of subsection (b) for any rule, the rule shall cease to be enforceable against any person.

(i)(1) For purposes of this subsection, the term "joint resolution" means only a joint resolution introduced after the date on which the rule referred to in subsection (b) is received by Congress the matter after the resolving clause of which is as follows: "That Congress disapproves the rule submitted by the _____ relating to _____, and such rule shall have no force or effect." (The blank spaces being appropriately filled in.)

(2)(A) In the Senate, a resolution described in paragraph (1) shall be referred to the committees with jurisdiction. Such a resolution shall not be reported before the eighth day after its submission or publication date.

(B) For purposes of this subsection, the term "submission or publication date" means the later of the date on which—

(i) the Congress receives the rule submitted under subsection (b)(1); or

(ii) the rule is published in the Federal Register.

(3) In the Senate, if the committee to which a resolution described in paragraph (1) is referred has not reported such resolution (or an identical resolution) at the end of 20 calendar days after its submission or publication date, such committee may be discharged on a petition approved by 30 Senators from further consideration of such resolution and such resolution shall be placed on the Senate calendar.

(4)(A) In the Senate, when the committee to which a resolution is referred has reported, or when a committee is discharged (under paragraph (3)) from further consideration of, a resolution described in paragraph (1), it shall at any time thereafter be in order (even though a previous motion to the same effect has been disagreed to) for any Senator to move to proceed to the consideration of the resolution, and all points of order against the resolution (and against consideration of the resolution) shall be waived. The motion shall be privileged in the Senate and shall not be debatable. The motion shall not be subject to amendment, or to a motion to postpone, or to a motion to proceed to the consideration of other business. A motion to reconsider the vote by which the motion is agreed to or disagreed to shall not be in order. If a motion to proceed to the consideration of the resolution is agreed to, the resolution shall remain the unfinished business of the Senate until disposed of.

(B) In the Senate, debate on the resolution, and on all debatable motions and appeals in connection therewith, shall be limited to not more than 10 hours, which shall be divided equally between those favoring and those opposing the resolution. A motion further to limit debate shall be in order and shall not be debatable. An amendment to, or a motion to postpone, or a motion to proceed to the consideration of other business, or a motion to recommit the resolution shall not be in order. A motion to reconsider the vote by which the resolution is agreed to or disagreed to shall not be in order.

(C) In the Senate, immediately following the conclusion of the debate on a resolution described in paragraph (1), and a single quorum call at the conclusion of the debate if requested in accordance with the Senate rules, the vote on final passage of the resolution shall occur.

(D) Appeals from the decisions of the Chair relating to the application of the rules of the Senate to the procedure relating to a resolution described in paragraph (1) shall be decided without debate.

(5) If, before the passage in the Senate of a resolution described in paragraph (1), the Senate receives from the House of Representatives a resolution described in paragraph (1), then the following procedures shall apply:

(A) The resolution of the House of Representatives shall not be referred to a committee.

(B) With respect to a resolution described in paragraph (1) of the Senate—

(i) the procedure in the Senate shall be the same as if no resolution had been received from the other House; but

(ii) the vote on final passage shall be on the resolution of the other House.

(6) This subsection is enacted by Congress—

(A) as an exercise of the rulemaking power of the Senate and House of Representatives, respectively, and as such it is deemed to be a part of the rules of each House, respectively, but applicable only with respect to the procedure to be followed in that House in the case of a resolution described in paragraph (1), and it supersedes other rules only to the extent that it is inconsistent with such rules; and

(B) with full recognition of the constitutional right of either House to change the rules (so far as relating to the procedure of that House) at any time, in the same manner, and to the same extent as in the case of any other rule of that House.

(j) No requirements under this chapter shall be subject to judicial review in any manner.

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