

Board, transmitting, pursuant to law, the report on the internal controls and financial systems in effect during fiscal year 1994; to the Committee on Governmental Affairs.

EC-303. A communication from the Administrator of the U.S. Small Business Administration, transmitting, pursuant to law, the report on the internal controls and financial systems in effect during fiscal year 1994; to the Committee on Governmental Affairs.

EC-304. A communication from the Office of the District of Columbia Auditor, transmitting, pursuant to law, the report entitled "Review of the Department of Human Services Foster Care Program Vendor Payments for Fiscal Years 1992, 1993, and 1994"; to the Committee on Governmental Affairs.

EC-305. A communication from the Inspector General of the General Services Administration, transmitting, pursuant to law, the semiannual report for the period April 1 through September 30, 1994; to the Committee on Governmental Affairs.

EC-306. A communication from the Secretary of Health and Human Services, transmitting, pursuant to law, the report of the study of the effectiveness of the State Long-Term Care Ombudsman Program; to the Committee on Labor and Human Services.

EC-307. A communication from the Architect of the Capitol, transmitting, pursuant to law, notice of a request to plant a tree on the Capitol Grounds; to the Committee on Rules and Administration.

EC-308. A communication from the Secretary of Veterans' Affairs, transmitting, pursuant to law, the annual report on contract care and services furnished by the Department to eligible veterans; to the Committee on Veterans' Affairs.

EC-309. A communication from the Director of the Office of Management and Budget, Executive Office of the President, transmitting, pursuant to law, the report on rescissions and deferrals dated December 1, 1994; referred jointly, pursuant to the order of January 30, 1975, as modified by the order of April 11, 1986, to the Committee on Appropriations, to the Committee on the Budget, to the Committee on Finance, and to the Committee on Foreign Relations.

EC-310. A communication from the Director of the Office of Management and Budget, Executive Office of the President, transmitting, pursuant to law, the report on rescissions and deferrals dated January 1, 1995; referred jointly, pursuant to the order of January 30, 1975, as modified by the order of April 11, 1986, to the Committee on Appropriations, to the Committee on the Budget, to the Committee on Finance, and to the Committee on Foreign Relations.

EC-311. A communication from the Comptroller General of the United States, transmitting, pursuant to law, the report of the summary of proposed and enacted rescissions for fiscal years 1974 through 1995; referred jointly, pursuant to the order of January 30, 1975, as modified by the order of April 11, 1986, to the Committee on Appropriations and to the Committee on the Budget.

EC-312. A communication from the Comptroller General of the United States, transmitting, pursuant to law, the compliance report for calendar year 1994; referred jointly, pursuant to the order of January 30, 1975, as modified by the order of April 11, 1986, to the Committee on Appropriations and to the Committee on the Budget.

## INTRODUCTION OF BILLS AND JOINT RESOLUTIONS

The following bills and joint resolutions were introduced, read the first and second time by unanimous consent, and referred as indicated:

By Mr. ROTH:

S. 291. A bill to reform the regulatory process, to make government more efficient and effective, and for other purposes; to the Committee on Governmental Affairs.

By Mr. SHELBY:

S. 292. A bill to provide Federal recognition of the Mowa Band of Choctaw Indians of Alabama; to the Committee on Indian Affairs.

## STATEMENTS ON INTRODUCED BILLS AND JOINT RESOLUTIONS

By Mr. ROTH:

S. 291. A bill to reform the regulatory process, to make government more efficient and effective, and for other purposes; to the Committee on Governmental Affairs.

### REGULATORY REFORM LEGISLATION

• Mr. ROTH. Mr. President, I rise to emphasize the critical need for a smarter, more cost-effective approach to Government regulation. Today, I introduce legislation intended to generate constructive debate on this important issue.

As chairman of the Committee on Governmental Affairs, I want to build consensus on how to regulate smarter among all engaged in the growing debate on regulatory reform—including the general public, businesses of all sizes, environmental and public interest groups, academia, State and local governments, the White House, and my colleagues on both sides of the aisle. Throughout my career, I have been committed to protecting the environment, health, and safety. I reaffirm that commitment today. We should not forget that many regulations provide important protections and benefits to the public. Let there be no mistake—we need a clean environment, safe workplaces, and safe medications.

Mr. President, it is clear that the regulatory process is broken. Too many regulations impose undue costs, and the regulatory process itself has become too cumbersome, unresponsive, and inefficient. The cumulative cost of regulation is enormous and is rising at an alarming rate. The annual cost of Federal regulation was conservatively estimated at about \$560 billion for 1992; it could exceed \$660 billion by the year 2000. About three-fourths of the cost increase is expected from upcoming risk regulations, such as environmental, health, and safety standards.

The rising cost of regulation affects us all—businesses large and small, governments at all levels, and the American worker and consumer. Regulations drive up prices and stifle wages, innovation, and economic growth. Although the direct costs of regulation generally are imposed on businesses and governments, these costs ultimately are passed on to the American consumer through higher prices, diminished wages, increased taxes, or reduced government services. The cost of regulation has been estimated at about \$6,000 per year for the average American household.

The recent elections brought to this Congress historic change, and with it,

and unprecedented opportunity to reform the regulatory process. However, it is important that we take a balanced approach to reform. In our zeal to implement substantial changes, we should act carefully so that we truly perfect needed Government programs—not cripple or stymie them. Building a smarter regulatory process will require the expertise and consensus of those on all sides of the regulatory reform debate. Together, we should strive to achieve desirable social goals in the most cost-effective manner practical.

My goal is to forge a consensus on effective legislation to make the regulatory process more efficient and effective. The bill I am introducing today is a first step in this direction, but it requires further debate and deliberation. It may be necessary to add further provisions, delete some, or revise others. I will chair a series of hearings, beginning on February 8, to provide a forum to discuss the broad principles of regulatory reform—those reflected in this bill as well as others we have not yet addressed.

My bill will require Federal agencies to seriously consider whether the benefits of regulating justify its costs. When regulating risks, regulators will be required to make realistic estimates of risk based on the available data, and disclose to the public any assumptions necessary to measure those risks. The bill also will encourage agencies to base their priorities on the relative risks posed by various substances, activities, and products to achieve the greatest overall reduction in risk at the least cost. More generally, my bill will require agencies to review existing regulations, to be sensitive to the cumulative regulatory burden, and to select the most cost-effective, market-driven method practical. These are but some of the principles to be discussed at the hearings on regulatory reform.

We can reinvent the regulatory process to ensure that when agencies choose to regulate, they will do so in a more effective and less costly manner. We can reduce the burden on governments, businesses, and the public, and still ensure that important benefits and protections are provided. We cannot afford to ignore the need to regulate smarter.

I ask unanimous consent that the legislation I introduce today be printed in the RECORD.

There being no objection, the bill was ordered to be printed in the RECORD, as follows:

S. 291

*Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,*

### SECTION 1. SHORT TITLE.

This Act may be cited as the "Regulatory Reform Act of 1995".

### SEC. 2. TABLE OF CONTENTS.

The table of contents for this Act is as follows:

Sec. 1. Short title.

Sec. 2. Table of Contents.

# TITLE I—REGULATORY ANALYSIS AND REVIEW

- Sec. 101. Cost/Benefit Analysis of Agency Proposals; Risk Assessment; Regulatory Review.  
 Sec. 102. Use of State or Local Requirements.  
 Sec. 103. Presidential Authority.

## TITLE II—RISK-BASED PRIORITIES

- Sec. 201. Short title.  
 Sec. 202. Purposes.  
 Sec. 203. Definitions.  
 Sec. 204. Department and Agency Program Goals.  
 Sec. 205. Comparative Risk Analysis.  
 Sec. 206. Reports to Congress and the President.  
 Sec. 207. Savings Provision and Judicial Review.

# TITLE III—REGULATORY ACCOUNTING

- Sec. 301. Short title.  
 Sec. 302. Accounting Statement.  
 Sec. 303. Associated Report to Congress.  
 Sec. 304. Guidance from Office of Management and Budget.  
 Sec. 305. Recommendations from Congressional Budget Office.  
 Sec. 306. Definitions.

# TITLE IV—MARKET INCENTIVES AND ECONOMICALLY EFFICIENT REGULATION

- Sec. 401. Short title.  
 Sec. 402. Program Design Requirements.  
 Sec. 403. Agency Assessment and OMB Review.  
 Sec. 404. Definitions.

# TITLE I: REGULATORY ANALYSIS AND REVIEW

## SEC. 101. COST/BENEFIT ANALYSIS OF AGENCY PROPOSALS; RISK ASSESSMENT; REGULATORY REVIEW.

(a) IN GENERAL.—Chapter 6 of title 5, United States Code, is amended by adding at the end thereof the following:

“Subchapter II—Analysis of Agency Proposals

### “§ 621. Definitions

“For purposes of this subchapter and subchapter III of this chapter:

“(1) The term ‘agency’ has the same meaning as in section 551(1) of this title.

“(2) The term ‘person’ has the same meaning as in section 551(2) of this title.

“(3) The term ‘rule’ has the same meaning as in section 551(4) of this title, except that such term does not include—

“(A) a rule of particular applicability that approves or prescribes for the future rates, wages, prices, services, or allowances therefor, corporate or financial structures, reorganizations, mergers or acquisitions, or 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

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

“(4) The term ‘major rule’ means—

“(A) a rule or a group of closely related rules that the agency, the President, or the officer selected under section 624 of this title 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, or has a significant impact on a subsection of the economy; and

“(B) a rule or a group of closely related rules that is otherwise designated a major rule by the agency proposing the rule, or is so designated by the President, or by the officer selected under section 624 of this title, 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, or local government agencies, or geographic regions; or

“(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.

For purposes of subparagraph (A) of this paragraph, the term ‘rule’ does not mean—

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

“(II) a rule that authorizes the introduction into commerce or recognizes the marketable status of a product, pursuant to sections 408, 409(c), and 706 of the Federal Food, Drug, and Cosmetic Act;

“(III) a rule exempt from notice and public procedure pursuant to section 553(a) of this title; or

“(IV) a rule relating to the viability, stability, asset powers, or categories of accounts of, or permissible interest rate ceilings applicable to, depository institutions the deposits or accounts of which are insured by the Federal Deposit Insurance Corporation, or the Share Insurance Fund of the National Credit Union Administration Board.

“(5) The term ‘benefit’ means the reasonably identifiable significant benefits and beneficial effects, including social and economic benefits and effects, that are expected to result directly or indirectly from implementation of a rule or an alternative to a rule.

“(6) The term ‘cost’ means the reasonably identifiable significant costs and adverse effects, including economic and social costs and effects, that are expected to result directly or indirectly from implementation of a rule or an alternative to a rule.

### “§ 622. Regulatory cost/benefit analysis

“(a) Prior to publishing notice of proposed rule making for any rule, each agency shall determine whether the rule is or is not a major rule within the meaning of section 621(4)(A) of this title and, if it is not, whether it should be designated a major rule under section 621(4)(B) of this title. For the purpose of any such determination or designation, a group of closely related rules shall be considered as one rule. Every notice of proposed rule making shall include a succinct statement and explanation of the agency’s determination of whether or not the rule is a major rule within the meaning of section 621(4)(A) of this title and, if applicable, of its designation as a major rule under section 621(4)(B) of this title.

“(b) The President or the officer selected by the President under section 624 of this title may determine that a rule is a major rule within the meaning of section 621(4)(A) of this title or may designate a rule as a major rule under section 621(4)(B) of this title not later than thirty days after the publication of the notice of proposed rule making for that rule. Such determination or designation shall be published in the Federal Register, together with a succinct statement of the basis for the determination or designation. The President or the officer selected by the President under section 624 of this title may designate not more than seventy-five rules as major rules under section 621(4)(B) of this title in any fiscal year.

“(c)(1) When the agency publishes a notice of proposed rule making for a major rule, the agency shall issue and place in the rule making file maintained under section 553(f) of this title a preliminary regulatory analysis and shall include in such notice of proposed rule making a summary of the analysis. When the President or the officer elected by

the President under section 624 of this title has published a determination or designation that a rule is a major rule after the publication of the notice of proposed rule making for that rule, the agency shall promptly issue and place in the rule making file maintained under section 553(f) of this title a preliminary regulatory analysis for the rule and shall publish in the Federal Register a summary of such analysis. Following the issuance of a preliminary regulatory analysis under the preceding sentence, the agency shall give interested persons an opportunity to comment thereon pursuant to section 553 of this title in the same manner as if the preliminary regulatory analysis had been issued with the notice of proposed rule making.

“(2) Each preliminary regulatory analysis shall contain—

“(A) a succinct description of the benefit of the proposed rule, including any beneficial effects that cannot be quantified, and an explanation of how the agency anticipates each benefit will be achieved by the proposed rule, including a description of the persons, classes of persons, or particular levels of Government likely to receive such benefits;

“(B) a succinct description of the costs of the proposed rule, including any costs that cannot be quantified as well as the cost-reduction effects of complying with the requirements of title IV, and an explanation of how the agency anticipates each such cost will result from the proposed rule, including a description of the persons, classes of persons, or particular levels of Government likely to incur such costs;

“(C) a succinct description of reasonable alternatives for achieving the identified benefits of the proposed rule, including alternatives that—

“(i) require no Government action;

“(ii) will accommodate differences between geographic regions; and

“(iii) employ performance or other market based standards which permit the greatest flexibility in achieving the identified benefits of the proposed rule and which comply with the requirements of title IV;

“(D) in any case in which the proposed rule is based on scientific evaluations or information, a description of action undertaken by the agency to verify the quality, reliability, and relevance of such scientific evaluations or scientific information in accordance with the requirements of title IV; and

“(E) where it is not expressly or by necessary implication inconsistent with the provisions of the enabling statute pursuant to which the agency is proposing the rule, an explanation of how the identified benefits of the proposed rule are likely to justify the identified costs of the proposed rule, and an explanation of how the proposed rule is likely to substantially achieve the rule making objectives in a more cost-effective manner than the alternatives to the proposed rule, including alternatives identified in accordance with title IV.

“(d)(1) When the agency publishes a final major rule, the agency shall also issue and place in the rule making file maintained under section 553(f) of this title a final regulatory analysis, and shall include a summary of the analysis in the statement of basis and purpose required by section 553(c)(6) of this title. Notwithstanding the preceding sentence, in any case in which an agency, under section 553(b)(2) of this title, is not required to comply with subsections (b) through (f) of section 553 of this title prior to the adoption of a final rule, any agency is not required to comply with the preceding sentence prior to the adoption of the final rule but shall comply with such sentence when complying with section 553(b)(2)(C) of this title.

“(2) Each final regulatory 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 rule making, including the market-based mechanisms identified pursuant to title IV; and

“(B) where it is not expressly or by necessary implication inconsistent with the provisions of the enabling statute pursuant to which the agency is acting, a reasonable determination, based upon the rule making file considered as a whole, that the benefits of the rule justify the costs of the rule, and that the rule will substantially achieve the rule making objectives in a more cost-effective manner than the alternatives described in the rule making, including the market-based incentives identified pursuant to title IV.

“(e)(1) An agency shall describe the nature and extent of the nonquantifiable benefits and costs of a proposed and a final rule pursuant to this section in as precise and succinct a manner as possible. The description of the benefits and costs of a proposed and a final rule required under this section shall include a quantification or numerical estimate of the quantifiable benefits and costs. Such quantification or numerical estimate shall be made in the most appropriate unit of measurement and shall specify the ranges of predictions and explain the margins of error involved in the quantification methods and in the estimates used.

“(2) In evaluating and comparing costs and benefits, the agency shall not rely on cost or benefit information submitted by any person that is not accompanied by data, analysis, or other supporting materials that would enable the agency and other persons interested in the rule making to assess the accuracy and reliability of such information. The agency evaluations of the relationships of the benefits of a proposed and final rule to its costs required by this section shall be clearly articulated in accordance with the provisions of this section. An agency is not required to make such evaluation primarily on a mathematical or numerical basis.

“(f) The preparation of the preliminary or final regulatory analysis required by this section shall only be performed by an officer or employee of the agency. The provisions of the preceding sentence do not preclude a person outside the agency from gathering data or information to be used by the agency in preparing any such regulatory 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 preliminary or final regulatory 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.

“(g) The requirements of this section do not alter the criteria for rule making otherwise applicable under other statutes.

#### “§ 623. Judicial review

“(a) Compliance or noncompliance by an agency with the provisions of this subchapter shall not be subject to judicial review except according to the provisions of this section.

“(b) Any determination by the President or by the officer selected under section 624 of this title that a rule is a major rule within the meaning of section 621(4)(A) of this title, and any designation by the President or the officer selected under section 624 of this title that a rule is a major rule under section

621(4)(B) of this title, or any failure to make such a designation, shall not be subject to judicial review in any manner.

“(c) The determination of an agency of whether a rule is or is not a major rule within the meaning of section 621(4)(A) of this title 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 it made the determination. Any designation by an agency that a rule is a major rule under section 621(4)(B) of this title, or any failure to make such a designation, shall not be subject to judicial review.

“(d) Any regulatory analysis prepared under section 622 of this title shall not be subject to judicial consideration separate or apart from review of the rule to which it relates. When an action for judicial review of a rule is instituted, any regulatory analysis for such rule shall constitute part of the whole rule making record of agency action for the purpose of judicial review of the rule and shall, to the extent relevant, be considered by a court in determining the legality of the rule.

#### “§ 624. Executive oversight

“(a) The President shall have the authority to establish procedures for agency compliance with this title and titles II, III, and IV of this Act. The President shall have the authority to monitor, review, and ensure agency implementation of such procedures. The President shall report annually to the Congress on agency compliance or non-compliance with the requirements of this chapter.

“(b) Any procedures established pursuant to the authority granted under subsection (a) of this section shall be adopted after the public has been afforded an opportunity to comment thereon, and shall be consistent with the prompt completion of rule making proceedings. If such procedures include review of preliminary or final regulatory analyses to ensure that they comply with the procedures established pursuant to subsection (a), the time for any such review of a preliminary regulatory analysis shall not exceed thirty days following the receipt of that analysis by the President or by an officer to whom the authority granted under subsection (a) of this section has been delegated pursuant to subsection (c) of this section, and the time for such review of a final regulatory analysis shall not exceed thirty days following the receipt of that analysis by the President or such officer. The times for each such review may be extended for good cause by the President or such officer for an additional thirty days. Notice of any such extension, together with a succinct statement of the reasons therefore, shall be inserted in the rule making file.

“(c) The President may delegate the authority granted by this Act to the Vice President or to an officer within the Executive Office of the President whose appointment has been subject to the advice and consent of the Senate. Any such notice with respect to a delegation to the Vice President shall contain a statement by the Vice President that the Vice President will make every reasonable effort to respond to Congressional inquiries concerning the exercise of the authority delegated under this subsection. Notice of any such delegation, or any revocation or modification thereof, shall be published in the Federal Register.

“(d) The authority granted under subsection (a) of this section and title II shall not apply to rules issued by the Nuclear Regulatory Commission.

“(e) Any exercise of the authority granted under this section, or any failure to exercise such authority, by the President or by an officer to whom such authority has been dele-

gated under subsection (c) of this section, shall not be subject to judicial review in any manner under this Act.

#### Subchapter III—Risk Assessments

#### “§ 631. Findings, purposes, and definitions

“(a) FINDINGS.—

“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; however, many regulations have been more costly and less effective than they could have been; 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 and the environment, regulatory priorities should be based upon realistic consideration of risk; the priority-setting process must include scientifically sound, objective, and unbiased risk assessments and risk management choices that are grounded in cost/benefit principles.

“(4) Risk assessment has proved to be a useful decision-making tool; however, improvements are needed in both the quality of assessments and the characterization and communication of findings; scientific and other data must be better collected, organized, and evaluated; most importantly, 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 must be fully involved in the decision-making 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. This knowledge will allow for public scrutiny and will promote the quality, integrity, and responsiveness of agency decisions.

“(b) PURPOSES.—

“The purposes of this subchapter are—

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

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

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

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

“(c) DEFINITIONS.—

“For purposes of this subchapter:

“(1) BEST ESTIMATE.—The term ‘best estimate’ means an estimate that, to the extent feasible and scientifically appropriate, is based on one of the following:

“(A) Central estimates of risk using the most plausible assumptions.

“(B) An approach that combines multiple estimates based on different scenarios and weighs the probability of each scenario.

“(C) Any other methodology designed to provide the most unbiased representation of the most plausible level of risk, given the current scientific information available to the Federal agency concerned.

“(2) COVERED AGENCY.—The term ‘covered agency’ means each of the following:

“(A) The Environmental Protection Agency.

“(B) The Department of Labor.

“(C) The Food and Drug Administration.

“(D) The Consumer Product Safety Commission.

“(E) The Department of Transportation.

“(F) The Department of Energy.

“(G) The Department of Agriculture.

“(H) The Department of Interior.

“(I) The Nuclear Regulatory Commission.

“(3) EMERGENCY.—The term ‘emergency’ means an imminent and substantial endangerment to public health, safety, or the environment.

“(4) HAZARD IDENTIFICATION.—The term ‘hazard identification’ means identification of a substance, activity, or condition as potentially posing a risk to human health or safety or the environment based on empirical data, measurements, or testing showing that it has caused significant adverse effects at some levels of dose or exposure not necessarily relevant to level of dose or exposure that are normally expected to occur.

“(5) RISK ASSESSMENT.—The term ‘risk assessment’ means—

“(A) the process of identifying hazards and quantifying or describing the degree of toxicity, exposure, or other risk they pose for exposed individuals, populations, or resources; and

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

“(6) RISK CHARACTERIZATION.—The term ‘risk characterization’—

“(A) means 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) includes discussions of uncertainties, conflicting data, estimates, extrapolations, inferences, and opinions.

“(7) SUBSTITUTION RISK.—The term ‘substitution risk’ means a potential increased risk to human health, safety, or the environment from a regulatory option designed to decrease other risks.

### “§632. Applicability

“(a) IN GENERAL.—Except as otherwise provided in subsection (b), this title shall apply to all risk assessments and risk characterizations prepared by, or on behalf of, or prepared by others and adopted by any covered agency in connection with health, safety, and environmental risks.

“(b) EXCEPTIONS.—

“(1) IN GENERAL.—This title shall not apply to risk assessments or risk characterizations performed with respect to—

“(A) a situation that the head of the agency considers to be an emergency; or

“(B) a screening analysis, including a screening analysis for the purposes of product registration, product reregistrations, or premanufacturing notices.

“(2) TREATMENT OF ANALYSIS AS SCREENING ANALYSIS.—An analysis shall not be treated as a screening analysis for the purposes of paragraph (1)(B) if the result of the analysis is used—

“(A) as the basis for imposing a restriction on a substance or activity; or

“(B) to characterize a positive finding of risks from a substance, product, or activity in any agency document or other commu-

nication made available to the general public, the media, or Congress.

“(3) LABELS.—This title shall not apply to any food, drug, or other product label or to any risk characterization appearing on any such label.

### “§633. Savings provisions

“Nothing in this title shall be construed to—

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

“(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 secrets or other confidential information.

### “§634. Requirement to prepare risk assessments

“Except as provided in subsection 632(b), the President shall require that the head of each covered agency prepare for each major rule relating to human health, safety, or the environment that is proposed by the agency after the date of enactment of this title—

“(1) a risk assessment in accordance with this title; and

“(2) 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.

### “§635. Principles for risk assessment

“(a) IN GENERAL.—The head of each covered agency shall ensure that risk assessments and all of their components—

“(1) distinguish scientific findings and best estimates of risk from other considerations;

“(2) are, to the maximum extent practicable, unbiased and inclusive of all reliable information and employ default assumptions only if situation-specific information is not reasonably available;

“(3) rely on scientific findings of risk;

“(4) result in the most plausible and realistic estimates feasible for the population, or, if only bounds can be estimated reliably, describe the range encompassed; and

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

“(b) HAZARD IDENTIFICATION AND RISK CHARACTERIZATION.—A risk assessment shall clearly separate hazard identification from risk characterization and make clear the relationship between the level of risk and the level of exposure to a hazard.

### “§636. Principles for risk characterization and risk communication

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

“(1) ESTIMATES OF RISK.—

“(A) SUBJECT.—A description of the populations or natural resources that are the subject of the risk characterization.

“(B) ASSUMPTIONS, INFERENCES, AND MODELS.—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) present a representative list and explanation of plausible and alternative assumptions, inferences, or models;

“(ii) explain the basis for any choices;

“(iii) identify any subjective policy decisions or value judgments; and

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

“(C) UNCERTAINTY.—The major uncertainties in the risk assessment.

“(D) EXPOSURE SCENARIOS.—Information about exposure scenarios used, including the likelihood of those scenarios.

“(E) RISK RANGE.—To the extent feasible, a range of risk estimates, including central estimates, for each exposure scenario.

“(F) SCIENTIFIC FINDINGS AND POLICY DECISIONS.—To the extent feasible, each risk characterization should distinguish between scientific findings and policy decisions.

“(2) SUBSTITUTION RISKS.—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 provided to the agency.

“(3) SUMMARIES OF OTHER RISK ESTIMATES.—If—

“(A) a covered agency provides a public comment period with respect to a risk assessment or regulation;

“(B) a commenter provides a risk assessment, and a summary of results of such risk assessment; and

“(C) such risk assessment is consistent with the principles and the guidance provided under this subtitle, the covered agency shall present such summary in connection with its presentation of the risk assessment or regulation.

### “§637. Guidelines, plan for assessing new information, and report

“(a) GUIDELINES.—

“(1) IN GENERAL.—Within 15 months after the date of enactment of this title, each covered agency shall issue, after notice and public comment, guidelines to implement the risk assessment and risk characterization principles set forth in sections 635 and 636 and shall provide a format for summarizing risk assessment results.

“(2) MATTERS TO BE ADDRESSED.—The guidelines under paragraph (1) shall—

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

“(B) address important decisional factors for the risk assessment or risk characterization at issue, such as criteria for scaling animal studies to assess risk to human health; use of different types of dose-response models; thresholds; definitions, use, and interpretations of the maximum tolerated dose; weighing of evidence with respect to extrapolating human health risks from sensitive species; evaluation of benign tumors; and evaluation of differences in human health endpoints, where relevant.

“(b) PLAN.—

“(1) IN GENERAL.—Within 18 months after the date of enactment of this title, the head of each covered agency shall publish a plan to review and revise any risk assessment published prior to 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.

“(2) CONTENTS.—A plan under paragraph (1) shall—

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

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

“(c) REPORT.—Within 3 years after the enactment of this title, each covered agency

shall provide a report to the Congress evaluating the categories of policy and value judgments identified under subparagraph (B)(iii) of section 636(1).

“(d) PUBLIC COMMENT AND CONSULTATION.—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.

“(e) REVIEW.—The President shall review the guidelines published under this section at least every 4 years.

“(f) LIMITATION ON JUDICIAL REVIEW.—The development, issuance, and publication of risk assessment and risk characterization guidelines under this section shall not be subject to judicial review.

#### “§ 638. Risk management criteria

“For each major rule subject to this title, the head of the agency or the President shall make a determination that—

“(1) the risk assessment under section 634(1) and the analysis under section 634(2) are based on a scientific evaluation of the risk addressed by the major rule and are supported by the best available scientific data; and

“(2) there is no regulatory alternative that is allowed by the statute under which the regulation is promulgated that would achieve an equivalent reduction in risk in a more cost-effective and flexible manner.

#### “§ 639. Interagency coordination

“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 one Federal agency, the Director of 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 coordination among Federal agencies conducting risk assessment with respect to the conduct, application, and practice of risk assessment and to promote 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-State cooperation in the development and application of risk assessment.

“Subchapter IV—Regulatory Priorities and Review

#### “§ 641. Review of agency rules

“(a) (1) (A) Not later than nine 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 which is in effect of such effective date and which, if adopted on such effective date, would be a major rule under section 621(4)(A) of this title, and

“(ii) each rule of the agency in effect on such effective date (in addition to the rules

described in clause (i)) which the agency has selected for review.

“(B) Each proposed scheduled required by subparagraph (A) shall include—

“(i) a brief explanation of the reasons the agency considers each rule on the schedule to be such a major rule under section 621(a) (4) (A) of this title or of the reasons why the agency selected the rule for review;

“(ii) a date set by the agency, in accordance with the provisions of subsection (b)(1) of this section, 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.

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

“(2) At least ninety days before publishing in the Federal Register the proposed schedule required under paragraph (1), each agency shall make the proposed schedule available to the President, or to the Vice President or other officer to whom oversight authority has been delegated under section 624(b) of this title. The President or that officer may select for review in accordance with this section any additional rule that the President or such officer determines to be a major rule under section 621(4) (A) of this title.

“(3) Not later than one 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) of this subsection.

Each agency shall publish with the final schedule the response of the agency to comments received concerning the proposed schedule.

“(b)(1) Except where explicitly provided otherwise by statute, the agency shall, pursuant to subsections (c) through (e) of this section, review:

“(A) each rule on the schedule promulgated pursuant to subsection (a) of this section;

“(B) each major rule under section 621(4) of this title promulgated, amended, or otherwise renewed by an agency after the date of the enactment of this section; and

“(C) each rule promulgated after the date of enactment of this section which the President or the officer designated by the President pursuant to subsection (a)(2) of this section determines to be a major rule under section 621(4)(A) of this title.

Except where an extension has been granted pursuant to subsection (f) of this section, the review of a rule required by this section shall be completed within ten years after the effective date of this section or within ten years after the date on which the rule is promulgated, amended, or renewed, whichever is later.

“(2) A rule required to be reviewed under the preceding subsection on grounds that it is major need not be reviewed if the agency determines that such rule, if adopted at the time of the planned review, would not be major under the definition previously applied to it. When the agency makes such a determination, it shall publish a notice and explanation of the determination in the Federal Register.

“(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 a statement specifying the agency's determination of whether the rule

continues to fulfill the intent of Congress in enacting that authority:

“(2) an assessment 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; 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, including alternatives developed in accordance with the provisions of title IV of this bill.

“(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) of this section, comply with the provisions of this chapter and chapter 5 of this title or other applicable law. The requirements of such provisions and related requirements of law 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 which is not taken pursuant to the review required by this section.

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

“(1) give interested persons not less than sixty days after the publication of the notice required by subsection (c) of this section to comment on the proposed renewal; and

“(2) publish in the Federal Register notice of the renewal of such rule and an explanation of the continued need for the rule, and, if the renewed rule is a major rule under section 621(4) of this title, include with such notice an explanation of the reasonable determination of the agency that the rule complies with the provisions of section 622(d)(2)(B) of this title.

“(f)(1) Any agency, which for good cause finds compliance with this section with respect to a particular rule to be impracticable during the period provided in subsection (b) of this section, may request the President, or the officer designated by the President pursuant to subsection (a)(2) of this section, to establish a period longer than ten 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 not more than fifteen years. Such extension shall be published in the Federal Register with an explanation of the reasons therefor.

“(2) An agency may, with the concurrence of the President or the officer designated by the President pursuant to subsection (a)(2) of this section, or shall, at the direction of the President or that officer, alter the timing of review of rules under any schedule required by this section for the review of rules if an explanation of such alteration is published in the Federal Register at the time such alteration is made.

“(g) In any case in which an agency has not completed the review of a rule within the period prescribed by subsection (b) or (f) of this section, the agency shall immediately publish in the Federal Register a notice proposing to amend, repeal, or renew the rule under subsection (c) of this section, and shall complete proceedings pursuant to subsection (d) or (e) of this section within one hundred and eighty days of the date on which the review was required to be completed under subsection (b) or (f) of this section.

“(h)(1) Agency compliance or noncompliance with the provisions of subsection (a) of this section shall not be subject to judicial review in any manner.

“(2) Agency compliance or noncompliance with the provisions of subsection (b), (c), (e), (f) and (g) of this section shall be subject to

judicial review only pursuant to section 706(a)(1) of this title.

“(i) 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 section 553(e) of this title.

#### **§642. Regulatory agenda and calendar**

“(a) Each agency shall publish in the Federal Register in April and October of each year an agenda of the rules that the agency expects to propose, promulgate, renew, or repeal in the succeeding twelve months. For each such rule, the agenda shall contain, at a minimum, and in addition to any other information required by law—

“(1) a general description of the rule, including a citation to the authority under which the action with respect to the rule is to be taken, or a specific explanation of the congressional intent to which the objectives of rule respond;

“(2) a statement of whether or not the rule is or is expected to be a major rule;

“(3) an approximate schedule of the significant dates on which the agency will take action relating to the rule, including the dates for any notice of proposed rulemaking, hearing, and final action on the rule;

“(4) the name, address, and telephone number of an agency official responsible for answering questions from the public concerning the rule;

“(5) a statement specifying whether each rule listed on the previous agenda has been published as a proposed rule, has been published as a final rule, has become effective, has been repealed, or is pending in some other status; and

“(6) a cumulative summary of the status of the rules listed on the previous agenda in accordance with clause (5) of this subsection.

“(b) The President or an officer in the Executive Office of the President whose appointment has been subject to the advice and consent of the Senate shall publish in the Federal Register in May and November of each year a Calendar of Federal Regulations listing each of the major rules identified in the regulatory agendas published by agencies in the preceding month. Each rule listed in the calendar shall be accompanied by a summary of the information relating to the rule that appeared in the most recent regulatory agenda in which the rule was identified.

“(c) An agency may propose or promulgate a major rule that was not listed in the regulatory agenda required by subsection (a) of this section only if the agency published with the rule an explanation of the omission of the rule from such agenda and otherwise complies with this section with respect to that rule.

“(d) Any compliance or noncompliance by the agency with the provisions of this section shall not be subject to judicial review.

#### **“§643. Establishment of deadlines**

“(a)(1) Whenever any agency published a notice of proposed rule making pursuant to section 553 of this title, the agency shall include in such notice an announcement of the date by which it intends to complete final agency action on the rule.

“(2) If any agency announcement under this section indicates that the proceeding relating to such rule will require more than one year to complete, the agency shall also indicate in the announcement the date by which the agency intends to complete each major portion of that proceeding. In carrying out the requirements of this subsection, the agency shall select dates for completing agency action which will assure that most expeditious consideration of the rule which is possible, consistent with the interests of fairness and other agency priorities.

“(3) The requirements of this subsection shall not apply to any rule on which the agency intends to complete action within one hundred and twenty days after providing notice of the proposed action.

“(b) If an agency fails to complete action in a proceeding, or a major portion of the proceeding, by the date announced pursuant to subsection (a) of this section, or, in the case of a proceeding described in paragraph (3) of such subsection, if an agency fails to complete action within one hundred and twenty days after providing notice of such proposed action, and the expected delay in completing action will exceed thirty days, the agency shall promptly announce the new date by which the agency intends to complete action in such proceeding and new dates by which the agency intends to complete action on each major portion of the proceeding.

“(c) Compliance or noncompliance by an agency with the provisions of this section shall not be subject to judicial review except in accordance with subsection (d).

“(d) In determining whether to compel agency action unreasonably delayed pursuant to section 706(a)(1) of this title, the reviewing court shall consider, in addition to any other relevant factors, the extent to which the agency has failed to comply with this section.”.

(b) TECHNICAL AND CONFORMING AMENDMENTS.—Part I of title 5, United States Code, is amended by striking out the chapter heading and table of sections for chapter 6 and inserting in lieu thereof the following:

#### **“CHAPTER 6—THE ANALYSIS OF REGULATORY FUNCTIONS**

##### **“SUBCHAPTER I—REGULATORY ANALYSIS**

“Sec.

“601. Definitions.

“602. Regulatory agenda.

“603. Initial regulatory flexibility analysis.

“604. Final regulatory flexibility analysis.

“605. Avoidance of duplicative or unnecessary analyses.

“606. Effect on other law.

“607. Preparation of analyses.

“608. Procedure for waiver or delay of completion.

“609. Procedures for gathering comments

“610. Periodic review of rules.

“611. Judicial review.

“612. Reports and intervention rights.

##### **“SUBCHAPTER II—ANALYSIS OF AGENCY PROPOSALS**

“621. Definitions.

“622. Regulatory cost/benefit analysis.

“623. Judicial review.

“624. Executive oversight.

##### **“SUBCHAPTER III—RISK ASSESSMENTS**

“631. Findings, purposes, and definitions.

“632. Applicability.

“633. Savings provisions.

“634. Requirement to prepare risk assessments.

“635. Principles for risk assessment.

“636. Principles for risk characterization and risk communication.

“637. Guidelines, plan for assessing new information, and report.

“638. Risk management criteria.

“639. Interagency coordination.

##### **“SUBCHAPTER IV—REGULATORY PRIORITIES AND REVIEW**

“641. Review of agency rules.

“642. Regulatory agenda and calendar.

“643. Establishment of deadlines.”.

#### **SEC. 102. USE OF STATE OR LOCAL REQUIREMENTS.**

(a) IN GENERAL.—Subchapter II of chapter 5 of title 5, United States Code, is amended by adding at the end thereof the following new section:

#### **“§560. Use of duplicative State or local requirements**

“(a) Except as otherwise provided by law, the head of each Federal agency is author-

ized, in the administration of a Federal statute with respect to any State or locality, to adopt as a Federal rule a regulation of that State or local government or use as a Federal recordkeeping or reporting requirement or implementation procedure a recordkeeping or reporting requirement or implementation procedure of that State or locality if the head of the agency determines—

“(1) that such State or local government regulation, implementation procedure, recordkeeping requirement, or reporting requirement duplicates a Federal regulation, procedure, recordkeeping requirement, or reporting requirement; and

“(2) that such State or local government regulation, implementation procedure, recordkeeping requirement, or reporting requirement is substantively equivalent to or more stringent than the Federal regulation, procedure, recordkeeping requirement, or reporting requirement.

“(b) When the head of an agency determines to use a State or local recordkeeping or reporting requirement, or implementation procedure, as a Federal recordkeeping or reporting requirement or implementation procedure in that State or locality, the head of the agency shall prepare at a minimum, a written statement of the reasons for any determination made under subsection (a), and shall make such statement available to the public.

“(c) This section does not limit the authority or responsibility of the head of any agency to enforce Federal law.”

(b) RULE MAKING.—Section 551 of title 5, United States Code, is amended by inserting the following between “rule” and the semicolon: “, or the adoption of a rule pursuant to section 561 of this title”.

(c) TABLE OF SECTIONS.—The table of sections for chapter 5 of such title is amended by inserting after the item relating to section 559 the following new item:

#### **“§560. Use of duplicative State or local requirements.”.**

#### **SEC. 103. PRESIDENTIAL AUTHORITY.**

Nothing in this Act (i) limits the exercise by the President of the authority and responsibility that he 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, or (ii) alters in any manner rulemaking authority vested by law in an agency to initiate or complete a rulemaking proceeding, or to issue, modify, or rescind a rule.

#### **TITLE II—RISK-BASED PRIORITIES**

#### **SEC. 201. SHORT TITLE.**

This title may be cited as the “Risk Reduction Priorities Act of 1995”.

#### **SEC. 202. PURPOSES.**

It is the purposes of this title 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.

#### **SEC. 203. DEFINITIONS.**

For the purposes of this title:

(1) COMPARATIVE RISK ANALYSIS.—The term “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.

(2) COVERED AGENCY.—The term “covered agency” means each of the following:

- (A) The Environmental Protection Agency.
- (B) The Department of Labor.
- (C) The Food and Drug Administration.
- (D) The Consumer Product Safety Commission.
- (E) The Department of Transportation.
- (F) The Department of Energy.
- (G) The Department of Agriculture.
- (H) The Department of Interior.
- (I) The Nuclear Regulatory Commission.

(3) DIRECTOR.—The term “Director” means the Director of the Office of Management and Budget.

(4) EFFECT.—The term “effect” means a deleterious change in the condition—

(A) of a human or other living thing (including death, cancer, or other chronic illness, decreased reproductive capacity, or disfigurement); or

(B) of an inanimate thing important to human welfare (including destruction, degeneration, the loss of intended function, and increased costs for maintenance).

(5) IRREVERSIBILITY.—The term “irreversibility” means the extent to which a return to conditions prior to the occurrence of an effect are either very slow or will never occur.

(6) LIKELIHOOD.—The term “likelihood” means the estimated probability that an effect will occur.

(7) MAGNITUDE.—The term “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.

(8) SERIOUSNESS.—The term “seriousness” means the intensity of effect, the likelihood, the irreversibility, and the magnitude.

#### SEC. 204. DEPARTMENT AND AGENCY PROGRAM GOALS.

(a) SETTING PRIORITIES.—In exercising authority under applicable laws protecting human health, safety, or the environment, the head of each covered agency should strive to set priorities and to use the resources available under those laws to address those risks to human health, safety, and the environment that—

(1) the covered agency determines to be the most serious; and

(2) can be addressed in a cost-effective manner, with the goal of achieving the greatest overall net reduction in risks with the public and private sector resources expended.

(b) DETERMINING THE MOST SERIOUS RISKS.—In identifying the greatest risks under subsection (a) of this section, each covered agency shall consider, at a minimum:

(1) the likelihood, irreversibility, and severity of the effect; and

(2) the number and groups of individuals potentially affected, and shall explicitly take into account the results of the comparative risk analysis conducted under section 205 of this Act.

(c) OMB REVIEW.—The covered agency’s determinations of the sources of the most serious risks for purposes of setting priorities shall be reviewed and approved by the Director of the Office of Management and Budget prior to submission of the covered agency’s annual budget requests to Congress.

(d) INCORPORATING RISK-BASED PRIORITIES INTO BUDGET AND PLANNING.—The head of each covered agency shall incorporate the priorities identified in subsection (a) of this section into the agency budget, strategic planning, regulatory agenda, enforcement, and research activities by—

(1) in the covered agency’s annual budget request to Congress—

(A) identifying which risks that the covered agency head has determined are the most serious and can be addressed in a cost-effective manner under subsection (a) and the basis for that determination;

(B) explicitly identifying how the covered agency’s requested funds will be used to reduce those risks, including the amount of funds requested to address each of those risks; and

(C) identifying any statutory, regulatory, or administrative obstacles to allocating agency resources in accordance with the mandates of subsection (a);

(2) explicitly considering the requirements of subsection (a) and the results of the comparative risk analysis prepared under section 205 of this title when preparing the covered agency’s regulatory agenda or other covered agency strategic plan and explaining how the agenda or plan reflects those requirements and the competitive risk analysis when publishing any such agenda or strategic plan;

(3) developing an annual enforcement strategic plan that targets the priority risks identified under subsection (a); and

(4) expressly considering the priority risks determined under subsection (a) in selecting research activities.

(e) EFFECTIVE DATE.—This section shall take effect 12 months from the date of enactment of his title.

#### SEC. 205. COMPARATIVE RISK ANALYSIS.

(a) REQUIREMENT.—Within 6 months of the enactment of this title, the Director of the Office of Management and Budget shall enter into appropriate arrangements with an accredited scientific body—

(1) to conduct a study of the methodologies for using comparative risk to rank dissimilar human health, safety, and environmental risks; and

(2) to conduct a comparative risk analysis. The comparative risk analysis shall compare and rank, to the extent feasible, human health, safety, and environmental risks potentially regulated across the spectrum of programs administered by all covered agencies.

The Director shall consult with the Office of Science and Technology Policy regarding the scope of the study and the conduct of the comparative risk analysis.

(b) CRITERIA.—In arranging for the comparative risk analysis referred to in subsection (a), the Director shall ensure that—

(1) the scope and specificity of the analysis are sufficient to provide the President and agency heads guidance in allocating resources agencies and among programs in agencies to achieve the greatest degree of risk prevention and reduction for the public and private resources expended;

(2) the analysis is conducted through an open process, which may include using panels of appropriate independent experts and public stakeholders;

(3) the methodologies and principal scientific determinations made in the analysis are subjected to independent and external peer review and that the conclusions of the peer review are made publicly available as part of the final report required by subsection (c);

(4) there is an opportunity for public comment on the results prior to making them final; and

(5) the results are presented in a manner that distinguishes between the scientific conclusions and any policy or value judgments embodied in the comparisons.

(c) REPORT.—The comparative risk analysis required by subsection (a) shall be completed and a report submitted to Congress and the President no later than 3 years fol-

lowing the enactment of this Act. The comparative risk analysis shall be reviewed and revised at least every 5 years thereafter for a minimum of 15 years following the release of the first Analysis. The Director shall arrange for such review and revision with an accredited scientific body in the same manner as provided in subsections (a) and (b) above.

(d) STUDY.—The study of methodologies provided in subsection (a) shall be conducted as part of the first comparative risk analysis. The goal of the study shall be to develop and rigorously test methods of comparative risk analysis. The study shall have sufficient scope and breadth to test approaches for improving comparative risk analysis and its use in setting priorities for human health, safety, and environmental risk prevention and reduction. As part of its analysis, the study shall review and evaluate the experiences of the states that have conducted comparative risk analyses.

(3) REPORT.—Within 180 days after the completion of the study, the Director shall issue a report of the study to the Congress, along with results of a scientific peer review of the study.

(f) TECHNICAL GUIDANCE.—Not later than 180 days after the enactment of this Act, the Director, in collaboration with other heads of covered agencies shall enter into a contract with the National Research Council to provide technical guidance to agencies on approaches to using comparative risk analysis in setting human health, safety, and environmental priorities to assist agencies in complying with section 204 of this title.

#### SEC. 206. REPORTS AND RECOMMENDATIONS TO CONGRESS AND THE PRESIDENT.

(a) IN GENERAL.—In addition to the statement submitted to Congress with each covered agency’s annual budget request required under section 204(d)(1) of this title, each covered agency shall submit a report to Congress and the President 24 months following the enactment of this legislation, and every 24 months thereafter—

(1) detailing how the agency has complied with section 204;

(2) describing the reasons for any departure from the requirement to establish priorities to achieve the greatest overall net reduction in risk; and

(3) estimating the total public and private costs of regulatory and voluntary risk reduction activities under programs administered by the agency that year, a comparison of that estimate with the previous year, and a projection for the following year.

(b) RECOMMENDATION.—In March of each year, the head of each covered agency shall submit to Congress specific recommendations for—

(1) modifying, repealing, or enacting laws to reform, eliminate, or enhance programs or mandates relating to human health, safety, and the environment; and

(2) modifying or eliminating statutorily or judicially mandated deadlines,

that would assist the covered agency to set priorities in its activities to address the risks to human health, safety, and the environment that are the most serious and can be addressed in a cost-effective manner consistent with the requirements of section 204(a).

#### SEC. 207. SAVINGS PROVISION AND JUDICIAL REVIEW.

(1) IN GENERAL.—Nothing in this title shall be construed to modify any statutory standard or requirement designed to protect human health, safety, or the environment.

(2) JUDICIAL REVIEW.—Compliance or non-compliance by an agency with the provisions of this title shall not be subject to judicial review.



(3) AGENCY ANALYSIS.—Any analysis prepared under this title shall not be subject to judicial consideration separate or apart from the requirement, rule, program, or law to which it relates. When an action for judicial review of a covered agency action is instituted, any analysis for, or relating to, the action shall constitute part of the whole record of agency action for the purpose of judicial review of the action and shall, to the extent relevant, be considered by a court in determining the legality of the covered agency action.

### TITLE III—REGULATORY ACCOUNTING

#### SEC. 301. SHORT TITLE

This title may be cited as the "Regulatory Accounting Act of 1995".

#### SEC. 302. ACCOUNTING STATEMENT

##### (a) IN GENERAL.—

(1) RESPONSIBILITY FOR IMPLEMENTATION.—The President shall be responsible for implementing and administering the requirements of this title.

(2) ACCOUNTING STATEMENT.—Every two years, not later than June of the second year, the President shall prepare and submit to Congress an accounting statement that estimates the costs of Federal regulatory programs and corresponding benefits in accordance with this section.

(b) YEARS COVERED BY ACCOUNTING STATEMENT.—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.

##### (c) TIMING AND PROCEDURES.—

(1) NOTICE AND COMMENT.—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.

(2) DEADLINES FOR FIRST STATEMENT.—The President shall propose the first accounting statement under this section not later than 2 years after the date of the enactment of this Act and shall issue the first accounting statement in final form not later than 3 years after the date of the enactment of this Act. Such statement shall cover, at a minimum, each of the 8 fiscal years beginning after the date of the enactment of this Act.

##### (d) CONTENT OF ACCOUNTING STATEMENT.—

(1) IN GENERAL.—Each accounting statement shall contain estimates of costs and benefits with respect to each fiscal year covered by the statement in accordance with this subsection. For each such fiscal year for which estimates were made in a previous accounting statement, the statement shall revise those estimates and state the reasons for the revisions.

##### (2) STATEMENT OF COSTS.—

(A) IN GENERAL.—An accounting statement shall estimate the costs of Federal regulatory programs by setting forth, for each year covered by the statement—

(i) the annual expenditure of national economic resources for the regulatory program; and

(ii) such other quantitative and qualitative measures of costs as the President considers appropriate.

(B) NATIONAL ECONOMIC RESOURCES.—For purposes of the estimate of costs in the accounting statement, national economic resources shall include, and shall be listed under, at least the following categories:

(i) Private sector costs.

(ii) Federal sector administrative costs.

(iii) Federal sector compliance costs.

(iv) State and local government administrative costs.

(v) State and local government compliance costs.

(3) STATEMENT OF CORRESPONDING BENEFITS.—An accounting statement shall estimate the benefits of Federal regulatory programs by setting forth, for each year covered by the statement, 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.

#### SEC. 303. ASSOCIATED REPORT TO CONGRESS.

(a) IN GENERAL.—At the same time as the President submits an accounting statement under section 302, the President, acting through the Director of the Office of Management and Budget, shall submit to Congress a report associated with the accounting statement (hereinafter referred to as an "associated report"). The associated report shall contain, in accordance with this section—

(1) analyses of impacts; and

(2) recommendations for reform.

(b) ANALYSES OF IMPACTS.—The President shall include in the associated report the following:

(1) Analyses prepared by the President of the cumulative impact of Federal regulatory programs covered in the accounting statement on the following:

(A) The ability of State and local governments to provide essential services, including police, fire protection, and education.

(B) Small business.

(C) Productivity.

(D) Wages.

(E) Economic growth.

(F) Technological innovation.

(G) Consumer prices for goods and services.

(H) Such other factors considered appropriate by the President.

(2) A summary of any independent analyses of impacts prepared by persons commenting during the comment period on the accounting statement.

(c) RECOMMENDATIONS FOR REFORM.—The President shall include in the associated report the following:

(1) 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.

(2) 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.

#### SEC. 304. GUIDANCE FROM OFFICE OF MANAGEMENT AND BUDGET.

The Director of the Office of Management and Budget shall, in consultation with the Council of Economic Advisers, provide guidance to agencies—

(1) to standardize measures of costs and benefits in accounting statements prepared pursuant to titles I and III, including:

(A) detailed guidance on estimating the costs and benefits of major rules;

(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.

#### SEC. 305. RECOMMENDATIONS FROM CONGRESSIONAL BUDGET OFFICE.

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 title, including recommendations on level of detail and accuracy; and

(2) for improving associated reports prepared pursuant to this title, including recommendations on the quality of analysis.

#### SEC. 306. DEFINITIONS.

For purposes of this title, the following definitions apply:

(1) The term "Federal regulatory program" means a program carried out pursuant to a related group of Federal statutes and regulations, as determined by the President.

(2) The term "regulation" means an agency statement of general applicability and future effect designed to implement, interpret, or prescribe law or policy or describing the procedure or practice requirements of an agency. The term does 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.

(3) 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 does not include—

(A) the General Accounting Office;

(B) 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.

### TITLE IV—MARKET INCENTIVES AND ECONOMICALLY EFFICIENT REGULATION

#### SEC. 401. SHORT TITLE.

This title may be cited as the "Market Incentives Act of 1995".

#### SEC. 402. PROGRAM DESIGN REQUIREMENTS.

(a) IN GENERAL.—To the maximum extent practicable, agencies shall ensure that major rules, especially, but not limited to, those that limit the emission of environmental pollutants or otherwise govern the use of natural resources, operate through the application of market-based mechanisms.

(b) FLEXIBLE ALTERNATIVES.—Where it is not practicable to rely on market-based mechanisms in designing regulatory programs, rules, or requirements, agencies shall ensure that major rules, to the maximum extent practicable, are comparable to market-based mechanisms with respect to (i) assuring the achievement of the regulatory objective, and (ii) affording flexibility to regulated persons.

(c) APPLICABILITY.—Section 402 shall apply, to the extent feasible, to rules in effect on the date of enactment of this Act and rules that take effect after the date of enactment of this Act.

#### SEC. 403. AGENCY ASSESSMENT AND OMB REVIEW.

(a) IN GENERAL.—Each agency shall include an assessment of market-based mechanisms in each proposed major rule. Each assessment shall demonstrate the extent to which the major rule complies with the requirements of section 402, or why section 402 is not applicable or appropriate.

(b) OMB REVIEW.—The Office of Management and Budget shall review, as part of its



regulatory review and oversight function, the agency assessments and statements prepared in section 403(a). OMB shall determine whether such assessments are detailed, thorough, and otherwise in compliance with section 402.

(c) **EFFECTIVE DATE.**—Section 403 shall take effect 3 months after the date of enactment of this Act:

**SEC. 404. DEFINITIONS.**

For the purposes of this title:

(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 does not include—

(A) the General Accounting Office;

(B) 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.

(2) The term "major rule" means—

(A) a rule or a group of closely related rules that the agency or 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, or has a significant impact on a subsector of the economy; and

(B) a rule or a group of closely related rules that is otherwise designated a major rule by the agency proposing the rule, or is so designated by 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, or local government agencies, or geographic regions; or

(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 and export markets.

For purposes of subparagraph (A) of this paragraph, the term "rule" does not mean—

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

(II) a rule that authorizes the introduction into commerce or recognizes the marketable status of a product, pursuant to sections 408, 409(c), and 706 of the Federal Food, Drug, and Cosmetic Act;

(III) a rule exempt from notice and public procedure pursuant to section 553(a) of title 5, United States Code; or

(IV) a rule relating to the viability, stability, asset powers, or categories of accounts of, or permissible interest rate ceilings applicable to, depository institutions the deposits or accounts of which are insured by the Federal Deposit Insurance Corporation, or the Share Insurance Fund of the National Credit Union Administration Board.

(3) The term "market-based mechanism" means a regulatory requirement that:

(a) imposes legal accountability for the achievement of an explicit regulatory objective on each regulated person;

(b) affords maximum flexibility to each regulated person in complying with mandatory regulatory objectives, which flexibility shall include, but not be limited to, 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 automatically 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.

(4) The term "rule" has the same meaning as in section 551(4) of title 5, United States Code, except that such term does not include—

(A) a rule of particular applicability that approves or prescribes for the future rates, wages, prices, services, or allowances therefor, corporate or financial structures, reorganizations, mergers or acquisitions, or 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

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

By Mr. SHELBY:

S. 292. A bill to provide Federal recognition of the Mowa Band of Choctaw Indians of Alabama; to the Committee on Indian Affairs.

THE MOWA BAND OF CHOCTAW INDIANS  
RECOGNITION ACT

● Mr. SHELBY. Mr. President, today I am reintroducing the Mowa Band of Choctaw Indians Recognition Act. This particular piece of legislation has passed the Senate three times in the past two Congresses. While I would prefer not to have to pursue congressionally granted recognition for the Mowa Choctaws, this course of action has been dictated by the institutional resistance of the Bureau of Indian Affairs to Federal recognition of the Mowa.

The Mowa Choctaws originally applied for Federal recognition in 1983. A State-recognized tribe with 3,500 members, the Mowa live within the boundaries of the original Choctaw Nation in Mobile and Washington Counties of Alabama. Mowa ancestors were signatories of the treaty of Dancing Rabbit Creek which provided for the nonremoval of Indian families. Under the treaty, the signatories and their descendants were entitled to retain their rights to Choctaw citizenship.

The Mowa Choctaws have maintained an intense Indian identity over the past 160 years and have petitioned Congress for Federal recognition or to redress treaty grievances several times, beginning as early as 1836. Because of the failure of the BIA to act upon their petition in a timely manner, the Senate Committee on Indian Affairs reported the bill in both the 102d and 103d Congress with the recommendation that the Mowa be granted full Federal recognition.

Only recently has the BIA acted upon the petition. In December, the BIA, after 12 years of delay, issued a preliminary finding denying the Mowa pe-

tition. However, the BIA only acted upon the petition when it became likely that the bill would pass the Congress and be sent to the President for his signature. I find this conduct at best suspicious, and most likely reflective of the BIA's longstanding bureaucratic disposition against the proposal.

Mr. President, I have no intention of dropping this issue, regardless of the position of the BIA. Indeed, Congress granted Federal recognition to one-half dozen Indian tribes last year without the approval of the BIA. Congress writes the laws of this land. Career and appointed bureaucrats do not. The Mowa case is stronger than scores of past petitions for recognition that were approved, and I will continue to work to see that Congress rectifies this bureaucratic injustice and grants the Mowa Choctaws the Federal recognition that they deserve.●

ADDITIONAL COSPONSORS

S. 230

At the request of Mr. DOLE, the names of the Senator from New Jersey [Mr. BRADLEY], the Senator from Idaho [Mr. CRAIG], and the Senator from Illinois [Ms. MOSELEY-BRAUN] were added as cosponsors of S. 230, a bill to prohibit United States assistance to countries that prohibit or restrict the transport or delivery of United States humanitarian assistance.

S. 250

At the request of Mr. MCCONNELL, the name of the Senator from Pennsylvania [Mr. SANTORUM] was added as a cosponsor of S. 250, a bill to amend chapter 41 of title 28, United States Code, to provide for an analysis of certain bills and resolutions pending before the Congress by the Director of the Administrative Office of the United States Courts, and for other purposes.

S. 262

At the request of Mr. GRASSLEY, the names of the Senator from Indiana [Mr. LUGAR] and the Senator from Wyoming [Mr. THOMAS] were added as cosponsors of S. 262, a bill to amend the Internal Revenue Code of 1986 to increase and make permanent the deduction for health insurance costs of self-employed individuals.

S. 270

At the request of Mr. SMITH, the name of the Senator from Pennsylvania [Mr. SANTORUM] was added as a cosponsor of S. 270, a bill to provide special procedures for the removal of alien terrorists.

SENATE RESOLUTION 37

At the request of Mr. PACKWOOD, the names of the Senator from California [Mrs. FEINSTEIN] and the Senator from Rhode Island [Mr. PELL] were added as cosponsors of Senate Resolution 37, a resolution designating February 2, 1995, and February 1, 1996, as "National Women and Girls in Sports Day."