Calendar No. 117

104TH CONGRESS
1ST SESSION

S. 291

[Report No. 104–88]

A BILL

To reform the regulatory process, to make Government more efficient and effective, and for other purposes.

MAY 25 (legislative day, MAY 15), 1995

Reported with an amendment

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To reform the regulatory process, to make Government more efficient and effective, and for other purposes.

IN THE SENATE OF THE UNITED STATES

JANUARY 27 (legislative day, JANUARY 10), 1995

Mr. ROTH introduced the following bill; which was read twice and referred to the Committee on Governmental Affairs

MAY 25 (legislative day, MAY 15), 1995

Reported by Mr. ROTH, with an amendment

[Strike out all after the enacting clause and insert the part printed in italic]

A BILL

To reform the regulatory process, to make Government more efficient and effective, and for other purposes.

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:

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 sec-

tions 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 in 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, 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 Corpora-

tion, 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 rulemaking 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 rulemaking 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 rulemaking 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 rulemaking for a major rule, the agency shall issue and place in the rulemaking file maintained under section 553(f) of this title a preliminary regulatory analysis and shall include in such notice of proposed rulemaking a summary of the analysis. When the President or the officer selected 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 rulemaking for that rule, the agency shall promptly

issue and place in the rulemaking 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 rulemaking.

''(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 marketbased 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 rulemaking 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 rulemaking 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, an 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 rulemaking, in-

cluding 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 rulemaking 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 rulemaking objectives in a more cost-effective manner than the alternatives described in the rulemaking, including the market-based incentives identified pursuant to title IV.

''(e)(1) An agency shall describe the nature and extent of the nonqualifiable 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 rulemaking 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 ar-

rangement 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 rulemaking 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 determina-

tion. 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 rulemaking 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 noncompliance 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 rulemaking 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 therefor, shall be inserted in the rulemaking 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. No-

tice 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 delegated 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 allo-

cated 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 decisionmaking 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 decisionmaking process for regulating risks. The public has the right to know about the risks addressed by regulation, the amount of risk re-

duced, 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 the 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' means—

‘‘(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) 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 communication 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;

‘‘(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 fifteen 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 eighteen 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 eighteen-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 three 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 de-

veloped 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 four 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 on 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 schedule 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) 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 man-

ner, 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 com-

plies 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 subsections (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 publishes 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 publishes a notice of proposed rulemaking 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 the 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 prompt-

ly 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

''SUBCHAPTER II—ANALYSIS OF AGENCY PROPOSALS

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 authorized, 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 re-

quirement, 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) RULEMAKING.—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 the 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 comparative 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 twelve months from the date of enactment of this title.

SEC. 205. COMPARATIVE RISK ANALYSIS.

(a) REQUIREMENT.—Within six 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 across 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 three years following the enactment of this Act. The comparative risk analysis shall be reviewed and revised at least every five years thereafter for a minimum of fifteen 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 experience of the States that have conducted comparative risk analyses.

(e) REPORT.—Within one hundred and eighty 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 one hundred and eighty 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 twenty-four months following the enactment of this legislation, and every twenty-four 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 noncompliance 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 five 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 dele-

gate 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 two years after the date of the enactment of this Act and shall issue the first accounting statement in final form not later than three years after the date of the enactment of this Act. Such statement shall cover, at a minimum, each of the eight 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 procedures 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) 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.

TITLE IV—MARKET INCENTIVES AND ECONOMICALLY EFFICIENT REGULATION

SEC. 401. SHORT TITLE.

This title maybe 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 three 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) 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.

(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 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 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.~~

SECTION 1. SHORT TITLE.

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

SEC. 2. DEFINITIONS.

Section 551 of title 5, United States Code, is amended—

(1) in paragraph (13), by striking out ''; and'' and inserting in lieu thereof a semicolon;

(2) in paragraph (14), by striking out the period and inserting in lieu thereof ''; and''; and

(3) by adding at the end thereof the following new paragraph:

''(15) 'Director' means the Director of the Office of Management and Budget.''.

SEC. 3. ANALYSIS OF AGENCY RULES.

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

''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 environmental 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 dif-

fering 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 determination 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 attention 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 expe-

rience 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 covered 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 re-

view 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 with-

in 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.''.

(b) REGULATORY FLEXIBILITY ANALYSIS.—

(1) IN GENERAL.—Section 611 of title 5, United States Code, is amended to read as follows:

''§ 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.

(d) TECHNICAL AND CONFORMING AMENDMENTS.—

(1) 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

''SUBCHAPTER II—ANALYSIS OF AGENCY RULES

''SUBCHAPTER III—RISK ASSESSMENTS

(2) Chapter 6 of title 5, United States Code, is amended by inserting immediately before section 601, the following subchapter heading:

''SUBCHAPTER I—REGULATORY ANALYSIS''.

SEC. 4. CONGRESSIONAL REVIEW.

(a) IN GENERAL.—Part I of title 5, United States Code, is amended by inserting after chapter 7 the following new chapter:

''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 subsection (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.''.

(b) TECHNICAL AND CONFORMING AMENDMENT.—The table of chapters for part I of title 5, United States Code, is amended by inserting after the item relating to chapter 7 the following:

''8. Congressional Review of Agency Rulemaking ..... 801''.

SEC. 5. STUDIES AND REPORTS.

(a) RISK ASSESSMENTS.—The Administrative Conference of the United States shall—

(1) develop and carry out an ongoing study of the operation of the risk assessment requirements of

subchapter III of chapter 6 of title 5, United States Code (as added by section 3 of this Act); and

(2) submit an annual report to the Congress on the findings of the study.

(b) ADMINISTRATIVE PROCEDURE ACT.—No later than December 31, 1996, the Administrative Conference of the United States shall—

(1) carry out a study of 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 Act; and

(2) submit a report to the Congress on the findings of the study, including proposals for revision, if any.

SEC. 6. RISK-BASED PRIORITIES.

(a) PURPOSES.—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 re-

garding environmental, health, and safety risks, and the prevention and management of those risks.

(b) DEFINITIONS.—For the purposes of this section:

(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 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.

(3) EFFECT.—The term ''effect'' means a deleterious change in the condition of—

(A) a human or other living thing (including 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.—The term ''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.—The term ''likelihood'' means the estimated probability that an effect will occur.

(6) 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.

(7) SERIOUSNESS.—The term ''seriousness'' means the intensity of effect, the likelihood, the irreversibility, and the magnitude.

(c) DEPARTMENT AND AGENCY PROGRAM GOALS.—

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

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

(B) 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.

(2) DETERMINING THE MOST SERIOUS RISKS.—In identifying the greatest risks under paragraph (1) of this subsection, each covered agency shall consider, at a minimum—

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

(B) the number and classes of individuals potentially affected, and shall explicitly take into account the results of the comparative risk analysis conducted under subsection (d) of this section.

(3) OMB REVIEW.—The covered agency's determinations of the most serious risks for purposes of set-

ting priorities shall be reviewed and approved by the Director of the Office of Management and Budget before submission of the covered agency's annual budget requests to Congress.

(4) INCORPORATING RISK-BASED PRIORITIES INTO BUDGET AND PLANNING.—The head of each covered agency shall incorporate the priorities identified under paragraph (1) into the agency budget, strategic planning, regulatory agenda, enforcement, and research activities. When submitting its budget request to Congress and when announcing its regulatory agenda in the Federal Register, each covered agency shall identify the risks that the covered agency head has determined are the most serious and can be addressed in a cost-effective manner under paragraph (1), the basis for that determination, and explicitly identify how the covered agency's requested budget and regulatory agenda reflect those priorities.

(5) EFFECTIVE DATE.—This subsection shall take effect 12 months after the date of enactment of this Act.

(d) COMPARATIVE RISK ANALYSIS.—

(1) REQUIREMENT.—(A)(i) No later than 6 months after the effective date of this Act, the Director of the Office of Management and Budget shall enter

into appropriate arrangements with an accredited scientific body—

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

(II) to conduct a comparative risk analysis.

(ii) 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.

(B) 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.

(2) CRITERIA.—In arranging for the comparative risk analysis referred to in paragraph (1) of this subsection, the Director shall ensure that—

(A) the scope and specificity of the analysis are sufficient to provide the President and agency heads guidance in allocating resources across agencies and among programs in agencies to achieve the greatest degree of risk prevention and

reduction for the public and private resources expended;

(B) the analysis is conducted through an open process, by individuals with relevant expertise, including toxicologists, biologists, engineers and experts in medicine, industrial hygiene and environmental effects;

(C) the analysis is conducted, to the extent feasible, consistent with the risk assessment and risk characterization principles in sections 635 and 636 of this title;

(D) the methodologies and principal scientific determinations made in the analysis are subjected to independent and external peer review consistent with section 637, and the conclusions of the peer review are made publicly available as part of the final report required under subsection (e);

(E) there is an opportunity for public comment on the results before making them final; and

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

(3) COMPLETION AND REVIEW.—No later than 3 years after the effective date of this Act, the comparative risk analysis required under paragraph (1) shall be completed. 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 under paragraphs (1) and (2).

(4) STUDY.—The study of methodologies provided under paragraph (1) shall be conducted as part of the first comparative risk analysis and shall be completed no later than 180 days after the completion of that 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.

(5) TECHNICAL GUIDANCE.—No later than 180 days after the effective date 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 subsection (c) of this section.

(e) REPORTS AND RECOMMENDATIONS TO CONGRESS AND THE PRESIDENT.—No later than 24 months after the effective date of this Act, each covered agency shall submit a report to Congress and the President—

(1) detailing how the agency has complied with subsection (c) and describing the reasons for any departure from the requirement to establish priorities to achieve the greatest overall net reduction in risk;

(2) recommending—

(A) modification, repeal, or enactment of laws to reform, eliminate, or enhance programs or mandates relating to human health, safety, or the environment; and

(B) modification or elimination of statutorily or judicially mandated deadlines,

that would assist the covered agency to set priorities in activities to address the risks to human health, safety, or the environment in a manner consistent with the requirements of subsection (c)(1);

(3) evaluating the categories of policy and value judgments used in risk assessment, risk characterization, or cost-benefit analysis; and

(4) discussing risk assessment research and training needs, and the agency's strategy and schedule for meeting those needs.

(f) SAVINGS PROVISION AND JUDICIAL REVIEW.—

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

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

(3) AGENCY ANALYSIS.—Any analysis prepared under this section 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.

SEC. 7. REGULATORY ACCOUNTING.

(a) DEFINITIONS.—For purposes of this section, the following definitions apply:

(1) AGENCY.—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.

(2) REGULATION.—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 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.

(b) ACCOUNTING STATEMENT.—

(1) IN GENERAL.—(A) The President shall be responsible for implementing and administering the requirements of this section.

(B) Every 2 years, no later than June of the second year, the President shall prepare and submit to Congress an accounting statement that estimates the annual costs of Federal regulatory programs and corresponding benefits in accordance with this subsection.

(2) 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.

(3) TIMING AND PROCEDURES.—(A) The President shall provide notice and opportunity for com-

ment 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.

(B) 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.

(4) CONTENT OF ACCOUNTING STATEMENT.—(A) Each accounting statement shall contain estimates of costs and benefits with respect to each fiscal year covered by the statement in accordance with this paragraph. 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.

(B)(i) 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 each regulatory program; and

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

(ii) 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 costs.

(III) State and local government costs.

(C) 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.

(c) ASSOCIATED REPORT TO CONGRESS.—

(1) IN GENERAL.—At the same time as the President submits an accounting statement under sub-

section (b), 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 subsection—

(A) analyses of impacts; and

(B) recommendations for reform.

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

(A) The cumulative impact on the economy of Federal regulatory programs covered in the accounting statement. Factors to be considered in such 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.

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

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

(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.

(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.

(d) 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 and the agencies, 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 Act, 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.

(e) 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 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.

(f) JUDICIAL REVIEW.—No requirements under this section shall be subject to judicial review in any manner.

SEC. 8. EFFECTIVE DATE.

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

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