

HATFIELD and Senator BYRD on this side and their House counterparts. If that can be done, I hope we can get an agreement on the Senate side that we do it by consent. Otherwise, it would be open to amendment and we would be here for days. But I believe that if the White House, the President, and bipartisan leaders on appropriations can agree on a package, perhaps we could obtain consent to do that. If we had to do that Friday morning, perhaps we could do it without a vote.

Mr. DASCHLE. That would be my hope as well. We have a lot of Senators we are trying to accommodate. This is an important effort. It has been under way now for a couple of weeks. We are so close, it would be nice to finish it and be convinced that it is our best product. Indeed, I think it would be.

The PRESIDING OFFICER. Without objection, the foregoing requests are agreed to.

### COMPREHENSIVE REGULATORY REFORM ACT

The PRESIDING OFFICER. The clerk will report the pending business.

The legislative clerk read as follows:

A bill (S. 343) to reform the regulatory process, and for other purposes.

The Senate proceeded to consider the bill which had been reported from the Committee on Governmental Affairs to strike out all after the enacting clause and inserting in lieu thereof the language shown in *italic*; and from the Committee on the Judiciary with amendments as follows:

(The parts of the bill intended to be stricken are shown in **boldface brackets**, and the parts of the bill intended to be inserted are shown in *italic*.)

#### **[SECTION 1. SHORT TITLE.]**

[This Act may be cited as the "Comprehensive 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 ex-

plicit 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 differing levels of resources with which to comply; and

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

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

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

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

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

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

["(G) if not expressly or implicitly inconsistent with the statute under which the agency is proposing the rule, an explanation of the extent to which the identified benefits of the proposed rule justify the identified costs of the proposed rule, and an explanation of how the proposed rule is likely to substantially achieve the rulemaking objectives in a more cost-effective manner than the alternatives to the proposed rule, including alternatives identified in accordance with subparagraph (C); and

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

["(g) The preparation of the initial or final cost-benefit analysis required by this section shall only be performed under the direction of an officer or employee of the agency. The preceding sentence shall not preclude a person outside the agency from gathering data or information to be used by the agency in preparing any such cost-benefit analysis or from providing an explanation sufficient to permit the agency to analyze such data or information. If any such data or information

is gathered or explained by a person outside the agency, the agency shall specifically identify in the initial or final cost-benefit analysis the data or information gathered or explained and the person who gathered or explained it, and shall describe the arrangement by which the information was procured by the agency, including the total amount of funds expended for such procurement.

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

#### ["§ 623. Judicial review

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

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

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

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

["(e) Any cost-benefit analysis or risk assessment prepared under this chapter shall not be subject to judicial consideration separate or apart from review of the agency action to which it relates. When an action for judicial review of an agency action is instituted, any regulatory analysis for such agency action shall constitute part of the whole administrative record of agency action for the purpose of judicial review of the agency action, and shall, to the extent relevant, be considered by a court in determining the legality of the agency action.

#### ["§ 624. Deadlines for rulemaking

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

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

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

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

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

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

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

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

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

#### ["§ 625. Agency review of rules

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

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

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

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

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

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

["(C) Each proposed schedule required under subparagraph (A) shall establish priorities for the review of rules that, in the joint 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 led 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 experience exposures at the upper end of the distribution should be included.

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

["(5) The term 'risk assessment' means—

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

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

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

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

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

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

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

#### ["§ 633. Applicability

["(a) Except as provided in subsection (c), this subchapter shall apply to all risk assessments and risk characterizations prepared by, or on behalf of, or prepared by others and adopted by any 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 review required under subsection (b). Such program shall be applicable throughout each covered agency and—

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

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

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

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

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

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

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

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

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

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

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

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

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

#### **["§638. Guidelines, plan for assessing new information, and report**

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

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

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

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

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

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

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

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

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

#### **["§639. Research and training in risk assessment**

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

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

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

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

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

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

#### **["§640. Interagency coordination**

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

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

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

["(3) establish appropriate interagency mechanisms to promote—

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

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

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

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

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

#### **["§640a. Plan for review of risk assessments**

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

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

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

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

#### **["§640b. Judicial review**

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

#### **["§640c. Deadlines for rulemaking**

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

### **["SUBCHAPTER IV—EXECUTIVE OVERSIGHT**

#### **["§641. Definition**

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

#### **["§642. Procedures**

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

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

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

#### **["§643. Promulgation and adoption**

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

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

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

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

["(B) Notice of any such extension, together with a succinct statement of the reasons therefor, shall be inserted in the rule-making file.

#### ["§ 644. Delegation of authority

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

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

#### ["§ 645. Public disclosure of information

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

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

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

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

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

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

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

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

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

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

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

#### ["§ 646. Judicial review

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

["(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

["Sec.

["601. Definitions.

["602. Regulatory agenda.

["603. Initial regulatory flexibility analysis.

["604. Final regulatory flexibility analysis.

["605. Avoidance of duplicative or unnecessary analyses.

["606. Effect on other law.

["607. Preparation of analysis.

["608. Procedure for waiver or delay of completion.

["609. Procedures for gathering comments.

["610. Periodic review of rules.

["611. Judicial review.

["612. Reports and intervention rights.

##### ["SUBCHAPTER II—ANALYSIS OF AGENCY RULES

["621. Definitions.

["622. Rulemaking cost-benefit analysis.

["623. Judicial review.

["624. Deadlines for rulemaking.

["625. Agency review of rules.

["626. Public participation and accountability.

##### ["SUBCHAPTER III—RISK ASSESSMENTS

["631. Findings and purposes.

["632. Definitions.

["633. Applicability.

["634. Savings provisions.

["635. Principles for risk assessment.

["636. Principles for risk characterization.

["637. Peer review.

["638. Guidelines, plan for assessing new information, and report.

["639. Research and training in risk assessment.

["640. Interagency coordination.

["640a. Plan for review of risk assessments.

["640b. Judicial review.

["640c. Deadlines for rulemaking.

##### ["SUBCHAPTER IV—EXECUTIVE OVERSIGHT

["641. Definition.

["642. Procedures.

["643. Promulgation and adoption.

["644. Delegation of authority.

["645. Public disclosure of information.

["646. Judicial review."

["(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 regarding 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 setting 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, regu-

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

[(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 subsection (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.]

## SECTION 1. SHORT TITLE.

This Act may be cited as the “Comprehensive Regulatory Reform Act of 1995”.

## SEC. 2. DEFINITIONS.

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

(1) in the matter preceding paragraph (1), by striking “this subchapter” and inserting “this chapter and chapters 6, 7, and 8”;

(2) in paragraph (13), by striking “and”;

(3) in paragraph (14), by striking the period at the end and inserting “; and”; and

(4) by adding at the end the following new paragraph:

“(15) ‘Director’ means the Director of the Office of Management and Budget.”.

## SEC. 3. RULEMAKING.

Section 553 of title 5, United States Code, is amended to read as follows:

### “§ 553. Rulemaking

“(a) This section applies to every rulemaking, according to the provisions thereof, except to the extent that there is involved—

“(1) a matter pertaining to a military or foreign affairs function of the United States;

“(2) a matter relating to the management and personnel practices of an agency;

“(3) an interpretive rule, general statement of policy, guidance, or rule of agency organization, procedure, or practice that is not generally applicable and does not alter or create rights or obligations of persons outside the agency; or

“(4) a rule relating to the acquisition, management, or disposal by an agency of real or personal property, or of services, that is promulgated in compliance with criteria and procedures established by the Administrator of General Services.

“(b)(1) General notice of proposed rulemaking shall be published in the Federal Register, unless all persons subject thereto are named and either personally served or otherwise have actual notice of the proposed rulemaking in accordance with law. Each notice of proposed rulemaking shall include—

“(A) a statement of the time, place, and nature of public rulemaking proceedings;

“(B) a succinct explanation of the need for and specific objectives of the proposed rule, including an explanation of the agency’s determination of whether or not the rule is a major rule within the meaning of section 621(4);

“(C) an explanation of the specific statutory interpretation under which a rule is proposed, including an explanation of—

“(i) whether the interpretation is expressly required by the text of the statute; or

“(ii) if the interpretation is not expressly required by the text of the statute, an explanation that the interpretation is within the range of permissible interpretations of the statute as identified by the agency, and an explanation why the interpretation selected by the agency is the agency’s preferred interpretation;

“(D) the proposed provisions of the rule;

“(E) a summary of any initial analysis of the proposed rule required to be prepared or issued pursuant to chapter 6;

“(F) a statement that the agency seeks proposals from the public and from State and local governments for alternative methods to accomplish the objectives of the rulemaking that are more effective or less burdensome than the approach used in the proposed rule;

“(G) a description of any data, methodologies, reports, studies, scientific evaluations, or other similar information available to the agency for the rulemaking, including an identification of each author or source of such information and the purposes for which the agency plans to rely on such information; and

“(H) a statement specifying where the file of the rulemaking proceeding maintained pursuant

to subsection (f) may be inspected and how copies of the items in the file may be obtained.

"(2) Except when notice or hearing is required by statute, a final rule may be adopted and may become effective without prior compliance with this subsection and subsections (c) and (f) if—

"(A) the agency for good cause finds that providing notice and public procedure thereon before the rule becomes effective is contrary to an important public interest or is unnecessary due to the insignificant impact of the rule;

"(B) the agency publishes the rule in the Federal Register with such finding and a succinct explanation of the reasons therefor; and

"(C) the agency complies with this subsection and subsections (c) and (f) to the maximum extent feasible prior to the promulgation of the final rule, and fully complies with such provisions as soon as reasonably practicable after the promulgation of the rule.

"(3) Whenever the provisions of a final rule that an agency plans to adopt are so different from the provisions of the proposed rule that the original notice of proposed rulemaking did not fairly apprise the public of the issues ultimately to be resolved in the rulemaking or of the substance of the rule, the agency shall publish in the Federal Register a notice of the final rule the agency plans to adopt, together with the information relevant to such rule that is required by the applicable provisions of this section and that has not previously been published in the Federal Register. The agency shall allow a reasonable period for comment on such final rule.

"(c)(1) After providing the notice required by this section, the agency shall give interested persons not less than 60 days to participate in the rulemaking through the submission of written data, views, or arguments.

"(2)(A) To collect relevant information, and to identify and elicit full and representative public comment on the significant issues of a particular rulemaking, the agency may use such other procedures as the agency determines are appropriate, including—

"(i) the publication of an advance notice of proposed rulemaking;

"(ii) the provision of notice, in forms which are more direct than notice published in the Federal Register, to persons who would be substantially affected by the proposed rule, but who are unlikely to receive notice of the proposed rulemaking through the Federal Register;

"(iii) the provision of opportunities for oral presentation of data, views, information, or rebuttal arguments at informal public hearings, which may be held in the District of Columbia and other locations;

"(iv) the provision of summaries, explanatory materials, or other technical information in response to public inquiries concerning the issues involved in the rulemaking; and

"(v) the adoption or modification of agency procedural rules to reduce the cost or complexity of participation in a rulemaking.

"(B) The decision of an agency to use or not to use such other procedures in a rulemaking pursuant to this paragraph shall not be subject to judicial review.

"(3) To ensure an orderly and expeditious proceeding, an agency may establish reasonable procedures to regulate the course of informal public hearings under paragraphs (1) and (2), including the designation of representatives to make oral presentations or engage in direct or cross-examination on behalf of several parties with a common interest in a rulemaking. Transcripts shall be made of all such public hearings.

"(4) An agency shall publish any final rule it adopts in the Federal Register, together with a concise statement of the basis and purpose of the rule and a statement of when the rule may become effective. The statement of basis and purpose shall include—

"(A) an explanation of the need for, objectives of, and specific statutory authority for, the rule;

"(B) a discussion of, and response to, any significant factual or legal issues raised by the

comments on the proposed rule prior to its promulgation, including a description of the reasonable alternatives to the rule proposed by the agency and by interested persons, and the reasons why each such alternative was rejected;

"(C)(i) an explanation of whether the specific statutory interpretation upon which the rule is based is expressly required by the text of the statute; or

"(ii) if the specific statutory interpretation upon which the rule is based is not expressly required by the text of the statute, an explanation that the interpretation is within the range of permissible interpretations of the statute as identified by the agency, and why the agency has rejected other interpretations proposed in comments to the agency;

"(D) an explanation of how the factual conclusions upon which the rule is based are substantially supported in the rulemaking file maintained pursuant to subsection (f); and

"(E) a summary of any final analysis of the rule required to be prepared or issued pursuant to chapter 6.

"(5) The provisions of sections 556 and 557 shall apply in lieu of this subsection in the case of rules that are required by statute to be made on the record after opportunity for an agency hearing.

"(d) An agency shall publish the final rule in the Federal Register not less than 60 days before the effective date of such rule. An agency may make a rule effective in less than 60 days after publication in the Federal Register if the rule grants or recognizes an exemption, relieves a restriction, or if the agency for good cause finds that such a delay in the effective date would be contrary to an important public interest and publishes such finding and an explanation of the reasons therefor, with the final rule.

"(e)(1) Each agency shall give an interested person the right to petition for the issuance, amendment, or repeal of a rule.

"(2) Each person subject to a major rule may petition—

"(A) for the issuance, amendment, or repeal of such rule;

"(B) for the amendment or repeal of an interpretive rule or general statement of policy or guidance;

"(C) for an interpretation regarding the meaning of the rule, interpretive rule, general statement of policy, or guidance; and

"(D) for a variance or exemption from the terms of the rule.

"(3)(A) Any person subject to a rule, interpretive rule, general statement of policy, or guidance may petition an agency for the amendment or repeal of any rule, interpretive rule, general statement of policy, or guidance.

"(B) If such petition presents a reasonable likelihood that, considering its future impact, the rule, interpretive rule, general statement of policy, or guidance is, or has the effect of, a major rule within the meaning of section 621(4), and its amendment or repeal is required to satisfy the decisional criteria of section 624, the agency shall grant the petition and shall, within one year, conduct a cost-benefit analysis under chapter 6.

"(C) If, considering its future impact, the rule, interpretive rule, general statement of policy, or guidance does not satisfy the requirements of chapter 6, including the decisional criteria set forth in section 624, the agency shall take immediate action either to revoke or to amend the rule, interpretive rule, general statement of policy, or guidance to conform it to the requirements of chapter 6, including the decisional criteria in section 624.

"(4) The agency shall grant or deny a petition made pursuant to this subsection, and give written notice of its determination to the petitioner, with reasonable promptness, but in no event later than 180 days after the petition was received by the agency. The written notice of the agency's determination shall include an explanation of the determination and a response to

each factual and legal claim that forms the basis of the petition. A decision to deny a petition shall be subject to judicial review immediately upon denial, as final agency action under the statute granting the agency authority to carry out its action.

"(5) Following a decision to grant or deny a petition to conduct a cost-benefit analysis for a rule, interpretive rule, general statement of policy, or guidance under this subsection, no further petition for such rule, interpretive rule, general statement of policy, or guidance, submitted by the same person, shall be considered by any agency unless such petition is based on a change in a fact, circumstance, or provision of law underlying or otherwise related to the rule, interpretive rule, general statement of policy, or guidance occurring since the initial petition was granted or denied, that warrants the amendment or repeal of the rule, interpretive rule, general statement of policy, or guidance.

"(f)(1) The agency shall maintain a file for each rulemaking proceeding conducted pursuant to this section and shall maintain a current index to such file. The file and the material excluded from the file pursuant to paragraph (4) shall constitute the rulemaking record for purposes of judicial review. Except as provided in paragraph (4), the file shall be made available to the public beginning on the date on which the agency makes an initial publication concerning the rule.

"(2) The rulemaking file shall include—

"(A) the notice of proposed rulemaking, any supplement to, or modification or revision of, such notice, and any advance notice of proposed rulemaking;

"(B) copies of all written comments received on the proposed rule;

"(C) a transcript of any public hearing conducted on the rulemaking;

"(D) copies, or an identification of the place at which copies may be obtained, of all material described by the agency pursuant to subsection (b)(1)(G) and of other factual and methodological material not described by the agency pursuant to such subsection that pertains directly to the rulemaking and that was available to the agency in connection with the rulemaking, or that was submitted to or prepared by or for the agency in connection with the rulemaking; and

"(E) any statement, description, analysis, or any other material that the agency is required to prepare or issue in connection with the rulemaking, including any analysis prepared or issued pursuant to chapter 6.

"(3) The agency shall place the materials described in paragraph (2) in the file as soon as practicable after such materials become available to the agency.

"(4) The file required by paragraph (1) need not include any material that need not be made available to the public under section 552(b)(4) if the agency includes in such file a statement that notes the existence of such material and the basis upon which the material is exempt from public disclosure under such section. The agency may not substantially rely on any such material in formulating a rule unless it makes the substance of such material available for adequate comment by interested persons. The agency may use summaries, aggregations of data, or other appropriate mechanisms to protect the confidentiality of such material to the maximum extent possible.

"(5) No court shall hold unlawful or set aside an agency rule because of a violation of this subsection unless the court finds that such violation has precluded fair public consideration of a material issue of the rulemaking taken as a whole. Judicial review of compliance or non-compliance with this subsection shall be limited to review of action or inaction on the part of an agency.

"(g) Notwithstanding any other provision of law, this section shall apply to and supplement the procedures governing rulemaking under statutes that are not generally subject to this section.

"(h) Nothing in this section authorizes the use of appropriated funds available to any agency to pay the attorney's fees or other expenses of persons participating or intervening in agency proceedings."

#### SEC. 4. 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—

"(1) the term 'benefit' means the reasonably identifiable significant incremental benefits, including social 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 incremental costs and adverse effects, including social and economic costs, reduced consumer choice, substitution effects, and impeded technological advancement, 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 \$50,000,000 or more in reasonably quantifiable increased direct and indirect costs, or has a significant impact on a sector of the economy; or

"(ii) a rule or a group of closely related rules that is otherwise designated 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, or local government agencies, or geographic regions;

"(II) significant adverse effects on competition, employment, investment, productivity, innovation, health, safety, or the environment, 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) disproportionate costs to a class of persons within the regulated sector, and relatively severe economic consequences for the class;

"(B) the term 'major rule' does not include—

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

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

"(5) the term 'market-based mechanism' means a regulatory program 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, where

feasible and appropriate, 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 freely 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;

"(6) the term 'performance-based standards' means requirements, expressed in terms of outcomes or goals rather than mandatory means of achieving outcomes or goals, that permit the regulated entity discretion to determine how best to meet specific requirements in particular circumstances;

"(7) the term 'reasonable alternatives' means the range of regulatory options that the agency has discretion to consider under the text of the statute granting rulemaking authority, interpreted, to the maximum extent possible, to embrace the broadest range of options that satisfy the decisional criteria of section 624(b); and

"(8) the term 'rule' has the same meaning as in section 551(4), and—

"(A) includes any statement of general applicability that alters or creates rights or obligations of persons outside the agency; and

"(B) does not include—

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

"(ii) a rule relating to monetary policy or 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), credit unions, Federal Home Loan Banks, government sponsored housing enterprises, farm credit institutions, foreign banks that operate in the United States and their affiliates, branches, agencies, commercial lending companies, or representative offices, (as those terms are defined in section 1 of the International Banking Act of 1978); or

"(iii) a rule relating to the payment system or the protection of deposit insurance funds or the farm credit insurance fund.

#### "§ 622. Rulemaking cost-benefit analysis

"(a) Prior to 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 date of enactment of this subchapter, not later than 30 days after such date of enactment), 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, whether it should be designated a major rule under section 621(4)(A)(ii). For the purpose of any such determination or designation, 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 within the meaning of section 621(4)(A)(i) and has not designated the rule a major rule within the meaning of section 621(4)(A)(ii), the Director or a designee of the President may, as appropriate, determine that the rule is a major rule or designate the rule a major rule not 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 date of enactment of this subchapter, not later than 60 days after such date of enactment).

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

"(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 or designation 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 in the same manner as if the initial 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, and an explanation of how the agency anticipates each benefit 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, and an explanation of how the agency anticipates each such cost will result from the proposed rule, including a description of the persons or groups of persons likely to bear such costs;

"(C) an identification (including an analysis of the costs and benefits) of reasonable alternatives that the agency has discretion to adopt under the decisional criteria of the statute granting the rulemaking authority, as supplemented by the decisional criteria in section 624, for achieving identified benefits, including, where appropriate, alternatives that—

"(i) require no government action;

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

"(iii) employ voluntary or performance-based standards, market-based mechanisms, or other flexible regulatory alternatives that permit the greatest flexibility in achieving the identified benefits of the proposed rule;

"(D) an assessment of the feasibility of establishing a regulatory program that operates through the application of voluntary programs, voluntary consensus standards, performance-based standards, market-based mechanisms, or other flexible regulatory alternatives;

"(E) in any case in which the proposed rule is based on one or more scientific evaluations, scientific information, or a risk assessment, or is subject to the risk assessment requirements of subchapter III, a description of the actions undertaken by the agency to verify the quality, reliability, and relevance of such scientific evaluations or scientific information in accordance with the requirements of subchapter III;

"(F) an analysis, to the extent practicable, of the effect of the rule on—

"(i) the cumulative burden of compliance with the rule and other existing regulations on persons complying with it; and

"(ii) the net effect on small businesses with fewer than 100 employees, including employment in such businesses;

"(G) an analysis of whether the identified benefits of the proposed rule justify the identified costs of the proposed rule, and an analysis of whether the proposed rule will achieve greater net benefits or, where applicable, lower net costs, than any of the alternatives to the proposed rule, including alternatives identified in accordance with subparagraphs (C) and (D).

"(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 flexible regulatory alternatives identified pursuant to subsection (c)(2) (C) and (D); and

“(B) an analysis, based upon the rulemaking record considered as a whole, of—

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

“(ii) whether the rule will achieve greater net benefits or, where section 624(c) applies, lower net costs, than any of the reasonable alternatives that the agency has discretion to adopt under the decisional criteria of the statute granting the rulemaking authority, as supplemented by the decisional criteria in section 624, for achieving identified benefits, including, where appropriate, alternatives referred to in subsection (c)(2) (C) and (D).

“(e)(1)(A) 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 unit 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.

“(B) Where practicable and appropriate, the description of the benefits and costs of a proposed and final rule required under this section shall describe such benefits and costs on an industry by industry basis.

“(2)(A) In evaluating and comparing costs and benefits and in evaluating the risk assessment information developed pursuant to subchapter III, the agency shall not rely on cost, benefit, or risk assessment information that is not accompanied by relevant information 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) The preparation of the initial or final cost-benefit analysis required by this section shall only be performed by 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.

#### “§623. Petition for cost-benefit analysis

“(a)(1) Any person subject to a major rule may petition the relevant agency, the Director, or a designee of the President to perform a cost-benefit analysis under this subchapter for the major rule, including a major rule in effect on the date of enactment of this subchapter for which a cost-benefit analysis pursuant to such subchapter has not been performed, regardless of whether a cost-benefit analysis was previously performed to meet requirements imposed before the date of enactment of this subchapter.

“(2) The petition shall identify with reasonable specificity the major rule to be reviewed and the amendment or repeal requested.

“(3) The agency, the Director, or a designee of the President shall grant the petition if the petition shows that there is a reasonable likelihood that, considering the future impact of the rule—

“(A) the rule is a major rule; and

“(B) the proposed amendment or repeal of the rule is required to satisfy the decisional criteria of section 624.

“(4) A decision to grant, or final agency action to deny, a petition under this subsection shall be made not later than 180 days after submittal.

“(5) Following a decision to grant or deny a petition to conduct a cost-benefit analysis for a rule under this subsection, no further petition for such rule, submitted by the same person, shall be considered by any agency, the Director, or a designee of the President, unless such petition is based on a change in a fact, circumstance, or provision of law underlying or otherwise related to the rule occurring since the initial petition was granted or denied, that warrants the amendment or repeal of the rule.

“(b) Not later than 1 year after the date on which a petition has been granted for a major rule under subsection (a), the agency shall conduct a cost-benefit analysis in accordance with this subchapter, and shall propose amendments to, or repeal of, the rule if required by the decisional criteria set forth in section 624.

“(c) For purposes of this section, the term ‘major rule’ means any major rule or portion thereof.

“(d)(1) Any person may petition the relevant agency to withdraw, as contrary to this subchapter, any agency interpretive rule, guidance, or general statement of policy that would have the effect of a major rule if the interpretive rule, guidance, or general statement of policy had been adopted as a rule.

“(2) The petition shall identify with reasonable specificity why the interpretive rule, guidance, or general statement of policy would have the effect of a major rule if adopted as a rule.

“(3) The agency shall grant the petition if the petition shows that there is a reasonable likelihood that the guidance or general statement of policy would have the effect of a major rule if adopted as a rule.

“(4) A decision to grant, or final agency action to deny, a petition under this subsection shall be made not later than 180 days after the petition is submitted.

“(e) For each interpretative rule, guidance, or general statement of policy for which a petition has been granted under subsection (d), the agency shall—

“(1) immediately withdraw the interpretive rule, guidance, or general statement of policy; or

“(2) within one year, propose a rule in compliance with this subchapter incorporating, with such modifications as the agency considers appropriate, the regulatory standards or criteria contained in such interpretive rule, general statement of policy, or guidance.

“(f) Upon withdrawing an interpretive rule, guidance, or general statement of policy, or where such interpretive rule, guidance, or general statement of policy is not withdrawn and a final rule is not promulgated within 2 years of granting a petition under subsection (d), the agency shall be prohibited from enforcing against any person the regulatory standards or criteria contained in such interpretive rule, guidance, or general statement of policy, unless and until they are included in a rule promulgated in accordance with this subchapter.

“(g)(1) Any person subject to a major rule may petition the relevant agency to modify or waive the specific requirements of the major rule and to authorize such person to demonstrate compliance through alternative means not otherwise permitted by the major rule. The petition shall identify with reasonable specificity the re-

quirements for which the waiver is sought and the alternative means of compliance being proposed.

“(2) The agency shall grant the petition if the petition shows that there is a reasonable likelihood that the proposed alternative means of compliance would achieve the specific benefits of the major rule with an equivalent or greater level of protection of health, safety, and the environment than would be provided by the major rule, and would not impose an undue burden on the agency that would be responsible for enforcing such alternative means of compliance.

“(3) Following a decision to grant or deny a petition under this subsection, no further petition for such rule, submitted by the same person, shall be considered by any agency unless such petition is based on a change in a fact, circumstance, or provision of law underlying or otherwise related to the rule occurring since the initial petition was granted or denied, that warrants the granting of such further petition.

#### “§624. Decisional criteria

“(a) The requirements of this section shall supplement any other decisional criteria otherwise provided by law.

“(b) Subject to subsection (c), no final rule subject to this subchapter shall be promulgated unless the agency finds that—

“(1) the potential benefits from the rule justify the potential costs of the rule; and

“(2) the rule will produce the most cost-effective result of any of the reasonable alternatives that the agency has discretion to adopt under the decisional criteria of the statute granting the rulemaking authority.

“(c) If a statute requires or permits that a rule be promulgated and that rule cannot, applying the express decisional criteria in the statute, satisfy the criteria provided in subsection (b), the agency shall not promulgate the rule unless the rule imposes—

“(1) lower costs than any of the reasonable alternatives; or

“(2) the least costs taking into account benefits that the agency has discretion to adopt under the decisional criteria of the statute granting the rulemaking authority.

“(d) If an agency promulgates a rule that is subject to subsection (c), the agency shall prepare a written explanation of why the agency was required to promulgate a rule with potential costs that were not justified by the potential benefits and shall transmit that explanation along with the final cost-benefit analysis to Congress when the final rule is promulgated.

#### “§625. Judicial review

“(a) Each court with jurisdiction to review final agency action under the statute granting the agency authority to conduct the rulemaking shall have jurisdiction to review final agency action under this subchapter.

“(b)(1) Any cost-benefit analysis of, or risk assessment concerning, a rule shall constitute part of the whole rulemaking record of agency action for the purpose of judicial review and shall be considered by a court in determining the legality of the agency action, but only to the extent that it relates to the agency's decisional responsibilities under section 624 or the statute granting the agency authority to take the agency action.

“(2) No analysis required by this subchapter shall be subject to judicial review separate or apart from judicial review of the agency action to which it relates.

“(3) The court shall apply the same standards of judicial review that govern the review of agency findings under the statute granting the agency authority to take the action.

“(4) The court shall set aside agency action that fails to satisfy the decisional criteria of section 624, applying the applicable judicial review standards.

#### “§626. Deadlines for rulemaking

“(a) Beginning on the date of enactment of this section, all deadlines in statutes that require agencies to propose or promulgate any

rule subject to this subchapter shall be suspended until such time as the requirements of this subchapter are satisfied.

“(b) Beginning on the date of enactment of this section, the jurisdiction of any court of the United States to enforce any deadline that would require an agency to propose or promulgate a rule subject to this chapter shall be suspended until such time as the requirements of this subchapter are satisfied.

“(c) In any case in which the failure to promulgate a rule by a deadline would create an obligation to regulate through individual adjudications by another deadline, the deadline for such regulation shall be suspended to allow the requirements of this subchapter to be satisfied.

#### “§627. Agency review of rules

“(a)(1)(A) Not later than 9 months after the date of enactment 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, considering its future impact, would be a major rule under this subchapter;

“(ii) each rule of the agency that is inconsistent or incompatible with, or duplicative of, 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

“(iii) each rule of the agency in effect on the date of enactment of this section (in addition to the rules described in clauses (i) and (ii)) that 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 a major rule under section 621(4)(A), or the reasons why the agency selected the rule for review;

“(ii) a date set by the agency, in accordance with subsection (b)(1), 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 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) Not 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, or to the Vice President or other officer to whom oversight authority has been delegated under section 643. The President or that officer may select for review in accordance with this section any additional rule.

“(3) Not later than 1 year after the date of enactment 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 under section 621(4) 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 that the President or the officer designated by the President selects for review pursuant to subsection (a)(2).

“(2) Except as provided in subsection (f)—

“(A) in the case of a regulation that takes effect after the date of enactment of this section, the regulation shall terminate on the date that is 5 years after the date on which the regulation takes effect, unless the review required by this section has been completed by the date that is 5 years after the date on which the regulation takes effect; and

“(B) in the case of a regulation in effect on the date of enactment of this section, the regulation shall terminate on the date that is 7 years after the date of enactment of the Regulatory Reform Act of 1995, unless the review required by this section has been completed by the date that is 7 years after the date of enactment of the Regulatory Reform Act of 1995.

“(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, an explanation that the interpretation is within the range of permissible interpretations of the statute as identified by the agency, and an explanation why the interpretation selected by the agency is the agency's preferred interpretation;

“(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 renew without amendment a rule under review pursuant to this section, the agency shall—

“(1) give interested persons not less than 60 days after the publication of the notice required by subsection (c) to comment on the proposed renewal; and

“(2) publish in the Federal Register notice of the renewal of such rule, an explanation of the continued need for the rule, and, if the renewed rule is a major rule under section 621(4), an explanation of how the rule complies with section 624.

“(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) is contrary to an important public interest, may request the President, or an officer designated by the President, to establish a period longer than 5 years, in the case of a regulation that takes effect after the date of enactment of this section, or 7 years, in the case of a regulation in effect on the date of enactment of this section, 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 10 years. Such extension shall be published in the Federal Register with an explanation of the reasons therefor.

“(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 issue the rule under subsection (c), and shall complete proceedings pursuant to subsection (d) or (e) not later than 180 days after the date on which the review was required to be completed under subsection (b) or (f).

“(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.

#### “§628. Special rule

“Notwithstanding any other provision of the Comprehensive Regulatory Reform Act of 1995, or the amendments made by such Act, for purposes of this subchapter and subchapter IV, the head of each appropriate Federal banking agency (as defined in section 3(q) of the Federal Deposit Insurance Act), the National Credit Union Administration, the Federal Housing Finance Board, the Office of Federal Housing Enterprise Oversight, and the Farm Credit Administration, shall have authority with respect to such agency that otherwise would be provided under such subchapters to the Director, a designee of the President, Vice President, or any officer designated or delegated with authority under such subchapters.

#### “SUBCHAPTER III—RISK ASSESSMENTS

##### “§631. Definitions

“For purposes of this subchapter—

“(1) the term ‘benefit’ has the meaning given such term in section 621(1);

“(2) the term ‘best estimate’ means an estimate that, to the extent feasible and scientifically appropriate, is based on—

“(A) central estimates of risk using the most plausible and realistic assumptions;

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

“(C) any other methodology designed to provide the most plausible and realistic level of risk, given the current scientific information available to the agency concerned;

“(3) the term ‘cost’ has the meaning given such term in section 621(2);

“(4) the term ‘cost-benefit analysis’ has the meaning given such term in section 621(3);

“(5) the term ‘emergency’ means an actual, immediate, and substantial endangerment to health, safety, or the human environment;

“(6) the term ‘hazard identification’ means identification of a substance, activity, or condition that may cause to health, 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 combined degree of toxicity and actual exposure, or other risk the hazards pose for individuals, populations, or natural resources; and

“(7) the term ‘major cleanup plan’ means any proposed or final environmental cleanup plan for a facility, or Federal guidelines for the issuance of any such plan, the expected costs, expenses, and damages of which are likely to exceed, in the aggregate, \$10,000,000, including a corrective action requirement under the Solid Waste Disposal Act (notwithstanding section 4(b)(1)(C) of such Act, but only to the extent of such requirement), a removal or remedial action under the Comprehensive Environmental Response, Compensation, and Liability Act of 1980, and any other environmental restoration or damage assessment carried out by, on behalf of, or as required or ordered by, an agency or Federal court, or pursuant to the authority of a Federal statute with respect to any substance;

“(8) the term ‘major rule’ has the meaning given such term in section 621(4);

“(9) the term ‘negative data’ means data that fail to show that a given substance or activity

induces an adverse effect under certain conditions;

“(10) the term ‘risk assessment’ means—

“(A) the process of identifying hazards, and of quantifying (to the maximum extent practicable) or describing the combined degree of toxicity and actual exposure, or other risk the hazards pose for individuals, populations, or natural resources; and

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

“(11) the term ‘risk characterization’—

“(A) means the element of a risk assessment that involves presentation of the degree of risk to individuals and populations expected to be protected, as presented in any regulatory proposal or decision, report to Congress, or other document that is made available to the public; and

“(B) may include discussions of uncertainties, conflicting data, estimates, extrapolations, inferences, and opinions, as appropriate;

“(12) the term ‘rule’ has the meaning given such term in section 621(7); and

“(13) the term ‘substitution risk’ means a potential increased risk to health, safety, or the environment resulting from market substitutions, a reduced standard of living, or a regulatory alternative designed to decrease other risks.

#### **“§632. Applicability**

“(a) Except as provided in subsection (b), 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 agency in connection with health, safety, and environmental risks.

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

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

“(B) a rule or agency action that authorizes the introduction into or removal from commerce, or initiation of manufacture, of a substance, mixture, or product, or recognizes the marketable status of a product;

“(C) a health, safety, or environmental inspection, compliance or enforcement action, or individual facility permitting action; or

“(D) a screening analysis clearly identified as such.

“(2)(A) An analysis shall not be treated as a screening analysis for the purposes of paragraph (1)(D) if the result of the analysis is used—

“(i) as the basis for imposing a restriction on a previously authorized substance, product, or activity after its initial introduction into manufacture or commerce; or

“(ii) to characterize a finding of risk from a substance or activity in any agency document or other communication made available to the public, the media, or Congress.

“(B) Among the analyses that may be treated as a screening analyses for the purposes of paragraph (1)(D) are product registrations, reregistrations, tolerance settings, and reviews of premanufacture notices under the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136 et seq.) and the Toxic Substances Control Act (15 U.S.C. 2601 et seq.).

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

#### **“§633. Principles for risk assessment**

“(a)(1) The head of each agency shall apply the principles set forth in subsection (b) when preparing any risk assessment for a major rule to ensure that the risk assessment and all of its components—

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

“(B) are, to the maximum extent practicable, scientifically objective, plausible, and realistic, and inclusive of all relevant data;

“(C) rely, to the extent available and practicable, on scientific findings; and

“(D) use situation- or decision-specific information to the maximum extent practicable.

“(2) An agency shall not be required to repeat discussions or explanations required under this section in each risk assessment document if there is an unambiguous reference to the relevant discussion or explanation in another reasonably available agency document that was prepared in accordance with this subchapter.

“(b) The principles to be applied when preparing risk assessments are as follows:

“(1)(A) When assessing human health risks, a risk assessment shall consider and discuss both the most important laboratory and epidemiological data, including negative data, and summarize the remaining data that finds, or fails to find, a correlation between a health risk and a substance or activity.

“(B) When conflicts among such data appear to exist, or when animal data are used as a basis to assess human health, the assessment shall include a discussion of possible reconciliation of conflicting information. Greatest emphasis shall be placed on data that indicates the biological basis of the resulting harm in humans. Animal data shall be reviewed with regard to relevancy to humans.

“(2) When a risk assessment involves a choice of any significant assumption (including the use of safety factors and default assumptions), inference, or model, the agencies or instrumentalities preparing the assessment shall—

“(A) present a representative description and explicit explanation of plausible and alternative similar assumptions, inferences, or models (including the assumptions incorporated into the model) and the sensitivity of the conclusions to them;

“(B) give preference to the model, assumption, input parameter that represents the most plausible or realistic inference from supporting scientific information;

“(C) identify any science policy or value judgments and employ those judgments only where the policy determination has been approved by the head of the agency, after notice and opportunity for public involvement, as appropriate for the circumstance under consideration;

“(D) describe any model used in the risk-assessment and make explicit the assumptions incorporated into the model; and

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

“(3) Risk assessments that provide a quantification or numerical output shall be calculated using the best estimate for each input parameter and shall use, as available, probabilistic descriptions of the uncertainty and variability associated with each input parameter.

“(4) 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 potential hazard.

“(5) A risk assessment shall be prepared 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.

“(6) Where relevant, practicable, and appropriate, data shall be developed consistent with standards for the development of test data promulgated pursuant to section 4 of the Toxic Substances Control Act, and standards for data requirements promulgated pursuant to section 3 of the Federal Insecticide, Fungicide, and Rodenticide Act.

“(c)(1) The head of each agency shall promote early involvement by all stakeholders in the development of risk assessments that may support or affect agency rules, guidance, and other significant actions, by publishing as part of its semiannual regulatory agenda, required under section 602—

“(A) a list of risk assessments and supporting assessments, including hazard, dose or exposure assessments, under preparation or planned by the agency;

“(B) a brief summary of relevant issues addressed or to be addressed by each listed risk assessment or supporting assessment;

“(C) an approximate schedule for completing each listed risk assessment and supporting assessment;

“(D) an identification of potential rules, guidance, or other agency actions supported or affected by each listed risk assessment and supporting assessment; and

“(E) the name, address, and telephone number of an agency official knowledgeable about each listed risk assessment and supporting assessment.

“(2)(A) The head of each agency shall provide an opportunity for meaningful public participation and comment on any risk assessment throughout the regulatory process commensurate with the consequences of the decision to be made.

“(B) In cases where the risk assessment will support a major rule, the agency shall publish, at the earliest opportunity in the process, an advanced notice of relevant risk assessment related information that includes, at a minimum, an identification of—

“(i) all relevant hazard, dose, exposure, and other risk related documents that the agency plans to consider;

“(ii) all risk related guidance that the agency considers relevant;

“(iii) all hazard, dose, exposure, and other risk assumptions on which the agency plans to rely and the bases therefor; and

“(iv) all data and information deficiencies that could affect agency decisionmaking.

“(d)(1) No agency shall automatically incorporate or adopt any recommendation or classification made by an entity described in paragraph (2) concerning the health effects or value of a substance without an opportunity for notice and comment. Any risk assessment or risk characterization document adopted by an agency on the basis of such a recommendation or classification shall comply with this title.

“(2) An entity referred to in paragraph (1) includes—

“(A) any foreign government and its agencies;

“(B) the United Nations or any of its subsidiary organizations;

“(C) any international governmental body or standards-making organization; and

“(D) any other organization or private entity without that does not have a place of business located in the United States or its territories.

#### **“§634. Principles for risk characterization and communication**

“In characterizing risk in any risk assessment document, regulatory proposal or decision, report to Congress, or other document relating in each case to a major rule that is made available to the public, each agency characterizing the risk shall comply with each of the following:

“(1) The head of the agency shall describe the exposure scenarios used in any risk assessment, and, to the extent feasible, provide an estimate of the size of the corresponding population or natural resource at risk and the likelihood of such exposure scenarios.

“(2) If a numerical estimate of risk is provided, the head of the agency, to the extent feasible and scientifically appropriate, shall provide—

“(A) the range and distribution of exposures derived from exposure scenarios used in a risk assessment, including, where appropriate, central and high-end estimates, but always including a best estimate of the risk to the general population;

“(B) the range and distribution of risk estimates, including best estimates and, where quantitative estimates of the range of distribution of risk estimates are not possible, a list of



qualitative factors influencing the range of possible risks; and

“(C) a statement of the major sources of uncertainties in the hazard identification, dose-response, and exposure assessment phases of risk assessment and their influence on the results of the assessment.

“(3) To the extent feasible, the head of the agency shall provide a statement that places the nature and magnitude of individual and population risks to human health in context.

“(4) When a Federal 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 to human health identified by the agency or contained in information provided to the agency by a commentator.

“(5) An agency shall present a summary in connection with the presentation of the agency's risk assessment or the regulation if—

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

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

“(C) such risk assessment is reasonably consistent with the principles and the guidance provided under this subtitle.

#### “§635. Requirement to prepare assessment

“(a) Except as provided in section 632 and in addition to any requirements applicable under subchapter II, the head of each agency shall prepare—

“(1) for each major rule relating to health, safety, or the environment, and for each major cleanup plan, that is proposed by the agency after the date of enactment of this subchapter, is pending on the date of enactment of this subchapter, or is subject to a granted petition for review pursuant to section 553(e) or 623, a risk assessment in accordance with this subchapter;

“(2) for each such proposed or final plan, and each reasonable alternative within the statutory authority of the agency taking action, a cost-benefit analysis equivalent to that which would be required under subchapter II if subchapter II were applicable; and

“(3) for each such proposed or final plan, quantified to the extent feasible, a comparison of any health, safety, or environmental risks addressed by the regulatory alternatives to other relevant risks chosen by the head of the agency, including at least 3 other risks regulated by the agency and to at least 3 other risks with which the public is familiar.

“(b) A major cleanup plan is subject to this subchapter if—

“(1) construction has not commenced on a significant portion of the work required by the plan; or

“(2) if construction has commenced on a significant portion of the work required by the plan, unless—

“(A) it is more cost-effective to complete construction of the work than to apply the provisions of this subchapter; or

“(B) the application of the provisions of this subchapter, including any delays caused thereby, will result in an actual and immediate risk to human health or welfare.

“(c) A risk assessment prepared pursuant to this subchapter shall be a component of and used to develop any cost-benefit analysis required by this subchapter or subchapter II, and shall, along with any cost-benefit analysis required by this subchapter, be made part of the administrative record for judicial review of any final agency action.

#### “§636. Requirements for assessments

“(a) The head of the agency, subject to review by the Director or a designee of the President, shall make a determination that, notwithstanding any other provision of law—

“(1) for each major rule and major cleanup plan subject to this subchapter, the risk assess-

ment required under section 635 is based on a scientific, plausible, and realistic evaluation, reflecting reasonable exposure scenarios, of the risk addressed by the major rule and is supported by the best available scientific data, as determined by a peer review panel in accordance with section 640; and

“(2) for each major cleanup plan subject to this subchapter, the plan has benefits that justify its costs and that there is no alternative that is allowed by the statute under which the plan is promulgated that would provide greater net benefits or that would achieve an equivalent reduction in risk in a more cost-effective and flexible manner.

“(b) Notwithstanding any other provision of law, no agency shall prohibit or refuse to approve a substance or product on the basis of safety where the substance or product presents a negligible or insignificant human risk under the intended conditions of use.

“(c) Notwithstanding any other provision of law, issuance of a record of decision or a final permit condition or administrative order containing a major cleanup plan, or denial of, or completion of agency review pursuant to, a petition for review of a major cleanup plan under section 637(c), shall constitute final agency action subject to judicial review at the time this action is taken.

#### “§637. Regulations; plan for assessing new information

“(a)(1) Not later than 1 year after the date of enactment of this subchapter, the Director or a designee of the President shall—

“(A) issue a final regulation that has been subject to notice and comment under section 553 that directs agencies to implement the risk assessment and risk characterization principles set forth in sections 633 and 634; and

“(B) provide a format for summarizing risk assessment results.

“(2) The regulation under paragraph (1) shall be sufficiently specific to ensure that risk assessments are conducted consistently by the various agencies.

“(b) Review of a risk assessment or any entry (or the evaluation underlying the entry) on an agency-developed database (including, but not limited to, the Integrated Risk Information System), shall be conducted by the head of the agency on the written petition of a person showing a reasonable likelihood that—

“(1) the risk assessment or entry is inconsistent with the principles set forth in sections 633 and 634;

“(2) the risk assessment or entry contains different results than if it had been properly conducted under sections 633 and 634;

“(3) the risk assessment or entry is inconsistent with a rule issued under subsection (a); or

“(4) the risk assessment or entry does not take into account material significant new scientific data or scientific understanding.

“(c) Review of a risk assessment, a cost-benefit analysis, or both, for a major cleanup plan shall be conducted by the head of the agency on the written petition of a person showing a reasonable likelihood that—

“(1) the risk assessment warrants revision under any of the criteria set forth in subsection (b); or

“(2) the cost-benefit analysis warrants revision under any of the criteria set forth in section 624.

“(d)(1) Not later than 90 days after receiving a petition under subsection (b), the head of the agency shall respond to the petition by agreeing or declining to review the risk entry, the cost-benefit analysis, or both, referred to in the petition, and shall state the basis for the decision.

“(2) If the head of the agency agrees to review the petition, the agency shall complete its review not later than 180 days after the decision made under paragraph (1), unless the Director agrees in writing with an agency determination that an extension is necessary in view of limita-

tions on agency resources. Prior to completion of the agency review, the agency's written conclusions concerning the review shall be subjected to peer review pursuant to section 640.

“(3) A risk assessment review completed pursuant to a petition may be the basis for initiating a petition pursuant to any other provision of law.

“(4) Following a decision to grant or deny a petition under subsection (b) or (c), no further petition for such risk assessment, entry, or cost-benefit analysis, submitted by the same person, shall be considered by any agency unless such petition is based on a change in a fact, circumstance, or provision of law underlying or otherwise related to the matters covered by the initial petition, occurring since the initial petition was granted or denied, that warrants the granting of such further petition.

“(e) The regulations 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, agencies, offices, organizations, or persons as may be advisable.

“(f) At least every 4 years, the Director or a designee of the President shall review, and when appropriate, revise, the regulations published under this section.

#### “§638. Rule of construction

“Nothing in this subchapter shall be construed to—

“(1) 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

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

#### “§639. Regulatory priorities

“(a)(1) Not later than 180 days after the date of enactment of this section, the Director of the Office of Management and Budget, in consultation with the Office of Science and Technology Policy, shall enter into appropriate arrangements with an accredited scientific body to—

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

“(B) to conduct a comparative risk analysis in accordance with paragraph (2).

“(2) The study of the methodologies under paragraph (1)(A) shall be conducted as part of the first comparative risk analysis under paragraph (1)(B). The study shall—

“(A) seek to develop and rigorously test methods of comparative risk analysis;

“(B) have sufficient scope and breadth to test approaches for improving comparative risk analysis and its use in setting priorities for health, safety, and environmental risk prevention and reduction; and

“(C) review and evaluate the experience of States that have conducted comparative risk analyses.

“(3)(A) The comparative risk analysis under paragraph (1)(B) shall compare and rank, to the extent feasible, health, safety, and environmental risks potentially regulated across the spectrum of programs relating to health, safety, and the environment administered by the departments, agencies, and instrumentalities of the Federal Government.

“(B) In carrying out the comparative risk analysis under this paragraph, the Director shall ensure that—

“(i) the scope and specificity of the analysis are sufficient to provide the President and the heads of agencies 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;

“(ii) the analysis is conducted through an open process, by individuals with relevant expertise, including, as appropriate—

“(I) toxicologists;



“(II) biologists;

“(III) engineers; and

“(IV) experts in the fields of medicine, industrial hygiene, and environmental effects;

“(iii) the analysis is conducted, to the extent feasible, consistent with the risk assessment and risk characterization principles described in sections 633 and 634;

“(iv) the methodologies and principal scientific determinations made in the analysis are subjected to peer review under section 640 and the conclusions of the peer review are made publicly available as part of the final report;

“(v) there is an opportunity for public comments on the results of the analysis prior to making them final; and

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

“(4) The comparative risk analysis shall be completed, and a report submitted to Congress not later than 3 years after the date of enactment of this section. The analysis shall be reviewed and revised not less often than every 5 years thereafter for a minimum of 15 years following the release of the initial analysis.

“(b) Not later than 180 days after the date of enactment of this section, the Director of the Office of Management and Budget, in collaboration with the head of each Federal agency, shall enter into a contract with the National Research Council to provide technical guidance to the agencies on approaches to using comparative risk analysis in setting health, safety, and environmental priorities to assist the agencies in complying with subsection (c).

“(c)(1) In exercising authority under any laws protecting health, safety, or the environment, the head of an agency shall prioritize the use of the resources available under such laws to address the risks to health, safety, and the environment that—

“(A) the agency determines are 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 to be expended.

“(2) In identifying the sources of the most serious risks under paragraph (1), the head of the agency shall consider, at a minimum—

“(A) the plausible likelihood and severity of the effect; and

“(B) the plausible number and groups of individuals potentially affected.

“(3) The head of the agency shall incorporate the priorities identified in paragraph (1) into the budget, strategic planning, and research activities of the agency by, in the agency's annual budget request to Congress—

“(A) identifying which risks the agency has determined are the most serious and can be addressed in a cost-effective manner under paragraph (1), and the basis for that determination;

“(B) explicitly identifying how the agency's requested funds will be used to address those risks;

“(C) identifying any statutory, regulatory, or administrative obstacles to allocating agency resources in accordance with the priorities established under paragraph (1); and

“(D) explicitly considering the requirements of paragraph (1) when preparing the agency's regulatory agenda or other strategic plan, and providing an explanation of how the agenda or plan reflects those requirements and the comparative risk analysis when publishing any such agenda or strategic plan.

“(4) In March of each year, the head of each agency shall submit to Congress specific recommendations for repealing or modifying laws that would better enable the agency to prioritize its activities to address the risks to health, safety, and the environment that are the most serious and can be addressed in a cost-effective manner consistent with the requirements of paragraph (1).

#### “§640. Establishment of program

“(a) The Director of the Office of Science and Technology or the Director, as appropriate, shall develop a systematic program for the peer review of work products covered by subsection (c), which program shall be used, in as uniform a manner as is practicable, across the agencies.

“(b) The program under subsection (a)—

“(1) shall provide for the creation of peer review panels consisting of independent and external experts who are broadly representative and balanced to the extent feasible;

“(2) shall not exclude peer reviewers merely because they represent entities that may have a potential interest in the outcome, if that interest is fully disclosed;

“(3) shall exclude experts who were associated with the generation of the specific work product either directly by substantial contribution to its development, or indirectly by consultation and development of the specific product;

“(4) shall provide for differing levels of peer review depending on the significance or complexity of the issue or the need for expedition;

“(5) shall contain balanced presentations of all considerations, including minority reports and an agency response to all significant peer review comments; and

“(6) shall provide an opportunity for interested parties to submit issues for consideration by peer review panels.

“(c) Matters requiring peer review shall include—

“(1) risk assessments and cost-benefit analyses for major rules;

“(2) quantitative estimates of risk or hazard that are used in making regulatory determinations, including all entries into the Integrated Risk Information System;

“(3) risk assessment and risk characterization regulations and cost-benefit guidelines; and

“(4) any other significant or technical work product, as designated by the head of each agency, the Director of the Office of Science and Technology, or the Director.

“(d) All underlying data shall be submitted to peer reviewers, except to the extent necessary to protect confidential business information and trade secrets. To ensure such protections, the head of the agency may require that peer reviewers enter into confidentiality agreements.

“(e) The peer review and the agency's responses shall be made available to the public for comment and the final peer review and the agency's responses shall be made part of the administrative record for purposes of judicial review.

“(f) The proceedings of peer review panels under this section shall be subject to the applicable provisions of the Federal Advisory Committee Act.

#### “SUBCHAPTER IV—EXECUTIVE OVERSIGHT

##### “§641. Procedures

“(a) The Director or a designee of the President shall—

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

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

“(b) Not later than 12 months after the date of enactment of this subchapter the Office of Management and Budget shall issue regulations to assist agencies in preparing the cost-benefit analyses required by this subchapter. The regulations shall—

“(1) ensure that cost and benefit evaluations are consistent with this subchapter and, to the extent feasible, represent realistic and plausible estimates;

“(2) be adopted following public notice and adequate opportunity for comment; and

“(3) be used consistently by all agencies covered by this subchapter.

##### “§642. Promulgation and adoption

“(a) Procedures established pursuant to section 641 shall only be implemented after oppor-

tunity for public comment. Any such procedures shall be consistent with the prompt completion of rulemaking proceedings.

“(b)(1) If procedures established pursuant to section 641 include review of any initial or final analyses of a rule required under chapter 6, the time for any such review of any initial analysis shall not exceed 30 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 641 has been delegated pursuant to section 643.

“(2) The time for review of any final analysis required under chapter 6 shall not exceed 30 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.

##### “§643. Delegation of authority

“(a) The President may delegate the authority granted by this subchapter 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.

“(b)(1) Notice of any delegation, or any revocation or modification thereof shall be published in the Federal Register.

“(2) Any 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 section.

##### “§644. 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 643 shall not be subject to judicial review in any manner under this chapter.”

(b) REGULATORY FLEXIBILITY ANALYSIS.—

(1) JUDICIAL REVIEW.—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), not later than 2 years 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;

“(B) prepared a final regulatory flexibility analysis pursuant to section 604; or

“(C) did not prepare an initial regulatory flexibility analysis pursuant to section 603 or a final regulatory flexibility analysis pursuant to section 604 except as permitted by sections 605 and 608,

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

“(2)(A) Notwithstanding any other provision of law, an affected small entity shall have 2 years to challenge such certification, analysis or lack of analysis.

“(B) If 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 not later than 2 years 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) Notwithstanding section 605, if the court determines, on the basis of the rulemaking record, that there is substantial evidence to conclude that the rule would have a significant economic impact on a substantial number of small entities, the court shall order the agency to prepare a final regulatory flexibility analysis pursuant to section 604.

“(B) If 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) The court may stay the rule or grant such other relief as it deems appropriate 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.

“(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 date of enactment 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 the date of enactment of this Act.

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

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

“SUBCHAPTER I—REGULATORY ANALYSIS

“Sec.

“601. Definitions.

“602. Regulatory agenda.

“603. Initial regulatory flexibility analysis.

“604. Final regulatory flexibility analysis.

“605. Avoidance of duplicative or unnecessary analyses.

“606. Effect on other law.

“607. Preparation of analysis.

“608. Procedure for waiver or delay of completion.

“609. Procedures for gathering comments.

“610. Periodic review of rules.

“611. Judicial review.

“612. Reports and intervention rights.

“SUBCHAPTER II—ANALYSIS OF AGENCY RULES

“621. Definitions.

“622. Rulemaking cost-benefit analysis.

“623. Petition for cost-benefit analysis.

“624. Decisional criteria.

“625. Judicial review.

“626. Deadlines for rulemaking.

“627. Agency review of rules.

“628. Special rule.

“SUBCHAPTER III—RISK ASSESSMENTS

“631. Definitions.

“632. Applicability.

“633. Principles for risk assessment.

“634. Principles for risk characterization and communication.

“635. Requirement to prepare risk assessment.

“636. Requirements for assessments.

“637. Regulations; plan for assessing new information.

“638. Rule of construction.

“639. Regulatory priorities.

“640. Establishment of program.

“SUBCHAPTER IV—EXECUTIVE OVERSIGHT

“641. Procedures.

“642. Promulgation and adoption.

“643. Delegation of authority.

“644. Judicial review.”

(2) **SUBCHAPTER HEADING.**—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. 5. JUDICIAL REVIEW.**

(a) **SCOPE OF REVIEW.**—Section 706 of title 5, United States Code, is amended to read as follows:

##### **“§706. Scope of review**

“(a) To the extent necessary to reach a decision and when presented, the reviewing court shall decide all relevant questions of law, interpret constitutional and statutory provisions, and determine the meaning or applicability of the terms of an agency action. The reviewing court shall—

“(1) compel agency action unlawfully withheld or unreasonably delayed; and

“(2) hold unlawful and set aside agency action, findings and conclusions found to be—

“(A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law;

“(B) contrary to constitutional right, power, privilege, or immunity;

“(C) in excess of statutory jurisdiction, authority, or limitations, or short of statutory right;

“(D) without observance of procedure required by law;

“(E) unsupported by substantial evidence in a proceeding subject to sections 556 and 557 or otherwise reviewed on the record of an agency hearing provided by statute;

“(F) without substantial support in the rulemaking file, viewed as a whole, for the asserted or necessary factual basis, as distinguished from the policy or legal basis, of a rule adopted in a proceeding subject to section 553; or

“(G) unwarranted by the facts to the extent that the facts are subject to trial de novo by the reviewing court.

“(b) In making the foregoing determinations, the court shall review the whole record or those parts of it cited by a party, and due account shall be taken of the rule of prejudicial error.

“(c) In reviewing an agency interpretation of a statute governing the authority for an agency action, including agency action taken pursuant to a statute that provides for review of final agency action, the reviewing court shall—

“(1) hold erroneous and unlawful—

“(A) an agency interpretation that is other than the interpretation of the statute clearly intended by Congress; or

“(B) an agency interpretation that is outside the range of permissible interpretations of the statute; and

“(2) hold arbitrary, capricious, or an abuse of discretion—

“(A) an agency action as to which the agency—

“(i) has improperly classified an interpretation as being within or outside the range of permissible interpretations; or

“(ii) has not explained in a reasoned analysis why it selected the interpretation and why it rejected other permissible interpretations of the statute; or

“(B) in the case of agency action subject to chapter 6, an interpretation that does not give the agency the broadest discretion to develop rules that will satisfy the decisional criteria of section 624.

“(d) Notwithstanding any other provision of law, the provisions of this subsection shall apply to, and supplement, the requirements contained in any statute for the review of final agency action which is not otherwise subject to this subsection.”

(b) **COURT OF FEDERAL CLAIMS.**—

(1) **IN GENERAL.**—Section 1491(a) of title 28, United States Code, is amended—

(A) in paragraph (1), by amending the first sentence to read as follows: “The United States Court of Federal Claims shall have jurisdiction to render judgment upon any claim against the United States for monetary relief founded either upon the Constitution or any Act of Congress or any regulation or action of an agency, or upon any expressed or implied contract with the United States, in cases not sounding in tort, or for invalidation of any Act of Congress or any regulation of an executive department that adversely affects private property rights in violation of the fifth amendment of the United States Constitution.”;

(B) in paragraph (2), by inserting before the first sentence the following: “In any case within its jurisdiction, the Court of Federal Claims shall have the power to grant injunctive and declaratory relief when appropriate.”; and

(C) by adding at the end the following new paragraphs:

“(4) In cases otherwise within its jurisdiction, the Court of Federal Claims shall also have ancillary jurisdiction, concurrent with the courts designated in section 1346(b), to render judgment upon any related tort claim authorized under section 2674.

“(5) In proceedings within the jurisdiction of the Court of Federal Claims which constitute judicial review of agency action (rather than de novo proceedings), the provisions of section 706 of title 5 shall apply.”

(2) **PENDENCY OF CLAIMS IN OTHER COURTS.**—Section 1500 of title 28, United States Code, is repealed.

(c) **JUDICIAL PROCEEDINGS.**—

(1) **CONSENT DECREES.**—Chapter 7 of title 5, United States Code, is amended by adding at the end the following new section:

##### **“§707. Consent decrees**

“In interpreting any consent decree in effect on or after the date of enactment of this section that imposes on an agency an obligation to initiate, continue, or complete rulemaking proceedings, the court shall not enforce the decree in a way that divests the agency of discretion granted to it by the Congress or the Constitution to respond to changing circumstances, make policy or managerial choices, or protect the rights of third parties.”

(2) **AFFIRMATIVE DEFENSE.**—Chapter 7 of title 5, United States Code, is further amended by adding at the end the following new section:

##### **“§708. Affirmative defense**

“Notwithstanding any other provision of law, it shall be an affirmative defense in any enforcement action brought by an agency that the regulated person or entity is complying with a rule, regulation, adjudication, directive, or order of such agency or any other agency that is inconsistent, incompatible, contradictory, or otherwise cannot be reconciled with the agency rule, regulation, adjudication, directive, or order being enforced.”

(3) AGENCY INTERPRETATIONS IN CIVIL AND CRIMINAL ACTIONS.—

(A) IN GENERAL.—Chapter 7 of title 5, United States Code, is further amended by adding at the end the following new section:

**“§709. Agency interpretations in civil and criminal actions**

“(a)(1) No civil or criminal penalty shall be imposed in any action brought in a Federal court, including an action pending on the date of enactment of this section, for the alleged violation of a rule, if the defendant, prior to the alleged violation—

“(A) reasonably determined, based upon a description, explanation, or interpretation of the rule contained in the rule’s statement of basis and purpose, that the defendant was in compliance with, exempt from, or otherwise not subject to, the requirements of the rule; or

“(B) was informed by the agency that promulgated the rule, or by a State authority to which had been delegated the responsibility for ensuring compliance with the rule, that the defendant was in compliance with, exempt from, or otherwise not subject to, the requirements of the rule.

“(2) In determining, for purposes of paragraph (1)(A), whether a defendant reasonably relied upon a description, explanation, or interpretation of the rule contained in the rule’s statement of basis and purpose, the court shall not give deference to any subsequent agency description, explanation, or interpretation of the rule relied on by the agency in the action that had not been published in the Federal Register or otherwise directly and specifically communicated to the defendant by the agency, or by a State authority to which had been delegated the responsibility for ensuring compliance with the rule, prior to the alleged violation.

“(b)(1) In a civil or criminal action in Federal court to redress an alleged violation of a rule, including an action pending on the date of enactment of this section, if the court determines that the rule in question is ambiguous, the court shall not give deference to an agency interpretation of the rule if the defendant relied upon an interpretation of the rule to the effect that the defendant was in compliance with or was exempt or otherwise not subject to the requirement of the rule, and the court determines that such determination is reasonable.

“(2) Without regard to whether the defendant relied upon an interpretation that the court determines is reasonable under paragraph (1), if the court determines that the rule failed to give the defendant fair warning of the conduct that the rule prohibits or requires, no civil or criminal penalty shall be imposed.

“(c)(1) No agency action shall be taken, or any action or other proceeding maintained, seeking the retroactive application of a requirement against any person that is based upon—

“(A) an interpretation of a statute, rule, guidance, agency statement of policy, or license requirement or condition; or

“(B) a determination of fact,

if such interpretation or determination is different from a prior interpretation or determination by the agency or by a State or local government exercising authority delegated or approved by the agency, and if such person relied upon the prior interpretation or determination.

“(2) This subsection shall take effect on the date of enactment of the Comprehensive Regulatory Reform Act of 1995 and shall apply to any matter for which a final unappealable judicial order has not been issued.

“(d) This section shall apply to the review by a Federal court of any order of an agency assessing civil administrative penalties.”

(B) UNPUBLISHED AGENCY GUIDANCE.—Section 552(a)(1) of title 5, United States Code, is amended by inserting at the end the following new sentence: “In an action brought in a Federal court seeking a civil or criminal penalty for the alleged violation of a rule, including actions pending on the date of enactment of this sen-

tence, no consideration shall be given to any interpretive rule, general statement of policy, or other agency guidance of general or specific applicability, relied upon by the agency in the action, that had not been published in the Federal Register or otherwise directly and specifically communicated to the defendant by the agency, or by a State authority to which had been delegated the responsibility for ensuring compliance with the rule, prior to the alleged violation.”

(4) TECHNICAL AMENDMENT.—The analysis for chapter 7 of title 5, United States Code, is amended by adding at the end the following new items:

“707. Consent decrees.

“708. Affirmative defense.

“709. Agency interpretations in civil and criminal actions.”

**SEC. 6. CONGRESSIONAL REVIEW.**

(a) IN GENERAL.—Title 5, United States Code, is amended by inserting immediately after chapter 7 the following new chapter:

**“CHAPTER 8—CONGRESSIONAL REVIEW OF AGENCY RULEMAKING**

**“§801. Congressional review of agency rule-making**

“(a)(1) Before a rule takes effect as a final rule, the agency promulgating such rule shall submit to the Congress a report containing a copy of the rule, the notice of proposed rule-making, and the statement of basis and purpose for the rule, including a complete copy of any analysis required under chapter 6, and the proposed effective date of the rule. In the case of a rule that is not a major rule within the meaning of section 621(4), summary of the rulemaking proceedings shall be submitted.

“(2) A rule relating to a report submitted under paragraph (1) shall take effect as a final rule, the latest of the following:

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

“(i) the Congress receives the report 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 (g) 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 (g) is approved).

“(b) A rule shall not take effect as a final rule if the Congress passes a joint resolution of disapproval described under subsection (g), which is signed by the President or is vetoed and overridden by the Congress.

“(c)(1) Notwithstanding any other provision of this section (except subject to paragraph (3)), a rule that would not take effect by reason of this section may take effect if the President makes a determination under paragraph (2) and submits written notice of such determination to the Congress.

“(2) Paragraph (1) applies to a determination made by the President by Executive order that the rule should take effect because such 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.

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

“(4) This subsection and an Executive order issued by the President under paragraph (2)

shall not be subject to judicial review by a court of the United States.

“(d)(1) Subsection (g) shall apply to any rule that is published in the Federal Register (as a rule that shall take effect 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 (g), a 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.

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

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

“(g)(1) For purposes of this subsection, the term ‘joint resolution’ means only a joint resolution introduced after the date on which the report referred to in subsection (a) 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) A resolution described in paragraph (1) shall be referred to the committees in each House of Congress 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 report submitted under subsection (a)(1); or

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

“(3) 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 by the Majority Leader of the Senate or the Majority Leader of the House of Representatives, as the case may be, from further consideration of such resolution and such resolution shall be placed on the appropriate calendar of the House involved.

“(4)(A) 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 Member of the respective House 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 highly privileged in the House of Representatives and 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 respective House until disposed of.

“(B) 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) 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 rules of the appropriate House, 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 or the House of Representatives, as the case may be, to the procedure relating to a resolution described in paragraph (1) shall be decided without debate.

“(5) If, before the passage by one House of a resolution of that House described in paragraph (1), that House receives from the other House a resolution described in paragraph (1), then the following procedures shall apply:

“(A) The resolution of the other House shall not be referred to a committee.

“(B) With respect to a resolution described in paragraph (1) of the House receiving the resolution—

“(i) the procedure in that House 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 supercedes 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.

“(h) This section shall not apply to rules that concern monetary policy proposed or implemented by the Board of Governors of the Federal Reserve System or the Federal Open Market Committee.”.

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

**“8. Congressional Review of Agency Rulemaking..... 801”.**

**SEC. 7. ACCOUNTING.**

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

(1) **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.

(2) **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.

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

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

(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 the 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 administrative costs.

(III) Federal sector compliance costs.

(IV) State and local government administrative costs.

(V) State and local government compliance costs.

(VI) Indirect costs, including opportunity 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 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 subsection (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) Analyses prepared by the President of the cumulative impact of Federal regulatory programs covered in the accounting statement 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, provide guidance to agencies—

(1) to standardize measures of costs and benefits in accounting statements prepared pursuant to sections 3 and 7 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.

**SEC. 8. 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 4 of this Act); and

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

(b) **ADMINISTRATIVE PROCEDURE ACT.**—Not later than December 31, 1996, the Administrative Conference of the United States shall—

(1) carry out a study of the operation of 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.

Mr. DOLE. Mr. President, I again thank the Democratic leader, Senator DASCHLE.

Mr. President, today we begin consideration of regulatory reform, one of the most important and fundamental reforms that this Congress will address. No doubt about it, the American people are fed up with a regulatory state that is out of control. That was one of the messages the American people delivered last November.

The regulatory state has become so pervasive that it lies on our economy like a blanket, stifling innovation, and killing infant industries and small businesses before they get off the ground. Although the Federal Government has a department for just about everything else, it does not have a department of lost opportunities. And that is what this is all about—getting the Government off the backs of the American people; and letting them have an honest opportunity to succeed, for example, when they open a small business.

I want to note at the outset that the reforms before us are the product of over a decade of bipartisan work. The first major attempt at regulatory reform took place here in the Senate in 1982, when we passed S. 1080 unanimously. S. 1080 itself grew out of a bill I introduced in 1981, again with bipartisan support.

S. 1080 contained sweeping revisions of the Administrative Procedures Act. Most of those revisions are included in the bill before us.

S. 1080 imposed a requirement that major rules be subjected to cost-benefit analyses. The structure of the cost-benefit analyses in the bill we consider today closely follow those in S. 1080.

S. 1080 required judicial review of cost-benefit analyses in order to provide meaningful enforcement. The bill before us does the same.

I have provided this brief history for two reasons. First, there are many Senators still in this body on both sides of the aisle who supported S. 1080 in 1982. And, second, there has been a concerted attempt by those who defend the status quo to ignore that history and act as if the bill under consideration today was a radically new approach with little thought for the consequences. Nothing could be further from the truth.

Every President since President Nixon, including President Clinton, has issued an Executive order that imposed such requirements on agencies, though Executive orders are necessarily limited in scope and cannot provide for court enforcement, the bill we consider today draws on two decades of agency experience with those Executive orders.

This bill is also the product of four major committees. I want to especially

commend the chairmen of those committees, Senators HATCH, ROTH, MURKOWSKI, and BOND, and their members for their hard work. This bill is the product of negotiations with the Clinton administration, and Democrat colleagues. From the beginning, it has had bipartisan support. I especially want to commend Senator HEFLIN for his leadership in working on the bill in the Judiciary Committee. And, finally, the text of the bill we consider today is the product of weeks of work with Senator JOHNSTON who has long championed reforms in risk assessment in this body.

Given this history and broad bipartisan support, it might be surprising that regulatory reform has been met with often strident opposition.

But this bill is about fundamental change—needed change—and those who defend the status quo will fight it tooth and nail. Apparently, they will do so without even pretending to read the legislation.

Let me be clear: These reforms will not place at risk human health or safety or protection of the environment.

I understand that Ralph Nader and Joan Claybrooke are out running ads in part of the country that Senator DOLE, the majority leader, is for dirty meat, for unhealthy meat. So we have a lot of these incredible statements being made, but they have nothing to do with this bill.

And the bill before us makes this explicit in any number of provisions. Those who argue otherwise should stop trying to scare people and take the time to actually read the bill.

What opponents of regulatory reform really mean, but are embarrassed to admit, is that they believe that strong laws must always mean the most costly laws. Now, they will not say that of course. No, they will pay lip service to common sense. But as soon as you actually propose a way to consider costs and benefits, they switch subjects and accuse reformers of endangering human health and safety. I doubt anyone outside Washington, DC, who has to deal with regulations in their daily lives really believes that line anymore.

Mr. President, I have enough faith in our ingenuity to believe that we can find better, smarter ways to achieve otherwise worthwhile goals.

Nor—as opponents of reform would phrase it—is this a debate about placing a value on human life. The bill makes clear that there are often nonquantifiable benefits, and that an agency decisionmaker may well have to make judgments that are not subject to quantification. What the bill demands is accountability, by insisting that the decisionmaker articulate the basis for these judgments on the record. The principles of judging risks and weighing costs and benefits are rational and widely used in our daily lives. What is unacceptable is to allow Government agencies to avoid these types of judgments when enacting regulations that impose huge costs on our economy.

These reforms are about limited government. For too long, decisionmakers in Washington, DC, have acted as though bigger government—taking more of our taxes and savings, and suppressing individual initiative—could exist without more coercion and more rules. But that is wrong. For 40 years, the number and scope of regulations have skyrocketed out of control. The costs and annoyances of regulations have grown unbearable. And what is worse: We have not even attempted to use common sense in order to determine whether the costs are worth it.

These reforms are about accountability. Open government. Forcing the Government to tell the rest of us why it chooses to regulate a certain way, and making it defend its choice. This aspect of regulatory reform is not often discussed, but I would argue that it may be the most important of all.

It has often been remarked by historians that the decline of great civilizations—such as ancient Rome—is typically marked by an overabundance of bureaucracy that relied on secret, often contradictory, rules. Eventually, the entire regulatory structure brings progress to a standstill and it collapses of its own weight. It is no accident that we described complex, inscrutable procedures as byzantine.

Mr. President, we are a long way from reaching that point certainly. But we should understand that this is a battle that we will fight again and again. I, for one, intend to win this battle. The reforms we take up today are a giant step forward for common sense and our great country.

So I am pleased that we are on the bill. I thank my colleagues on the other side for not objecting to moving to the bill. We will have a brief debate today. We will have a longer debate tomorrow and probably some debate on Friday of this week. Hopefully, when we return from the July 4 recess, we will be able to finish this bill in the week following the recess, because I think it is probably the most important legislation we will have considered so far this year.

Mr. President, I would ask the distinguished Senator from Utah to be in charge of the time on this side. I guess Senator JOHNSTON will be in charge of the time on that side.

Mr. HATCH addressed the Chair.

The PRESIDING OFFICER. The Senator from Utah.

Mr. HATCH. How much time does this side have?

The PRESIDING OFFICER. There are 20 minutes remaining.

Mr. HATCH. I yield myself 7 minutes.

Mr. President, today we begin the debate on one of the most important pieces of legislation this Congress will address this year: the Comprehensive Regulatory Reform Act of 1995. This is a bill that will change the way the Government does business.

It is high time that we respond to the American people's loud and clear demands that government become smaller and more streamlined—their demand

that government become more responsive. It is high time that we realize just who is working for whom.

The fact that government often takes forever to carry out its functions; spends a fortune in doing so; at best inconveniences citizens in the process; and yet still does not seem to get the job done properly, is reason enough for this legislation.

It is high time that Congress acted to require government to act in a timely, sensible, and rational manner.

If this bill becomes law, the Federal bureaucrats will, from now on, have to prove to America that their regulations do more good than harm to society.

I submit that nothing could be more basic to our democracy and to our federal system of government than the notion that the Federal Government should only act when it helps people and when its actions are justified. That is just plain common sense, and that is what this bill is about.

This bill forces the Federal bureaucracy to justify the costs of the rules and regulations that it places on hard-working Americans.

#### I. THE NEED FOR REFORM

I do not disagree that there is a need for some government regulation. Unfortunately, under the current system, there is little notion of restraint or balance in the way that government agencies operate. The Federal bureaucracy has become bloated, inefficient, and wasteful. Excessive, needless government regulation is running rampant. It has done tremendous damage to our economy, and it continues to do so every year.

#### A. STATISTICS

The bottom line is that American people pay for this bureaucracy several times over.

First, of course, they have to pay for the salaries and other expenses for the Federal agencies to operate. These direct expenditures, of course, figure in to our budget. To the extent that such expenditures are not offset by cuts elsewhere, the cost of maintaining the Federal bureaucracy adds to the national deficit and to the national debt, which is already at about \$18,500 for every man, woman, and child in America.

Second, there are the hidden costs of complying with all this regulation. The American people have to pay to comply with the regulations the bureaucracy churns out. It has been estimated that complying with Federal regulation costs the average American family \$4,000 a year. [The Heritage Foundation, citing Jonathan Adler, "Regulated . . . out of this world", the Washington Times, June 3, 1992].

And that is the low estimate. If you include indirect costs—such as increased prices for goods and services because sellers are passing on some of their regulatory burden to buyers—some estimates run as high as \$8,000 to \$17,000 a year. [William Laffer, the Heritage Foundation].

That is staggering, particularly when compared with the average annual income tax of \$5,491 [IRS, 1992]. The costs of regulation are operating as a hidden tax on the system. Not only should that tax be cut, but the agencies should be made accountable so that the American people know what they are paying and what they are getting.

Third, these costs have indirect consequences and impose opportunity costs. It has been estimated that the costs of Federal regulation have reduced the total output of the Nation, the GDP, by nearly 6 percent. [Thomas Hopkins, "Costs of Regulation: Filling the Gaps," citing a study by Hazilla and Kopp]. How does this happen?

It is simple enough. When businesses have to devote resources to meeting a Federal directive, alternative—and more productive—uses of those resources cannot be made. That means that the economy is slower, and jobs are lost because of regulatory excesses.

Mr. President, the status quo is simply unacceptable. Federal regulation is stifling the American Dream. It used to be said that America was the land of opportunity, where the streets were paved with gold. Today, the streets are paved with redtape.

#### B. EXAMPLES

Where regulation is doing its jobs and is helping society, there is no problem. The supporters of beneficial regulations have nothing to fear from this bill. But, too often regulations not only fail to do the job, but also they are downright dumb. Those are the regulations that this bill seeks to eliminate.

For example, there is a regulatory requirement that drive-through cash machines must be equipped with Braille pads. Now, how many blind Americans are driving cars to drive-through ATMs? [The Heritage Foundation, citing Insight which was quoting TCF Bank Savings of Minneapolis Chairman William Cooper]. That type of regulation is simply ridiculous on its face.

In another instance, a rancher was fined \$4,000 for killing a grizzly bear that had eaten his sheep previously and was attacking him. [The Heritage Foundation, citing a Wall Street Journal article by Ike Scrugg, dated June 23, 1993].

What is worse is that excessive regulations have often thwarted the very ends those regulations seek to further. Take the case of the Abyssinian Baptist Church in Harlem. That church struggled for 4 years to get approval for a Head Start Program in a newly renovated building. Most of those 4 long years was spent arguing with Federal bureaucrats concerning the dimensions of rooms.

Now, we do not want Head Start Programs in unsafe facilities. I agree with that. But, where is the common sense here? What exactly are we trying to do? Provide early childhood educational opportunities for low-income children? Or, keep regulators busy with their tape measures? Clearly, we failed

at the former and were a great success in the latter. An entire generation of head starters were unable to participate in that valuable program.

This is really a shameful waste of resources that could have been provided by this church in Harlem for the benefit of neighborhood children.

A representative from the church complained about the unresponsiveness of the people in Washington.

All the bureaucrats wanted to tell her, she said, was what could not be done rather than what could be done. She said that when she told them that they were talking about pieces of paper, and she was talking about children, they did not seem to care. ["The Death of Common Sense"].

Mr. President, I believe this particular example is an excellent illustration of how our regulatory system has gone haywire. It is hard to believe that regulators do not care about children and their access to Head Start or any other kind of service.

But, this example clearly shows that our regulatory policy has become more concerned with process than with outcomes. It has become so obsessed with the objective that room size not deviate an inch from the Federal standard that it has completely lost sight of what Head Start is supposed to accomplish.

I have to believe that similar examples of form over substance exist at the Department of Labor, the EPA, the Interior Department, and just about every other Federal agency.

Regulation has also reached deep into our smallest businesses. Take the case of Dutch Noteboom. Mr. Noteboom is 72 years old and has owned a small meat-packing plant in Springfield, OR, for 33 years.

Despite the fact that Mr. Noteboom employs only four people, the U.S. Department of Agriculture has one full-time inspector on his premises. Another inspector spends over half his time there. This level of attention is astonishing and must be extremely costly.

Mr. Noteboom says that he is swimming in paperwork, and that he does not even know a tenth of the rules. He says, "You should see all these USDA manuals." ["The Death of Common Sense"].

Well, I have seen some of the Government's manuals and regulations and they are shocking in their length and complexity.

Consider, for example, the Federal regulations on the sale of cabbage. Now, the Gettysburg Address is 286 words in length, and the Declaration of Independence contain 1,322 words. But Government regulations on the sale of cabbage total an eye-popping 26,911 words. [Heritage, citing a letter from Congressman McIntosh to Grover Norquist].

I am frankly wondering just how much there is to restrict about the sale of cabbage that would justify nearly 27,000 words. I had my staff do a quick



calculation: 27,000 words is approximately the same length as the Federalist Papers Nos. 1 through 15. We have transformed regulatory compliance into an industry all by itself. We have gone from simple rules that reasonable people could understand and comply with to a Code of Federal Regulations that by itself takes up a whole wall of shelf space—not counting other agency guidance and field memos. We forget how fast is mount up.

Could I ask how much time I have left?

The PRESIDING OFFICER. The Senator has 11 minutes remaining.

Mr. HATCH. I will yield 1 more minute to me, and the rest of my time to Senator ROTH, after Senator JOHNSTON finishes.

Since 27,000 words is approximately the same length as the Federalist papers Nos. 1 through 15, how can there be any question that we have gone too far?

Mr. President, Mr. Noteboom's story highlights another major mutation of U.S. regulatory policy.

I can go on and on, but the point I am making is this: They are taking away our properties, our private properties, and interfering with small business. They are hurting people and stopping kids from getting the care they need. And, frankly, it is all because of ridiculous regulations in large part written by people who are not thinking about what is best for the American people and what is cost efficient in doing so. This bill will make a terrific difference. It will make our bureaucrats better and make us better. And, frankly, it is high time we did it.

I want to compliment the distinguished Senator from Kansas, our majority leader, and also my good friend and colleague from Louisiana, who both worked long and hard to get together, and a whole raft of others. I will put their names in the RECORD by unanimous consent.

Mr. President, I reserve the balance of our time.

Mr. JOHNSTON addressed the Chair.

The PRESIDING OFFICER. The Senator from Louisiana.

PRIVILEGE OF THE FLOOR

Mr. JOHNSTON. I ask unanimous consent that Dr. Robert Simon be given the privilege of the floor for the pendency of S. 343 and any votes thereon.

The PRESIDING OFFICER. Without objection, it is so ordered.

Mr. JOHNSTON. Mr. President, I want to thank my colleague, Mr. HATCH, as well as Senator DOLE, and their staffs, and Senator ROTH, and others on the other side of the aisle, for making this bill and the negotiation on it thus far a true bipartisan effort.

The Judiciary Committee bill was, indeed, the product of last Congress' risk assessment legislation, which I sponsored, as well as S. 1020, which dealt with regulatory reform from earlier in the 1980's. Since that time, Mr. President, the distinguished Senator

from Kansas, Senator DOLE, and I, worked together over a period of some 10 hours—excuse me—12 hours of direct negotiation in working out what we called the Dole-Johnston draft, discussion draft. Since that was filed in the RECORD, we have spent an additional—or at least I have spent 20 hours in negotiation with both Republicans and Democrats, seeking to work out the problems in that draft.

All of our problems have not yet been worked out. But if I may give my colleagues and others the state of play on it, I think the mood is there, the will is there, and I think eventually substantial agreement can be arrived at, dealing with nine major points:

First, judicial review. The argument about judicial review is now not about the principle, it is about the language. I believe our language achieves the result. We will continue to listen, but I believe it achieves the result that everyone wishes.

Supermandate has been eliminated from the bill. I believe that is also clear. And both sides agree that underlying statutes are not superseded. Whatever the requirements of the Clean Air Act are, for example, are still in place. And we believe that the language of the draft now reflects that. We are willing to work further to clarify that—not to clarify, but to reassure Senators that that is so.

With respect to decisional criteria, Mr. President, I believe that from our side of the aisle the language now in the draft fully gives the discretion to the agencies that we wish.

I call attention of my colleagues to the language of section 624, which states certain requirements, such as the benefits rule to justify the cost. But it goes on to say that if scientific, technical, or economic uncertainties or nonquantifiable benefits to the health or safety of the environment identified by the agency in the rulemaking record make a more costly alternative that achieves the objective of the statute appropriate and in the public interest, and the agency head provides an explanation of that, that they may chose the more costly alternative.

Mr. President, we will listen to further elucidation on this.

But it seems to me that this is a complete victory for those on our side of the aisle who have always said the difficulty with risk assessment is sometimes scientific uncertainty, where scientists do not agree in some areas, where the data is uncertain or where you have values that are nonquantifiable by their nature, such as the value of life, the value of good health, the value of environment, the value of clean air which are, by their nature, nonquantifiable.

As I say, the theme, the idea is there, and I believe is clear. But to the extent it is not, we are certainly willing to negotiate, I believe, on both sides of the aisle. The question, again, is not whether to grant discretion for these things, but rather the question is how best to phrase the language.

With respect to petition, appeal on that petition, sunset, consolidation, we believe, Mr. President, that we now have complete agreement on that. It covers the issue of agency overload, and we will soon be filing in the RECORD language that will reflect that agreement. Anything, of course, is subject to further wordsmithing, but we believe both Democrats and Republicans have arrived at a decision in that very difficult area.

With respect to effective date, I hope we can come to agreement on that. On the Democratic side, we do not want to have to go back and redo regulations which have, in some cases, been 2 or 3 years in the making. On the Republican side, the concern has been that they do not want to have a flood of new regulations come in at the last minute to escape the requirements of this bill. I believe effective date can be appropriately worked out and pick some date such as July 1 of this year.

With respect to threshold, I believe the threshold should be 100 million, and 50 million is now in the bill. I believe also that is a doable thing. My prediction is that we will end up agreeing on 100 million with some language with respect to small business because small business has really been a concern here. At least I am in good hopes we can agree on that.

I hope we can agree to drop Superfund at some point. Not that anybody thinks a process of risk assessment should not be applicable to Superfund, it should definitely be applicable to Superfund, but we believe that is best done by the Environment and Public Works Committee, working their will against special requirements of the Superfund site. To put it in this bill, I believe, would be very difficult.

With respect to toxic release inventory, the language now in the Dole-Johnston draft, I believe, can be much improved. It, in turn, was an improvement over the Judiciary Committee draft. Frankly, we are waiting for some kind of improvement language that we hope will solve this problem.

Toxic release inventory is a high-profile issue, but I believe, in terms of importance of the issue, it is clearly one of the lesser issues in this bill and should not stand in our way of getting a bill.

The final point I have has to do with the Delaney rule. We greatly improve the Judiciary Committee draft on the Delaney rule. The language now in the Dole-Johnston draft says that an administrator or an agency head cannot fail to license a chemical if it has negligible or insignificant foreseeable risk to human health resulting from its intended use. It seems to me that this ought to be the standard. It is a good standard. I have heard no defense of keeping the Delaney rule as it is, and I submit that the votes will be on the floor to change the Delaney rule.

Our request is that those who think the standard we have in this draft is not appropriate should come up with



alternative language which we are happy to consider. We have given notice of consideration of alternative language now for a week or two, and I have not yet received it. So I urge people who want that to be reconsidered to please submit language.

The point I am making, Mr. President, is that the most difficult things about this bill—things like decisional criteria, judicial review, supermandate—have been agreed upon in principle, and the problem now is to determine language that carries out the principle.

We all understand that language and wordsmithing in this area is very important, is crucial, is critical, and we will continue to negotiate to seek very precise language that carries this out, and we solicit that from both sides of the aisle.

But, Mr. President, frankly, given the attitudes on both sides of the aisle, I believe it is going to be possible to come to those agreements, not with all Senators. We are not going to get 100 votes, but I believe that there is a real possibility for a broad consensus, and I am happy to be part of the group that is putting together what I consider to be the most important bill in this field that has ever been enacted by the Congress.

Mr. President, I reserve the remainder of my time.

Mr. ROTH addressed the Chair.

The PRESIDING OFFICER. Who yields time? The Senator from Delaware.

Mr. HATCH. I yield the remainder of our time to the Senator from Delaware.

The PRESIDING OFFICER. There are 9 minutes 51 seconds remaining.

Mr. ROTH. Mr. President, first of all, I would like to thank the distinguished Senator from Louisiana for the constructive role he has played in the effort to bring the two sides together. Like him, I am optimistic that we are going to be able to fashion legislation that will satisfy the large majority on both sides of the aisle.

I, frankly, can think of no legislation of more critical importance, both from the standpoint of enforcement of the legislation or statutes on the books, but also from getting a better bang for the taxpayers' buck. So, again, I congratulate and thank the distinguished Senator for his contribution.

Mr. President, today marks a milestone in the effort to build a smarter, more effective regulatory process. From all quarters, Americans are calling for change from the often overbearing and counterproductive regulatory monolithic that has grown out of control these past couple of decades. President Clinton has admitted that many regulations, regulations that are costing our Nation billions of dollars, are bad regulations.

George McGovern has described in brilliant detail how overbearing regulations put him out of business when all he was trying to fulfill was the

dream of being an entrepreneur of owning his own New England inn.

Economists are telling us that Federal regulations are costing our households some \$6,000 annually, costing our country about \$600 billion a year, and this at a time when our policies must be those that make our Nation competitive abroad, economically secure at home and confident within our families.

Financial costs are not the only burden. As we move further into the information age, the old adage, "Time is money," rings truer than ever before. Time alone is becoming one of America's most vital economic resources. In a competitive world of instant information, a world where time is measured in cyberseconds, businesses, entrepreneurs, service providers, researchers, scientists, farmers, and others must be able to accelerate their response time in providing their services and bringing new products to market.

In our age of information, time is often the difference between profit and loss. But today, Federal regulations, like cholesterol clogging a vital artery, not only slow down the process but often disrupts it. Well over 5 billion hours—I repeat—well over 5 billion hours a year are spent by our private sector just trying to meet government paperwork demands.

The legislation we are considering today, S. 343, the comprehensive regulatory reform act of 1995, is a real and workable solution to the problems being expressed on both sides of the aisle. That is why I am supporting this legislation. It is the most comprehensive reform of the regulatory process since the enactment of the Administrative Procedure Act of 1946. Since then, efforts to reform Federal regulations have been like a man trying to save himself by running up the aisle in the opposite direction on a runaway train. What this legislation does, Mr. President, is get that runaway train under control and places it back on the right track.

This legislation substantially changes the requirements for the issuance of Federal regulations. It requires regulators to directly consider whether the benefits of a new regulation would justify its cost. Regulators who want to issue environmental and health and safety regulation regulations under this legislation have to make realistic estimates of the risks to be addressed. They have to disclose to the public any assumptions they make to measure the risk.

The bill encourages agencies to set priorities to achieve the greatest overall risk reduction at the least cost. More generally, this bill requires agencies to review existing regulations, to be sensitive to the cumulative regulatory burden, and to select the most cost effective, market-driven method feasible.

This, Mr. President, is smarter regulation. Smarter regulation benefits us all—our farmers, our businesses of all

sizes; it benefits State and local government, and, most important, it benefits the consumer, the wage earner, the taxpayer, and the family.

I support this legislation because it is a reform of Federal regulations, not a rollback. And the distinction is extremely important. I am an environmentalist and honored to be called an environmentalist. On this floor, I have fought many battles to stop ocean dumping and incineration, to preserve the northern coastal plain of Alaska, to protect forests and precious wildlife. I can say with pride that Federal regulations have made our air cleaner. They have made our water purer, and they have improved conditions in our cities, lakes, and along our shores.

Regulation in itself is not bad. The problem is that the huge regulatory enterprise, like that runaway train, has gained so much inertia these past few decades that it is posing a real and dangerous threat to our future. What we are looking for is balance, and this legislation provides that balance. It will restore common sense to the regulatory process.

This legislation helps us achieve necessary regulation in the most flexible and cost-effective way possible. We have learned with experience that regulations often have been more costly and less effective than they could have been. This legislation addresses that problem by making Government more efficient, more effective. I believe, as best they can, regulators should issue regulations whose benefits justify their cost. I believe that a fair, common-sense test requiring that the benefits of a regulation justify its cost should be consistent with environmentalism, not contrary to it.

Environmentalists and conservationists have long recognized that we live in a world of limited resources. In this vein, we must use those limited resources to achieve the greatest benefit at the least cost. This is absolutely consistent with our objectives.

Throughout my career, Mr. President, I have advocated reducing Government waste and inefficiency. I have led efforts to reduce waste in Government procurement practices, particularly in defense contracts. At the time, some critics suggested that I was undermining support for a strong military. How could I support a strong military, they asked, if I challenged the practices of the Department of Defense? The answer was simple. I pushed for reform to make the Department of Defense work better, reform to make it more efficient and effective in carrying out its mission. And toward this end, we have been successful. Our reform of the procurement process improved the department. DOD was strengthened as precious resources were spared to be used much more efficiently and effectively.

In the same way, as a committed environmentalist, I want to reduce the inefficiency of the Environmental Protection Agency as well as other Federal

agencies that serve the public interest. Some critics suggest that we cannot support strong cost benefit analysis, and the Dole-Johnston compromise bill requires and still favors protecting the environment, health and safety, but these critics are wrong. Without effective regulatory reform, the EPA and other agencies will not carry out their mission in an efficient and effective manner.

Mr. President, this legislation simply requires commonsense in the regulatory process. We should require no less. I urge my colleagues to support this commonsense legislation. Thank you, Mr. President.

Mr. JOHNSTON. Mr. President, I yield 10 minutes to the Senator from Ohio, with the understanding that he will yield some time to Senator LEVIN.

The PRESIDING OFFICER. The Senator from Louisiana has 13 minutes total remaining.

The Senator from Ohio is recognized.

Mr. GLENN. Mr. President, I hope that when the press writes about what happened on the floor today, they get away from the idea that this is the ultimate in confrontation, which seems to be what the questions lead to when we go out of the Chamber—talking about regulatory reform—because, today, I would hope the message would go out that we are united in the Senate of the United States, Democrat and Republican, on one thing: we need regulatory reform.

Sometimes we get strident here and give people the wrong impression. But we have a need for regulatory reform, and that is felt by those who have been negotiating on the particulars of this legislation over the past several days. So the importance of regulatory reform is well understood, and we all share in a devotion to what we are trying to do here.

I think a lot of people wonder why we have regulations and rules. We need to remember that we pass laws here on the Senate floor, in the Congress, that are signed by the President requiring agencies to issue rules. After we pass laws, rules and regulations written by the agencies become applicable in every community across this country.

I say to those listening that your children today, your family today, can have milk that is safe because of rules and regulations. You can eat food that is safe. You do not have to worry about it, because of rules and regulations to ensure safety to public health. Transportation, whether by air, bus, or plane, comes under certain rules and regulations that let your family travel safely.

The problem is that we have gone too far in some of these matters with some rules, and some regulation writers have been overzealous.

So we have come full circle in needing to put a rein on some of the rules and regulations. We need to set up new processes for making sure that we do not get into the quagmires of where we do not use common sense. Some of

them are ridiculous. We can all cite anecdotal evidence.

On the Governmental Affairs Committee, we started working on what was landmark regulatory reform, doing a study back in 1977. This issue is not something that is brand new. Through the years, we dealt with OMB and OIRA, and it has been an open process.

While I was chair of the committee, we had a number of hearings, and this year, Senator ROTH, our chairman this year, has had four hearings on our bill, S. 291. We took a bipartisan and deliberative approach to it and voted that bill out of committee, unanimously, 15-0. Republicans and Democrats united together.

Any bill must have a balance. On the Governmental Affairs Committee, I believe we achieved that balance. I would like to run through very briefly some of the central issues for regulatory reform in the limited time I have here today.

My approach, and the approach taken by our committee, on regulatory reform is the following: First, agencies should be required to perform risk assessment and cost-benefit analysis for all major rules; second, cost-benefit analysis should inform agency decisionmaking, but it should not override other statutory rulemaking criteria; third, risk assessment requirements should apply only to major risk assessments, and these requirements must not be overly prescriptive; fourth, agencies should review existing rules, but the reviews should not be dictated by special interests; fifth, Government accountability requires sunshine in the regulatory review process; sixth, judicial review should be available to ensure the final agency rules are based on adequate analysis; it should not be a lawyer's dream with unending ways for special interest to bog down agencies with litigation; seventh, regulatory reform should not be the fix for every special interest.

Now, Mr. President, the Senator from Louisiana mentioned a number of the areas that are still in contention with this legislation. While we will have to work these issues out, we are all united in the need for regulatory reform.

The decision criteria: Will it be least cost, or will it be the cost effectiveness? Judicial reform has yet to be ironed out completely. Can we get a threshold of \$100 million? How about the petition process, the sunset, special interest additions? These are issues we still need to work together on. We have yet to iron out exactly how we do these things.

Mr. President, any bill on the subject of regulatory reform to be deserving of support must pass a test. This test is twofold. I close with this: No. 1, does the bill provide for reasonable, logical, appropriate changes to regulatory procedures that eliminate unnecessary burdens on businesses and individuals? No. 2, at the same time, does the bill maintain the ability to protect the

health, the safety, and the environment of the American people?

Now, that is a dual test that is very simple, and one we need to keep in mind as we debate this legislation. If the answer is "yes," to both questions, the bill should be supported. Any bill that relieves regulatory burdens but threatens the protections for the American people in health or safety or environment should be opposed.

I will come back to this test many times when we debate regulatory reform the rest of this week and after the Fourth of July break.

I thank my colleague from Louisiana for yielding time. I yield the balance of my time to Senator LEVIN.

The PRESIDING OFFICER. The Senator from Michigan has 6 minutes remaining.

Mr. LEVIN. Let me commend all those involved in this effort. It is a very complicated effort, and most importantly perhaps, an essential and bipartisan effort. It has been that way from the beginning. I hope it stays that way throughout this process.

The original bill which was introduced was flawed. It did not achieve both goals we need to achieve, which is regulatory reform, to make this process more responsive to cost, to allow Members to review rules. We all, I hope, want to do that.

We all, I hope, want cost effective rules. We all, I hope, want to try to protect some basic health, safety, and environmental concerns. And I think we all believe that we can achieve all of that.

The original bill which was introduced in the bill that is now pending had some real limitations in those regards. The Senator from Louisiana and the Senator leader, the majority leader, and people on both sides of the aisle worked to come up with a substitute. I think they made some significant progress. They should be commended for it.

After that happened, there were a number of deficiencies that were pointed out by various people—the Senator from Louisiana and others who were open to the process of considering suggestions to improve their product—and we have made some significant progress in our private discussions to improve the so-called Dole-Johnston substitute.

Right now, assuming that the language is agreed upon, even though we have only reached two or three of the key nine issues, there has been some significant changes in that draft, which I think most of the people that have been involved in these negotiations, say represent improvements.

Now, there are still some outstanding issues. For instance, the majority leader and others have said "We don't want a supermandate." This bill is intended to supplement and not to supersede.

Some have raised the question, what happens if the material in this bill, which is intended to supplement, conflicts with what it is intended not to supersede. Then what?

We are assured that the underlying legislation governs. Some have said "Why don't we just simply say that?" The answer has been, "There is no need to because there is no conflict," yet the concern remains, and we are trying to figure out language which will address the concern of those who want to be sure that what the Republican leader says is the intent, the majority leader says is the intent—that there not be a supermandate, in fact, implemented in this bill.

We made some real progress in the so-called petitions area. Before this progress was made, I am afraid we were going to substitute a judicial quagmire for what is already a complicated regulatory process.

Nobody is benefited if we throw to the drowning folks who are drowning in regulations another bucket of water. What they need is a lifeline, not another complicating superstructure of judicial consideration.

That is what I am afraid we were about to do in the so-called petition area, until we had some very fruitful discussions, which have now, I think, reached a point where we can hope to avoid adding a judicial superstructure of huge complication to a regulatory process.

Mr. President, I am glad that these discussions are going to continue. I want to commend, particularly, Senator GLENN, Senator ROTH, others on the Governmental Affairs Committee who have worked on the Governmental Affairs bill which contained so many elements of the bill which we are going to consider during the days that we do consider regulatory reform.

We need regulatory reform. We must have cost benefit analysis. We need risk assessment. But we also need to be sure that what we are achieving protects, in a sensible way, the environment and the health and the safety of the people of the United States.

Some people say, "Why don't you just have the cheapest regulation automatically?" Well, the answer is because the cheapest may not be the most cost effective. Just like the cheapest pair of shoes is not the sensible pair of shoes. The cheapest car is not the best car to buy, or else we would all be driving Yugos.

We need cost-benefit analysis, but that assumes that something which is slightly more costly might have huge benefits, and in that case we surely want to be able to consider the cost effectiveness of the regulation and not be required to always go with what is the cheapest, because that may not be the most cost effective.

I think there is kind of an understanding, almost a consensus that that is correct; that we do not want to be driven always to the cheapest, that a marginal increase might be sensible and might achieve some great benefits and that ought to be permitted under this process.

Let me close by again commending my colleagues on Governmental Af-

fairs, Senators GLENN and ROTH and others; the majority leader and Senator DASCHLE have been critical in this, Senator JOHNSTON, Senator HATCH, and others—so many who have been involved in getting us where we are today. We are making progress. I hope that progress will be allowed to continue and will not be thwarted in any way that is inconsistent with what our common goal is.

I thank the Chair.

The PRESIDING OFFICER. The Senator from Louisiana is recognized. All time has expired.

Mr. JOHNSTON. Mr. President, I ask unanimous consent I be able to proceed for 2 minutes.

The PRESIDING OFFICER. Without objection, it is so ordered.

Mr. JOHNSTON. Mr. President, I commend my colleagues on this side of the aisle who have been involved in this negotiation, particularly Senator LEVIN, Senator GLENN, Senator BIDEN, Senator BAUCUS, Senator KERREY, and Senator LAUTENBERG especially, who have contributed so much in bringing the draft up to where it is now.

As I say, it is not a done deal yet in terms of satisfying everyone's concerns, but it is much, much closer to that than when the Judiciary Committee bill started out.

Mr. President, I am advised it is the majority leader's intention Friday afternoon to withdraw the committee amendments to S. 343 and send the substitute to the desk. That substitute is, in effect, the Dole-Johnston discussion draft filed a few days ago, which is being supplemented by the agreement identified by myself and Senator LEVIN, and with other modifications which we have worked on during these hours.

So I ask unanimous consent that be printed in the RECORD tonight, when submitted to the Chair.

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

On page 33, beginning with line 5, strike all through the end of the bill and insert the following:

#### **SECTION 1. SHORT TITLE.**

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

#### **SEC. 2. DEFINITIONS.**

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

(1) in the matter preceding paragraph (1), by striking "this subchapter" and inserting "this chapter and chapters 7 and 8";

(2) in paragraph (13), by striking "and";

(3) in paragraph (14), by striking the period at the end and inserting "; and"; and

(4) by adding at the end the following new paragraph:

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

#### **SEC. 3. RULEMAKING.**

Section 553 of title 5, United States Code, is amended to read as follows:

##### **"§ 553. Rulemaking**

"(a) **APPLICABILITY.**—This section applies to every rulemaking, according to the provisions thereof, except to the extent that there is involved—

"(1) a matter pertaining to a military or foreign affairs function of the United States;

"(2) a matter relating to the management or personnel practices of an agency;

"(3) an interpretive rule, general statement of policy, guidance, or rule of agency organization, procedure, or practice, unless such rule, statement, or guidance has general applicability and substantially alters or creates rights or obligations of persons outside the agency; or

"(4) a rule relating to the acquisition, management, or disposal by an agency of real or personal property, or of services, that is promulgated in compliance with otherwise applicable criteria and procedures.

"(b) **NOTICE OF PROPOSED RULEMAKING.**—General notice of proposed rulemaking shall be published in the Federal Register, unless all persons subject thereto are named and either personally served or otherwise have actual notice of the proposed rulemaking in accordance with law. Each notice of proposed rulemaking shall include—

"(1) a statement of the time, place, and nature of public rulemaking proceedings;

"(2) a succinct explanation of the need for and specific objectives of the proposed rule, including an explanation of the agency's determination of whether or not the rule is a major rule within the meaning of section 621(5);

"(3) a succinct explanation of the specific statutory basis for the proposed rule, including an explanation of—

"(A) whether the interpretation is clearly required by the text of the statute; or

"(B) if the interpretation is not clearly required by the text of the statute, an explanation that the interpretation is within the range of permissible interpretations of the statute as identified by the agency, and an explanation why the interpretation selected by the agency is the agency's preferred interpretation;

"(4) the terms or substance of the proposed rule;

"(5) a summary of any initial analysis of the proposed rule required to be prepared or issued pursuant to chapter 6;

"(6) a statement that the agency seeks proposals from the public and from State and local governments for alternative methods to accomplish the objectives of the rulemaking that are more effective or less burdensome than the approach used in the proposed rule; and

"(7) a statement specifying where the file of the rulemaking proceeding maintained pursuant to subsection (j) may be inspected and how copies of the items in the file may be obtained.

"(c) **PERIOD FOR COMMENT.**—The agency shall give interested persons not less than 60 days after providing the notice required by subsection (b) to participate in the rulemaking through the submission of written data, views, or arguments.

"(d) **GOOD CAUSE EXCEPTION.**—Unless notice or hearing is required by statute, a final rule may be adopted and may become effective without prior compliance with subsections (b) and (c) and (e) through (g) if the agency for good cause finds that providing notice and public procedure thereon before the rule becomes effective is impracticable, unnecessary, or contrary to the public interest. If a rule is adopted under this subsection, the agency shall publish the rule in the Federal Register with the finding and a succinct explanation of the reasons therefor.

"(e) **PROCEDURAL FLEXIBILITY.**—To collect relevant information, and to identify and elicit full and representative public comment on the significant issues of a particular rulemaking, the agency may use such other procedures as the agency determines are appropriate, including—

"(1) the publication of an advance notice of proposed rulemaking;

"(2) the provision of notice, in forms which are more direct than notice published in the Federal Register, to persons who would be substantially affected by the proposed rule but who are unlikely to receive notice of the proposed rulemaking through the Federal Register;

"(3) the provision of opportunities for oral presentation of data, views, information, or rebuttal arguments at informal public hearings, meetings, and round table discussions, which may be held in the District of Columbia and other locations;

"(4) the establishment of reasonable procedures to regulate the course of informal public hearings, meetings and round table discussions, including the designation of representatives to make oral presentations or engage in direct or cross-examination on behalf of several parties with a common interest in a rulemaking, and the provision of transcripts, summaries, or other records of all such public hearings and summaries of meetings and round table discussions;

"(5) the provision of summaries, explanatory materials, or other technical information in response to public inquiries concerning the issues involved in the rulemaking; and

"(6) the adoption or modification of agency procedural rules to reduce the cost or complexity of the procedural rules.

"(f) **PLANNED FINAL RULE.**—If the provisions of a final rule that an agency plans to adopt are so different from the provisions of the original notice of proposed rulemaking that the original notice did not fairly apprise the public of the issues ultimately to be resolved in the rulemaking or of the substance of the rule, the agency shall publish in the Federal Register a notice of the final rule the agency plans to adopt, together with the information relevant to such rule that is required by the applicable provisions of this section and that has not previously been published in the Federal Register. The agency shall allow a reasonable period for comment on such planned final rule prior to its adoption.

"(g) **STATEMENT OF BASIS AND PURPOSE.**—An agency shall publish each final rule it adopts in the Federal Register, together with a concise statement of the basis and purpose of the rule and a statement of when the rule may become effective. The statement of basis and purpose shall include—

"(1) an explanation of the need for, objectives of, and specific statutory authority for, the rule;

"(2) a discussion of, and response to, any significant factual or legal issues presented by the rule, or raised by the comments on the proposed rule, including a description of the reasonable alternatives to the rule proposed by the agency and by interested persons, and the reasons why such alternatives were rejected;

"(3) a succinct explanation of whether the specific statutory basis for the rule is expressly required by the text of the statute, or if the specific statutory interpretation upon which the rule is based is not expressly required by the text of the statute, an explanation that the interpretation is within the range of permissible interpretations of the statute as identified by the agency, and why the agency has rejected other interpretations proposed in comments to the agency;

"(4) an explanation of how the factual conclusions upon which the rule is based are substantially supported in the rulemaking file; and

"(5) a summary of any final analysis of the rule required to be prepared or issued pursuant to chapter 6.

"(h) **NONAPPLICABILITY.**—In the case of a rule that is required by statute to be made on the record after opportunity for an agen-

cy hearing, sections 556 and 557 shall apply in lieu of subsections (c), (e), (f), and (g).

"(i) **EFFECTIVE DATE.**—An agency shall publish the final rule in the Federal Register not later than 60 days before the effective date of such rule. An agency may make a rule effective in less than 60 days after publication in the Federal Register if the rule grants or recognizes an exemption, relieves a restriction, or if the agency for good cause finds that such a delay in the effective date would be contrary to the public interest and publishes such finding and an explanation of the reasons therefor, with the final rule.

"(j) **RULEMAKING FILE.**—(1) The agency shall maintain a file for each rulemaking proceeding conducted pursuant to this section and shall maintain a current index to such file.

"(2) Except as provided in subsection (k), the file shall be made available to the public not later than the date on which the agency makes an initial publication concerning the rule.

"(3) The rulemaking file shall include—

"(A) the notice of proposed rulemaking, any supplement to, or modification or revision of, such notice, and any advance notice of proposed rulemaking;

"(B) copies of all written comments received on the proposed rule;

"(C) a transcript, summary, or other record of any public hearing conducted on the rulemaking;

"(D) copies, or an identification of the place at which copies may be obtained, of factual and methodological material that pertains directly to the rulemaking and that was considered by the agency in connection with the rulemaking, or that was submitted to or prepared by or for the agency in connection with the rulemaking; and

"(E) any statement, description, analysis, or other material that the agency is required to prepare or issue in connection with the rulemaking, including any analysis prepared or issued pursuant to chapter 6.

The agency shall place each of the foregoing materials in the file as soon as practicable after each such material becomes available to the agency.

"(k) **CONFIDENTIAL TREATMENT.**—The file required by subsection (j) need not include any material described in section 552(b) if the agency includes in the file a statement that notes the existence of such material and the basis upon which the material is exempt from public disclosure under such section. The agency may not substantially rely on any such material in formulating a rule unless it makes the substance of such material available for adequate comment by interested persons. The agency may use summaries, aggregations of data, or other appropriate mechanisms to protect the confidentiality of such material to the maximum extent possible.

"(l) **RULEMAKING PETITION.**—(1) Each agency shall give an interested person the right to petition—

"(A) for the issuance, amendment, or repeal of a rule;

"(B) for the amendment or repeal of an interpretive rule or general statement of policy or guidance;

"(C) for an interpretation regarding the meaning of a rule, interpretive rule, general statement of policy, or guidance; and

"(D) for a variance or exemption from the terms of a rule to which the petitioner is otherwise subject, provided the statute authorizing the rule does not prohibit a variance or exemption.

"(2) The agency shall grant or deny a petition made pursuant to paragraph (1), and give written notice of its determination to the petitioner, with reasonable promptness,

but in no event later than 18 months after the petition was received by the agency.

"(3) The written notice of the agency's determination shall include an explanation of the determination and a response to each significant factual and legal claim that forms the basis of the petition.

"(m) **JUDICIAL REVIEW.**—(1) The decision of an agency to use or not to use procedures in a rulemaking under subsection (e) shall not be subject to judicial review.

"(2) The rulemaking file required under subsection (j) shall constitute the rulemaking record for purposes of judicial review.

"(3) No court shall hold unlawful or set aside an agency rule based on a violation of subsection (j), unless the court finds that such violation has precluded fair public consideration of a material issue of the rulemaking taken as a whole.

"(4)(A) Judicial review of compliance or noncompliance with subsection (j) shall be limited to review of action or inaction on the part of an agency.

"(B) A decision by an agency to deny a petition under subsection (l) shall be subject to judicial review immediately upon denial, as final agency action under the statute granting the agency authority to carry out its action.

"(n) **CONSTRUCTION.**—(1) Notwithstanding any other provision of law, this section shall apply to and supplement the procedures governing informal rulemaking under statutes that are not generally subject to this section.

"(2) Nothing in this section authorizes the use of appropriated funds available to any agency to pay the attorney's fees or other expenses of persons intervening in agency proceedings."

#### SEC. 4. 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—

"(1) except as otherwise provided, the definitions under section 551 shall apply to this subchapter;

"(2) the term 'benefit' means the reasonably identifiable significant favorable effects, including social, environmental, health, and economic effects, that are expected to result directly or indirectly from implementation of a rule or other agency action;

"(3) the term 'cost' means the reasonably identifiable significant adverse effects, including social, environmental, health, and economic effects that are expected to result directly or indirectly from implementation of a rule or other agency action;

"(4) 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;

"(5) the term 'major rule' means—

"(A) a rule or set of closely related rules that the agency proposing the rule, the Director, or a designee of the President determines is likely to have a gross annual effect on the economy of \$50,000,000 or more in reasonably quantifiable increased costs; or

"(B) a rule that is otherwise designated a major rule by the agency proposing the rule, the Director, or a designee of the President

(and a designation or failure to designate under this clause shall not be subject to judicial review);

“(6) the term ‘market-based mechanism’ means a regulatory program 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, where feasible and appropriate, 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 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;

“(7) the term ‘performance-based standards’ means requirements, expressed in terms of outcomes or goals rather than mandatory means of achieving outcomes or goals, that permit the regulated entity discretion to determine how best to meet specific requirements in particular circumstances;

“(8) the term ‘reasonable alternatives’ means the range of reasonable regulatory options that the agency has authority to consider under the statute granting rulemaking authority, including flexible regulatory options of the type described in section 622(c)(2)(C)(iii), unless precluded by the statute granting the rulemaking authority; and

“(9) the term ‘rule’ has the same meaning as in section 551(4), and—

“(A) includes any statement of general applicability that substantially alters or creates rights or obligations of persons outside the agency; and

“(B) does not include—

“(i) a rule that involves the internal revenue laws of the United States, or the assessment and collection of taxes, duties, or other revenues or receipts;

“(ii) subject to section 633(c)(6), a rule or agency action that implements a treaty or international trade agreement to which the United States is a party;

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

“(iv) a rule exempt from notice and public procedure under section 553(a);

“(v) a rule or agency action relating to the public debt;

“(vi) a rule required to be promulgated at least annually pursuant to statute, or that provides relief, in whole or in part, from a statutory prohibition, other than a rule promulgated pursuant to subtitle C of title II of the Solid Waste Disposal Act (42 U.S.C. 6921 et seq.);

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

“(viii) a rule relating to monetary policy or 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, Federal Home Loan Banks, government sponsored housing enterprises, farm credit institutions, foreign banks that operate in the United States and their affiliates, branches, agencies, commercial lending companies, or representative offices, (as those terms are defined in section 1 of the International Banking Act of 1978 (12 U.S.C. 3101));

“(ix) a rule relating to the payment system or the protection of deposit insurance funds or the farm credit insurance fund;

“(x) any order issued in a rate or certificate proceeding by the Federal Energy Regulatory Commission, or a rule of general applicability that the Federal Energy Regulatory Commission certifies would increase reliance on competitive market forces or reduce regulatory burdens;

“(xi) a rule or order relating to the financial responsibility of brokers and dealers or futures commission merchants, the safeguarding of investor securities and funds or commodity future or options customer securities and funds, the clearance and settlement of securities, futures, or options transactions, or the suspension of trading under the Securities Exchange Act of 1934 (15 U.S.C. 78a et seq.) or emergency action taken under the Commodity Exchange Act (7 U.S.C. 1 et seq.), or a rule relating to the protection of the Securities Investor Protection Corporation, that is promulgated under the Securities Investor Protection Act of 1970 (15 U.S.C. 78aaa et seq.); or

“(xii) a rule that involves the international trade laws of the United States.

#### “§ 622. Rulemaking cost-benefit analysis

“(a) DETERMINATION OF MAJOR RULE.—Prior to publishing a notice of proposed rulemaking for any rule (or, in the case of a notice of proposed rulemaking that has been published but not issued on or before the date of enactment of this subchapter, not later than 30 days after such date of enactment), each agency shall determine whether the rule is or is not a major rule within the meaning of section 621(5)(A)(i) and, if it is not, whether it should be designated as a major rule under section 621(5)(A)(ii).

“(b) DESIGNATION.—(i) If an agency has determined that a rule is not a major rule within the meaning of section 621(5)(A)(i) and has not designated the rule as a major rule within the meaning of section 621(5)(A)(ii), the Director or a designee of the President may, as appropriate, determine that the rule is a major rule or designate the rule as a major rule not 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 date of enactment of this subchapter, not later than 1 year after such date of enactment).

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

“(c) INITIAL COST-BENEFIT ANALYSIS.—(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 an agency, the Director, or a designee of the President has published a determination or designation 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 in the same manner as if the initial cost-benefit analysis had been issued with the notice of proposed rulemaking.

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

“(A) a succinct analysis of the benefits of the proposed rule, including any beneficial

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

“(C) a succinct description (including an analysis of the costs and benefits) of reasonable alternatives for achieving the identified benefits of the proposed rule, including, where such alternatives exist, alternatives that—

“(i) require no government action, where the agency has discretion under the statute granting the rulemaking authority not to promulgate a rule;

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

“(iii) employ performance-based standards, market-based mechanisms, or other flexible regulatory options that permit the greatest flexibility in achieving the regulatory result that the statutory provision authorizing the rule is designed to produce; or

“(iv) employ voluntary standards;

“(D) in any case in which the proposed rule is based on one or more scientific evaluations, scientific information, or a risk assessment, or is subject to the risk assessment requirements of subchapter III, a description of the actions undertaken by the agency to verify the quality, reliability, and relevance of such scientific evaluation, scientific information, or risk assessment; and

“(E) an explanation of whether the proposed rule is likely to meet the decisional criteria of section 624.

“(d) FINAL COST-BENEFIT ANALYSIS.—(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 record, including flexible regulatory options of the type described in subsection (c)(2)(C)(iii), and a description of the persons likely to receive such benefits and bear such costs; and

“(B) an analysis, based upon the rulemaking record considered as a whole, of whether and how the rule meets the decisional criteria in section 624.

“(3) In considering the benefits and costs, the agency, when appropriate, shall consider the benefits and costs incurred by all of the affected persons or classes of persons (including specially affected subgroups).

“(e) REQUIREMENTS FOR COST-BENEFIT ANALYSES.—(1)(A) The description 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.

“(B) The quantification or numerical estimate shall—

“(i) be made in the most appropriate unit of measurement, using comparable assumptions, including time periods;

“(ii) specify the ranges of predictions; and

“(iii) explain the margins of error involved in the quantification methods and the uncertainties and variabilities in the estimates used.

“(C) 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.

“(D) The agency evaluation of the relationship of benefits to costs shall be clearly articulated.

“(E) An agency shall not be required to make such evaluation primarily on a mathematical or numerical basis.

“(F) Nothing in this subsection shall be construed to expand agency authority beyond the delegated authority arising from the statute granting the rulemaking authority.

“(2) Where practicable and when understanding industry-by-industry effects is of central importance to a rulemaking, the description of the benefits and costs of a proposed and final rule required under this section shall describe such benefits and costs on an industry by industry basis.

“(f) HEALTH, SAFETY, OR EMERGENCY EXEMPTION FROM COST-BENEFIT ANALYSIS.—(1) A major rule may be adopted and may become effective without prior compliance with this subchapter if—

“(A) the agency for good cause finds that conducting cost-benefit analysis is impracticable due to an emergency or health or safety threat that is likely to result in significant harm to the public or natural resources; and

“(B) the agency publishes in the Federal Register, together with such finding, a succinct statement of the basis for the finding.

“(2) Not later than 180 days after the promulgation of a final major rule to which this section applies, the agency shall comply with the provisions of this subchapter and, if thereafter necessary, revise the rule.

#### “§ 623. Agency regulatory review

“(a) PRELIMINARY SCHEDULE FOR RULES.—(1) Not later than 1 year after the date of the enactment of this section, and every 5 years thereafter, the head of each agency shall publish in the Federal Register a notice of proposed rulemaking under section 553 that contains a preliminary schedule of rules selected for review under this section by the head of the agency and in the sole discretion of the head of the agency, and request public comment thereon, including suggestions for additional rules warranting review. The agency shall allow at least 180 days for public comment.

“(2) In selecting rules for the preliminary schedule, the head of the agency shall consider the extent to which, in the judgment of the head of the agency—

“(A) a rule is unnecessary, and the agency has discretion under the statute authorizing the rule to repeal the rule;

“(B) a rule would not meet the decisional criteria of section 624, and the agency has discretion under the statute authorizing the rule to repeal the rule; or

“(C) a rule could be revised in a manner allowed by the statute authorizing the rule so as to meet the decisional criteria of section 624 and to—

“(i) substantially decrease costs;

“(ii) substantially increase benefits; or

“(iii) provide greater flexibility for regulated entities, through mechanisms including, but not limited to, those listed in section 622(c)(2)(C)(iii).

“(3) The preliminary schedule under this subsection shall propose deadlines for review of each rule listed thereon, and such deadlines shall occur not later than 11 years from the date of publication of the preliminary schedule.

“(4) Any interpretive rule, general statement of policy, or guidance that has the force and effect of a rule under section 621(9) shall be treated as a rule for purposes of this section.

“(b) SCHEDULE.—(1) Not later than 1 year after publication of a preliminary schedule under subsection (a), and subject to subsection (c), the head of each agency shall publish a final rule that establishes a schedule of rules to be reviewed by the agency under this section.

“(2) The schedule shall establish a deadline for completion of the review of each rule listed on the schedule, taking into account the criteria in subsection (d) and comments received in the rulemaking under subsection (a). Each such deadline shall occur not later than 11 years from the date of publication of the preliminary schedule.

“(3) The schedule shall contain, at a minimum, all rules listed on the preliminary schedule.

“(4) The head of the agency shall modify the agency's schedule under this section to reflect any change ordered by the court under subsection (e) or subsection (g)(3) or contained in an appropriations Act under subsection (f).

“(c) PETITIONS AND COMMENTS PROPOSING ADDITION OF RULES TO THE SCHEDULE.—(1) Notwithstanding section 553(j), a petition to amend or repeal a major rule or an interpretive rule, general statement of policy, or guidance may only be filed during the 180-day comment period under subsection (a) and not at any other time. Such petition shall be reviewed only in accordance with this subsection.

“(2) The head of the agency shall, in response to petitions received during the rulemaking to establish the schedule, place on the final schedule for review within the first 3 years of the schedule any rule for which a petition, on its face, together with any relevant comments received in the rulemaking under subsection (a), establishes that there is a substantial likelihood that, considering the future impact of the rule—

“(A) the rule is a major rule under section 621(5)(A); and

(B) the head of the agency would not be able to make the findings required by section 624 with respect to the rule.

“(3) For the purposes of paragraph (2), the head of the agency may consolidate multiple petitions on the same rule into 1 determination with respect to review of the rule.

“(4) The head of the agency may, at the sole discretion of the head of the agency, add to the schedule any other rule suggested by a commentator during the rulemaking under subsection (a).

“(d) CRITERIA FOR ESTABLISHING DEADLINES FOR REVIEW.—The schedules in subsections (a) and (b) shall establish deadlines for review of each rule on the schedule that take into account—

“(i) the extent to which, for a particular rule, the preliminary views of the agency are that—

“(A) the rule is unnecessary, and the agency has discretion under the statute authorizing the rule to repeal the rule;

“(B) the rule would not meet the decisional criteria of section 624, and the agency has discretion under the statute authorizing the rule to repeal the rule; or

“(C) the rule could be revised in a manner allowed by the statute authorizing the rule so as to meet the decisional criteria under section 624 and to—

“(i) substantially decrease costs;

“(ii) substantially increase benefits; or

“(iii) provide greater flexibility for regulated entities, through mechanisms including, but not limited to, those listed in section 622(c)(2)(C)(iii);

“(2) the importance of each rule relative to other rules being reviewed under this section; and

“(3) the resources expected to be available to the agency under subsection (f) to carry out the reviews under this section.

“(e) JUDICIAL REVIEW.—(1) Notwithstanding section 625 and except as provided otherwise in this subsection, agency compliance or noncompliance with the requirements of this section shall be subject to judicial review in accordance with section 706 of this title.

“(2) The United States Court of Appeals for the District of Columbia Circuit shall have exclusive jurisdiction to review agency action pursuant to subsection (b) and subsection (c).

“(3) A petition for review of final agency action under subsection (b) or subsection (c) shall be filed not later than 60 days after the agency publishes the final rule under subsection (b).

“(4) The court upon review, for good cause shown, may extend the 3-years deadline under subsection (c)(2) for a period not to exceed an additional year.

“(5) The court shall remand to the agency any schedule under subsection (b) only if final agency action under subsection (b) is arbitrary or capricious. Agency action under subsection (d) shall not be subject to judicial review.

“(f) ANNUAL BUDGET.—(1) The President's annual budget proposal submitted under section 1105(a) of title 31 for each agency subject to this section shall—

“(A) identify as a separate sum the amount requested to be appropriated for implementation of this section during the upcoming fiscal year; and

“(B) include a list of rules which may terminate during the year for which the budget proposal is made.

“(2) Amendments to the schedule under subsection (b) that change a deadline for review of a rule may be included in annual appropriations Acts for the relevant agencies. An authorizing committee with jurisdiction may submit, to the House of Representatives or Senate appropriations committee (as the case may be), amendments to the schedule published by an agency under subsection (b) that change a deadline for review of a rule. The appropriations committee to which such amendments have been submitted shall include or propose the amendments in the annual appropriations Act for the relevant agency. Each agency shall modify its schedule under subsection (b) to reflect such amendments.

“(g) REVIEW OF RULE.—(1) For each rule on the schedule under subsection (b), the agency shall—

“(A) not later than 2 years before the deadline in such schedule, publish in the Federal Register a notice that solicits public comment regarding whether the rule should be continued, amended, or repealed;

“(B) not later than 1 year before the deadline in such schedule, publish in the Federal Register a notice that—

“(i) addresses public comments generated by the notice in subparagraph (A);

“(ii) contains a preliminary analysis provided by the agency of whether the rule is a major rule, and if so, whether it satisfies the decisional criteria of section 624;

“(iii) contains a preliminary determination as to whether the rule should be continued, amended, or repealed; and

“(iv) solicits public comment on the preliminary determination for the rule; and

“(C) not later than 60 days before the deadline in such schedule, publish in the Federal Register a final notice on the rule that—

“(i) addresses public comments generated by the notice in subparagraph (B); and

"(ii) contains a final determination of whether to continue, amend, or repeal the rule; and

"(iii) if the agency determines to continue the rule and the rule is a major rule, contains findings necessary to satisfy the decisional criteria of section 624; and

"(iv) if the agency determines to amend the rule, contains a notice of proposed rulemaking under section 553.

"(2) If the final determination of the agency is to continue or repeal the rule, that determination shall take effect 60 days after the publication in the Federal Register of the notice in paragraph (1)(C).

"(3) An interested party may petition the U.S. Court of Appeals for the District of Columbia Circuit to extend the period for review of a rule on the schedule for up to two years and to grant such equitable relief as is appropriate, if such petition establishes that—

"(A) the rule is likely to terminate under subsection (i);

"(B) the agency needs additional time to complete the review under this subsection;

"(C) terminating the rule would not be in the public interest; and

"(D) the agency has not expeditiously completed its review.

"(h) DEADLINE FOR FINAL AGENCY ACTION ON MODIFIED RULE.—If an agency makes a determination to amend a major rule under subsection (g)(1)(C)(ii), the agency shall complete final agency action with regard to such rule not later than 2 years of the date of publication of the notice in subsection (g)(1)(C) containing such determination. Nothing in this subsection shall limit the discretion of an agency to decide, after having proposed to modify a major rule, not to promulgate such modification. Such decision shall constitute final agency action for the purposes of judicial review.

"(i) TERMINATION OF RULES.—If the head of an agency has not completed the review of a rule by the deadline established in the schedule published or modified pursuant to subsection (b) and subsection (c), the head of the agency shall not enforce the rule, and the rule shall terminate by operation of law as of such date.

"(j) FINAL AGENCY ACTION.—(1) The final determination of an agency to continue or repeal a major rule under subsection (g)(1)(C) shall be considered final agency action.

"(2) Failure to promulgate an amended major rule or to make other decisions required by subsection (h) by the date established under such subsection shall be considered final agency action.

#### **"§624. Decisional criteria**

"(a) CONSTRUCTION WITH OTHER LAWS.—The requirements of this section shall supplement, and not supersede, any other decisional criteria otherwise provided by law.

"(b) REQUIREMENTS.—Except as provided in subsection (c), no final major rule subject to this subchapter shall be promulgated unless the agency head publishes in the Federal Register a finding that—

"(1) the benefits from the rule justify the costs of the rule;

"(2) the rule employs to the extent practicable flexible reasonable alternatives of the type described in section 622(c)(2)(C)(iii); and

"(3)(A) the rule adopts the least cost alternative of the reasonable alternatives that achieves the objectives of the statute; or

"(B) if scientific, technical, or economic uncertainties or nonquantifiable benefits to health, safety, or the environment identified by the agency in the rulemaking record make a more costly alternative that achieves the objectives of the statute appropriate and in the public interest and the agency head provides an explanation of those considerations, the rule adopts the least cost alternative of the reasonable alternatives necessary to take into account such uncertainties or benefits; and

"(4) if a risk assessment is required by section 632—

"(A) the rule is likely to significantly reduce the human health, safety, and environmental risks to be addressed; or

"(B) if scientific, technical, or economic uncertainties or nonquantifiable benefits to health, safety, or the environment, preclude making the finding under subparagraph (A), promulgating the final rule is nevertheless justified for reasons stated in writing accompanying the rule and consistent with subchapter III.

"(c) ALTERNATIVE REQUIREMENTS.—If, applying the statutory requirements upon which the rule is based, a rule cannot satisfy the criteria of subsection (b), the agency head may promulgate the rule if the agency head finds that—

"(1) the rule employs to the extent practicable flexible reasonable alternatives of the type described in section 622(c)(2)(C)(iii);

"(2)(A) the rule adopts the least cost alternative of the reasonable alternatives that achieves the objectives of the statute; or

"(B) if scientific, technical, or economic uncertainties or nonquantifiable benefits to health, safety, or the environment identified by the agency in the rulemaking record make a more costly alternative that achieves the objectives of the statute appropriate and in the public interest, and the agency head provides an explanation of those considerations, the rule adopts the least cost alternative of the reasonable alternatives necessary to take into account such uncertainties or benefits; and

"(3) if a risk assessment is required by section 632—

"(A) the rule is likely to significantly reduce the human health, safety, and environmental risks to be addressed; or

"(B) if scientific, technical, or economic uncertainties or nonquantifiable benefits to health, safety, or the environment, preclude making the finding under subparagraph (A), promulgating the final rule is nevertheless justified for reasons stated in writing accompanying the rule and consistent with subchapter III.

"(d) PUBLICATION OF REASONS FOR NON-COMPLIANCE.—If an agency promulgates a rule to which subsection (c) applies, the agency head shall prepare a written explanation of why the agency was required to promulgate a rule that does not satisfy the criteria of subsection (b) and shall transmit the explanation with the final cost-benefit analysis to Congress when the final rule is promulgated.

#### **"§625. Jurisdiction and judicial review**

"(a) REVIEW.—Compliance or noncompliance by an agency with the provisions of this subchapter and subchapter III shall be subject to judicial review only in accordance with this section.

"(b) JURISDICTION.—(1) Subject to paragraph (2), each court with jurisdiction under a statute to review final agency action to which this title applies, has jurisdiction to review any claims of noncompliance with this subchapter and subchapter III.

"(2) No claims of noncompliance with this subchapter or subchapter III shall be reviewed separate or apart from judicial review of the final agency action to which they relate.

"(c) RECORD.—Any analysis or review required under this subchapter or subchapter III shall constitute part of the rulemaking record of the final agency action to which it pertains for the purposes of judicial review.

"(d) STANDARDS FOR REVIEW.—In any proceeding involving judicial review under section 706 or under the statute granting the rulemaking authority, failure to comply with this subchapter or subchapter III may be considered by the court solely for the purpose of determining whether the final agency action is arbitrary and capricious or an abuse of discretion (or unsupported by substantial evidence where that standard is otherwise provided by law).

"(e) INTERLOCUTORY REVIEW.—(1) The United States Court of Appeals for the District of Columbia Circuit shall have jurisdiction to review—

"(A) an agency determination that a rule is not a major rule pursuant to section 622(a); and

"(B) an agency determination that a risk assessment is not required pursuant to section 632(a).

"(2) A petition for review of agency action under paragraph (1) shall be filed within 60 days after the agency makes the determination or certification for which review is sought.

"(3) Except as provided in this subsection, no court shall have jurisdiction to review any agency determination or certification specified in paragraph (1).

#### **"§626. Deadlines for rulemaking**

"(a) STATUTORY.—All deadlines in statutes that require agencies to propose or promulgate any rule subject to section 622 or subchapter III during the 5-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 2 years after the date of the applicable deadline.

"(b) COURT-ORDERED.—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 5-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 2 years after the date of the applicable deadline.

"(c) OBLIGATION TO REGULATE.—In any case in which the failure to promulgate a rule by a deadline occurring during the 5-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 2 years after the date of the applicable deadline.

#### **"§627. Special rule**

"Notwithstanding any other provision of the Comprehensive Regulatory Reform Act of 1995, or the amendments made by such Act, for purposes of this subchapter and subchapter IV, the head of each appropriate Federal banking agency (as defined in section 3(q) of the Federal Deposit Insurance Act), the National Credit Union Administration, the Federal Housing Finance Board, the Office of Federal Housing Enterprise Oversight, and the Farm Credit Administration, shall have authority with respect to such agency that otherwise would be provided under such subchapters to the Director, a designee of the President, Vice President, or any officer designated or delegated with authority under such subchapters.

#### **"§628. Requirements for major environmental management activities**

"(a) DEFINITION.—For purposes of this section, the term 'major environmental management activity' means—



"(1) a corrective action requirement under the Solid Waste Disposal Act;

"(2) a response action or damage assessment under the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (42 U.S.C. 9601 et seq.);

"(3) the treatment, storage, or disposal of radioactive or mixed waste in connection with site restoration activity; and

"(4) Federal guidelines for the conduct of such activity, including site-specific guidelines,

the expected costs, expenses, and damages of which are likely to exceed, in the aggregate, \$10,000,000.

"(b) **APPLICABILITY.**—A major environmental management activity is subject to this section unless construction has commenced on a significant portion of the activity, and—

"(1) it is more cost-effective to complete construction of the work than to apply the provisions of this subchapter; or

"(2) the application of the provisions of this subchapter, including any delays caused thereby, will result in an actual and immediate risk to human health or welfare.

"(c) **REQUIREMENT TO PREPARE RISK ASSESSMENT.**—(1) For each major environmental management activity or significant unit thereof that is proposed by the agency after the date of enactment of this subchapter, is pending on the date of enactment of this subchapter, or is subject to a granted petition for review pursuant to section 623, the head of an agency shall prepare—

"(A) a risk assessment in accordance with subchapter III; and

"(B) a cost-benefit analysis equivalent to that which would be required under this subchapter, if such subchapter were applicable.

"(2) In conducting a risk assessment or cost-benefit analysis under this section, the head of the agency shall incorporate the reasonably anticipated probable future use of the land and its surroundings (and any associated media and resources of either) affected by the environmental management activity.

"(3) For actions pending on the date of enactment of this section or proposed during the year following the date of enactment of this section, in lieu of preparing a risk assessment in accordance with subchapter III or cost-benefit analysis under this subchapter, an agency may use other appropriately developed analyses that allow it to make the judgments required under subsection (d).

"(d) **REQUIREMENT.**—The requirements of this subsection shall supplement, and not supersede, any other requirement provided by any law. A major environmental management activity under this section shall meet the decisional criteria under section 624 as if it is a major rule under such section.

#### "SUBCHAPTER III—RISK ASSESSMENTS

##### "§ 631. Definitions

"For purposes of this subchapter—

"(1) except as otherwise provided, the definitions under section 551 shall apply to this subchapter;

"(2) the term 'exposure assessment' means the scientific determination of the intensity, frequency and duration of actual or potential exposures to the hazard in question;

"(3) the term 'hazard assessment' means the scientific determination of whether a hazard can cause an increased incidence of one or more significant adverse effects, and a scientific evaluation of the relationship between the degree of exposure to a perceived cause of an adverse effect and the incidence and severity of the effect;

"(4) the term 'major rule' has the meaning given such term in section 621(5);

"(5) the term 'risk assessment' means the systematic process of organizing and analyz-

ing scientific knowledge and information on potential hazards, including as appropriate for the specific risk involved, hazard assessment, exposure assessment, and risk characterization;

"(6) the term 'risk characterization' means the integration and organization of hazard and exposure assessment to estimate the potential for specific harm to an exposed population or natural resource including, to the extent feasible, a characterization of the distribution of risk as well as an analysis of uncertainties, variabilities, conflicting information, and inferences and assumptions in the assessment;

"(7) the term 'screening analysis' means an analysis using simple conservative postulates to arrive at an estimate of upper and lower bounds as appropriate, that permits the manager to eliminate risks from further consideration and analysis, or to help establish priorities for agency action; and

"(8) the term 'substitution risk' means an increased risk to human health, safety, or the environment reasonably likely to result from a regulatory option.

##### "§ 632. Applicability

"(a) **IN GENERAL.**—Except as provided in subsection (c), for each proposed and final major rule, a primary purpose of which is to protect human health, safety, or the environment, or a consequence of which is a substantial substitution risk, that is proposed by an agency after the date of enactment of this subchapter, or is pending on the date of enactment of this subchapter, the head of each agency shall prepare a risk assessment in accordance with this subchapter.

"(b) **APPLICATION OF PRINCIPLES.**—(1) Except as provided in subsection (c), the head of each agency shall apply the principles in this subchapter to any risk assessment conducted to support a determination by the agency of risk to human health, safety, or the environment, if such determination would be likely to have an effect on the United States economy equivalent to that of a major rule.

"(2) In applying the principles of this subchapter to risk assessments other than those in subsections (a), (b)(1), and (c), the head of each agency shall publish, after notice and public comment, guidelines for the conduct of such other risk assessments that adopt the principles of this subchapter in a manner consistent with section 633(a)(4) and the risk assessment and risk management needs of the agency.

"(3) An agency shall not, as a condition for the issuance or modification of a permit, conduct, or require any person to conduct, a risk assessment, except if the agency finds that the risk assessment meets the requirements of section 633 (a) through (f).

"(c) **EXCEPTIONS.**—(1) This subchapter shall not apply to risk assessments performed with respect to—

"(A) a situation for which the agency finds good cause that conducting a risk assessment is impracticable due to an emergency or health and safety threat that is likely to result in significant harm to the public or natural resources;

"(B) a rule or agency action that authorizes the introduction into commerce, or initiation of manufacture, of a substance, mixture, or product, or recognizes the marketable status of a product;

"(C) a human health, safety, or environmental inspection, an action enforcing a statutory provision, rule, or permit, or an individual facility or site permitting action, except to the extent provided by subsection (b)(3);

"(D) a screening analysis clearly identified as such; or

"(E) product registrations, reregistrations, tolerance settings, and reviews of

premanufacture notices under the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136 et seq.) and the Toxic Substances Control Act (15 U.S.C. 2601 et seq.).

"(2) An analysis shall not be treated as a screening analysis for the purposes of paragraph (1)(D) if the result of the analysis is used—

"(A) as the basis for imposing a restriction on a previously authorized substance, product, or activity after its initial introduction into manufacture or commerce; or

"(B) as the basis for a formal determination by the agency of significant risk from a substance or activity.

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

##### "§ 633. Principles for risk assessments

"(a) **IN GENERAL.**—(1) The head of each agency shall design and conduct risk assessments in a manner that promotes rational and informed risk management decisions and informed public input into the process of making agency decisions.

"(2) The head of each agency shall establish and maintain a distinction between risk assessment and risk management.

"(3) An agency may take into account priorities for managing risks, including the types of information that would be important in evaluating a full range of alternatives, in developing priorities for risk assessment activities.

"(4) In conducting a risk assessment, the head of each agency shall employ the level of detail and rigor considered by the agency as appropriate and practicable for reasoned decisionmaking in the matter involved, proportionate to the significance and complexity of the potential agency action and the need for expedition.

"(5) An agency shall not be required to repeat discussions or explanations in each risk assessment required under this subchapter if there is an unambiguous reference to a relevant discussion or explanation in another reasonably available agency document that was prepared consistent with this section.

"(b) **ITERATIVE PROCESS.**—(1) Each agency shall develop and use an iterative process for risk assessment, starting with relatively inexpensive screening analyses and progressing to more rigorous analyses, as circumstances or results warrant.

"(2) In determining whether or not to proceed to a more detailed analysis, the head of the agency shall take into consideration whether or not use of additional data or the analysis thereof would significantly change the estimate of risk and the resulting agency action.

"(c) **DATA QUALITY.**—(1) The head of each agency shall base each risk assessment only on the best reasonably available scientific data and scientific understanding, including scientific information that finds or fails to find a correlation between a potential hazard and an adverse effect, and data regarding exposure and other relevant physical conditions that are reasonably expected to be encountered.

"(2) The agency shall select data for use in a risk assessment based on a reasoned analysis of the quality and relevance of the data, and shall describe such analysis.

"(3) In making its selection of data, the agency shall consider whether the data were published in the peer-reviewed scientific literature, or developed in accordance with good laboratory practice or published or other appropriate protocols to ensure data quality, such as the standards for the development of test data promulgated pursuant to section 4 of the Toxic Substances Control Act (15 U.S.C. 2603), and the standards for

data requirements promulgated pursuant to section 3 of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136a), or other form of independent evaluation.

"(4) Subject to paragraph (3), relevant scientific data submitted by interested parties shall be reviewed and considered by the agency in the analysis under paragraph (2).

"(5) When conflicts among scientific data appear to exist, the risk assessment shall include a discussion of all relevant information including the likelihood of alternative interpretations of the data and emphasizing—

"(A) postulates that represent the most reasonable inferences from the supporting scientific data; and

"(B) when a risk assessment involves an extrapolation from toxicological studies, data with the greatest scientific basis of support for the resulting harm to affected individuals, populations, or resources.

"(6) The head of an agency shall not automatically incorporate or adopt any recommendation or classification made by any foreign government, the United Nations, any international governmental body or standards-making organization, concerning the health effects value of a substance except as provided in paragraph (2) of this subsection. Nothing in this paragraph shall be construed to affect the implementation or application of any treaty or international trade agreement to which the United States is a party.

"(d) USE OF POLICY JUDGMENTS.—(1) To the maximum extent practicable, each agency shall use policy judgments, including default assumptions, inferences, models or safety factors, only when relevant scientific data and scientific understanding, including site-specific data, are lacking. The agency shall modify or decrease the use of policy judgments to the extent that higher quality scientific data and understanding become available.

"(2) When a risk assessment involves choice of a postulate, the head of the agency shall—

"(A) identify the postulate and its scientific or policy basis, including the extent to which the policy judgment has been validated by, or conflicts with, empirical data;

"(B) explain the basis for any choices among policy judgments; and

"(C) describe reasonable alternative policy judgments that were not selected by the agency for use in the risk assessment, and the sensitivity of the conclusions of the risk assessment to the alternatives, and the rationale for not using such alternatives.

"(3) An agency shall not inappropriately combine or compound multiple policy judgments.

"(4) The agency shall, subject to notice and opportunity for public comment, develop and publish guidelines describing the agency's default policy judgments and how they were chosen, and guidelines for deciding when and how, in a specific risk assessment, to adopt alternative policy judgments or to use available scientific information in place of a policy judgment.

"(e) RISK CHARACTERIZATION.—In each risk assessment, the agency shall include in the risk characterization, as appropriate, each of the following:

"(1) A description of the hazard of concern.

"(2) A description of the populations or natural resources that are the subject of the risk assessment.

"(3) An explanation of the exposure scenarios used in the risk assessment, including an estimate of the corresponding population at risk and the likelihood of such exposure scenarios.

"(4) A description of the nature and severity of the harm that could plausibly occur.

"(5) A description of the major uncertainties in each component of the risk assess-

ment and their influence on the results of the assessment.

"(f) PRESENTATION OF RISK ASSESSMENT CONCLUSIONS.—(1) To the extent feasible and scientifically appropriate, the head of an agency shall—

"(A) express the overall estimate of risk as a range or probability distribution that reflects variabilities, uncertainties and data gaps in the analysis;

"(B) provide the range and distribution of risks and the corresponding exposure scenarios, identifying the reasonably expected risk to the general population and, where appropriate, to more highly exposed or sensitive subpopulations; and

"(C) where quantitative estimates of the range and distribution of risk estimates are not available, describe the qualitative factors influencing the range of possible risks.

"(2) When scientific data and understanding that permits relevant comparisons of risk are reasonably available, the agency shall use such information to place the nature and magnitude of risks to human health, safety, and the environment being analyzed in context.

"(3) When scientifically appropriate information on significant substitution risks to human health, safety, or the environment is reasonably available to the agency, or is contained in information provided to the agency by a commentator, the agency shall describe such risks in the risk assessments.

"(g) PEER REVIEW.—(1) Each agency shall provide for peer review in accordance with this section of any risk assessment subject to the requirements of this subchapter that forms that basis of any major rule or a major environmental management activity.

"(2) Each agency shall develop a systematic program for balanced, independent, and external peer review that—

"(A) shall provide for the creation or utilization of peer review panels, expert bodies, or other formal or informal devices that are balanced and comprised of participants selected on the basis of their expertise relevant to the sciences involved in regulatory decisions and who are independent of the agency program that developed the risk assessment being reviewed;

"(B) shall not exclude any person with substantial and relevant expertise as a participant on the basis that such person has a potential interest in the outcome, if such interest is fully disclosed to the agency, and the agency includes such disclosure as part of the record, unless the result of the review would have a direct and predictable effect on a substantial financial interest of such person;

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

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

"(3) Each peer review shall include a report to the Federal agency concerned detailing the scientific and technical merit of data and the methods used for the risk assessment, and shall identify significant peer review comments. Each agency shall provide a written response to all significant peer review comments. All peer review comments, conclusions, composition of the panels, 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.

"(4)(A) The Director of the Office of Science and Technology Policy shall develop

a systematic program to oversee the use and quality of peer review of risk assessments.

"(B) The Director or the designee of the President may order an agency to conduct peer review for any risk assessment or cost-benefit analysis that is likely to have a significant impact on public policy decisions, or that would establish an important precedent.

"(5) The proceedings of peer review panels under this section shall not be subject to the Federal Advisory Committee Act.

"(h) PUBLIC PARTICIPATION.—The head of each agency shall provide appropriate opportunities for public participation and comment on risk assessments.

#### "§634. Rule of construction

"Nothing in this subchapter shall be construed to—

"(1) preclude the consideration of any data or the calculation of any estimate to more fully describe or analyze risk, scientific uncertainty, or variability; or

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

#### "§635. Comprehensive risk reduction

"(a) SETTING PRIORITIES.—The head of each agency with programs to protect human health, safety, or the environment shall set priorities for the use of resources available to address those risks to human health, safety, and the environment, with the goal of achieving the greatest overall net reduction in risks with the public and private sector resources expended.

"(b) INCORPORATING RISK-BASED PRIORITIES INTO BUDGET AND PLANNING.—The head of each agency in subsection (a) shall incorporate the priorities identified under subsection (a) 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 using the priorities set under subsection (a), the basis for that determination, and explicitly identify how the agency's requested budget and regulatory agenda reflect those priorities.

"(c) REPORTS BY THE NATIONAL ACADEMY OF SCIENCES.—(1) Not later than 6 months after the date of enactment of this section, the Director of the Office of Science and Technology Policy shall enter into an arrangement with the National Academy of Sciences to investigate and report on comparative risk analysis. The arrangement shall provide, to the extent deemed appropriate and feasible by the Academy, for—

"(A) 1 or more reports evaluating methods of comparative risk analysis that would be appropriate for agency programs related to human health, safety, and the environment to use in setting priorities for activities; and

"(B) a report providing a comprehensive and comparative analysis of the risks to human health, safety, and the environment that are addressed by agency programs under subsection (a), along with companion activities to disseminate the conclusions of the report to the public.

"(2) The report or reports prepared under paragraph (1)(A) shall be completed not later than 3 years after the date of enactment of this section. The report under paragraph (1)(B) shall be completed not later than 4 years after the date of enactment of this section, and shall draw, as appropriate, upon the insights and conclusions of the report or reports made under paragraph (1)(A). The companion activities under paragraph (1)(B) shall be completed not later than 5 years after the date of enactment of this section.

"(3)(A) The head of an agency with programs to protect human health, safety, and

the environment shall incorporate the recommendations of reports under paragraph (1) in revising any priorities under subsection (a).

“(B) The head of the agency shall submit a report to the appropriate Congressional committees of jurisdiction responding to the recommendations from the National Academy of Sciences and describing plans for utilizing the results of comparative risk analysis in agency budget, strategic planning, regulatory agenda, enforcement, and research and development activities.

“(4) Following the submission of the report in paragraph (2), for the next 5 years, the head of the agency shall submit, with the budget request submitted to Congress under section 1105(a) of title 31, a description of how the requested budget of the agency and the strategic planning activities of the agency reflect priorities determined using the recommendations of reports issued under subsection (a). The head of the agency shall include in such description—

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

“(B) recommendation on the modification or elimination of statutory or judicially mandated deadlines,

that would assist the head of the agency to set priorities in activities to address the risks to human health, safety, or the environment that incorporate the priorities developed using the recommendations of the reports under subsection (a), resulting in more cost-effective programs to address risk.

“(5) For each budget request submitted in accordance with paragraph (4), the Director shall submit an analysis of ways in which resources could be reallocated among Federal agencies to achieve the greatest overall net reduction in risk.

#### “SUBCHAPTER IV—EXECUTIVE OVERSIGHT

##### “§ 641. Procedures

“(a) IN GENERAL.—The Director or a designee of the President shall—

“(1) establish and, as appropriate, revise procedures for agency compliance with this chapter; and

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

“(b) PUBLIC COMMENT.—Procedures established pursuant to subsection (a) shall only be implemented after opportunity for public comment. Any such procedures shall be consistent with the prompt completion of rule-making proceedings.

“(c) TIME FOR REVIEW.—(1) If procedures established pursuant to subsection (a) include review of any initial or final analyses of a rule required under chapter 6, the time for any such review of any initial analysis shall not exceed 90 days following the receipt of the analysis by the Director, or a designee of the President.

“(2) The time for review of any final analysis required under chapter 6 shall not exceed 90 days following the receipt of the analysis by the Director, a designee of the President.

“(3)(A) The times for each such review may be extended for good cause by the President or by an officer to whom the President has delegated his authority pursuant to section 642 for an additional 45 days. At the request of the head of an agency, the President or such an officer may grant an additional extension of 45 days.

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

##### “§ 642. Delegation of authority

“(a) IN GENERAL.—The President may delegate the authority granted by this sub-

chapter to an officer within the Executive Office of the President whose appointment has been subject to the advice and consent of the Senate.

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

##### “§ 643. 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 642 and agency compliance or noncompliance with the procedure under section 641 shall not be subject to judicial review.

##### “§ 644. Regulatory agenda

“The head of each agency shall provide, as part of the semiannual regulatory agenda published under section 602—

“(1) a list of risk assessments subject to subsection 632 (a) or (b)(1) under preparation or planned by the agency;

“(2) a brief summary of relevant issues addressed or to be addressed by each listed risk assessment;

“(3) an approximate schedule for completing each listed risk assessment;

“(4) an identification of potential rules, guidance, or other agency actions supported or affected by each listed risk assessment; and

“(5) the name, address, and telephone number of an agency official knowledgeable about each listed risk assessment.”

##### (b) REGULATORY FLEXIBILITY ANALYSIS.—

(1) FINAL REGULATORY FLEXIBILITY ANALYSIS.—Section 604 of title 5, United States Code, is amended by adding at the end thereof the following new subsection:

“(c)(1) Except as provided in paragraph (2), no final rule for which a final regulatory flexibility analysis is required under this section shall be promulgated unless the agency finds that the final rule minimizes significant economic impact on small entities to the maximum extent possible, consistent with the purposes of this subchapter, the objectives of the rule, and the requirements of applicable statutes.

“(2) If an agency determines that a statute requires a rule to be promulgated that does not satisfy the criterion of paragraph (1), the agency shall—

“(A) include a written explanation of such determination in the final regulatory flexibility analysis; and

“(B) transmit the final regulatory flexibility analysis to Congress when the final rule is promulgated.”

(2) JUDICIAL REVIEW.—Section 611 of title 5, United States Code, is amended to read as follows:

##### “§ 611. Judicial review

“(a)(1) For any rule described in section 603(a), and with respect to which the 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;

“(B) prepared a final regulatory flexibility analysis pursuant to section 604; or

“(C) did not prepare an initial regulatory flexibility analysis pursuant to section 603 or a final regulatory flexibility analysis pursuant to section 604 except as permitted by sections 605 and 608,

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

“(2)(A) Notwithstanding any other provision of law, an affected small entity shall

have 1 year after the effective date of the final rule to challenge the certification, analysis or failure to prepare an analysis required by this subchapter with respect to any such rule.

“(B) If an agency delays the issuance of a final regulatory flexibility analysis pursuant to section 608(b), a petition for judicial review under this subsection may be filed not later than 1 year 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 subject to the provisions of, or otherwise required to comply with, the final rule.

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

“(5)(A) Notwithstanding section 605, if the court determines, on the basis of the court’s review of the rulemaking record, that there is substantial evidence that the rule would have a significant economic impact on a substantial number of small entities, the court shall order the agency to prepare a final regulatory flexibility analysis that satisfies the requirements of section 604.

“(B) If the agency prepared a final regulatory flexibility analysis, the court shall order the agency to take corrective action consistent with section 604 if the court determines, on the basis of the court’s review of the rulemaking record, that the final regulatory flexibility analysis does not satisfy the requirements of section 604.

“(6) The court shall stay the rule and grant such other relief as the court determines to be appropriate if, by the end of the 90-day period beginning on the date of the order of the court pursuant to paragraph (5), the agency fails, as appropriate—

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

“(B) to take corrective action consistent with section 604.

“(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) Except as otherwise required by the provisions of this subchapter, the court shall apply the same standards of judicial review that govern the review of agency findings under the statute granting the agency authority to conduct the rulemaking.”

(c) REVISION OF CERTAIN PROVISIONS OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT RELATING TO TESTING.—In applying section 409(c)(3)(A), 512(d)(1), or 721(b)(5)(B) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 348(c)(3)(A), 360b(d)(1), 379e(b)(5)(B)), the Secretary of Health and Human Services and the Administrator of the Environmental Protection Agency shall not prohibit or refuse to approve a substance or product on the basis of safety, where the substance or product presents a negligible or insignificant foreseeable risk to human health resulting from its intended use.

##### (d) TOXIC RELEASE INVENTORY REVIEW.—

(1) Not later than 180 days after the date of enactment of this subsection, the Administrator of the Environmental Protection Agency shall carry out a review of each characterization or listing of a substance added since November 8, 1994, to the Toxic Release Inventory under section 313(c) of the Emergency Planning and Community Right to Know Act of 1986 (42 U.S.C. 11023(c)).

(2) In this review, the Administrator shall determine with respect to each such characterization or listing whether removal of the substance from the Toxic Release Inventory

presents a foreseeable significant risk to human health or the environment.

(3) The Administrator shall remove from the Toxic Release Inventory any substance the removal of which is justified by a determination under paragraph (2).

(4)(A) Not later than 90 days after the date of enactment of this section, the Administrator shall publish a draft review and the Administrator's preliminary plans to use the authority under paragraph (3), and afford interested persons an opportunity to comment.

(B) Promptly upon completion of the review, the Administrator shall provide Congress with a written report summarizing the review and the reasons for action or inaction on each characterization or listing subject to this subsection.

(e) TECHNICAL AND CONFORMING AMENDMENTS.—

(1) CHAPTER ANALYSIS.—Part I of title 5, United States Code, is amended by striking the chapter heading and table of sections for chapter 6 and inserting the following:

**"CHAPTER 6—THE ANALYSIS OF REGULATORY FUNCTIONS**

**"SUBCHAPTER I—REGULATORY ANALYSIS**

"Sec.

"601. Definitions.

"602. Regulatory agenda.

"603. Initial regulatory flexibility analysis.

"604. Final regulatory flexibility analysis.

"605. Avoidance of duplicative or unnecessary analyses.

"606. Effect on other law.

"607. Preparation of analysis.

"608. Procedure for waiver or delay of completion.

"609. Procedures for gathering comments.

"610. Periodic review of rules.

"611. Judicial review.

"612. Reports and intervention rights.

**"SUBCHAPTER II—ANALYSIS OF AGENCY RULES**

"621. Definitions.

"622. Rulemaking cost-benefit analysis.

"623. Agency regulatory review.

"624. Decisional criteria.

"625. Jurisdiction and judicial review.

"626. Deadlines for rulemaking.

"627. Special rule.

"628. Requirements for major environmental management activities.

**"SUBCHAPTER III—RISK ASSESSMENTS**

"631. Definitions.

"632. Applicability.

"633. Principles for risk assessments.

"634. Rule of construction.

"635. Comprehensive risk reduction.

**"SUBCHAPTER IV—EXECUTIVE OVERSIGHT**

"641. Procedures.

"642. Delegation of authority.

"643. Judicial review.

"644. Regulatory agenda."

(2) SUBCHAPTER HEADING.—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. 5. JUDICIAL REVIEW.**

(a) IN GENERAL.—Chapter 7 of title 5, United States Code, is amended—

(1) by striking section 706; and

(2) by adding at the end the following new sections:

**"§ 706. Scope of review**

"(a) To the extent necessary to reach a decision and when presented, the reviewing court shall decide all relevant questions of law, interpret constitutional and statutory provisions, and determine the meaning or ap-

plicability of the terms of an agency action. The reviewing court shall—

"(1) compel agency action unlawfully withheld or unreasonably delayed; and

"(2) hold unlawful and set aside agency action, findings and conclusions found to be—

"(A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law;

"(B) contrary to constitutional right, power, privilege, or immunity;

"(C) in excess of statutory jurisdiction, authority, or limitations, or short of statutory right;

"(D) without observance of procedure required by law;

"(E) unsupported by substantial evidence in a proceeding subject to sections 556 and 557 or otherwise reviewed on the record of an agency hearing provided by statute;

"(F) without substantial support in the rulemaking file, viewed as a whole, for the asserted or necessary factual basis, in the case of a rule adopted in a proceeding subject to section 553; or

"(G) unwarranted by the facts to the extent that the facts are subject to trial de novo by the reviewing court.

"(b) In making the determinations set forth in subsection (a), the court shall review the whole record or those parts of it cited by a party, and due account shall be taken of the rule of prejudicial error.

**"§ 707. Consent decrees**

"In interpreting any consent decree in effect on or after the date of enactment of this section that imposes on an agency an obligation to initiate, continue, or complete rulemaking proceedings, the court shall not enforce the decree in a way that divests the agency of discretion clearly granted to the agency by statute to respond to changing circumstances, make policy or managerial choices, or protect the rights of third parties.

**"§ 708. Affirmative defense**

"Notwithstanding any other provision of law, it shall be an affirmative defense in any enforcement action brought by an agency that the regulated person or entity reasonably relied on and is complying with a rule, regulation, adjudication, directive, or order of such agency or any other agency that is incompatible, contradictory, or otherwise cannot be reconciled with the agency rule, regulation, adjudication, directive, or order being enforced."

(b) TECHNICAL AMENDMENT.—The analysis for chapter 7 of title 5, United States Code, is amended by striking the item relating to section 706 and inserting the following new items:

"706. Scope of review.

"707. Consent decrees.

"708. Affirmative defense."

**SEC. 6. CONGRESSIONAL REVIEW.**

(a) FINDING.—The Congress finds that effective steps for improving the efficiency and proper management of Government operations will be promoted if a moratorium on the implementation of certain significant final rules is imposed in order to provide Congress an opportunity for review.

(b) IN GENERAL.—Title 5, United States Code, is amended by inserting immediately after chapter 7 the following new chapter:

**"CHAPTER 8—CONGRESSIONAL REVIEW OF AGENCY RULEMAKING**

"801. Congressional review.

"802. Congressional disapproval procedure.

"803. Special rule on statutory, regulatory, and judicial deadlines.

"804. Definitions.

"805. Judicial review.

"806. Applicability; severability.

"807. Exemption for monetary policy.

**"§ 801. Congressional review**

"(a)(1)(A) Before a rule can take effect as a final rule, the Federal agency promulgating such rule shall submit to each House of the Congress and to the Comptroller General a report containing—

"(i) a copy of the rule;

"(ii) a concise general statement relating to the rule; and

"(iii) the proposed effective date of the rule.

"(B) The Federal agency promulgating the rule shall make available to each House of Congress and the Comptroller General, upon request—

"(i) a complete copy of the cost-benefit analysis of the rule, if any;

"(ii) the agency's actions relevant to sections 603, 604, 605, 607, and 609;

"(iii) the agency's actions relevant to sections 202, 203, 204, and 205 of the Unfunded Mandates Reform Act of 1995; and

"(iv) any other relevant information or requirements under any other Act and any relevant Executive orders, such as Executive Order No. 12866.

"(C) Upon receipt, each House shall provide copies to the Chairman and Ranking Member of each committee with jurisdiction.

"(2)(A) The Comptroller General shall provide a report on each major rule to the committees of jurisdiction to each House of the Congress by the end of 12 calendar days after the submission or publication date as provided in section 802(b)(2). The report of the Comptroller General shall include an assessment of the agency's compliance with procedural steps required by paragraph (1)(B).

"(B) Federal agencies shall cooperate with the Comptroller General by providing information relevant to the Comptroller General's report under subparagraph (A).

"(3) A major rule relating to a report submitted under paragraph (1) shall take effect as a final rule, the latest of—

"(A) the later of the date occurring 60 days after the date on which—

"(i) the Congress receives the report 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 section 802 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; or

"(C) the date the rule would have otherwise taken effect, if not for this section (unless a joint resolution of disapproval under section 802 is enacted).

"(4) Except for a major rule, a rule shall take effect as otherwise provided by law after submission to Congress under paragraph (1).

"(5) Notwithstanding paragraph (3), the effective date of a rule shall not be delayed by operation of this chapter beyond the date on which either House of Congress votes to reject a joint resolution of disapproval under section 802.

"(b) A rule shall not take effect (or continue) as a final rule, if the Congress passes a joint resolution of disapproval described under section 802.

"(c)(1) Notwithstanding any other provision of this section (except subject to paragraph (3)), a rule that would not take effect by reason of this chapter may take effect, if the President makes a determination under paragraph (2) and submits written notice of such determination to the Congress.

“(2) Paragraph (1) applies to a determination made by the President by Executive order that the rule should take effect because such rule is—

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

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

“(C) necessary for national security; or

“(D) issued pursuant to a statute implementing an international trade agreement.

“(3) An exercise by the President of the authority under this subsection shall have no effect on the procedures under section 802 or the effect of a joint resolution of disapproval under this section.

“(d)(1) In addition to the opportunity for review otherwise provided under this chapter, in the case of any rule that is published in the Federal Register (as a rule that shall take effect 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, section 802 shall apply to such rule in the succeeding Congress.

“(2)(A) In applying section 802 for purposes of such additional review, a rule described under paragraph (1) shall be treated as though—

“(i) such rule were published in the Federal Register (as a rule that shall take effect as a final rule) on the 15th session day after the succeeding Congress first convenes; and

“(ii) a report on such rule were submitted to Congress under subsection (a)(1) on such date.

“(B) Nothing in this paragraph shall be construed to affect the requirement under subsection (a)(1) that a report shall be submitted to Congress before a final rule can take effect.

“(3) A rule described under paragraph (1) shall take effect as a final rule as otherwise provided by law (including other subsections of this section).

“(e)(1) Section 802 shall apply in accordance with this subsection to any major rule that is published in the Federal Register (as a rule that shall take effect as a final rule) during the period beginning on November 20, 1994, through the date on which the Comprehensive Regulatory Reform Act of 1995 takes effect.

“(2) In applying section 802 for purposes of Congressional review, a rule described under paragraph (1) shall be treated as though—

“(A) such rule were published in the Federal Register (as a rule that shall take effect as a final rule) on the date of enactment of the Comprehensive Regulatory Reform Act of 1995; and

“(B) a report on such rule were submitted to Congress under subsection (a)(1) on such date.

“(3) The effectiveness of a rule described under paragraph (1) shall be as otherwise provided by law, unless the rule is made of no force or effect under section 802.

“(f) Any rule that takes effect and later is made of no force or effect by enactment of a joint resolution under section 802 shall be treated as though such rule had never taken effect.

“(g) If the Congress does not enact a joint resolution of disapproval under section 802, no court or agency may infer any intent of the Congress from any action or inaction of the Congress with regard to such rule, related statute, or joint resolution of disapproval.

#### “§ 802. Congressional disapproval procedure

“(a) For purposes of this section, the term ‘joint resolution’ means only a joint resolution introduced during the period beginning on the date on which the report referred to

in section 801(a) is received by Congress and ending 60 days thereafter, 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.)

“(b)(1) A resolution described in paragraph (1) shall be referred to the committees in each House of Congress with jurisdiction. Such a resolution may not be reported before the eighth day after its submission or publication date.

“(2) For purposes of this subsection the term ‘submission or publication date’ means the later of the date on which—

“(A) the Congress receives the report submitted under section 801(a)(1); or

“(B) the rule is published in the Federal Register.

“(c) If the committee to which is referred a resolution described in subsection (a) has not reported such resolution (or an identical resolution) at the end of 20 calendar days after the submission or publication date defined under subsection (b)(2), such committee may be discharged from further consideration of such resolution in the Senate upon a petition supported in writing by 30 Members of the Senate and in the House upon a petition supported in writing by one-fourth of the Members duly sworn and chosen or by motion of the Speaker supported by the Minority Leader, and such resolution shall be placed on the appropriate calendar of the House involved.

“(d)(1) When the committee to which a resolution is referred has reported, or when a committee is discharged (under subsection (c)) from further consideration of, a resolution described in subsection (a), it is at any time thereafter in order (even though a previous motion to the same effect has been disagreed to) for a motion to proceed to the consideration of the resolution, and all points of order against the resolution (and against consideration of resolution) are waived. The motion is not 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 respective House until disposed of.

“(2) 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 is in order and not 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 is not in order.

“(3) Immediately following the conclusion of the debate on a resolution described in subsection (a), and a single quorum call at the conclusion of the debate if requested in accordance with the rules of the appropriate House, the vote on final passage of the resolution shall occur.

“(4) Appeals from the decisions of the Chair relating to the application of the rules of the Senate or the House of Representatives, as the case may be, to the procedure relating to a resolution described in subsection (a) shall be decided without debate.

“(e) If, before the passage by one House of a resolution of that House described in subsection (a), that House receives from the other House a resolution described in subsection (a), then the following procedures shall apply:

“(1) The resolution of the other House shall not be referred to a committee.

“(2) With respect to a resolution described in subsection (a) of the House receiving the resolution—

“(A) the procedure in that House shall be the same as if no resolution had been received from the other House; but

“(B) the vote on final passage shall be on the resolution of the other House.

“(f) This section is enacted by Congress—

“(1) as an exercise of the rulemaking power of the Senate and House of Representatives, respectively, and as such it is deemed 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 subsection (a), and it supersedes other rules only to the extent that it is inconsistent with such rules; and

“(2) 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.

#### “§ 803. Special rule on statutory, regulatory, and judicial deadlines

“(a) In the case of any deadline for, relating to, or involving any rule which does not take effect (or the effectiveness of which is terminated) because of enactment of a joint resolution under section 802, that deadline is extended until the date 1 year after the date of the joint resolution. Nothing in this subsection shall be construed to affect a deadline merely by reason of the postponement of a rule's effective date under section 801(a).

“(b) The term ‘deadline’ means any date certain for fulfilling any obligation or exercising any authority established by or under any Federal statute or regulation, or by or under any court order implementing any Federal statute or regulation.

#### “§ 804. Definitions

“(a) For purposes of this chapter—

“(1) the term ‘Federal agency’ means any agency as that term is defined in section 551(1) (relating to administrative procedure);

“(2) the term ‘major rule’ has the same meaning given such term in section 621(5); and

“(3) the term ‘final rule’ means any final rule or interim final rule.

“(b) As used in subsection (a)(3), the term ‘rule’ has the meaning given such term in section 551, except that such term does not include any rule of particular applicability including a rule that approves or prescribes for the future rates, wages, prices, services, or allowances therefor, corporate or financial structures, reorganizations, mergers, or acquisitions thereof, or accounting practices or disclosures bearing on any of the foregoing or any rule of agency organization, personnel, procedure, practice or any routine matter.

#### “§ 805. Judicial review

“No determination, finding, action, or omission under this chapter shall be subject to judicial review.

#### “§ 806. Applicability; severability

“(a) This chapter shall apply notwithstanding any other provision of law.

“(b) If any provision of this chapter or the application of any provision of this chapter to any person or circumstance, is held invalid, the application of such provision to other persons or circumstances, and the remainder of this chapter, shall not be affected thereby.

#### “§ 807. Exemption for monetary policy

“Nothing in this chapter shall apply to rules that concern monetary policy proposed or implemented by the Board of Governors of the Federal Reserve System or the Federal Open Market Committee.”

(c) **EFFECTIVE DATE.**—The amendment made by subsection (b) shall take effect on the date of enactment of this Act and shall apply to any rule that takes effect as a final rule on or after such effective date.

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

**"8. Congressional Review of Agency Rulemaking ..... 801".**  
**SEC. 7. REGULATORY ACCOUNTING.**

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

(1) **MAJOR RULE.**—The term "major rule" has the same meaning as defined in section 621(5)(A)(i) of title 5, United States Code. 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 a statute implementing an international trade agreement; or

(C) regulations related to agency organization, management, or personnel.

(2) **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.

(b) **ACCOUNTING STATEMENT.**—

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

(B) Not later than June 1, 1997, and each June 1 thereafter, the President shall prepare and submit to Congress an accounting statement that estimates the annual costs of major rules 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 comment for each accounting statement. The President may delegate to an agency the requirement to provide notice and opportunity to comment for the portion of the accounting statement relating to that agency.

(B) The President shall propose the first accounting statement under this subsection not later than 2 years after the date of enactment of this Act and shall issue the first accounting statement in final form not later than 3 years after such effective date. Such statement shall cover, at a minimum, each of the fiscal years beginning after the date of enactment 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 major rules by setting forth, for each year covered by the statement—

(I) the annual expenditure of national economic resources for major rules, grouped by 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 administrative costs.

(C) An accounting statement shall estimate the benefits of major rules 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 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 subsection (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) Analyses prepared by the President of the cumulative impact of major rules in Federal regulatory programs covered in the accounting statement 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, provide guidance to agencies—

(I) to standardize measures of costs and benefits in accounting statements prepared

pursuant to sections 3 and 7 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. 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 4 of this Act); and

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

(b) **ADMINISTRATIVE PROCEDURE ACT.**—Not later than December 31, 1996, the Administrative Conference of the United States shall—

(1) carry out a study of the operation of 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. 9. MISCELLANEOUS PROVISIONS.

(a) **EFFECTIVE DATE.**—Except as otherwise provided, this Act and the amendments made by this Act shall take effect on the date of enactment.

(b) **SEVERABILITY.**—If any provision of this Act, an amendment made by this Act, or the application of such provision or amendment to any person or circumstance is held to be unconstitutional, the remainder of this Act, the amendments made by this Act, and the application of the provisions of such to any person or circumstance shall not be affected thereby.

Mr. JOHNSTON. Mr. President, I understand that will be the pending business when the Senate returns from recess. In the meantime, we will continue to discuss this package with our colleagues and, hopefully, will be able to arrive at further modifications along the lines we have talked about. I believe those negotiations will happen tomorrow.

Mr. LEVIN. Reserving the right to object, Mr. President, there was a unanimous-consent agreement that had been entered into previously between Senator DOLE and Senator DASCHLE. Is there any intent in what the Senator from Louisiana has just said to modify in any way the previous unanimous-consent agreement that had been entered into?

Mr. JOHNSTON. No, the only unanimous consent I asked is that when this draft is prepared, that it be printed in the RECORD for notice.

The majority leader, I was just informed, will ask on tomorrow afternoon—I did not ask unanimous consent but I was just advised that he would ask for permission to withdraw the committee amendments to S. 343 and send a substitute to the desk.

I am not asking that be done. I was just giving the Senate notice because his staff just gave me that notice. I wanted to make the Senate aware of that.

I hope tomorrow we can reassure Senators on matters, or change that which needs to be changed, and get a very broad consensus bill so when we come back after the recess we will have a bill that passes overwhelmingly.

Mr. President, I said a moment ago Senator DOLE intended to put in the substitute tomorrow afternoon. I meant on Friday afternoon, because that is what he meant. I wanted to give my colleagues notice of that.

#### THE BUDGET RESOLUTION

The PRESIDING OFFICER (Mr. DEWINE). Under the previous order, the Senate will resume debate on the conference report to House Concurrent Resolution 67, the budget resolution for fiscal year 1996.

The PRESIDING OFFICER. The Senator from Minnesota.

Mr. GRAMS. Mr. President, I rise this afternoon to voice my strong support for the budget conference report, which I believe is a historic document that looks forward and not back; one that promises freedom, not Government servitude; and one that delivers hope and not despair.

Mr. DOMENICI. Mr. President, I wonder if the Senator will yield for a moment?

Mr. GRAMS. Yes, go ahead.

Mr. DOMENICI. Mr. President, I understand we are going to be on this resolution for 1 hour now; is that correct?

The PRESIDING OFFICER. There is not an hour to end the debate, or to begin debate.

Mr. DOMENICI. We will be going back and forth? I ask the Senator, how much time would the Senator like?

Mr. GRAMS. No more than 10 minutes.

Mr. DOMENICI. I yield 10 minutes to the distinguished Senator.

Mr. GRAMS. Mr. President, talking about the budget, this historic budget is a budget unlike any other approved by Congress in more than a quarter of a century because, not only does it balance the budget within 7 years without raising taxes, it actually cuts taxes for middle-class Americans.

It marks the first time since 1969 that Congress has committed itself to a balanced budget, and reflects the change demanded by the voters in November: Get government off our backs and out of our back pockets.

Mr. President, our budget resolution provides \$245 billion in tax relief, making it the largest tax refund in history.

I am proud that the centerpiece of the tax relief package will be the \$500

per-child tax credit originally proposed by me and my very good friend from Indiana, Senator COATS, in our families-first legislation, and by Representative TIM HUTCHINSON in the House.

Along with my freshman colleague, Senator ABRAHAM, and the leadership of Senator DOLE, we have ensured that this Senate goes on record supporting middle-class tax relief, and incentives to stimulate savings, investment, job creation, and economic growth.

And, Mr. President, this tax relief could not have come at a better time.

Government has become a looming presence in the lives of the American people, mostly through the encouragement of Congress.

Each year, the people are asked to turn more and more responsibilities over to the Federal Government—for Government regulation, for Government support.

From the time they get up in the morning till the time they go to bed at night, there are very few aspects of daily American life that are not touched by the hand of government.

So government has been forced to grow just to keep up.

Consider that government spending at the Federal State, and local levels has jumped from less than 12 percent of national income in the 1930's to more than 42 percent today.

And the burden for keeping these ever-ballooning bureaucracies in operation has fallen on the taxpayers, of course—through more and higher taxes.

As a sign of just how big the Federal Government has grown—and how the number of tax dollars sent to Washington have grown right along with it—look what has happened to the IRS.

Today, it has an annual operating budget in excess of \$7.5 billion. If it were a private company, its gross receipts—more than \$1 trillion—would put it at the top of the Fortune 500 list.

All that—just by processing tax dollars.

Most middle-class American families pay more in Federal taxes than they spend for food, clothing, and shelter combined.

Families with children are now the lowest after-tax income group in America—below elderly households, below single persons, below families without children.

Since 1948, when Americans paid just 22 cents per dollar of their personal income in taxes, the Gallup organization has asked Americans what they think about the taxes they pay.

That first year, 57 percent of the people said yes, taxes are too high. Today, nearly 50 cents of every dollar earned by middle-class Americans goes to taxes of some sort—and 67 percent of the people say they're handing over too much of their own money to the Federal Government.

They might feel differently if they were getting a fair return on their investment. But Americans see their hard-earned dollars being wasted by

the Federal Government. They look at the services they are getting in return and they feel like they are being taken to the cleaners.

The 1993 tax bill offered by President Clinton did not help, either. As the largest tax increase in American history, it hit middle-class Americans right where it hurt the most—their wallets.

The President's 1993 tax hike actually increased their tax burden, making it more difficult for the middle class to care for themselves and their children.

And I remind you—not a single Republican voted for it.

The tax burden has become so heavy in my home State of Minnesota that it took until May 14 this year—134 days into 1995—for us to finally reach Tax Freedom Day.

That is the day when Minnesotans are no longer working just to pay off taxes, and can finally begin working for themselves. Nearly 20 weeks, over 800 hours on the job just to pay Uncle Sam and his cousins at the State level.

In order to pay all these taxes, Americans are spending more time on the job. Within the past three decades, the average American has added about 160 hours annually to their work schedule. That is about 4 extra weeks of work a year.

They are overworked, overstressed, and they are moonlighting more than ever before.

In 1995, one in six Americans holds more than one job. One out of every three is regularly working on weekends and evenings. And it is not because they necessarily want to—it is because they must.

A significant number of families are relying on that second job just to pull themselves above the poverty line and meet their annual tax obligations.

The majority of families who have reached a middle-class standard of living are families relying on two incomes. They are still pursuing the American dream, but the ever-increasing tax burden keeps pushing it out of reach.

Imagine what those longer work hours are doing to the family. Or better yet, listen to taxpayers like Natalie Latzka-Wolstad of Coon Rapids, MN, who struggle with the demands of family life, the job, and the Government—while pursuing their own version of the American Dream.

I went to the floor of the Senate last month to talk about Natalie and her family, after she wrote me a moving letter about the enormous tax burden her family is forced to bear.

It hit home for Natalie after she and her husband met with their realtor, only to learn that they simply could not afford to purchase a new home on their own.

Let me quote just a few paragraphs from Natalie's letter: "I have finally reached the point of complete frustration and anger over the amount of taxes being deducted from my check each month," she wrote.