

¶143.17 WORDS TAKEN DOWN

Mr. HOYER during debate, addressed the House and, during the course of his remarks,

Mr. HASTERT demanded that certain words be taken down.

The Clerk read the words taken down as follows:

Ladies and gentlemen of this House, ladies and gentlemen of America, this bill is a patently petty political terrorist tactic, that is what it is, an attempt to force the President of the United States to adopt things that you cannot get through your own Senate, not just the Congress. This bill adopts tactics that put America as a hostage to an extremist agenda.

The SPEAKER pro tempore, Mr. HOBSON, responded to the demand for words to be taken down, and said:

The Chair rules that since this is not a reference to an individual Member, that the remarks are in order.

However, the Chair would observe that there is a civility within the House in addressing bills and Members that should be observed, and it would be hoped that in the future that would be observed by all Members.

After further debate,

Pursuant to House Resolution 258, the amendment recommended by the Committee on Ways and Means and the amendments specified in House Report 104-328 were considered as adopted.

Mr. WALKER submitted the following amendment:

At the appropriate place in the bill, add the following:

TITLE III-REGULATORY REFORM**SEC. 3001. SHORT TITLE.**

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

SEC. 3002. ANALYSIS OF AGENCY RULES.

(a) IN GENERAL.—(1) Section 551 of title 5, United States Code, is amended by striking "and" at the end of paragraph (13), by striking the period at the end of paragraph (14) and inserting a semicolon, and by adding at the end the following:

"(15) 'major rule' means any rule subject to section 553(c) that is likely to result in—

"(A) an annual effect on the economy of \$100,000,000 or more;

"(B) a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions, or

"(C) significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets;

"(16) 'Director' means the Director of the Office of Management and Budget;

"(17) 'cost' means the reasonably identifiable significant adverse effects, quantifiable and nonquantifiable, including social, environmental, health, and economic effects that are expected to result directly or indirectly from implementation of a rule or other agency action;

"(18) '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 decision making on the matter involved, taking into consideration the significance and complexity of the decision and any need for expedition; and

"(19) '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, unless precluded by the statute granting the rulemaking authority."

(2) Section 553 of title 5, United States Code, is amended by adding at the end the following:

"(f)(1) Each agency shall for a proposed major rule publish in the Federal Register, at least 90 days before the date of publication of the general notice required under subsection (b), a notice of intent to engage in rulemaking.

"(2) A notice under paragraph (1) for a proposed major rule shall include, to the extent possible, the information required to be included in a regulatory impact analysis for the rule under subsection (i)(4)(B) and (D).

"(3) For a major rule proposed by an agency, the head of the agency shall include in a general notice under subsection (b), a preliminary regulatory impact analysis for the rule prepared in accordance with subsection (i).

"(4) For a final major rule, the agency shall include with the statement of basis and purpose—

"(A) a summary of a final regulatory impact analysis of the rule in accordance with subsection (i); and

"(B) a clear delineation of all changes in the information included in the final regulatory impact analysis under subsection (i) from any such information that was included in the notice for the rule under subsection (b).

The agency shall provide the complete text of a final regulatory impact analysis upon request.

"(5) The issuance of a notice of intent to engage in rulemaking under paragraph (1) and the issuance of a preliminary regulatory impact analysis under paragraph (3) shall not be considered final agency action for purposes of section 704.

"(6) In a rulemaking involving a major rule, the agency conducting the rulemaking shall make a written record describing the subject of all contacts the agency made with persons outside the agency relating to such rulemaking. If the contact was made with a non-governmental person, the written record of such contact shall be made available, upon request to the public."

(3)(A) HEARING REQUIREMENT.—Section 553 of title 5, United States Code, is further amended by adding after subsection (f) the following:

"(g) If more than 100 interested persons acting individually submit requests for a hearing to an agency regarding any major rule proposed by the agency, the agency shall hold such a hearing on the proposed rule."

(B) EXTENSION OF COMMENT PERIOD.—Section 553 of title 5, United States Code is further amended by adding after subsection (g) the following:

"(h) If during the 90-day period beginning on the date of publication of a notice under subsection (f) for a proposed major rule, or if during the period beginning on the date of publication or service of notice required by subsection (b) for a proposed major rule, more than 100 persons individually contact the agency to request an extension of the period for making submissions under subsection (c) pursuant to the notice, the agency—

"(1) shall provide an additional 30-day period for making those submissions; and

"(2) may not adopt the rule until after the additional period."

(C) RESPONSE TO COMMENTS.—Section 553(c) of title 5, United States Code, is amended—

(i) by inserting "(1)" after "(c)"; and

(ii) by adding at the end the following:

"(2) Each agency shall publish in the Federal Register, with each rule published under section 552(a)(1)(D), responses to the substance of the comments received by the agency regarding the rule."

(4) Section 553 of title 5, United States Code, is further amended by adding after subsection (h) the following:

"(i)(1) Each agency shall, in connection with every major rule, prepare, and, to the extent permitted by law, consider, a regulatory impact analysis. Such analysis may be combined with any regulatory flexibility analysis performed under sections 603 and 604.

"(2) Each agency shall initially determine whether a rule it intends to propose or issue is a major rule. The Director shall have authority to order a rule to be treated as a major rule and to require any set of related rules to be considered together as a major rule.

"(3) Except as provided in subsection (j), agencies shall prepare—

"(A) a preliminary regulatory impact analysis, which shall be transmitted, along with a notice of proposed rulemaking, to the Director at least 60 days prior to the publication of notice of proposed rulemaking, and

"(B) a final regulatory impact analysis, which shall be transmitted along with the final rule at least 30 days prior to the publication of a major rule.

"(4) Each preliminary and final regulatory impact analysis shall contain the following information:

"(A) A description of the potential benefits of the rule, including any beneficial effects that cannot be quantified in monetary terms and the identification of those likely to receive the benefits.

"(B) An explanation of the necessity, legal authority, and reasonableness of the rule and a description of the condition that the rule is to address.

"(C) A description of the potential costs of the rule, including any adverse effects that cannot be quantified in monetary terms, and the identification of those likely to bear the costs.

"(D) An analysis of alternative approaches, including market based mechanisms or other flexible regulatory options that could substantially achieve the same regulatory goal at a lower cost and an explanation of the reasons why such alternative approaches were not adopted, together with a demonstration that the rule provides for the least costly approach.

"(E) A statement that the rule does not conflict with, or duplicate, any other rule or a statement of the reasons why such a conflict or duplication exists.

"(F) A statement of whether the rule will require on-site inspections or whether persons will be required by the rule to maintain any records which will be subject to inspection, and a statement of whether the rule will require persons to obtain licenses, permits, or other certifications, including specification of any associated fees or fines.

"(G) An estimate of the costs to the agency for implementation and enforcement of the rule and of whether the agency can be reasonably expected to implement the rule with the current level of appropriations.

"(5)(A) the Director is authorized to review and prepare comments on any preliminary or final regulatory impact analysis, notice of proposed rulemaking, or final rule based on the requirements of this subsection.

"(B) Upon the request of the Director, an agency shall consult with the Director concerning the review of a preliminary impact analysis or notice of proposed rulemaking and shall refrain from publishing its preliminary regulatory impact analysis or notice of

proposed rulemaking until such review is concluded. The Director's review may not take longer than 90 days after the date of the request of the Director.

"(6)(A) An agency may not adopt a major rule unless the final regulatory impact analysis for the rule is approved or commented upon in writing by the Director or by an individual designated by the Director for that purpose.

"(B) Upon receiving notice that the Director intends to comment in writing with respect to any final regulatory impact analysis or final rule, the agency shall refrain from publishing its final regulatory impact analysis or final rule until the agency has responded to the Director's comments and incorporated those comments in the agency's response in the rulemaking file.

"(7)(A) Except as provided in subparagraph (B), no final major rule subject to this section shall be promulgated unless the agency head publishes in the Federal Register a finding that—

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

"(ii) the rule employs to the extent practicable flexible alternatives as set forth in paragraph (4)(D) and adopts the reasonable alternative which has the greater net benefits and achieves the objectives of the statute.

"(B) If, applying the statutory requirements upon which the rule is based, a rule cannot satisfy the criteria of subparagraph (A), the agency head may promulgate the rule if the agency head finds that—

"(i) the rule employs to the extent practicable flexible reasonable alternatives of the type described in paragraph (4)(D); and

"(ii) the rule adopts the alternative with the least net cost of the reasonable alternatives that achieve the objectives of the statute.

"(8) Notwithstanding section 551(16), for purposes of this subsection with regard to any rule proposed or issued by an appropriate Federal banking agency (as that term is defined in section 3(q) of the Federal Deposit Insurance Act (12 U.S.C. 1813(q)), the National Credit Union Administration, or the Office of Federal Housing Enterprise Oversight, the term 'Director' means the head of such agency, Administration, or Office."

(5) Section 553 of title 5, United States Code, is further amended by adding after subsection (i) the following:

"(j) To the extent practicable, the head of an agency shall seek to ensure that any proposed major rule or regulatory impact analysis of such a rule is written in a reasonably simple and understandable manner and provides adequate notice of the content of the rule to affected persons."

(6) Section 553 of title 5, United States Code, is further amended by adding after subsection (j) the following:

"(k)(1) The provisions of this section regarding major rules shall not apply if—

"(A) the agency for good cause finds that conducting cost-benefit analysis is impracticable due to an emergency, or health or safety threat, or a food 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 one year after the promulgation of a final major rule to which paragraph (1) applies, the agency shall comply with the provisions of this subchapter and, as thereafter necessary, revise the rule.

(7) Section 553 of title 5, United States Code, is further amended by adding after subsection (k) the following:

"(l) The provisions of this section regarding major rules shall not apply to—

"(1) any regulation proposed or issued in connection with the implementation of monetary policy or to ensure the safety and soundness of federally insured depository institutions, any affiliate of such institution, credit unions, or government sponsored housing enterprises regulated by the Office of Federal Housing Enterprise Oversight;

"(2) any agency action that the head of the agency certifies is limited to interpreting, implementing, or administering the internal revenue laws of the United States, including any regulation proposed or issued in connection with ensuring the collection of taxes from a subsidiary of a foreign company doing business in the United States; and

"(3) any regulation proposed or issued pursuant to section 553 of title 5, United States Code, in connection with imposing trade sanctions against any country that engages in illegal trade activities against the United States that are injurious to American technology, jobs, pensions, or general economic well-being."

(8) The Director of the Office of Management and Budget shall submit a report to the Congress no later than 24 months after the date of the enactment of this Act containing an analysis of rulemaking procedures of Federal agencies and an analysis of the impact of those rulemaking procedures on the regulated public and regulatory process.

(9) The amendments made by this subsection shall apply only to final agency rules issued after rulemaking begun after the date of enactment of this Act.

SEC. 3003. RISK ASSESSMENT.

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

"SUBCHAPTER III—RISK ASSESSMENTS

"§ 631. Short title

"This subchapter may be cited as the 'Risk Assessment and Communication Act of 1995'.

"§ 632. Purposes

"The purposes of this subchapter are—

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

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

"(3) to require explanation of significant choices in the risk assessment process which will allow for better peer review and public understanding; and

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

"§ 633. Effective date; applicability; savings provisions

"(a) EFFECTIVE DATE.—Except as otherwise specifically provided in this subchapter, the provisions of this subchapter shall take effect 18 months after the date of enactment of this subchapter.

"(b) APPLICABILITY.—

"(1) IN GENERAL.—Except as provided in paragraph (3), this subchapter applies to all significant risk assessment documents and significant risk characterization documents, as defined in paragraph (2).

"(2) SIGNIFICANT RISK ASSESSMENT DOCUMENT OR SIGNIFICANT RISK CHARACTERIZATION DOCUMENT.—(A) As used in this subchapter, the terms 'significant risk assessment document' and 'significant risk characterization document' include, at a minimum, risk assessment documents or risk characterization documents prepared by or on behalf of a covered Federal agency in the implementation of a regulatory program designed to protect human health, safety, or the environment,

used as a basis for one of the items referred to in subparagraph (B), and—

"(i) included by the agency in that item; or

"(ii) inserted by the agency in the administrative record for that item.

"(B) The items referred to in subparagraph (A) are the following:

"(i) Any proposed or final major rule, including any analysis or certification under subchapter II, promulgated as part of any Federal regulatory program designed to protect human health, safety, or the environment.

"(ii) Any proposed or final environmental clean-up plan for a facility or Federal guidelines for the issuance of any such plan. As used in this clause, the term 'environmental clean-up' means a corrective action under the Solid Waste Disposal Act, a removal or remedial action under the Comprehensive Environmental Response, Compensation, and Liability Act of 1980, and any other environmental restoration and waste management carried out by or on behalf of a covered Federal agency with respect to any substance other than municipal waste.

"(iii) Any proposed or final permit condition placing a restriction on facility siting or operation under Federal laws administered by the Environmental Protection Agency or the Department of the Interior. Nothing in this section (iii) shall apply to the requirements of section 404 of the Clean Water Act.

"(iv) Any report to Congress.

"(v) Any regulatory action to place a substance on any official list of carcinogens or toxic or hazardous substances or to place a new health effects value on such list, including the Integrated Risk Information System Database maintained by the Environmental Protection Agency.

"(vi) Any guidance, including protocols of general applicability, establishing policy regarding risk assessment or risk characterization.

"(C) The terms 'significant risk assessment document' and 'significant risk characterization document' shall also include the following:

"(i) Any such risk assessment and risk characterization documents provided by a covered Federal agency to the public and which are likely to result in an annual effect on the economy of \$75,000,000 or more.

"(ii) Environmental restoration and waste management carried out by or on behalf of the Department of Defense with respect to any substance other than municipal waste.

"(D) Within 15 months after the date of the enactment of this subchapter, each covered Federal agency administering a regulatory program designed to protect human health, safety, or the environment shall promulgate a rule establishing those additional categories, if any, of risk assessment and risk characterization documents prepared by or on behalf of the covered Federal agency that the agency will consider significant risk assessment documents or significant risk characterization documents for purposes of this subchapter. In establishing such categories, the head of the agency shall consider each of the following:

"(i) The benefits of consistent compliance by documents of the covered Federal agency in the categories.

"(ii) The administrative burdens of including documents in the categories.

"(iii) The need to make expeditious administrative decisions regarding documents in the categories.

"(iv) The possible use of a risk assessment or risk characterization in any compilation of risk hazards or health or environmental effects prepared by an agency and commonly made available to, or used by, any Federal, State, or local government agency.

“(v) Such other factors as may be appropriate.

“(E)(i) Not later than 18 months after the date of the enactment of this subchapter, the President, acting through the Director of the Office of Management and Budget, shall determine whether any other Federal agencies should be considered covered Federal agencies for 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—

“(I) regulatory programs administered by that agency; and

“(II) the communication of risk information by that agency to the public. The effective date of such a determination shall be no later than 6 months after the date of the determination.

“(ii) Not later than 15 months after the President, acting through the Director of the Office of Management and Budget, determines pursuant to clause (i) that a Federal agency should be considered a covered Federal agency for purposes of this subchapter, the head of that agency shall promulgate a rule pursuant to subparagraph (D) to establish additional categories of risk assessment and risk characterization documents described in that subparagraph.

“(3) EXCEPTIONS.—(A) This subchapter does not apply to risk assessment or risk characterization documents containing risk assessments or risk characterizations performed with respect to the following:

“(i) A screening analysis, where appropriately labeled as such, including a screening analysis for purposes of product regulation or premanufacturing notices.

“(ii) Any health, safety, or environmental inspections.

“(iii) The sale or lease of Federal resources or regulatory activities that directly result in the collection of Federal receipts.

“(B) No analysis shall be treated as a screening analysis for purposes of subparagraph (A) if the results of such analysis are used as the basis for imposing restrictions on substances or activities.

“(C) The risk assessment principle set forth in this 634(b)(1) need not apply to any risk assessment or risk characterization document described in clause (iii) of paragraph (2)(B). The risk characterization and communication principle set forth in section 635(4) need not apply to any risk assessment or risk characterization document described in clause (v) or (vi) of paragraph (2)(B).

“(c) SAVINGS PROVISIONS.—The provisions of this subchapter shall be supplemental to any other provisions of law relating to risk assessments and risk characterizations, except that nothing in this subchapter shall be construed to modify any statutory standard or statutory requirement designed to protect health, safety, or the environment. Nothing in this subchapter shall be interpreted to 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. Nothing in this subchapter shall be construed to require the disclosure of any trade secret or other confidential information.

“§ 634. Principles for risk assessment

“(a) IN GENERAL.—The head of each covered Federal agency shall apply the principles set forth in subsection (b) in order to assure that significant risk assessment documents and all of their components distinguish scientific findings from other considerations and are, to the extent feasible, scientifically objective, unbiased, and inclusive of all relevant data and rely, to the extent available and practicable, on scientific findings. Discussions or explanations required under this section need not be repeated in

each risk assessment document as long as there is a reference to the relevant discussion or explanation in another agency document which is available to the public.

“(b) PRINCIPLES.—The principles to be applied are as follows:

“(1) When discussing human health risks, a significant risk assessment document shall contain a discussion of both relevant laboratory and relevant epidemiological data of sufficient quality which finds, or fails to find, a correlation between health risks and a potential toxin or activity. Where conflicts among such data appear to exist, or where animal data is used as a basis to assess human health, the significant risk assessment document shall, to the extent feasible and appropriate, include discussion of possible reconciliation of conflicting information, and as relevant, differences in study designs, comparative physiology, routes of exposure, bioavailability, pharmacokinetics, and any other relevant factor, including the sufficiency of basic data for review. The discussion of possible reconciliation should indicate whether there is a biological basis to assume a resulting harm in humans. Animal data shall be reviewed with regard to its relevancy to humans.

“(2) Where a significant risk assessment document involves selection of any significant assumption, inference, or model, the document shall, to the extent feasible—

“(A) present a representative list and explanation of plausible and alternative assumptions, inferences, or models;

“(B) explain the basis for any choices;

“(C) identify any policy or value judgments;

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

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

“§ 635. Principles for risk characterization and communication

“Each significant risk characterization document shall meet each of the following requirements:

“(1) ESTIMATES OF RISK.—The risk characterization shall describe the populations or natural resources which are the subject of the risk characterization. If a numerical estimate of risk is provided, the agency shall, to the extent feasible, provide—

“(A) the best estimate or estimates for the specific populations or natural resources which are the subject of the characterization (based on the information available to the Federal agency); and

“(B) a statement of the reasonable range of scientific uncertainties.

In addition to such best estimate or estimates, the risk characterization document may present plausible upper-bound or conservative estimates in conjunction with plausible lower bound estimates. Where appropriate, the risk characterization document may present, in lieu of a single best estimate, multiple best estimates based on assumptions, inferences, or models which are equally plausible, given current scientific understanding. To the extent practical and appropriate, the document shall provide descriptions of the distribution and probability of risk estimates to reflect differences in exposure variability or sensitivity in populations and attendant uncertainties. Sensitive subpopulations or highly exposed subpopulations include, where relevant and appropriate, children, the elderly, pregnant women, and disabled persons.

“(2) EXPOSURE SCENARIOS.—The risk characterization document shall explain the exposure scenarios used in any risk assessment, and, to the extent feasible, provide a statement of the size of the corresponding

population at risk and the likelihood of such exposure scenarios.

“(3) COMPARISONS.—The document shall contain a statement that places the nature and magnitude of risks to human health, safety, or the environment in context. Such statement shall, to the extent feasible, provide comparisons with estimates of greater, lesser, and substantially equivalent risks that are familiar to and routinely encountered by the general public as well as other risks, and, where appropriate and meaningful, comparisons of those risks with other similar risks regulated by the Federal agency resulting from comparable activities and exposure pathways. Such comparisons should consider relevant distinctions among risks, such as the voluntary or involuntary nature of risks and the preventability or non-preventability of risks.

“(4) SUBSTITUTION RISKS.—Each significant risk assessment or risk characterization document shall include a statement of any significant substitution risks to human health, where information on such risks has been provided to the agency.

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

“(A) a commenter provides a covered Federal agency with a relevant risk assessment document or a risk characterization document, and a summary thereof, during a public comment provided by the agency for a significant risk assessment document or a significant risk characterization document, or, where no comment period is provided but a commenter provides the covered Federal agency with the relevant risk assessment document or risk characterization document, and a summary thereof, in a timely fashion, and

“(B) the risk assessment document or risk characterization document is consistent with the principles and the guidance provided under this subchapter,

the agency shall, to the extent feasible, present such summary in connection with the presentation of the agency's significant risk assessment document or significant risk characterization document. Nothing in this paragraph shall be construed to limit the inclusion of any comments or material supplied by any person to the administrative record of any proceeding.

A document may satisfy the requirements of paragraph (3), (4) or (5) by reference to information or material otherwise available to the public if the document provides a brief summary of such information or material.

“§ 636. Recommendations or classifications by a non-United States-based entity

“No covered Federal agency shall automatically incorporate or adopt any recommendation or classification made by a non-United States-based entity concerning the health effects value of a substance without an opportunity for notice and comment, and any risk assessment document or risk characterization document adopted by a covered Federal agency on the basis of such a recommendation or classification shall comply with the provisions of this subchapter. For the purposes of this section, the term ‘non-United States-based entity’ means—

“(1) any foreign government and its agencies;

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

“(3) any other international governmental body or international standards-making organization; or

“(4) any other organization or private entity without a place of business located in the United States or its territories.

“§ 637. Guidelines and report

“(a) GUIDELINES.—Within 15 months after the date of enactment of this subchapter, the

President shall issue guidelines for Federal agencies consistent with the risk assessment and characterization principles set forth in sections 634 and 635 and shall provide a format for summarizing risk assessment results. In addition, such guidelines shall include guidance on at least the following subjects: criteria for scaling animal studies to assess risks to human health; use of different types of dose-response models; thresholds; definitions, use, and interpretations of the maximum tolerated dose; weighting of evidence with respect to extrapolating human health risks from sensitive species; evaluation of benign tumors, and evaluation of different human health endpoints.

“(b) REPORT.—Within 3 years after the date of the enactment of this subchapter, each covered Federal agency shall provide a report to the Congress evaluating the categories of policy and value judgments identified under subparagraph (C) of section 634(b)(2).

“(c) PUBLIC COMMENT AND CONSULTATION.—The guidelines and report under this section, shall be developed after notice and opportunity for public comment, and after consultation with representatives of appropriate State, local, and tribal governments, and such other departments and agencies, offices, organizations, or persons as may be advisable.

“(d) REVIEW.—The President shall review and, where appropriate, revise the guidelines published under this section at least every 4 years.

“§ 638. Research and training in risk assessment

“(a) EVALUATION.—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) STRATEGY AND ACTIONS TO MEET IDENTIFIED NEEDS.—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).

“(c) REPORT.—Not later than 6 months after the date of the enactment of this subchapter, the head of each covered agency shall submit to the Congress a report on the evaluations conducted under subsection “(a) and the strategy and schedule developed under subsection “(b). The head of each covered agency shall report to the Congress periodically on the evaluations, strategy, and schedule.

“§ 639. Study of comparative risk analysis

“(a) IN GENERAL.—(1) The Director of the Office of Management and Budget, in con-

sultation with the Office of Science and Technology Policy, shall conduct, or provide for the conduct of, a study using comparative risk analysis to rank health, safety, and environmental risks and to provide a common basis for evaluating strategies for reducing or preventing those risks. The goal of the study shall be to improve methods of comparative risk analysis.

“(2) Not later than 90 days after the date of the enactment of this subchapter, the Director, in collaboration with the heads of appropriate Federal agencies, shall enter into a contract with the National Research Council to provide technical guidance on approaches to using comparative risk analysis and other considerations in setting health, safety, and environmental risk reduction priorities.

“(b) SCOPE OF STUDY.—The study shall have sufficient scope and breadth to evaluate comparative risk analysis and to test approaches for improving comparative risk analysis and its use in setting priorities for health, safety, and environmental risk reduction. The study shall compare and evaluate a range of diverse health, safety, and environmental risks.

“(c) STUDY PARTICIPANTS.—In conducting the study, the Director shall provide for the participation of a range of individuals with varying backgrounds and expertise, both technical and nontechnical, comprising broad representation of the public and private sectors.

“(d) DURATION.—The study shall begin within 180 days after the date of the enactment of this subchapter and terminate within 2 years after the date on which it began.

“(e) RECOMMENDATIONS FOR IMPROVING COMPARATIVE RISK ANALYSIS AND ITS USE.—Not later than 90 days after the termination of the study, the Director shall submit to the Congress the report of the National Research Council with recommendations regarding the use of comparative risk analysis and ways to improve the use of comparative risk analysis for decision-making in appropriate Federal agencies.

“§ 639a. Definitions

“For purposes of this subchapter:

“(1) RISK ASSESSMENT DOCUMENT.—The term ‘risk assessment document’ means a document containing the explanation of how hazards associated with a substance, activity, or condition have been identified, quantified, and assessed. The term also includes a written statement accepting the findings of any such document.

“(2) RISK CHARACTERIZATION DOCUMENT.—The term ‘risk characterization document’ means a document quantifying or describing the degree of toxicity, exposure, or other risk posed by hazards associated with a substance, activity, or condition to which individuals, populations, or resources are exposed. The term also includes a written statement accepting the findings of any such document.

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

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

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

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

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

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

“(A) The Environmental Protection Agency.

“(B) The Occupational Safety and Health Administration.

“(C) The Department of Transportation (including the National Highway Transportation Safety Administration).

“(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 Mine Safety and Health Administration.

“(L) The Nuclear Regulatory Commission.

“(M) Any other Federal agency considered a covered Federal agency pursuant to section 413(b)(2)(E).

“(6) FEDERAL AGENCY.—The term ‘Federal agency’ means an executive department, military department, or independent establishment as defined in part I of title 5 of the United States Code, except that such term also includes the Office of Technology Assessment.

“(7) DOCUMENT.—The term ‘document’ includes material stored in electronic or digital form.

“§ 639b. Peer review program

“(a) ESTABLISHMENT.—For regulatory programs designed to protect human health, safety, or the environment, the head of each Federal agency shall develop a systematic program for independent and external peer review required by subsection (b). Such program shall be applicable across the agency and—

“(1) shall provide for the creation of peer review panels consisting of experts and shall be broadly representative and balanced and to the extent relevant and appropriate, may include representatives of State, local, and tribal governments, small businesses, other representatives of industry, universities, agriculture, labor, consumers, conservation organizations, or other public interest groups and organizations;

“(2) may provide for differing levels of peer review and differing numbers of experts on peer review panels, depending on the significance or the complexity of the problems or the need for expeditiousness;

“(3) shall not exclude peer reviewers with substantial and relevant expertise merely because they represent entities that may have a potential interest in the outcome, provided that 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;

“(4) may provide specific and reasonable deadlines for peer review panels to submit reports under subsection (c); and

“(5) shall provide adequate protections for confidential business information and trade secrets, including requiring peer reviewers to enter into confidentiality agreements.

“(b) REQUIREMENT FOR PEER REVIEW.—In connection with any rule that is likely to result in an annual increase in costs of \$100,000,000 or more (other than any rule or other action taken by an agency to authorize or approve any individual substance or product), each Federal agency shall provide for peer review in accordance with this section of any risk assessment or cost analysis which forms the basis for such rule or of any analysis under section 431(a). In addition, the Director of the Office of Management and

Budget may order that peer review be provided for any major risk assessment or cost assessment that is likely to have a significant impact on public policy decisions.

“(c) CONTENTS.—Each peer review under this section shall include a report to the Federal agency concerned with respect to the scientific and economic merit of data and methods used for the assessments and analyses.

“(d) RESPONSE TO PEER REVIEW.—The head of the Federal agency shall provide a written response to all significant peer review comments.

“(e) AVAILABILITY TO PUBLIC.—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.

“(f) PREVIOUSLY REVIEWED DATA AND ANALYSIS.—No peer review shall be required under this section for any data or method which has been previously subjected to peer review or for any component of any analysis or assessment previously subjected to peer review.

“(g) NATIONAL PANELS.—The President shall appoint National Peer Review Panels to annually review the risk assessment and cost assessment practices of each Federal agency for programs designed to protect human health, safety, or the environment. The Panel shall submit a report to the Congress no less frequently than annually containing the results of such review.

“§ 639c. Petition for review of a major free-standing risk assessment

“(a) Any interested person may petition an agency to conduct a scientific review of a risk assessment conducted or adopted by the agency, except for a risk assessment used as the basis for a major rule or a site-specific risk assessment.

“(b) The agency shall utilize external peer review, as appropriate, to evaluate the claims and analyses in the petition, and shall consider such review in making its determination of whether to grant the petition.

“(c) The agency shall grant the petition if the petition establishes that there is a reasonable likelihood that—

“(1)(A) the risk assessment that is the subject of the petition was carried out in a manner substantially inconsistent with the principles in section 633; or

“(B) the risk assessment that is the subject of the petition does not take into account material significant new scientific data and scientific understanding;

“(2) the risk assessment that is the subject of the petition contains significantly different results than if it had been properly conducted pursuant to subchapter III; and

“(3) a revised risk assessment will provide the basis for reevaluating an agency determination of risk, and such determination currently has an effect on the United States economy equivalent to that of major rule.

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

“(e) If the agency grants the petition, it shall complete its review of the risk assessment not later than 1 year after its decision to grant the petition. If the agency revises the risk assessment, in response to its review, it shall do so in accordance with section 633.

“§ 639d. 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 shall set priorities for the use of resources available under those laws to address those risks to human health, safety, and the environment that—

“(A) the covered agency determines to be 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, regulatory agenda, enforcement, and research activities. When submitting its budget request to Congress and when announcing its regulatory agenda in the Federal Register, each covered agency shall identify the risks that the covered agency head has determined are the most serious and can be addressed in a cost-effective manner under paragraph (1), the basis for that determination, and explicitly identify how the covered agency's requested budget and regulatory agenda reflect those priorities.

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

“(d) COMPARATIVE RISK ANALYSIS.—

“(1) REQUIREMENT.—

“(A)(i) No later than 6 months after the effective date of this Act, the Director of the Office of Management and Budget shall enter into appropriate arrangements with a nationally recognized scientific institution or scholarly organization—

“(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.

“(C) Nothing in this subsection should be construed to prevent the Director from entering into a sole-source arrangement with a nationally recognized scientific institution or scholarly organization.

“(2) CRITERIA.—The Director shall ensure that the arrangement under paragraph (1) provides 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, including opportunities for the public to submit views, data, and analyses and to provide public comment on the results before making them final;

“(C) the analysis is conducted by a balanced group of individuals with relevant expertise, including toxicologists, biologists, engineers, and experts in medicine, industrial hygiene, and environmental effects, and the selection of members for such study shall be at the sole discretion of the scientific institution or scholarly organization;

“(D) the analysis is conducted, to the extent feasible and relevant, consistent with the risk assessment and risk characterization principles in section 633 of this subchapter;

“(E) the methodologies and principal scientific determinations made in the analysis are subjected to independent peer review consistent with section 633(g), and the conclusions of the peer review are made publicly

available as part of the final report required under subsection (e); 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 by 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 reason 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 statutory 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 judgment 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 ju-

dicial review of the action and shall, to the extent relevant, be considered by a court in determining the legality of the covered agency action.”

(b) CLERICAL AMENDMENT.—The table of sections appearing at the beginning of chapter 6 of title 5, United States Code, is amended—

(1) by inserting immediately below the chapter heading the following:

“SUBCHAPTER I—REGULATORY ANALYSIS”; and

(2) by adding at the end the following:

“SUBCHAPTER III—RISK ASSESSMENTS

“631. Short title.

“632. Purposes.

“633. Effective date; applicability; savings provisions.

“634. Principles for risk assessment.

“635. Principles for risk characterization and communication.

“636. Recommendations or classifications by a non-United States-based entity.

“637. Guidelines and report.

“638. Research and training in risk assessment.

“639. Study of comparative risk analysis.

“639a. Definitions.

“639b. Peer review program.

“639c. Petition for review of a major free-standing risk assessment.

“639d. Risk-based priorities.”

SEC. 3004. REGULATORY FLEXIBILITY ANALYSIS.

(a) IN GENERAL.—

(1) JUDICIAL REVIEW.—

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

“§ 611. Judicial review

“(a)(1) Not later than one year, notwithstanding any other provision of law, 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 the terms of this subsection. A court having jurisdiction to review such rule for compliance with the provisions of section 553 or under any other provision of law shall have jurisdiction to review such certification or analysis. In the case where 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 one year, notwithstanding any other provision of law, after the date the analysis is made available to the public.

“(2) 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.

“(3) 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.

“(4)(A) In the case where the agency certified 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 the case where the agency prepared a final regulatory flexibility analysis, the

court may order the agency to take corrective action consistent with the requirements of 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 observance of procedure required by section 604.

“(5) If, by the end of the 90-day period beginning on the date of the order of the court pursuant to paragraph (4) (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 the requirements of section 604,

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

“(6) 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)(4)) 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.”

(B) EFFECTIVE DATE.—The amendment made by subsection (a) shall apply only to final agency rules issued after the date of enactment of this Act.

(2) RULES COMMENTED ON BY SBA CHIEF COUNSEL FOR ADVOCACY.—

(A) IN GENERAL.—Section 612 of title 5, United States Code, is amended by adding at the end the following new subsection:

“(d) ACTION BY THE SBA CHIEF COUNSEL FOR ADVOCACY.—

“(1) TRANSMITTAL OF PROPOSED RULES AND INITIAL REGULATORY FLEXIBILITY ANALYSIS TO SBA CHIEF COUNSEL FOR ADVOCACY.—On or before the 30th day preceding the date of publication by an agency of general notice of proposed rulemaking for a rule, the agency shall transmit to the Chief Counsel for Advocacy of the Small Business Administration—

“(A) a copy of the proposed rule; and

“(B)(i) a copy of the initial regulatory flexibility analysis for the rule if required under section 603; or

“(ii) a determination by the agency that an initial regulatory flexibility analysis is not required for the proposed rule under section 603 and an explanation for the determination.

“(2) STATEMENT OF EFFECT.—On or before the 15th day following receipt of a proposed rule and initial regulatory flexibility analysis from an agency under paragraph (1), the Chief Counsel for Advocacy may transmit to the agency a written statement of the effect of the proposed rule on small entities.

“(3) RESPONSE.—If the Chief Counsel for Advocacy transmits to an agency a statement of effect on a proposed rule in accordance with paragraph (2), the agency shall publish the statement, together with the response of the agency to the statement, in the Federal Register at the time of publication of general notice of proposed rulemaking for the rule.

“(4) SPECIAL RULE.—Any proposed rules issued by an appropriate Federal banking agency (as that term is defined in section 3(q) of the Federal Deposit Insurance Act (12 U.S.C. 1813(q))), the National Credit Union Administration, or the Office of Federal Housing Enterprise Oversight, in connection with the implementation of monetary policy or to ensure the safety and soundness of federally insured depository institutions, any affiliate of such an institution, credit unions, or government sponsored housing en-

terprises or to protect the Federal deposit insurance funds shall not be subject to the requirements of this subsection.”

(B) CONFORMING AMENDMENT.—Section 603(a) of title 5, United States Code, is amended by inserting “in accordance with section 612(d)” before the period at the end of the last sentence.

(3) SENSE OF CONGRESS REGARDING SBA CHIEF COUNSEL FOR ADVOCACY.—It is the sense of Congress that the Chief Counsel for Advocacy of the Small Business Administration should be permitted to appear as amicus curiae in any action or case brought in a court of the United States for the purpose of reviewing a rule.

(b) 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. 3005. GUIDANCE FOR JUDICIAL INTERPRETATION.

(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 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; or

“(F) 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 rule-making 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.

“§ 709. Agency interpretations in civil and criminal actions

“(a) No civil or criminal penalty shall be imposed by a court, and no civil administrative penalty shall be imposed by an agency, for the violation of a rule—

“(1) if the court or agency, as appropriate, finds that the rule failed to give the defendant fair warning of the conduct that the rule prohibits or requires; or

“(2) if the court or agency, as appropriate, finds that the defendant acted reasonably in good faith based upon the language of the rule as published in the Federal Register.

“(b) Nothing in this section shall be construed to preclude an agency:

“(1) from revising a rule or changing its interpretation of a rule in accordance with sections 552 and 553 of this title, and subject to the provisions of this section, prospectively enforcing the requirements of such rule as revised or reinterpreted and imposing or seeking a civil or criminal penalty for any subsequent violation of such rule as revised or reinterpreted;

“(2) from making a new determination of fact, and based upon such determination, prospectively applying a particular legal requirement.

“(c) This section shall apply to any action filed after the date of the enactment of the Comprehensive Regulatory Reform Act of 1995.”

(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.

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

SEC. 3006. 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 major final and proposed 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

“Sec.

“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 (excluding days either House of Congress is adjourned for more than 3 days during a session of Congress) 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)(1) A rule or proposed rule shall not take effect (or continue) as a final rule, if the Congress passes a joint resolution of disapproval described under section 802.

“(2) A rule or proposed rule that does not take effect (or does not continue) under paragraph (1) may not be reissued in substantially the same form, and a new rule that is substantially the same as such a rule or proposed rule may not be issued, unless the reissued or new rule is specifically authorized by a law enacted after the date of the joint resolution disapproving the original rule.

“(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 a session of Congress through the date on which the same or succeeding Congress first convenes its next session, section 802 shall apply to such rule in the succeeding session of 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 its terms to any major rule that was published in the Federal Register (as a rule that shall take effect as a final rule) in the period beginning on November 20, 1994, through the date of enactment of the Comprehensive Regulatory Reform Act of 1995.

“(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) JOINT RESOLUTION DEFINED.—For purposes of this section, the term ‘joint resolution’ means only—

“(1) a joint resolution introduced in 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 (excluding days either House of Congress is adjourned for more than 3 days during a session of 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); or

“(2) a joint resolution the matter after the resolving clause of which is as follows: ‘That

the Congress disapproves the proposed rule published by the ___ relating to ___, and such proposed rule shall not be issued or take effect as a final rule.’ (the blank spaces being appropriately filled in)

“(b)(1) A joint resolution described in subsection (a) shall be referred to the committees in each House of Congress with jurisdiction.

“(2) For purposes of this section, the term ‘submission or publication date’ means—

“(A) in the case of a joint resolution described in subsection (a)(1) the later of the date on which—

“(i) the Congress receives the report submitted under section 801(a)(1); or

“(ii) the rule is published in the Federal Register; or

“(B) in the case of a joint resolution described in subsection (a)(2), the date of introduction of the joint resolution.

“(c) In the Senate, if the committee to which is referred a joint resolution described in subsection (a) has not reported such joint resolution (or an identical joint 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 joint resolution upon a petition supported in writing by 30 Members of the Senate, and such joint resolution shall be placed on the appropriate calendar.

“(d)(1) In the Senate, when the committee to which a joint resolution is referred has reported, or when a committee is discharged (under subsection (c)) from further consideration of, a joint 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 joint resolution, and all points of order against the joint resolution (and against consideration of the joint 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 joint resolution is agreed to, the joint resolution shall remain the unfinished business of the Senate until disposed of.

“(2) In the Senate, debate on the joint 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 joint 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 joint resolution is not in order.

“(3) In the Senate, immediately following the conclusion of the debate on a joint 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 Senate, the vote on final passage of the joint resolution shall occur.

“(4) Appeals from the decisions of the Chair relating to the application of the rules of the Senate to the procedure relating to a joint resolution described in subsection (a) shall be decided without debate.

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

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

“(2) With respect to a joint resolution described in subsection (a) of the House receiving the joint resolution—

“(A) the procedure in that House shall be the same as if no joint resolution had been received from the other House; but

“(B) the vote on final passage shall be on the joint 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 joint 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.

(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. 3007. REGULATORY ACCOUNTING STATEMENT.

(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—

(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.

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

SEC. 3008. 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. 3009. 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.

After debate,
The question being put, viva voce,
Will the House agree to said amendment?

The SPEAKER pro tempore, Mr. HOBSON, announced that the nays had it.

Mr. WALKER objected to the vote on the ground that a quorum was not present and not voting.

A quorum not being present,
The roll was called under clause 4, rule XV, and the call was taken by electronic device.

When there appeared { Yeas 257
Nays 165

¶143.18 [Roll No. 779]
YEAS—257
Allard Baker (CA) Barrett (NE)
Archer Baker (LA) Bartlett
Armey Ballenger Barton
Bachus Barcia Bass
Baesler Barr Bateman