

Tiahrt	Wamp	Williams
Torkildsen	Watts (OK)	Wolf
Torricelli	Weldon (FL)	Young (AK)
Upton	Weldon (PA)	Young (FL)
Vucanovich	Weller	Zeliff
Waldholtz	White	Zimmer
Walker	Whitfield	
Walsh		

NAYS—165

Abercrombie	Hall (OH)	Ortiz
Ackerman	Hamilton	Orton
Baessler	Harman	Owens
Baldacci	Hastings (FL)	Pallone
Barrett (WI)	Hayes	Pastor
Beilenson	Hefner	Payne (NJ)
Bentsen	Hilliard	Payne (VA)
Berman	Hinchev	Pelosi
Bishop	Holden	Peterson (FL)
Bonior	Hoyer	Pomeroy
Borski	Jackson-Lee	Poshard
Boucher	Jacobs	Rangel
Brown (CA)	Jefferson	Reed
Brown (FL)	Johnson (SD)	Reynolds
Brown (OH)	Johnson, E. B.	Richardson
Bryant (TX)	Johnston	Rivers
Cardin	Kanjorski	Roemer
Clay	Kaptur	Rose
Clayton	Kennedy (MA)	Roybal-Allard
Clement	Kennedy (RI)	Sabo
Clyburn	Kennelly	Sanders
Coleman	Kildee	Sawyer
Collins (IL)	Klecza	Schroeder
Collins (MI)	Klink	Schumer
Conyers	LaFalce	Scott
Costello	Lantos	Serrano
Coyne	Levin	Skaggs
Danner	Lewis (GA)	Slaughter
DeFazio	Lofgren	Spratt
DeLauro	Lowe	Stark
Dellums	Luther	Stokes
Deutsch	Maloney	Studds
Dicks	Manton	Stupak
Dingell	Markey	Tanner
Dixon	Martinez	Tejeda
Doggett	Mascara	Thompson
Dooley	Matsui	Thornton
Doyle	McDermott	Thurman
Durbin	McHale	Torres
Engel	McNulty	Towns
Eshoo	Meehan	Trafficant
Evans	Meek	Tucker
Farr	Menendez	Velazquez
Fattah	Miller (CA)	Vento
Fazio	Mineta	Visclosky
Fields (LA)	Minge	Volkmer
Filner	Mink	Ward
Foglietta	Moakley	Waters
Frank (MA)	Mollohan	Watt (NC)
Frost	Moran	Waxman
Furse	Nadler	Wise
Gejdenson	Neal	Woolsey
Gephardt	Oberstar	Wyden
Green	Obey	Wynn
Gutierrez	Olver	Yates

NOT VOTING—16

Andrews	Gibbons	Rahall
Becerra	Gonzalez	Roukema
Chapman	Hunter	Rush
Flake	Lipinski	Wilson
Ford	McKinney	
Gallegly	Mfume	

So the resolution was agreed to.

A motion to reconsider the vote whereby said resolution was agreed to was, by unanimous consent, laid on the table.

133.10 PROVIDING FOR THE CONSIDERATION OF H.R. 926

Mr. SOLOMON, by direction of the Committee on Rules, reported (Rept. No. 104-52) the resolution (H. Res. 100) providing for the consideration of the bill (H.R. 926) to promote regulatory flexibility and enhance public participation in Federal agency rulemaking, and for other purposes.

When said resolution and report were referred to the House Calendar and ordered printed.

133.11 RESOLUTION OF INQUIRY—STABILIZATION OF MEXICAN ECONOMY

Mr. LEACH, by direction of the Committee on Banking and Financial Services, reported (Rept. No. 104-53) the resolution (H. Res. 80) requesting the President to submit information to the House of Representatives concerning actions taken through the exchange stabilization fund to strengthen the Mexican peso and stabilize the economy of Mexico.

When said resolution and report were referred to the House Calendar and ordered printed.

133.12 RISK ASSESSMENT AND COST-BENEFIT

The SPEAKER pro tempore, Mr. MCHUGH, pursuant to House Resolution 96 and rule XXIII, declared the House resolved into the Committee of the Whole House on the state of the Union for the further consideration of the bill (H.R. 1022) to provide regulatory reform and to focus national economic resources on the greatest risks to human health, safety, and the environment through scientifically objective and unbiased risk assessments and through the consideration of costs and benefits in major rules, and for other purposes.

Mr. HASTINGS of Washington, Chairman of the Committee of the Whole, resumed the chair; and after some time spent therein,

133.13 RECORDED VOTE

A recorded vote by electronic device was ordered in the Committee of the Whole on the following amendment in the nature of a substitute submitted by Mr. BROWN of California:

Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE.

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

SEC. 2. PURPOSES.

The purposes of this Act are the following:

(1) To direct the head of each covered agency to establish appropriate regulatory priorities among regulatory initiatives based on the seriousness of the risks to be addressed and available resources, and other appropriate factors.

(2) To require the head of each covered agency to conduct a risk assessment and cost benefit analysis for all major rules.

(3) To require the head of each covered agency to—

(A) oversee the development, periodic revision, and implementation of risk assessment guidelines throughout the covered agency, which reflect scientific advances;

(B) provide for appropriate scientific peer review of and public comment on risk assessment guidelines and for peer review of risk assessments and cost-benefit analyses throughout the process of development and implementation;

(C) develop risk characterization guidance and oversee its implementation in order to communicate an accurate description of the full range of risks and uncertainties; and

(D) identify, prioritize, and conduct research and training needed to advance the science and practice of risk assessment and cost-benefit analysis.

(4) To establish a study to improve comparative risk analysis and to direct the Of-

fice of Science and Technology Policy to establish an interagency coordinating process to promote more compatible risk assessment procedures across Federal agencies.

SEC. 3. ESTABLISHING AGENCY PRIORITIES.

(a) PRIORITIES FOR REGULATION.—Each covered agency shall establish, after notice and opportunity for comment, priorities for regulatory purposes among threats to human health, safety, and the environment according to—

(1) the seriousness of the risk they pose;

(2) the opportunities available to achieve the greatest overall net reduction in those risks with the public and private resources available; and

(3) other factors as appropriate.

(b) REPORT.—Each covered agency shall submit an annual report to Congress setting forth the agency's regulatory priorities. The report shall recommend priorities, consistent with otherwise applicable law, for the use of resources available to the agency to reduce those risks in accordance with the priorities established under subsection (a), including strategic planning and research activities of the agency. The report shall also explain any statutory priorities which are inconsistent with the priorities established according to the factors set forth in this section.

SEC. 4. ANALYSIS OF RISKS, BENEFITS, AND COSTS.

For all major rules protecting human health, safety, or the environment, the head of each covered agency shall—

(1) conduct a risk assessment and cost-benefit analysis that uses sound scientific, technical, economic, and other data. Such an analysis shall be conducted with as much specificity as practicable, of—

(A) the risk to human health, safety, or the environment, and any combination thereof, addressed by the rule, including, where applicable and practicable, the health and safety risks to persons who are disproportionately exposed or particularly sensitive, including children, the elderly, and disabled individuals;

(B) the costs, including the incremental costs, associated with implementation of, and compliance with, the rule;

(C) the quantitative or qualitative benefits of the rule, including the incremental benefits, reduction or prevention of risk, or other benefits expected from the rule; and

(D) where appropriate and meaningful, a comparison of that risk relative to other similar risks, regulated by that Federal agency or another 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 and nonpreventability of risks); and

(2) include with the rule a statement that, to the extent consistent with otherwise applicable law—

(A) the rule will substantially advance the purpose of protecting against the risk referred to in paragraph (1)(A);

(B) the rule will produce benefits and reduce risks to human health, safety, or the environment, and any combination thereof, in a cost-effective manner taking into account the costs of the implementation of and compliance with the rule, by local, State, and Federal Government and other public and private entities;

(C) the benefits, quantitatively or qualitatively, will be likely to justify the costs; and

(D) the most cost-effective option allowed by the statute under which the rule is promulgated has been employed, or if such option has not been employed, the head of the agency shall include a summary of the analysis justifying why it is not employed.

SEC. 5. RISK ASSESSMENT GUIDELINES.

(a) **FUNCTIONS OF THE AGENCY HEAD.**—The head of each covered agency shall ensure that any risk assessments conducted by the agency are performed in accordance with risk assessment guidelines issued by the agency head under subsection (b) and use relevant, reliable, and reasonably available data.

(b) **ISSUANCE OF RISK ASSESSMENT GUIDELINES.**—

(1) **IN GENERAL.**—The head of each covered agency shall develop and publish in the Federal Register risk assessment guidelines that provide appropriate consistency and technical quality among risk assessments performed by the agency.

(2) **PROCEDURES FOR PUBLISHING GUIDELINES.**—Before issuing guidelines under this subsection, the head of a covered agency shall—

(A) publish notice of intent to revise as appropriate existing guidelines or to develop new guidelines and a list of the issues the agency head intends to address and upon which the agency head seeks public comment;

(B) publish all proposed guidelines for the purpose of seeking public comment; and

(C) conduct scientific peer review of such guidelines.

(3) **REVIEW AND UPDATES.**—Not less than once every 3 years, the head of a covered agency shall review and, as necessary, update guidelines issued under this subsection.

(4) **PROCEDURES FOR REVIEW OF RISK ASSESSMENTS.**—Within 1 year after the date of the enactment of this Act, the head of each covered agency shall develop and publish procedures for the review of significant new information made available to the agency relative to risk assessments performed by the agency that are (or if this Act had been in effect would have been) covered by section 4.

(c) **USE OF GUIDELINES.**—The agency head shall ensure—

(1) consistency in the use of such guidelines to the extent such consistency is appropriate;

(2) that risk assessments are scientifically supportable; and

(3) that significant uncertainties regarding facts, scientific knowledge, and the validity of analytical techniques, or numerical risk estimates are clearly disclosed in terms readily understandable to the public.

(d) **CONTENTS.**—Risk assessments conducted by the Agency should be carried out at a level of effort and accuracy appropriate to the decision being made and the need for accuracy of the risk estimate and should be conducted according to risk assessment guidelines that include:

(1) An explanation of the scope and applicability of the guidelines, including appropriate limitations or restrictions on their use.

(2) Criteria for accepting and evaluating data.

(3) A complete description of any mathematical models or other assumptions used in the risk assessment, including a discussion of their validation, limitations and plausibility.

(4) A description of the default options, the scientific justification supporting the default options, and an explicit statement of the rationale for selecting a particular default option, in the absence of adequate data, based on explicitly stated science policy choices and consideration of relevant scientific information.

(5) The technical justification for, and a description of the degree of conservatism each model selection, default option, or assumption imposes upon the risk assessment.

(6) Criteria for conducting uncertainty analysis during the course of the risk assess-

ment, and an explanation of the data needs for such analysis.

(e) **REGIONAL COMPLIANCE.**—The regional offices of each agency shall comply with, and follow, the risk assessment guidelines and policies established by the head of the agency. Where credible information has been received from an affected party that a region is violating such guidelines, the head of the agency shall examine the information and resolve the matter.

SEC. 6. RISK CHARACTERIZATION.

(a) **IN GENERAL.**—The head of each covered agency shall ensure that all risk assessments required by section 4, and the risk characterizations that are components of such assessments, make apparent the distinction between data and policy assumptions to facilitate interpretation and appropriate use of the characterization by decisionmakers.

(b) **CONTENTS.**—

(1) **IN GENERAL.**—As scientifically appropriate, such risk characterizations shall contain the following:

(A) Relevant information on data selection and rejection in the risk assessment, including a specific rationale justifying the basis for the selection or rejection, and the influence of the selection or rejection on the risk estimate.

(B) Identification of significant limitations, assumptions, and default options included in the risk assessment and the rationale and extent of scientific support for their use.

(C) A discussion of significant uncertainties and data gaps and their influence upon the risk assessment.

(2) **QUANTITATIVE ESTIMATES OF CERTAIN RISKS.**—As scientifically appropriate, any such risk characterization that includes quantitative estimates of carcinogenic risk shall contain the following:

(A) The range and distribution of exposures derived from exposure scenarios used in the risk assessment of which the risk characterization is a component, including upper bound estimates and central estimates and, when appropriate and practicable, the identification of susceptible groups, species, and subpopulations, including children, the elderly, and disabled individuals, or groups whose exposure exceeds the general population.

(B) A description of appropriate statistical expressions of the range and variability of the risk estimate, including the population or populations addressed by any risk estimates, central estimates of risk for each such specific population, any appropriate upper bound estimates, the reasonable range, or other description of uncertainties in the risk characterization which is contained in the risk assessment.

To the extent the types of information referred to in subparagraphs (A) and (B) are scientifically appropriate for risk characterizations other than for carcinogenic risks, such characterizations shall include such information. As other scientifically appropriate methods are developed for quantitatively estimating carcinogenic risks, such methods may be used in lieu of the methods described in subparagraphs (A) and (B).

SEC. 7. PEER REVIEW.

(a) **ESTABLISHMENT.**—For regulatory programs addressing human health, safety, or the environment, the head of each Federal agency shall develop a systematic program for peer review of risk assessments used by the agency. Such program shall be applicable across the agency and—

(1) shall provide for peer review by independent and well-qualified experts;

(2) to the extent a peer review panel is used, the panel shall be broadly representative and balanced to the extent feasible;

(3) may provide for differing levels of peer review depending on the significance or the complexity of the problems or the need for expeditiousness;

(4) shall exclude peer reviewers who are associated with entities that may have a financial interest in the outcome unless such interest is disclosed to the agency and the agency has determined that such interest will not reasonably be expected to create a bias in favor of obtaining an outcome that is consistent with such interest;

(5) shall result in the appointment of peer reviewers who are qualified on the basis of their professional training or expertise as reflected in their record of peer-reviewed publications or equivalent;

(6) may provide specific and reasonable deadlines for peer review comments; and

(7) 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.**—Each Federal agency shall provide for appropriate peer review of scientific information used for purposes of any risk assessment required by section 4. For any such risk assessment, the head of a covered agency shall provide a written response to comments made by the peer reviewers. The response shall indicate that the agency head explicitly considered the comments, the degree to which such comments have been incorporated into the risk assessment guidelines or risk assessment, as applicable, and the reason why a comment has not been incorporated.

(c) **AVAILABILITY TO PUBLIC.**—For all peer review to which this section applies, a summary of all peer review comments or conclusions and any response of the agency shall be made available to the public.

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

(e) **REPORTS.**—Not later than 180 days after the date of the enactment of this Act, the head of each covered agency shall submit to the Congress a report on a plan for conducting peer review under this section, and shall also report to the Congress whenever significant modifications are made to the plan.

SEC. 8. REVIEW OF AGENCY COMPLIANCE.

During the 3-year period beginning 1 year after the date of the enactment of this Act, the Comptroller General of the United States shall annually conduct a review to determine the extent of compliance by each covered Federal agency with the provisions of this Act and shall annually submit to Congress a report on such review.

SEC. 9. 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 the following:

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

(2) Research leading to improvement of methods to quantify and communicate uncertainty and variability throughout risk assessment, and risk assessment reporting methods that clearly distinguish between uncertainty and variability.

(3) Research to examine the causes and extent of variability within and among individuals, species, populations, and, in the case of ecological risk assessment, ecological communities.

(4) 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.

(5) Long-term needs to adequately train individuals in risk assessment and risk assessment applications. Evaluations under this paragraph shall include an estimate of the resources needed to provide necessary training and recommendations on appropriate educational risk assessment curricula.

(b) STRATEGY AND ACTIONS TO MEET IDENTIFIED NEEDS.—The head of each covered agency shall develop a strategy, schedule, and delegation of responsibility for carrying out research and training to meet the needs identified in subsection (a) consistent with available resources.

(c) REPORT.—Not later than 6 months after the date of the enactment of this Act, 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 whenever the evaluations, strategy, and schedule are updated or modified.

SEC. 10. STUDY OF COMPARATIVE RISK ANALYSIS.

(a) IN GENERAL.—The Director of the Office of Science and Technology Policy shall conduct, or provide for the conduct of, a study of the methods for conducting comparative risk analysis of 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 survey and rigorously evaluate methods of comparative risk analysis.

(b) 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.

(c) REPORT.—Not later than 90 days after the termination of the study, the Director shall submit to the Congress a report on the results of the study referred to in subsection (a).

SEC. 11. INTERAGENCY COORDINATION.

To promote the conduct, application, and practice of risk assessment in a consistent manner under Federal and to identify risk assessment data needs common to more than one Federal agency, the Director of the Office of Science and Technology Policy shall—

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

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

(3) establish appropriate interagency mechanisms to promote coordination among Federal agencies conducting risk assessment with respect to the conduct, application, and practice of risk assessment and to promote the use of state-of-the-art risk assessment practices throughout the Federal Government;

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

(5) periodically convene meetings with State government representatives and Fed-

eral and other leaders to assess the effectiveness of Federal-State cooperation in the development and application of risk assessment.

SEC. 12. SAVINGS PROVISION.

Nothing in this Act shall be construed to modify any statutory standard or requirement designed to protect health, safety, or the environment or shall delay any action required to meet a deadline imposed by a statute or a court.

SEC. 13. DEFINITIONS.

For the purposes of this Act:

(1) The term “major rule” means any rule (as that term is defined in section 551(4) of title 5, United States Code) that is likely to result in an annual effect on the economy of \$100,000,000 or more.

(2) The term “risk assessment” means a process that uses a factual base to—

(A) identify, characterize, and to the extent practicable and appropriate, quantify or describe the potential adverse effects of exposure of individuals, populations, habitats, ecosystems, or materials to hazardous pollutants or other stressors; and

(B) to the extent practicable and appropriate, identify and characterize important uncertainties.

(3) The term “risk characterization” means the final component of a risk assessment, that qualitatively or quantitatively (or both) describes the magnitude and consequences of that risk in terms of the population exposed to the risk and the types of potential effects of exposure.

(4) The term “covered agency” means each of the following:

(A) The Environmental Protection Agency.
(B) The Consumer Product Safety Commission.

(C) The Department of Labor (including the Occupational Health and Safety Administration).

(D) The Department of Transportation.

(E) The Department of Energy.

(F) The Department of Agriculture.

(G) The Department of the Interior.

(H) The Food and Drug Administration.

SEC. 14. EXCEPTIONS.

This Act does not apply to risk assessments or risk characterizations performed with respect to either of the following:

(1) A situation that the head of the agency considers to be an emergency.

(2) A situation the head of the agency considers to be reasonably expected to cause death or serious injury or illness to humans, or substantial endangerment to private property or the environment unless prompt action is taken to avoid death or to avoid or mitigate serious injury or illness to humans, or substantial endangerment to private property or the environment.

SEC. 15. JUDICIAL REVIEW.

Nothing in this Act creates any right to judicial or administrative review, nor creates any right or benefit, substantive or procedural, enforceable at law or equity by a party against the United States, its agencies or instrumentalities, its officers or employees, or any other person. If an agency action is subject to judicial or administrative review under any other provision of law, the adequacy of any document prepared pursuant to this Act, and any alleged failure to comply with this Act, may not be used as grounds for affecting or invalidating such agency action, but statements and information prepared pursuant to this Act which are otherwise part of the record, may be considered as part of the record for the judicial or administrative review conducted under such other provision of law.

SEC. 16. UNFUNDED MANDATES.

Nothing in this Act shall create an obligation or burden on any State or local govern-

ment or otherwise impose any financial burden on any State or local government. Nothing in this Act shall force a State to change its laws.

It was decided in the

{	Yeas	174
	Nays	246

<p>¶33.14</p> <p>Abercrombie Ackerman Andrews Baldacci Barcia Barrett (WI) Beilenson Bentsen Berman Bevill Bishop Boehlert Bonior Borski Boucher Browder Brown (CA) Brown (FL) Brown (OH) Bryant (TX) Cardin Clay Clayton Clement Clyburn Coleman Collins (IL) Collins (MI) Conyers Costello Coyne Cramer Danner de la Garza DeFazio DeLauro Dellums Deutsch Dingell Dixon Doggett Doyle Durbin Engel Eshoo Evans Farr Fattah Fazio Fields (LA) Filner Foglietta Ford Frank (MA) Frost Furse Gejdenson Gephardt</p>	<p>[Roll No. 176]</p> <p>AYES—174</p> <p>Gilchrest Gilman Gordon Green Gutierrez Hall (OH) Hamilton Harman Hastings (FL) Hefner Hilliard Hinchey Holden Hoyer Jackson-Lee Jacobs Jefferson Johnson (SD) Johnson, E. B. Johnston Kanjorski Kaptur Kennedy (MA) Kennedy (RI) Kennelly Kildee Klecza Klink LaFalce Lantos Levin Lewis (GA) Lincoln Lofgren Lowey Luther Maloney Manton Markey Martinez Mascara Matsui McCarthy McDermott McHale Meehan Meek Menendez Miller (CA) Mineta Minge Mink Moakley Moran Morella Murtha Nadler Neal</p>	<p>Oberstar Obey Olver Owens Pallone Pastor Payne (NJ) Payne (VA) Pelosi Peterson (FL) Pomeroy Porter Reed Reynolds Richardson Rivers Roemer Rose Roukema Roybal-Allard Sabo Sanders Sanford Sawyer Schroeder Schumer Scott Serrano Shays Skaggs Slaughter Spratt Stark Stokes Studds Stupak Tanner Thompson Thornton Torres Torricelli Towns Traficant Tucker Velazquez Vento Visclosky Volkmmer Ward Waters Watt (NC) Waxman Wise Woolsey Wyden Wynn Yates Zimmer</p>
<p>NOES—246</p>		
<p>Allard Archer Armey Bachus Baesler Baker (CA) Baker (LA) Ballenger Barr Barrett (NE) Bartlett Barton Bass Bateman Bereuter Bilbray Bilirakis Bliley Blute Boehner Bonilla Bono Brewster Brownback Bryant (TN) Bunn Bunning Burr Burton</p>	<p>Buyer Callahan Calvert Camp Canady Castle Chabot Chambliss Chapman Chenoweth Christensen Chryslers Clinger Coble Coburn Collins (GA) Combest Condit Cooley Cox Crane Crapo Creameans Cubin Cunningham Davis Deal DeLay Diaz-Balart</p>	<p>Dickey Dooley Doolittle Dorman Dreier Duncan Dunn Edwards Ehlers Ehrlich Emerson English Ensign Everett Ewing Fawell Fields (TX) Flanagan Foley Forbes Fowler Fox Franks (CT) Franks (NJ) Frelinghuysen Frisa Funderburk Ganske Gekas</p>